

VU Medical Zone

EFFORT BY: **Amaan Khan**

BT605 - BIOSAFETY & BIOETHICS

LESSONS (80 – 165 FULL) Final term PPT

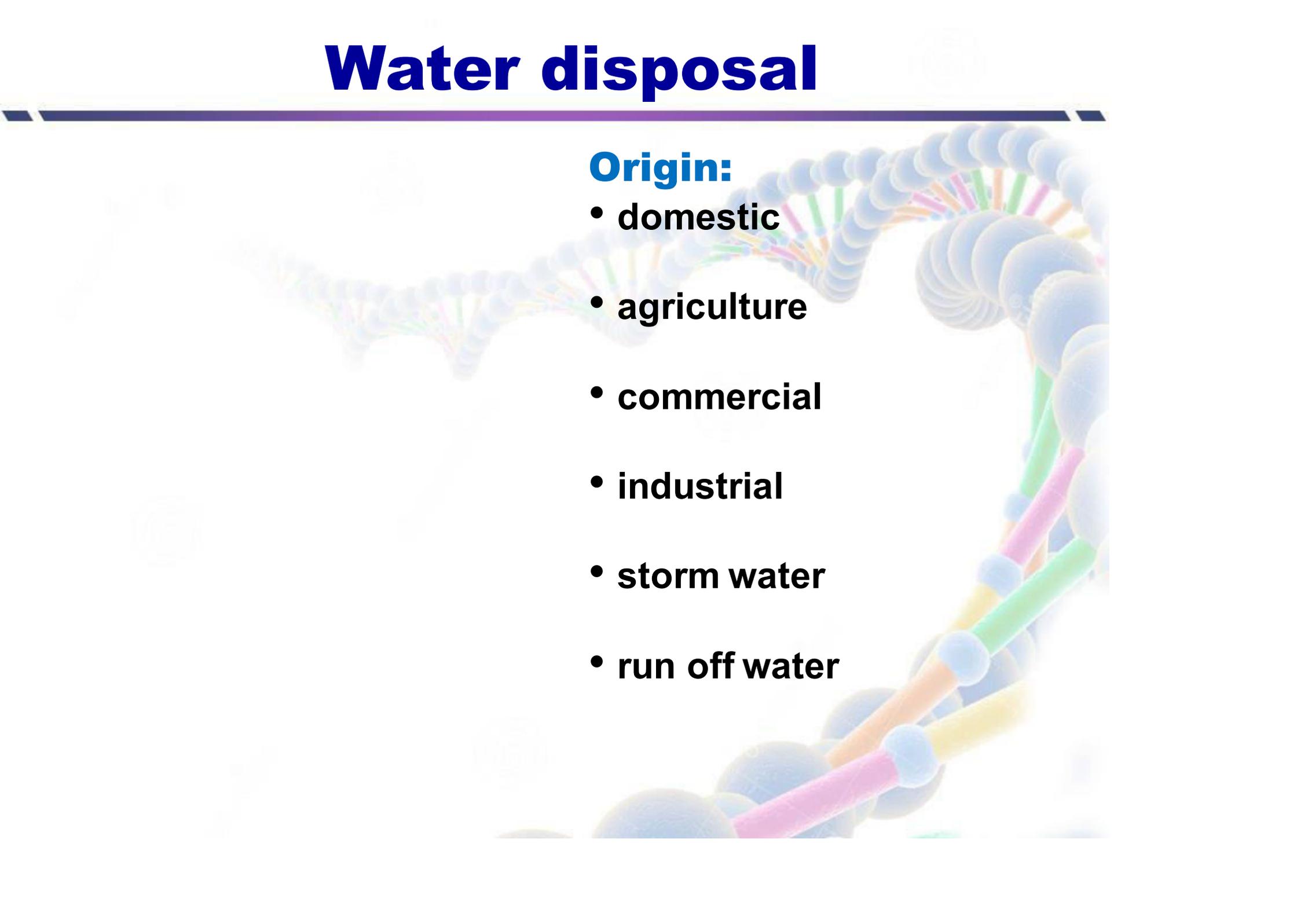


Biosafety



Water disposal

Water disposal



Origin:

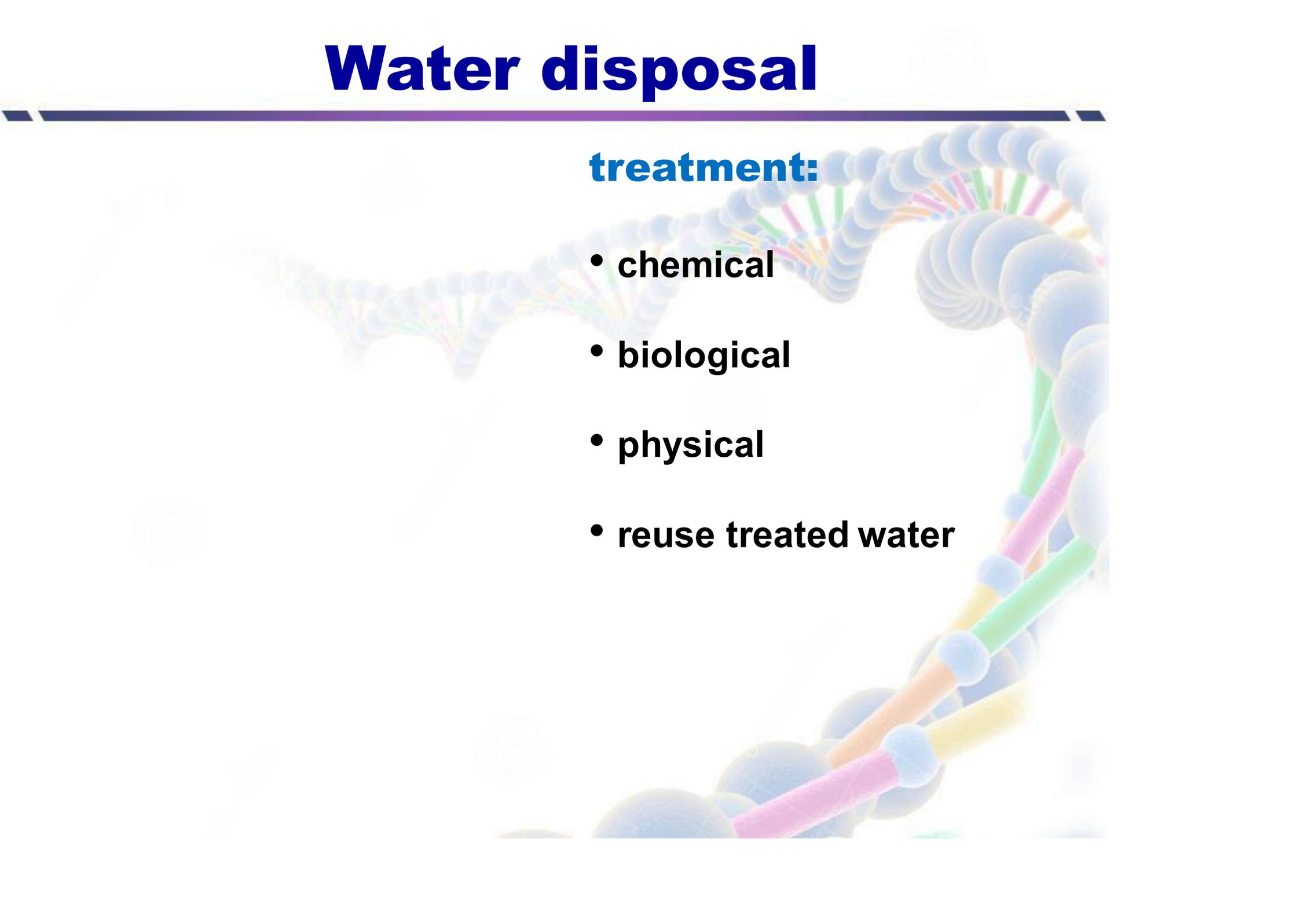
- **domestic**
- **agriculture**
- **commercial**
- **industrial**
- **storm water**
- **run off water**

Water disposal

Constituents:

- pathogens
- non-pathogens
- organic/soluble
organic/inorganic
particles
- animals
- gases/emulsion/toxin

Water disposal



treatment:

- **chemical**
- **biological**
- **physical**
- **reuse treated water**

Biosafety



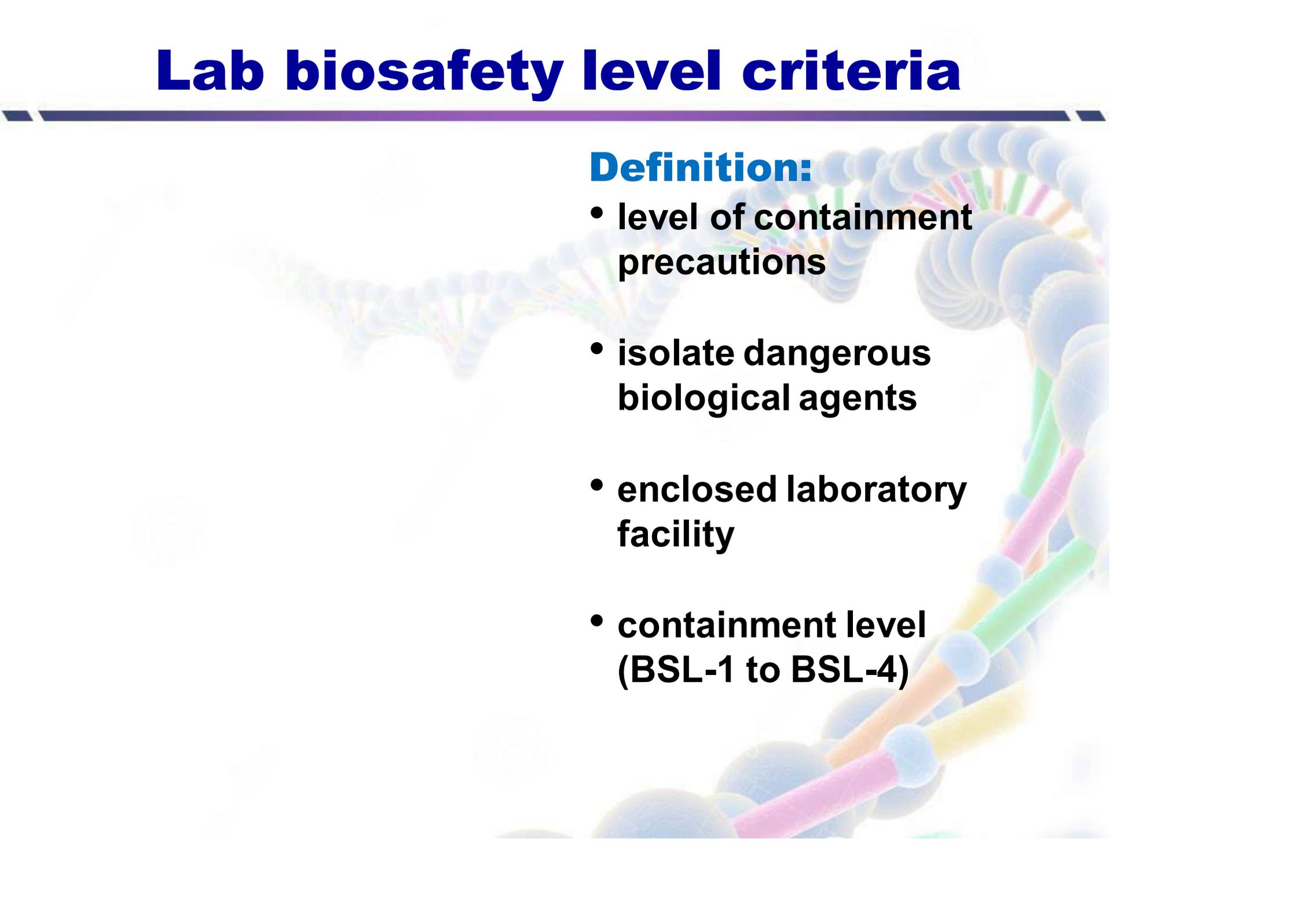
Lesson # 82

Biosafety



**Lab biosafety
level criteria**

Lab biosafety level criteria



Definition:

- level of containment precautions
- isolate dangerous biological agents
- enclosed laboratory facility
- containment level (BSL-1 to BSL-4)

Lab biosafety level criteria



History:

- USA- CDC/European union-directives
- biosafety cabinet, 1943—Hubert
- biological warfare labs ----- 1955
- American Biological Safety Association -- 1984

Lab biosafety level criteria

Containment zone:

- only be a chemical fume hood
- isolation of microorganisms
- building systems, sealed rooms, sealed containers and personnel suits

Lab biosafety level criteria

Procedures:

- entering the room
- decontamination procedures for leaving the room
- high security
- “hot zone”

Biosafety



Lesson # 83

3/1/2018

Amaan Khan

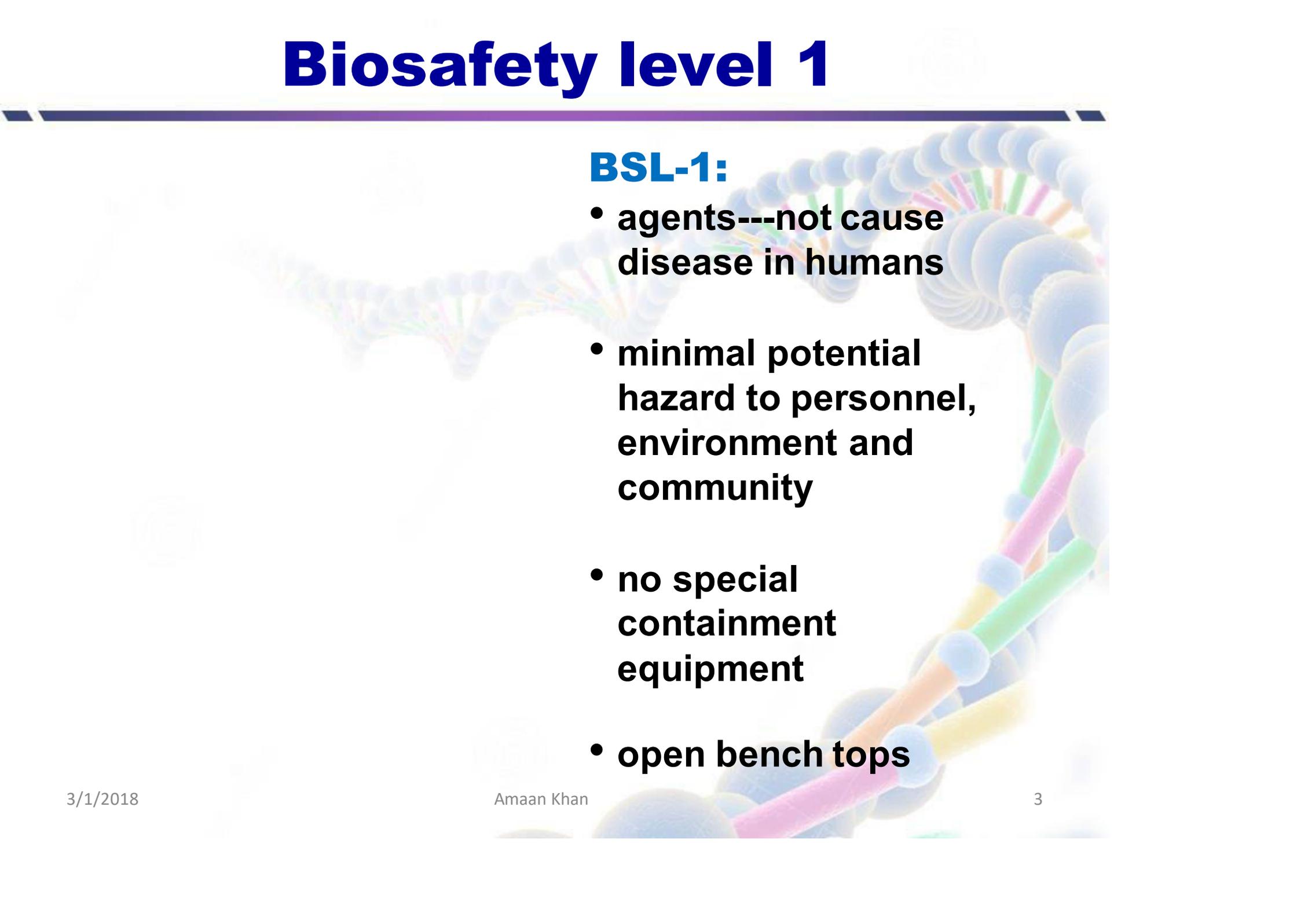
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Biosafety



Biosafety level 1

Biosafety level 1



BSL-1:

- **agents---not cause disease in humans**
- **minimal potential hazard to personnel, environment and community**
- **no special containment equipment**
- **open bench tops**

Biosafety level 1

Microbiological practices:

- workers must be trained
- supervisor enforce institutional policies
- workers must wash their hands
- eating, drinking, smoking

Biosafety level 1

Microbiological practices:

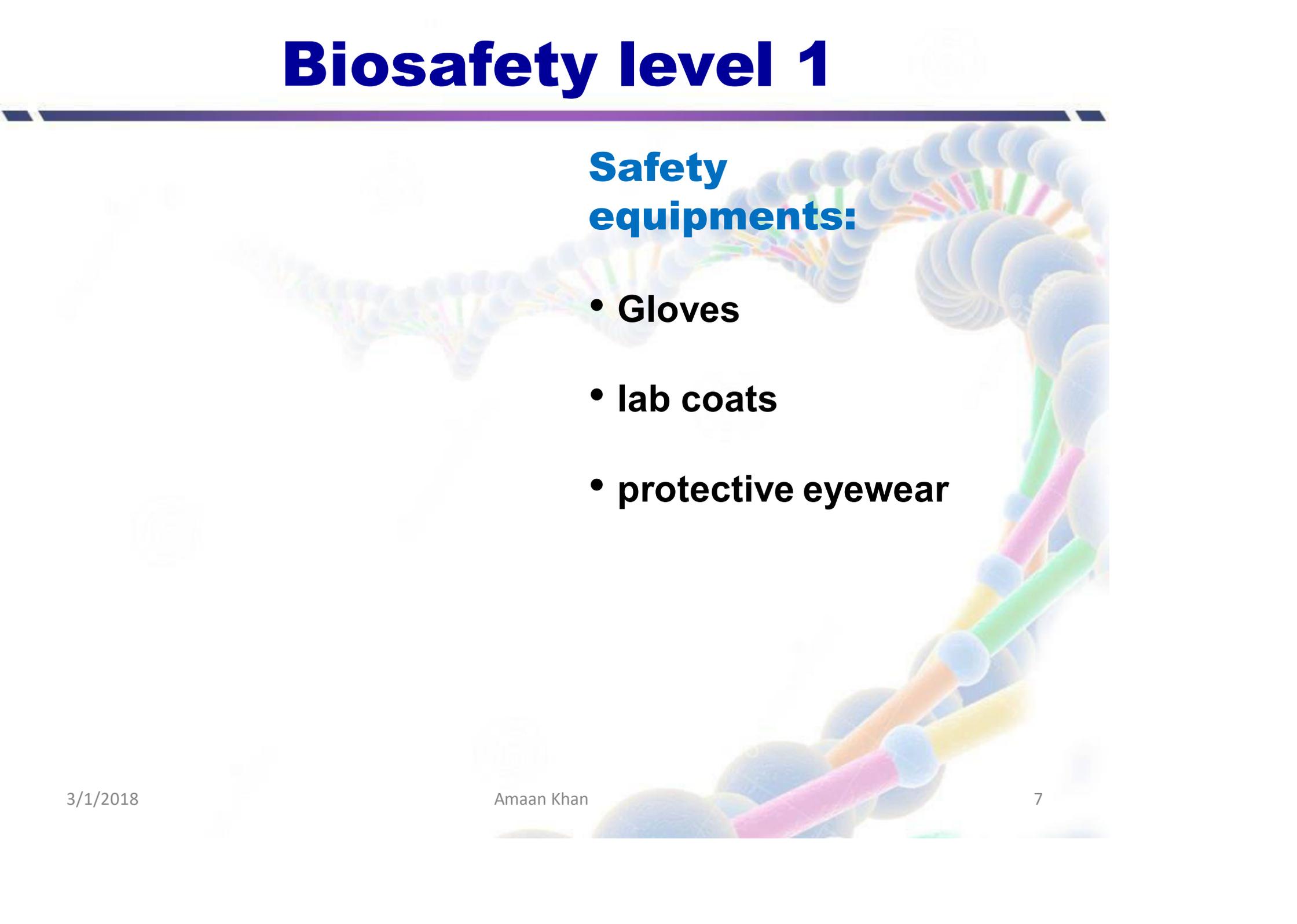
- mouth pipetting is prohibited
- policies for the safe handling of sharps
- procedures to minimize aerosols and splashes
- decontaminate work places

Biosafety level 1

Microbiological practices:

- decontaminate cultures
- biohazard symbol
- pest management programs
- special practices not required

Biosafety level 1



Safety equipments:

- **Gloves**
- **lab coats**
- **protective eyewear**

Biosafety level 1

Laboratory facilities:

- doors for access controls
- sink for hand washing
- bench tops-resistant
- chairs-easy to disinfect
- lab windows fitted with screens

Biosafety



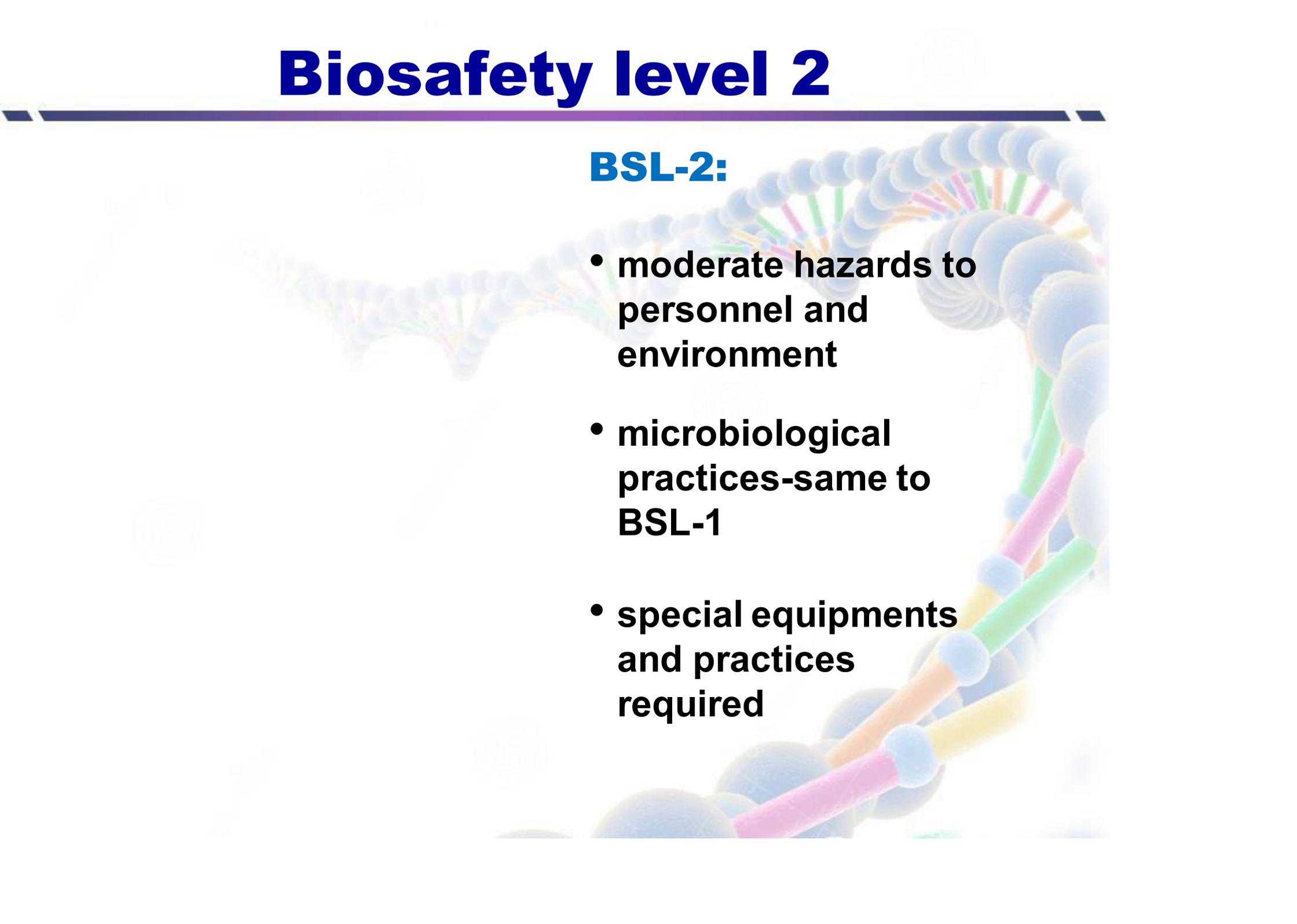
Lesson # 84

Biosafety



**Biosafety level
2**

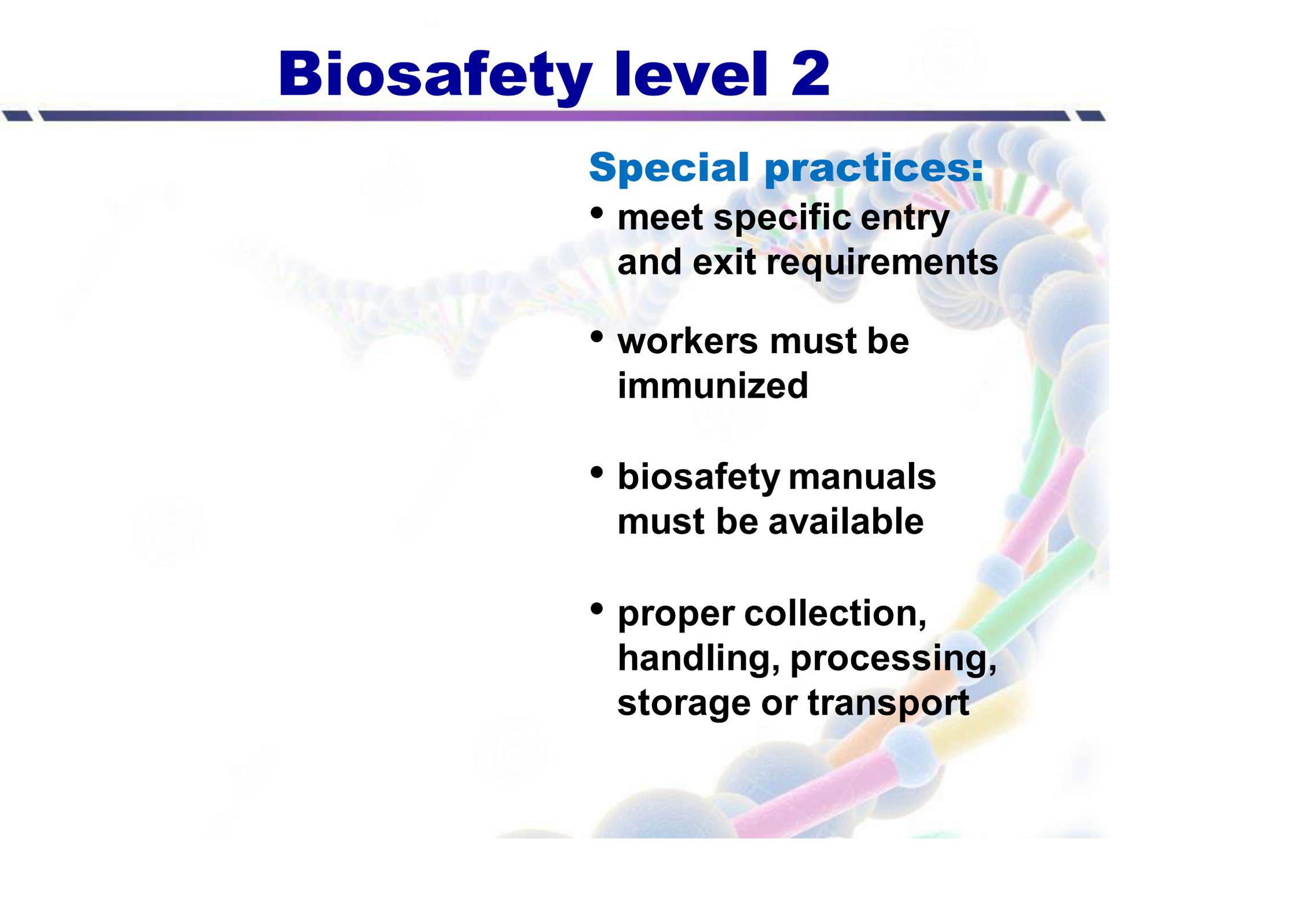
Biosafety level 2



BSL-2:

- moderate hazards to personnel and environment
- microbiological practices-same to BSL-1
- special equipments and practices required

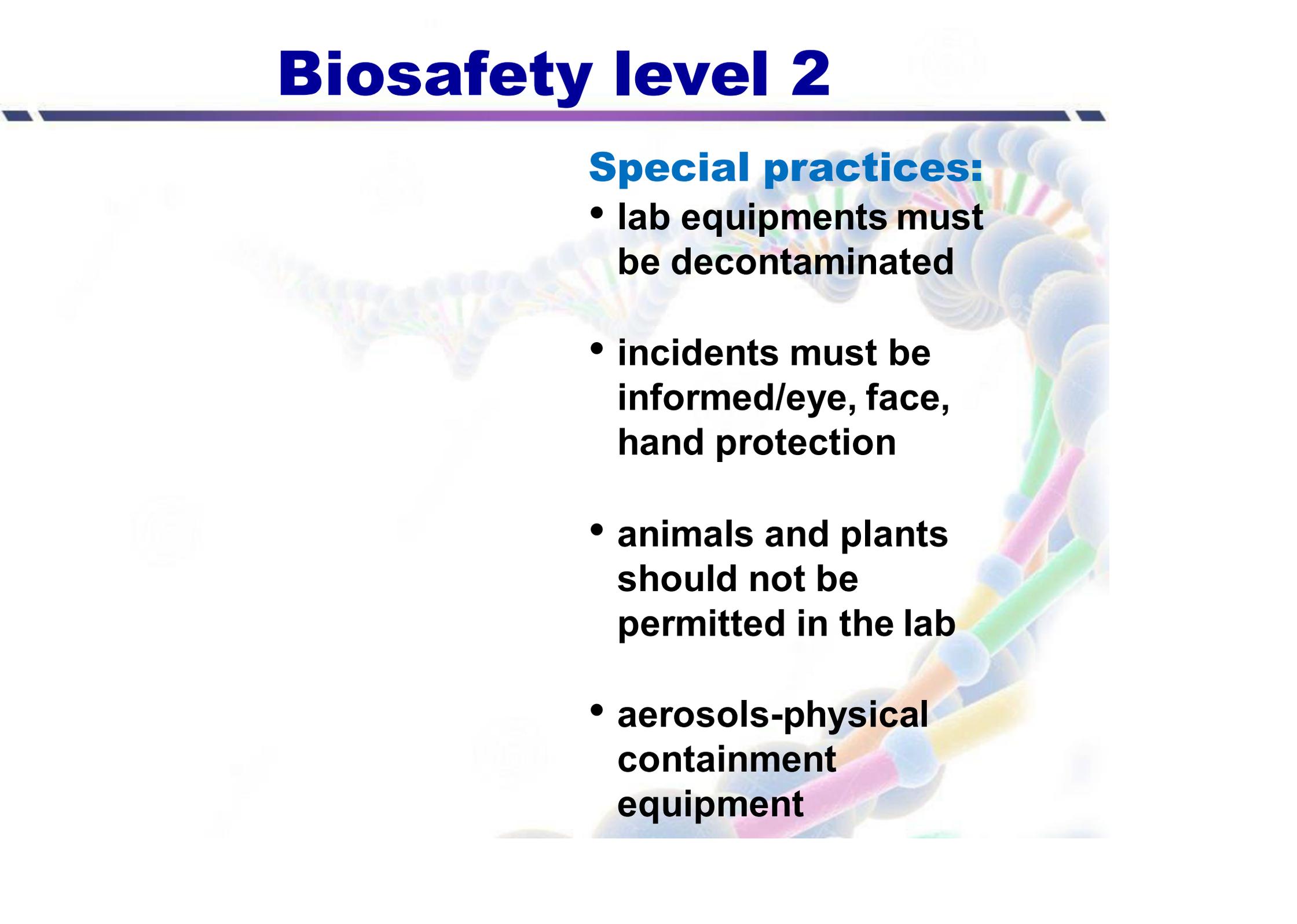
Biosafety level 2



Special practices:

- **meet specific entry and exit requirements**
- **workers must be immunized**
- **biosafety manuals must be available**
- **proper collection, handling, processing, storage or transport**

Biosafety level 2



Special practices:

- lab equipments must be decontaminated
- incidents must be informed/eye, face, hand protection
- animals and plants should not be permitted in the lab
- aerosols-physical containment equipment

Biosafety



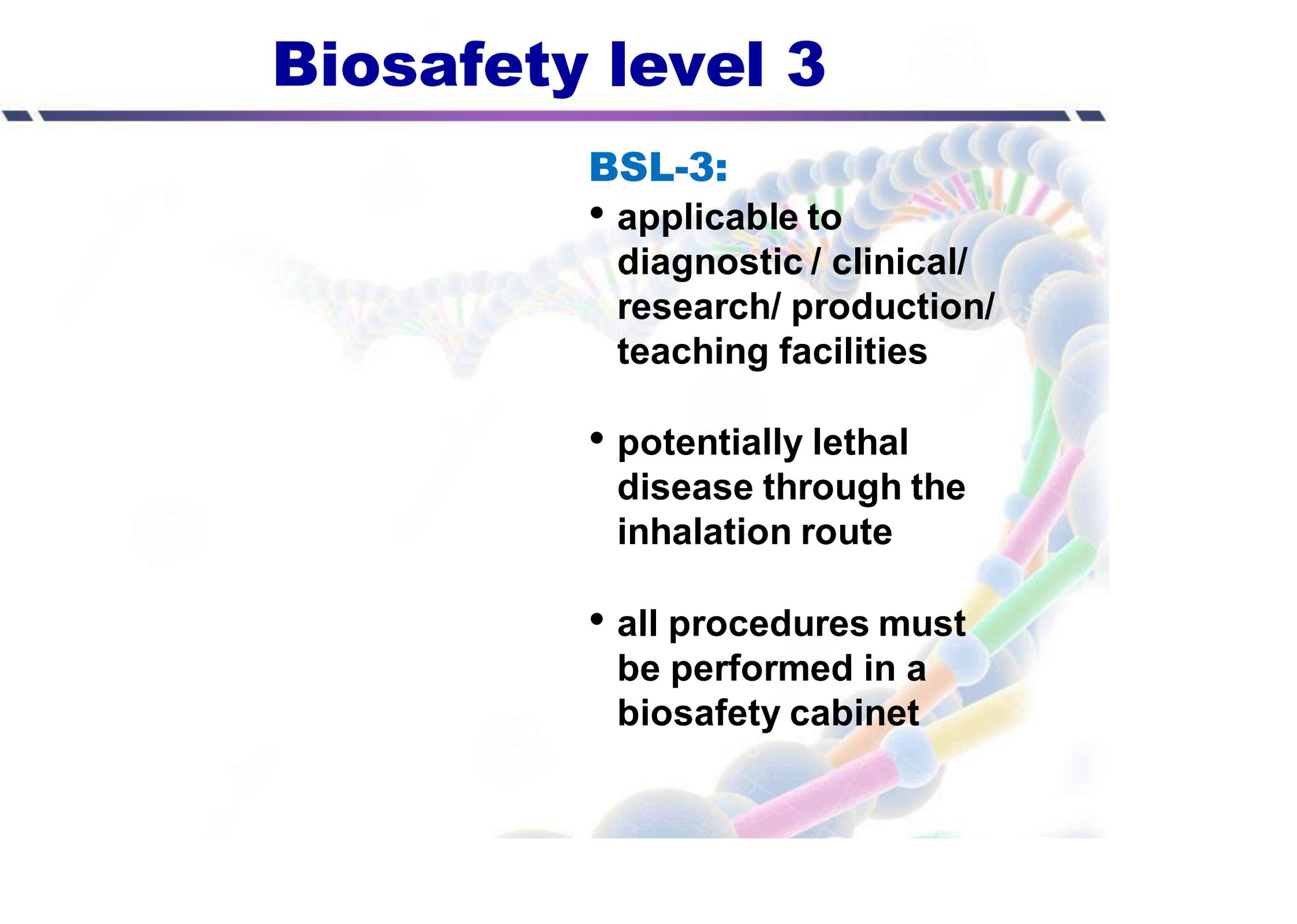
Lesson # 85

Biosafety

**Biosafety level
3**



Biosafety level 3



BSL-3:

- **applicable to diagnostic / clinical/ research/ production/ teaching facilities**
- **potentially lethal disease through the inhalation route**
- **all procedures must be performed in a biosafety cabinet**

Biosafety level 3

Equipments:

- vacuum lines must be protected with HEPA filters
- ducted air ventilation system
- HEPA filter exhaust air
- BSL-3 facility design, operational/parameter/procedures must be documented

Biosafety



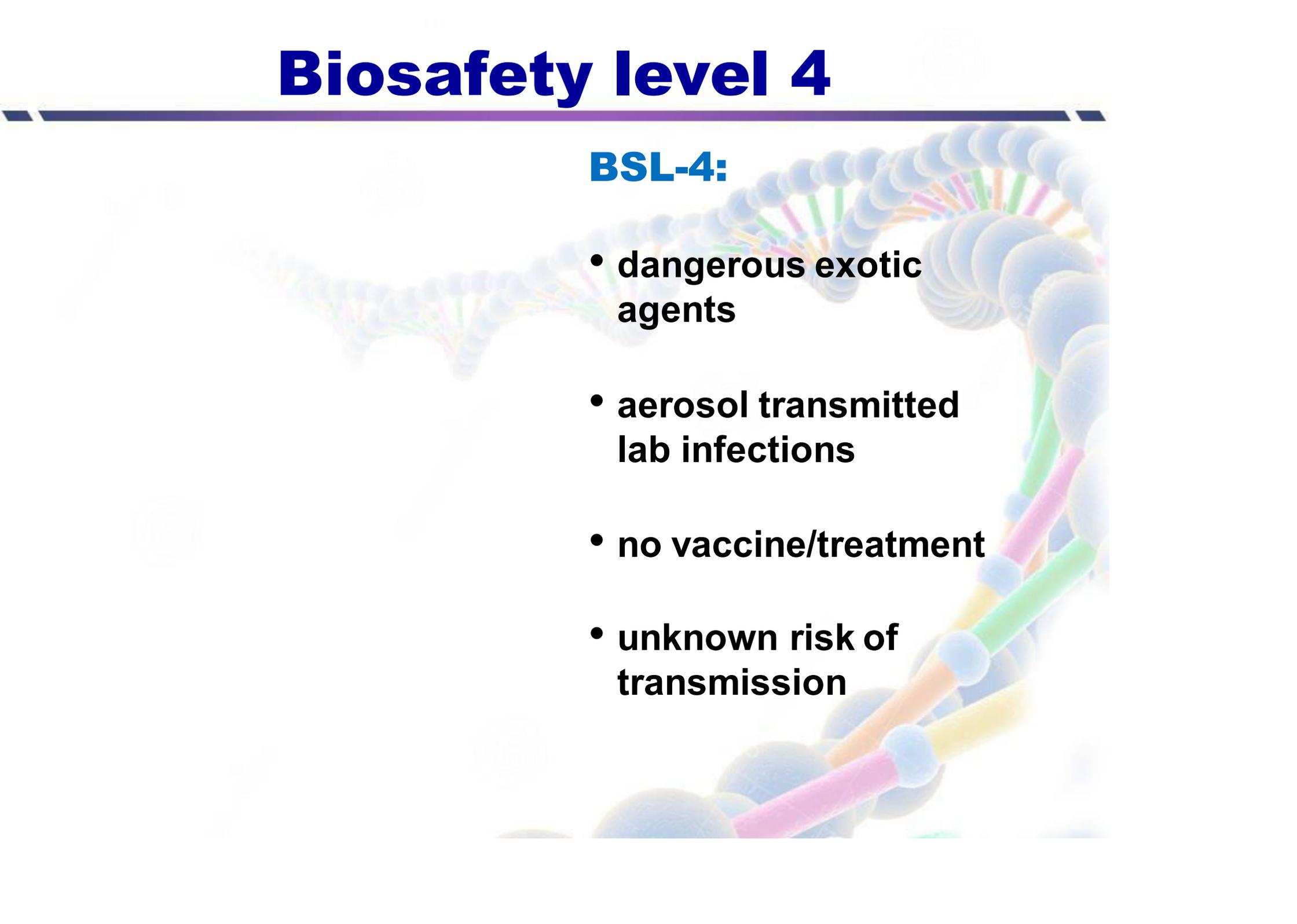
Lesson # 86

Biosafety



**Biosafety level
4**

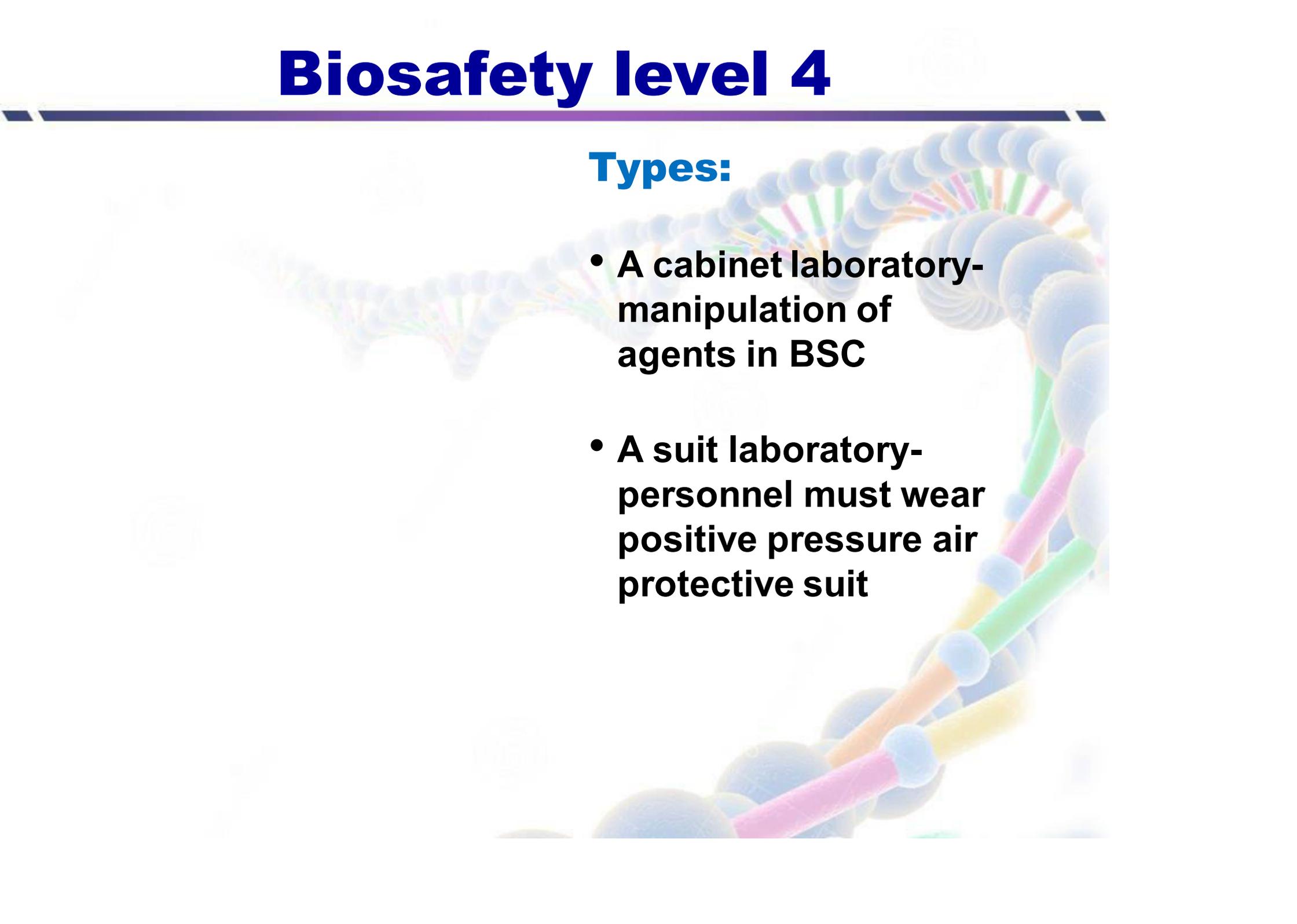
Biosafety level 4



BSL-4:

- **dangerous exotic agents**
- **aerosol transmitted lab infections**
- **no vaccine/treatment**
- **unknown risk of transmission**

Biosafety level 4



Types:

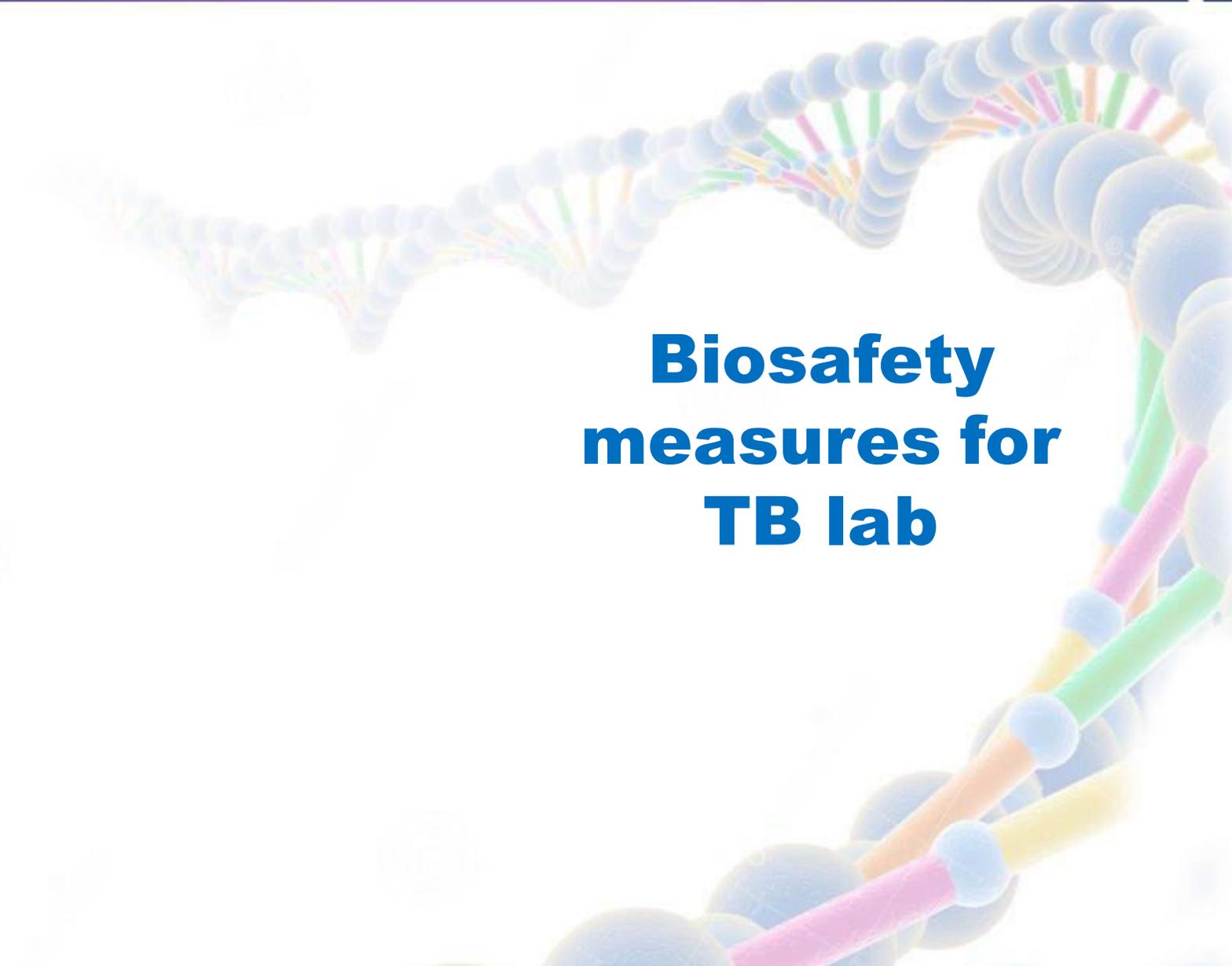
- A cabinet laboratory-
manipulation of
agents in BSC
- A suit laboratory-
personnel must wear
positive pressure air
protective suit

Biosafety



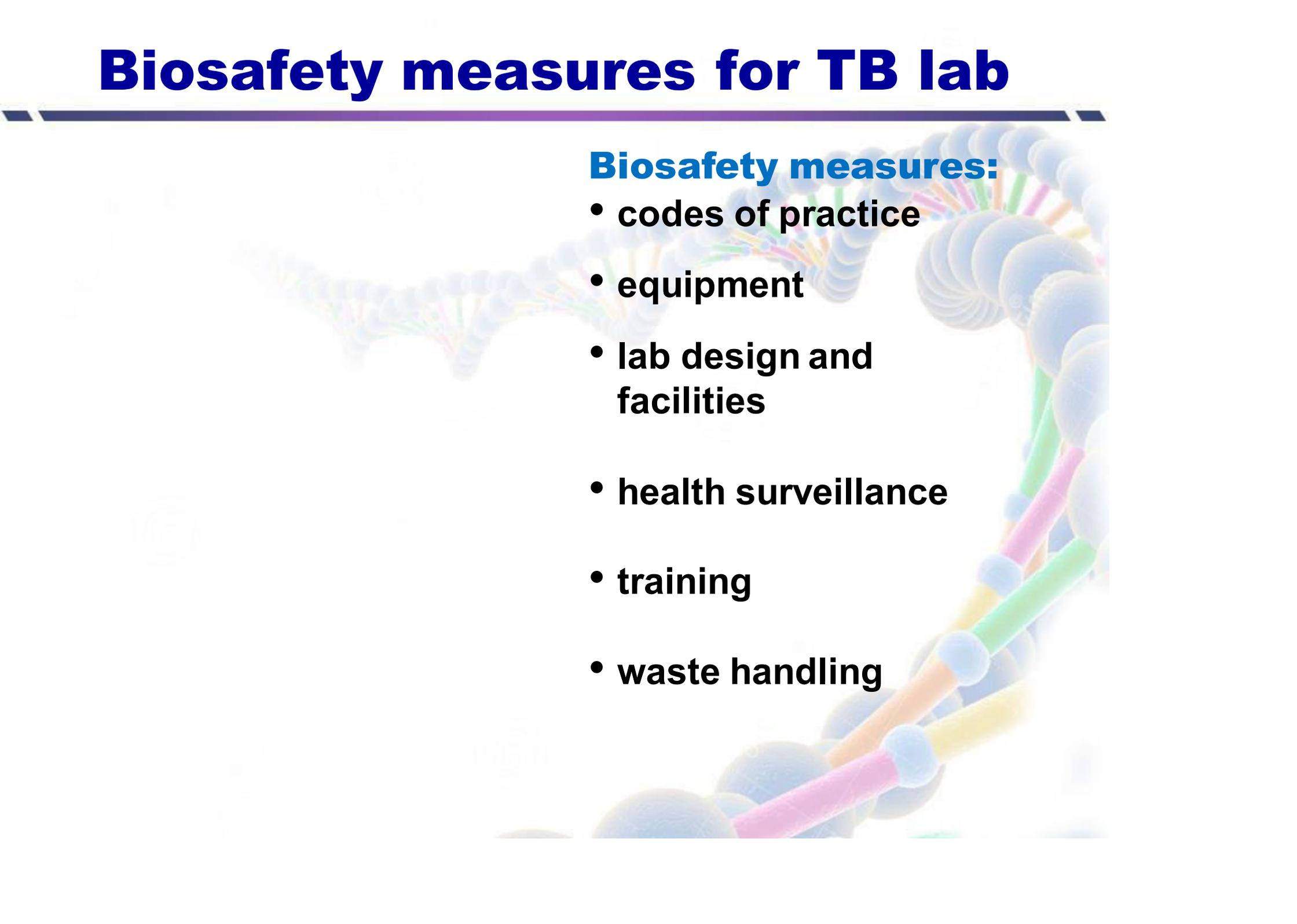
Lesson # 87

Biosafety



**Biosafety
measures for
TB lab**

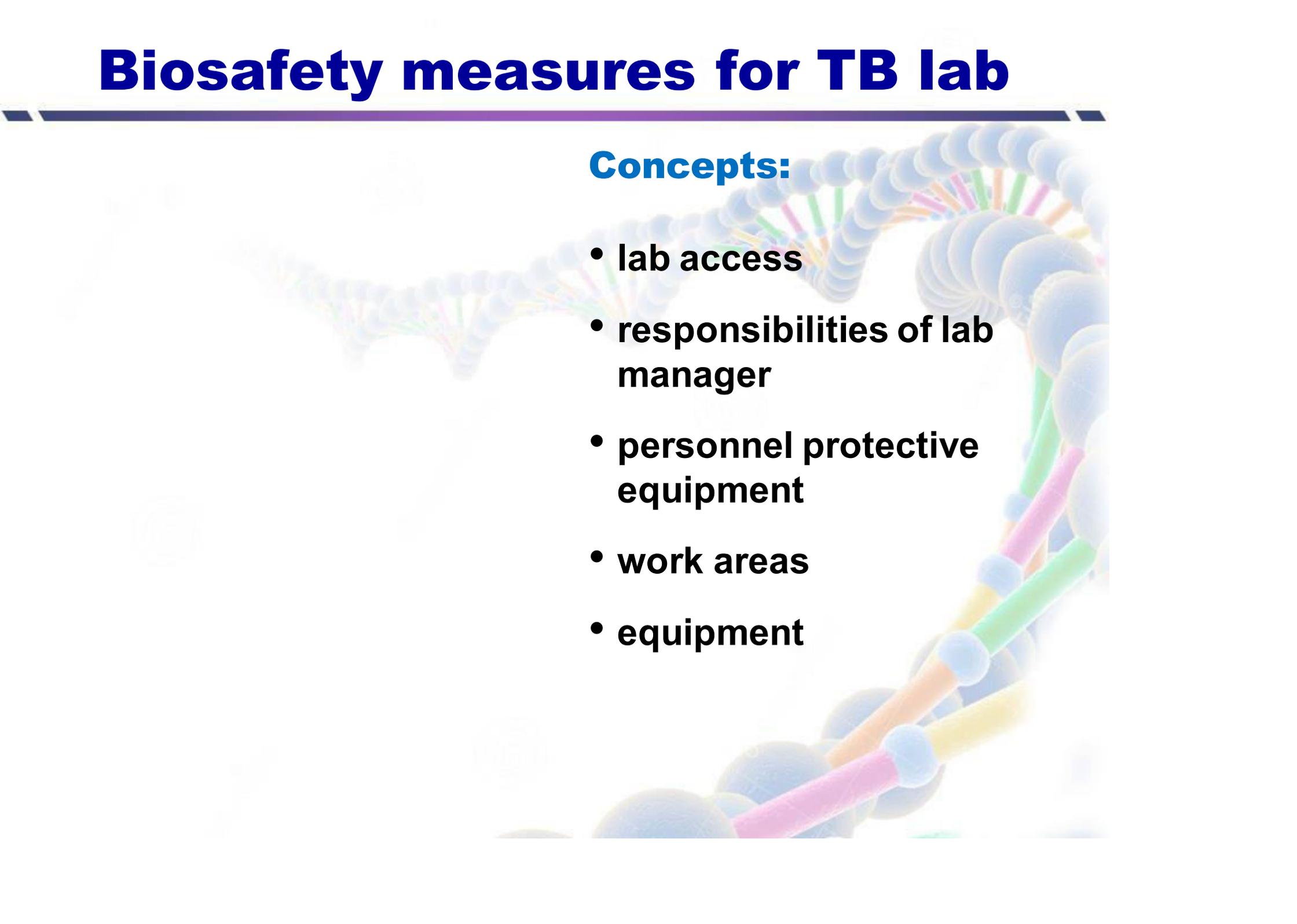
Biosafety measures for TB lab



Biosafety measures:

- codes of practice
- equipment
- lab design and facilities
- health surveillance
- training
- waste handling

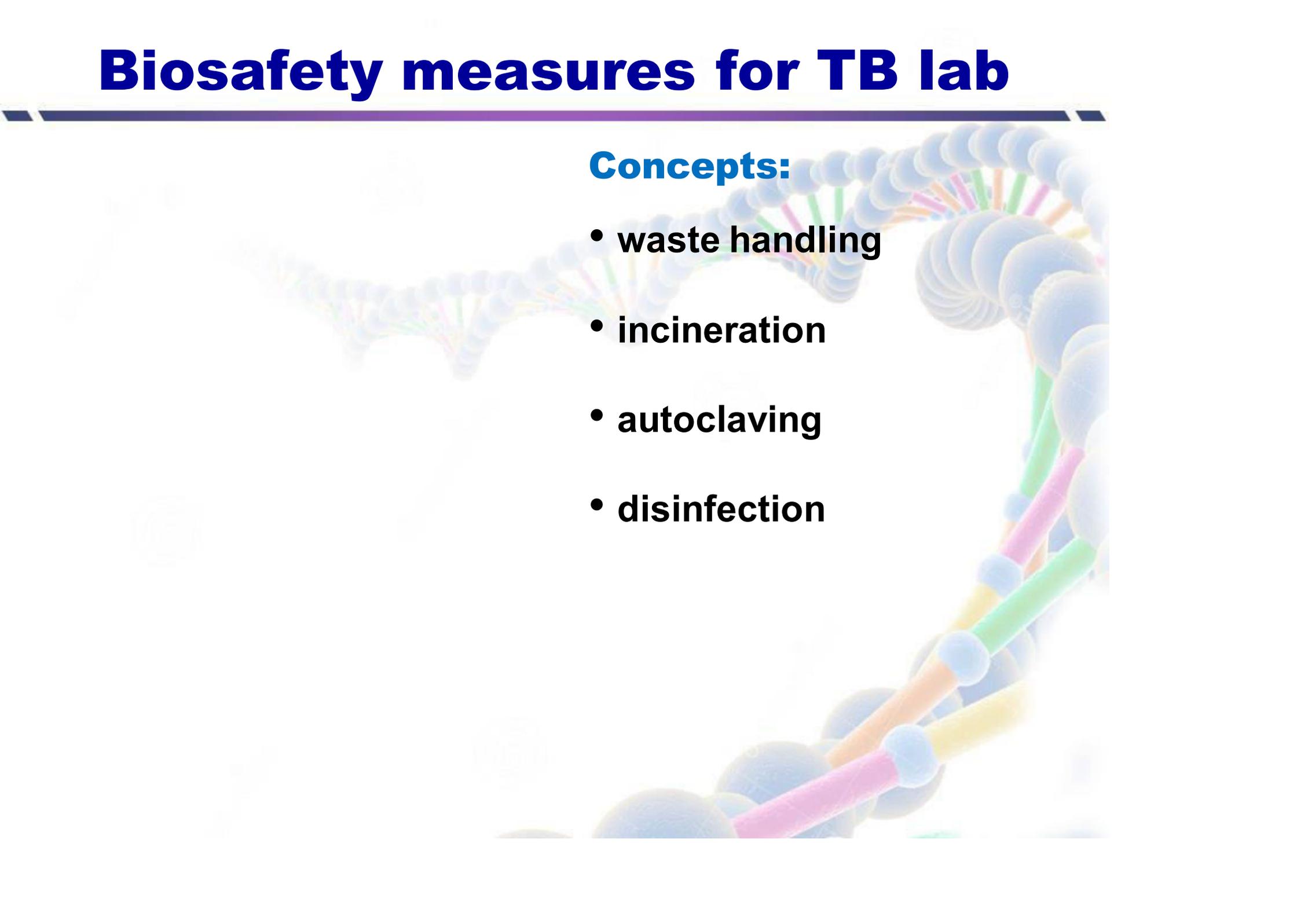
Biosafety measures for TB lab



Concepts:

- lab access
- responsibilities of lab manager
- personnel protective equipment
- work areas
- equipment

Biosafety measures for TB lab



Concepts:

- waste handling
- incineration
- autoclaving
- disinfection

Biosafety



Lesson # 88

Biosafety



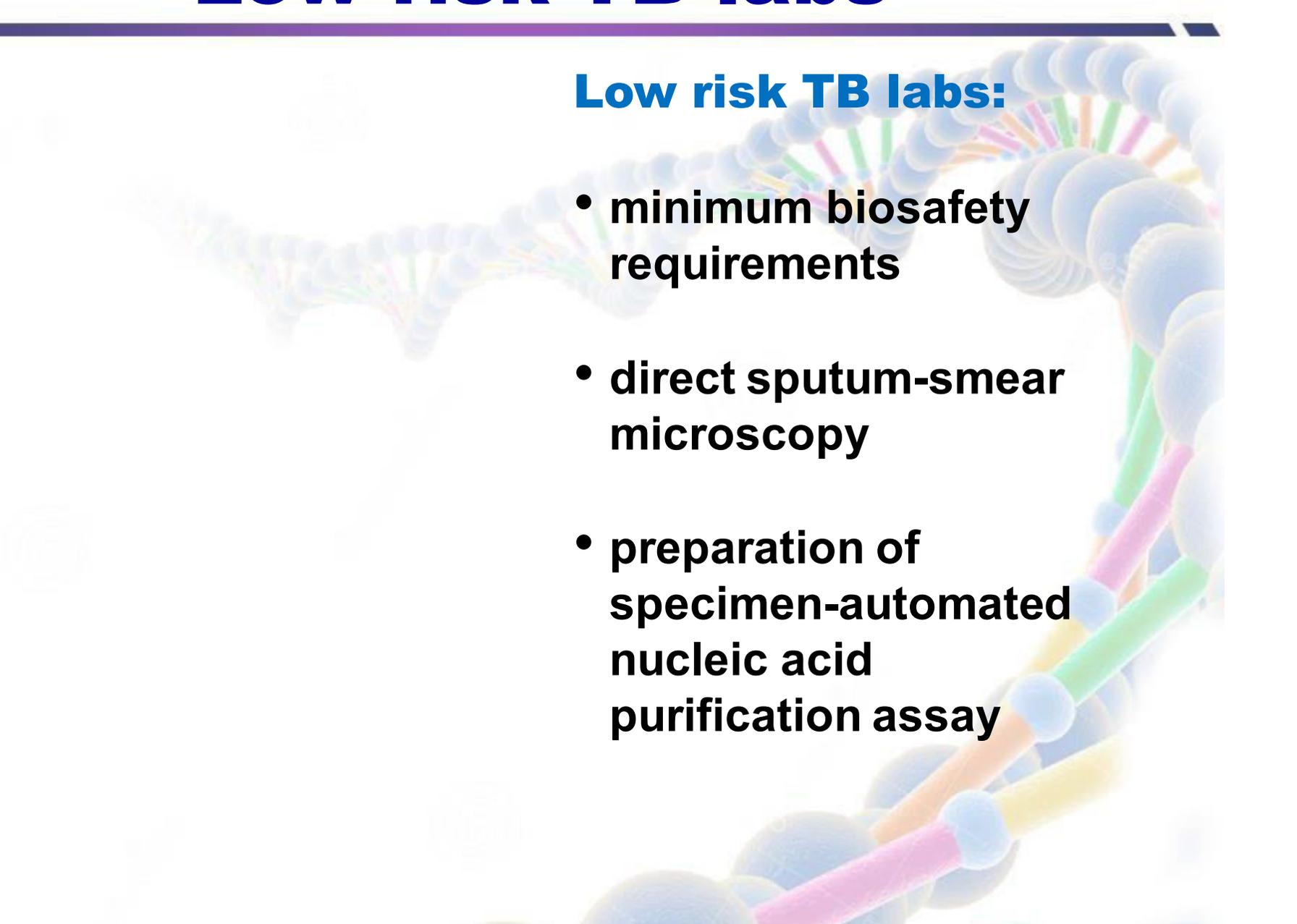
**Low risk TB
labs**

Low risk TB labs

Classification:

- aerosol generated----
level of risk measured
- low risk TB labs
- moderate risk TB labs
- high risk TB labs

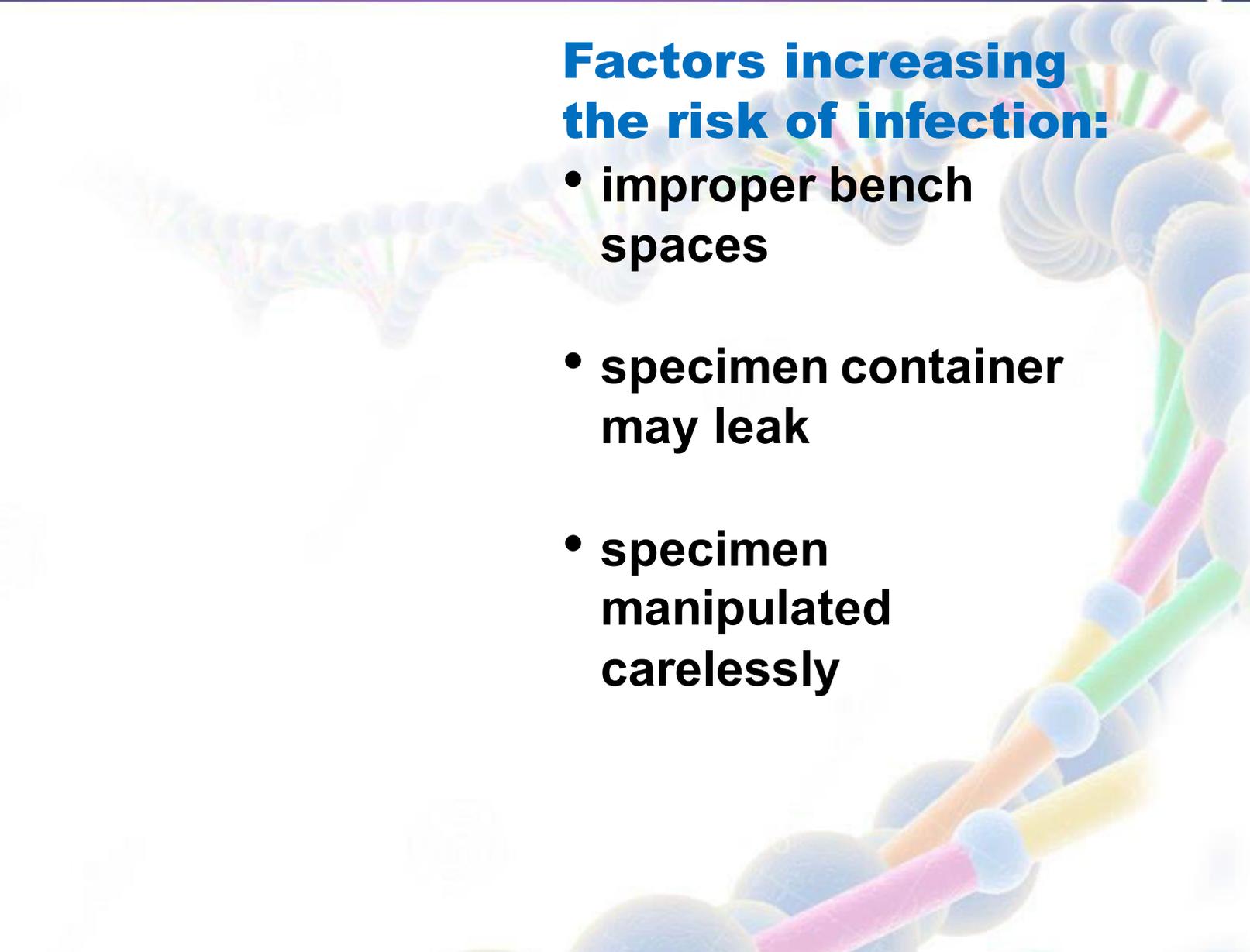
Low risk TB labs



Low risk TB labs:

- **minimum biosafety requirements**
- **direct sputum-smear microscopy**
- **preparation of specimen-automated nucleic acid purification assay**

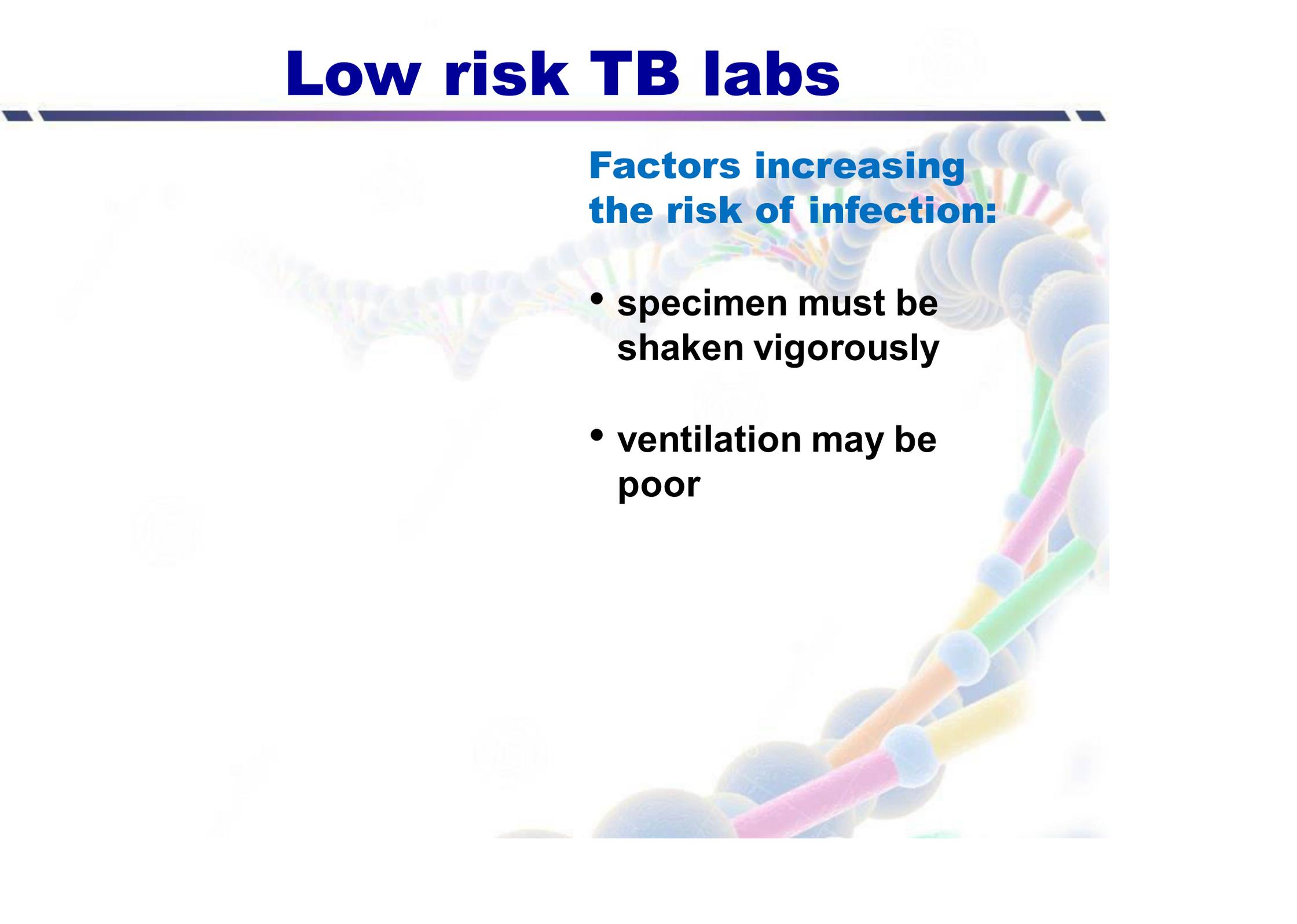
Low risk TB labs



Factors increasing the risk of infection:

- improper bench spaces
- specimen container may leak
- specimen manipulated carelessly

Low risk TB labs



Factors increasing the risk of infection:

- specimen must be shaken vigorously
- ventilation may be poor

Biosafety



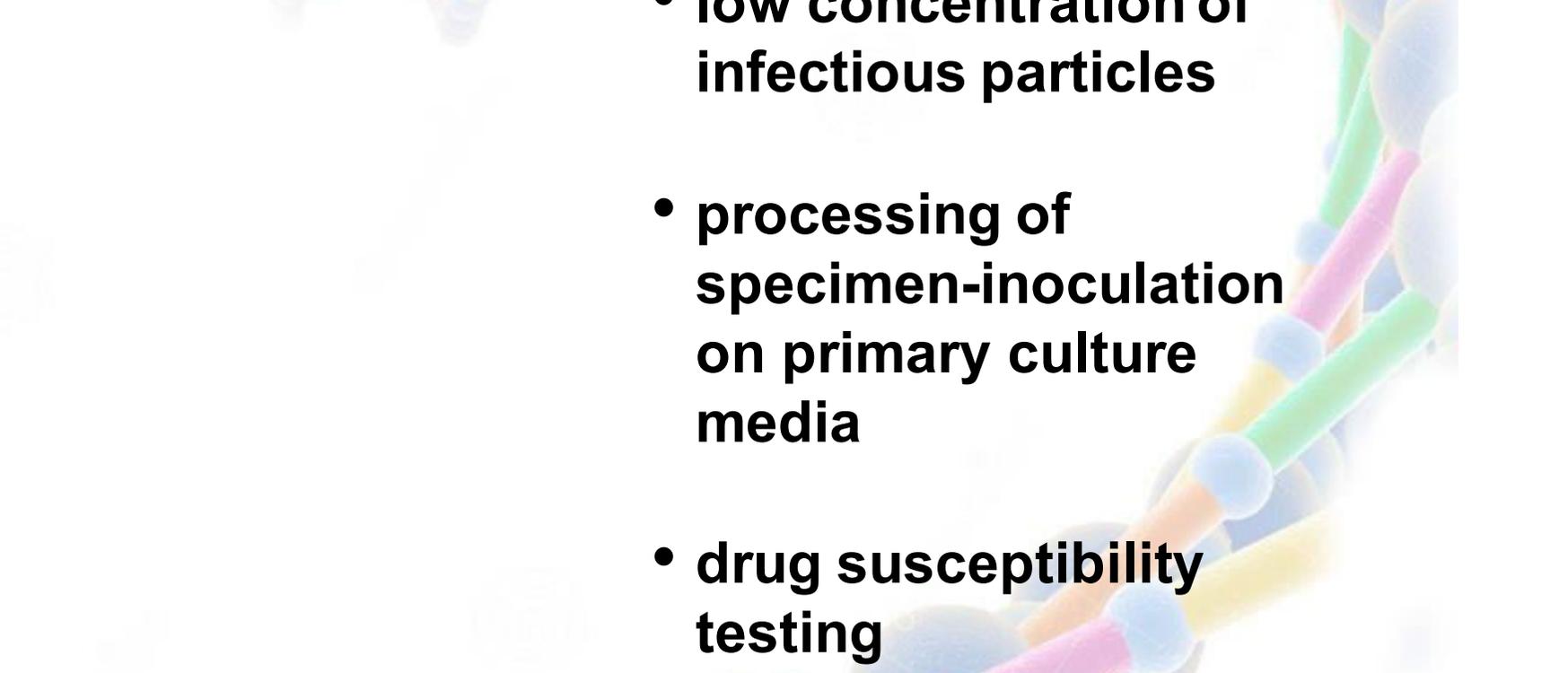
Lesson # 89

Biosafety



**Moderate risk
TB labs**

Moderate risk TB labs



Risk:

- moderate risk of generating aerosols
- low concentration of infectious particles
- processing of specimen-inoculation on primary culture media
- drug susceptibility testing

Moderate risk TB labs

Factors that increase the risk:

- work in areas with poor ventilation
- work with poor illumination
- BSC not maintained
- HEPA filters may be blocked

Moderate risk TB labs

Factors:

- **careless manipulation of specimens**
- **vortex should not be used**
- **specimen container may break**
- **cooling or heating system-not work properly**

Moderate risk TB labs

Factors:

- opening centrifuge bucket outside the BSC
- information of biohazards may be inadequate

Biosafety



Lesson # 90

Biosafety



**High risk TB
labs**

High risk TB labs



Risk:

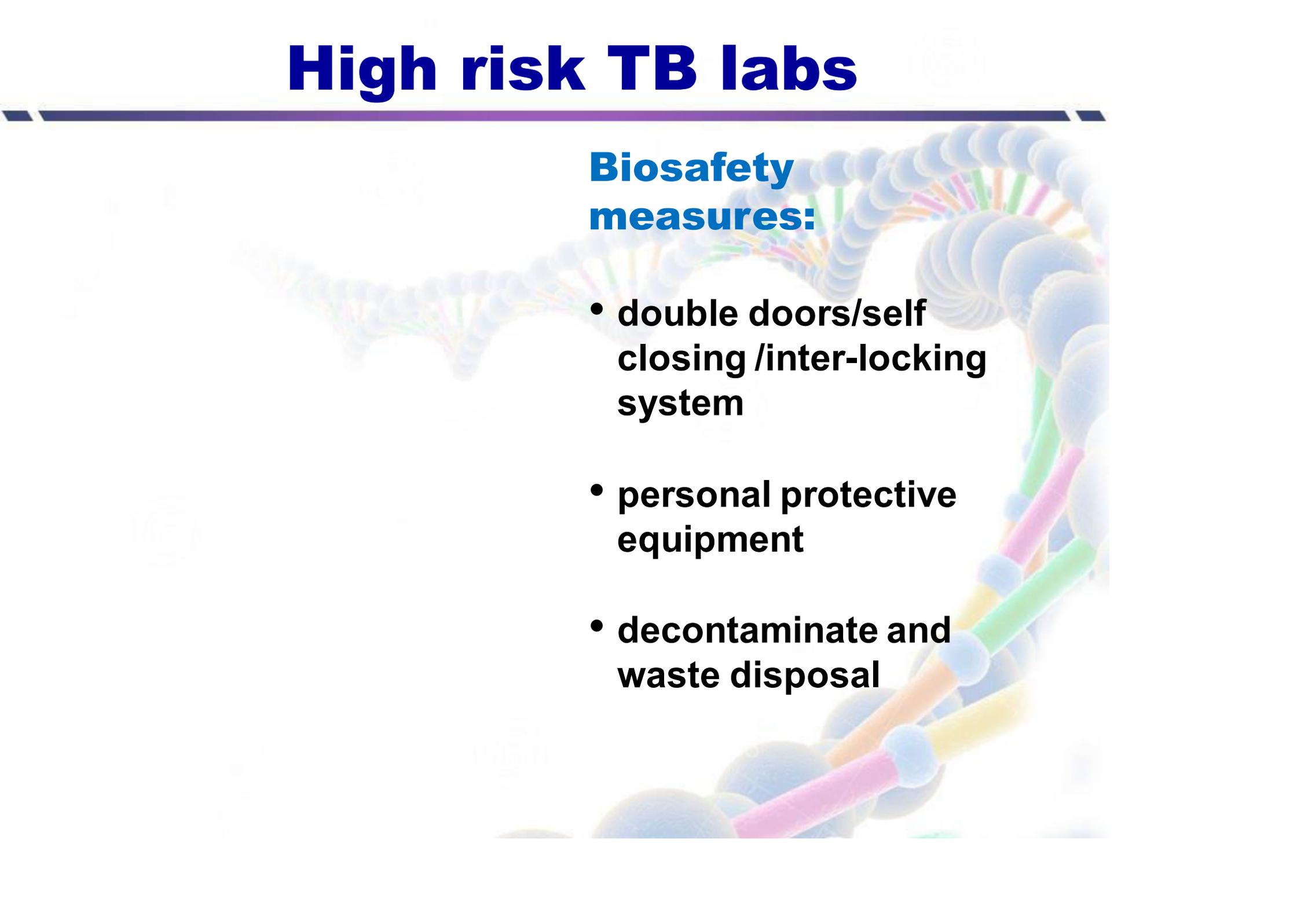
- **work with high concentrations of bacilli**
- **engage in procedures that pose increase risk of aerosol spread**
- **manipulate cultures for identification**
- **manipulate cultures and suspensions for DST**

High risk TB labs

Factors:

- staff-open positive culture vials
- prepare smears from positive cultures
- DNA extraction-performed
- broken culture containers/spills

High risk TB labs



Biosafety measures:

- double doors/self closing /inter-locking system
- personal protective equipment
- decontaminate and waste disposal

Biosafety



Lesson # 91

Biosafety



**Safety
equipment**

Safety equipment

Biological safety cabinets:

- Class I, II, III BSC
- air intake velocity
- amount of air circulated
- exhaust system
- pressure system

Safety equipment

Negative pressure flexible-film isolators:

- **mounted on a mobile stand----- field work**
- **high risk microbes**
- **workspace enclosed in PVC envelope**
- **internal pressure lower-atmospheric pressure/HEPA filters**

Safety equipment

others:

- pipetting aids
- spatter shield
- disposable loops
- autoclave
- screw-capped bottles

Safety equipment

Microincinerators:

- shielded in an open ended glass or ceramic tubes
- heated by gas or electricity
- disposable

Safety equipment

Vaccum line protection:

- filters prevent the passage of microbes
- flask contain the disinfectants
- rubber bulb-prevent overflow-close off vaccum
- unit - autoclavable

Biosafety



Lesson # 92

Biosafety



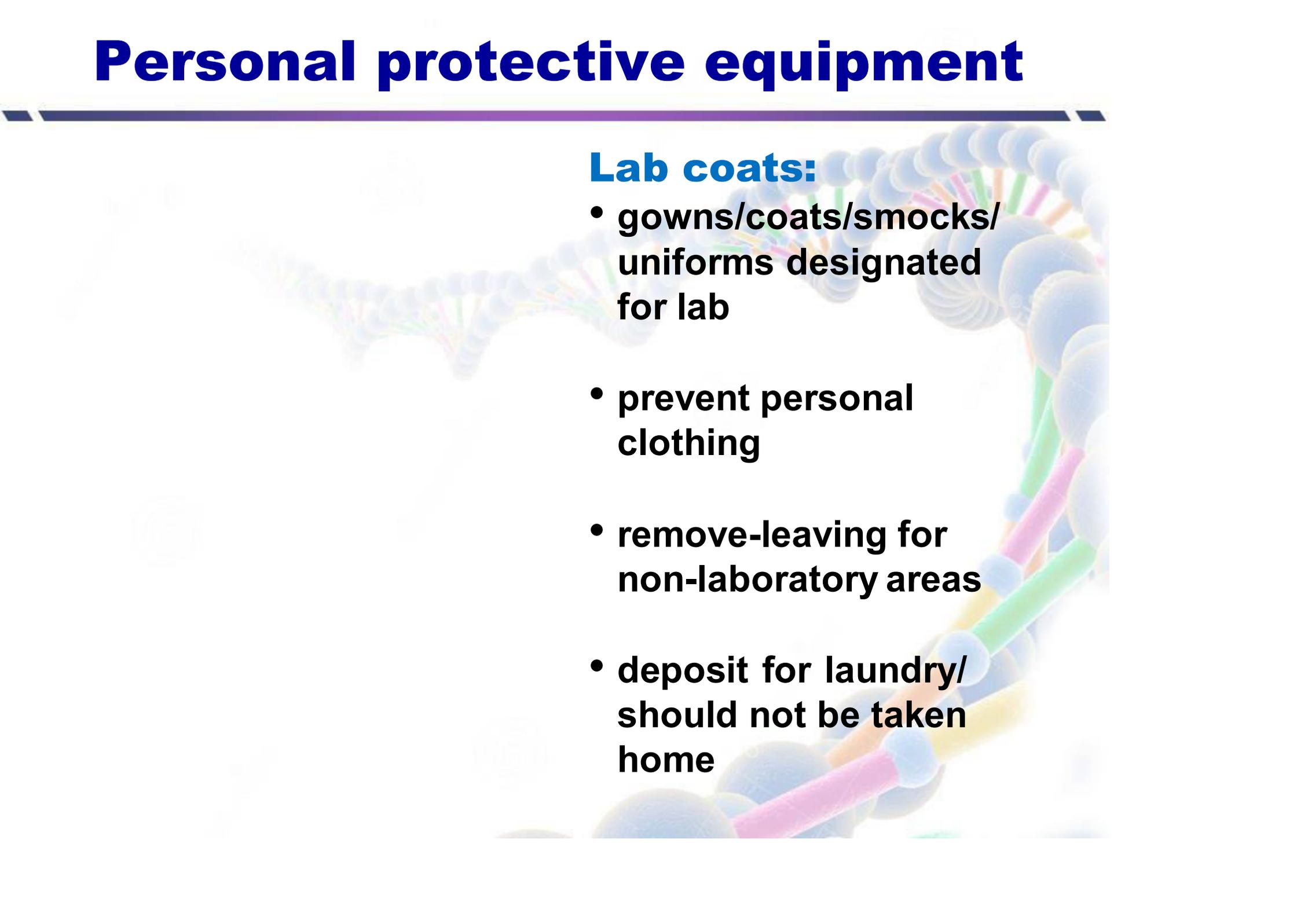
**Personal
protective
equipment**

Personal protective equipment

Gloves:

- to protect hands from hazardous materials
- glove selection---- risk assessment
- latex gloves-available
- wear outside-lab
- wear two pairs ----- required

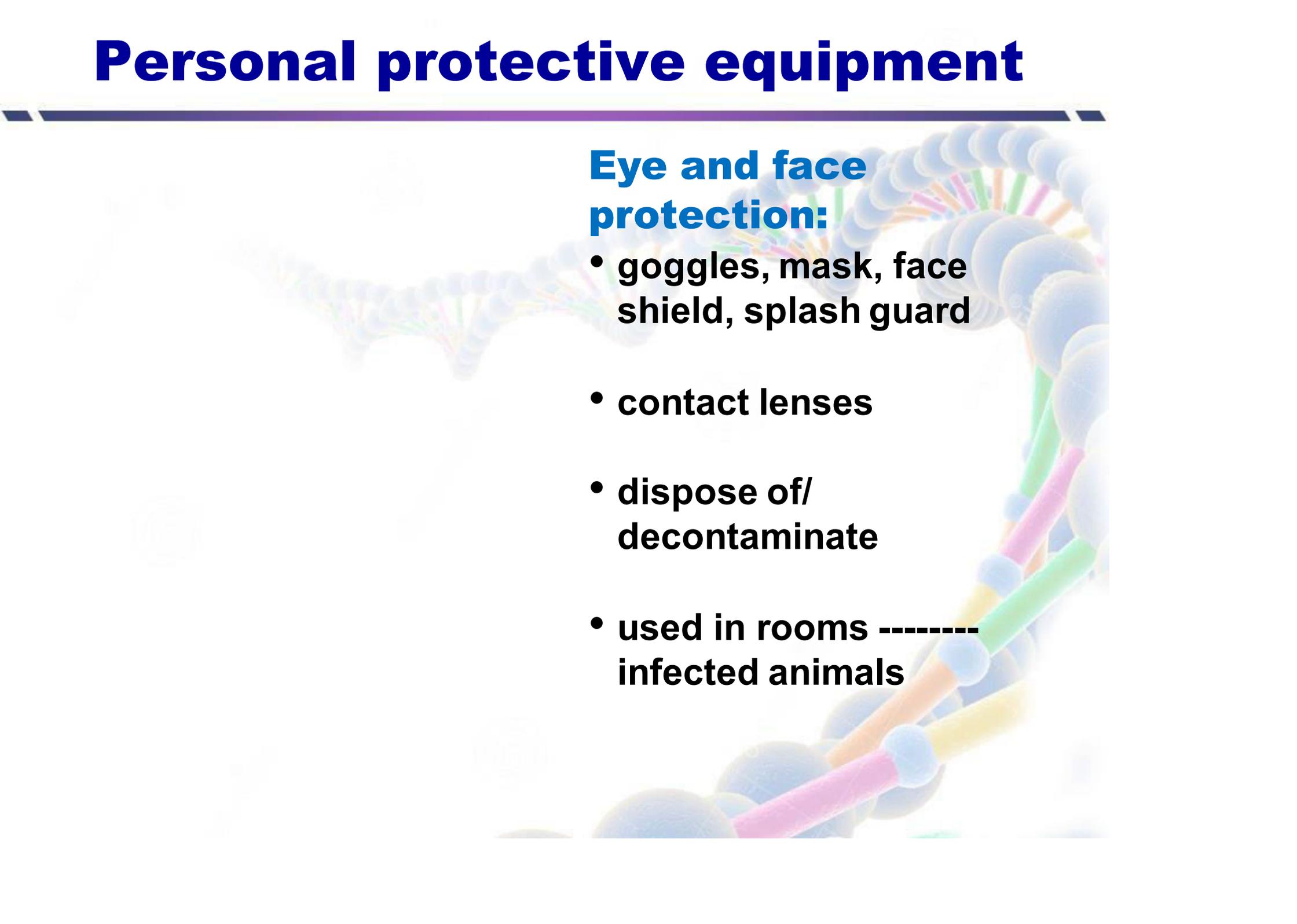
Personal protective equipment



Lab coats:

- gowns/coats/smocks/uniforms designated for lab
- prevent personal clothing
- remove-leaving for non-laboratory areas
- deposit for laundry/should not be taken home

Personal protective equipment



Eye and face protection:

- goggles, mask, face shield, splash guard
- contact lenses
- dispose of/
decontaminate
- used in rooms -----
infected animals

Personal protective equipment

Respirators:

- **inhalation of aerosols**
- **full/half face**
- **interchangeable filters**
- **shouldn't worn-
outside lab**
- **disposable-respirator**

Biosafety



Lesson # 93

Biosafety



**Plans for
emergency**

Plans for emergency

Puncture wounds, cuts and abrasion:

- **remove protective clothing**
- **wash hands and affected area**
- **apply skin disinfectant**
- **seek medical attention**

Plans for emergency

Ingestion of hazardous material:

- **identification of Ingested material**
- **circumstances of the incidence**
- **complete medical record**

Plans for emergency



Aerosol release:

- vacate the affected area/exposed person—
medical advise
- 1h aerosols carried away/heavier particles settle down
- no entry
- decontaminate-----
protective measures

Plans for emergency

Others:

- broken containers
- breakage of tubes in a centrifuge machine
- natural disasters

Plans for emergency

Emergency services:

- addresses/phone numbers
- emergency equipments
- first aid box

Biosafety



Lesson # 94

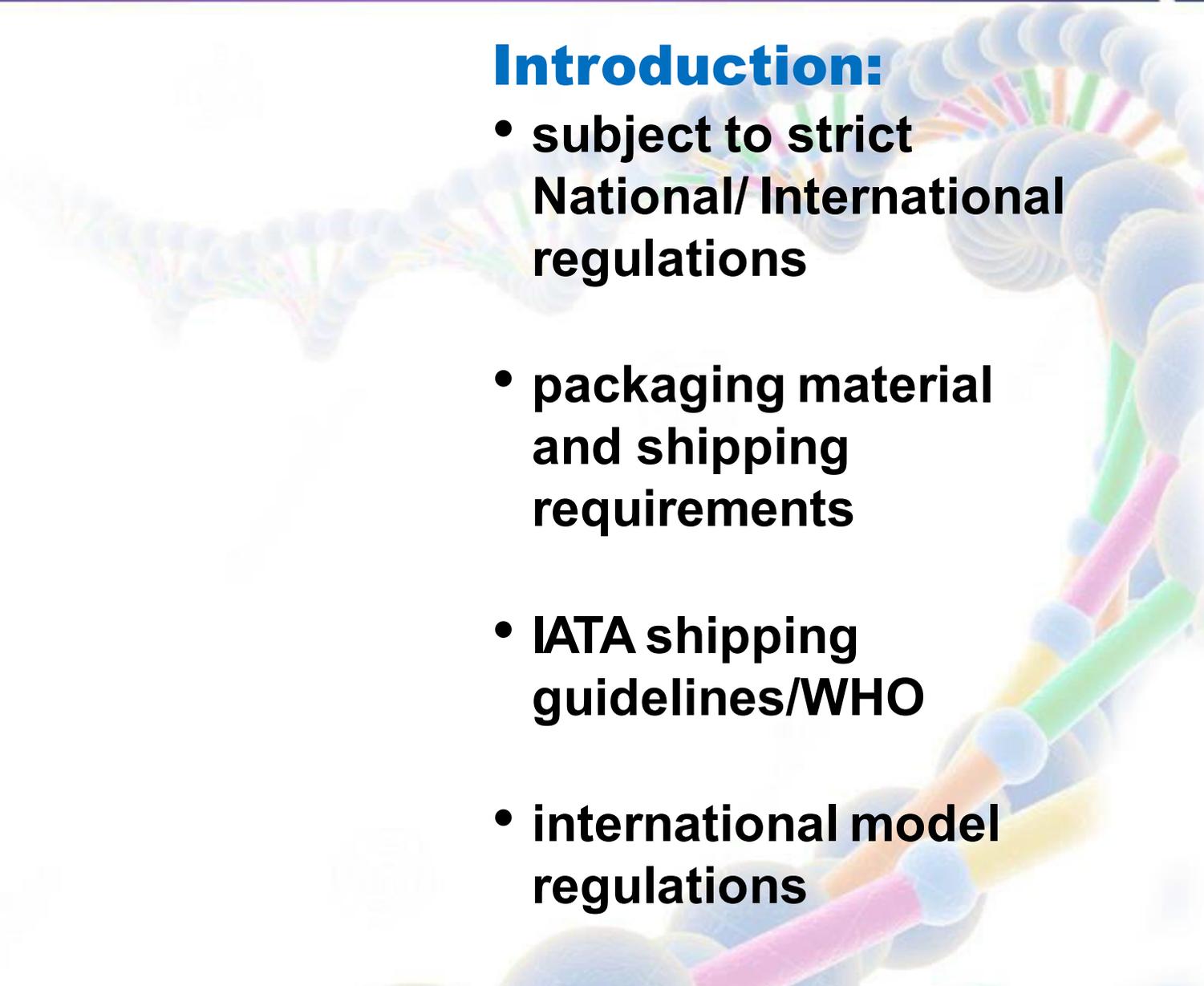
Biosafety



**Transport
of
infectious
material**

Transport of infectious material

Introduction:

- **subject to strict National/ International regulations**
 - **packaging material and shipping requirements**
 - **IATA shipping guidelines/WHO**
 - **international model regulations**
- 

Transport of infectious material

Packaging system:

- triple packaging system
- three layers: receptacle, leak proof packaging
- third layer protects second layer-physical damage while in transit

Transport of infectious material

Information:

- **specimen data form**
- **letters**
- **identify and describe specimen**
- **identify shipper and receiver**
- **any other documentation**

Biosafety



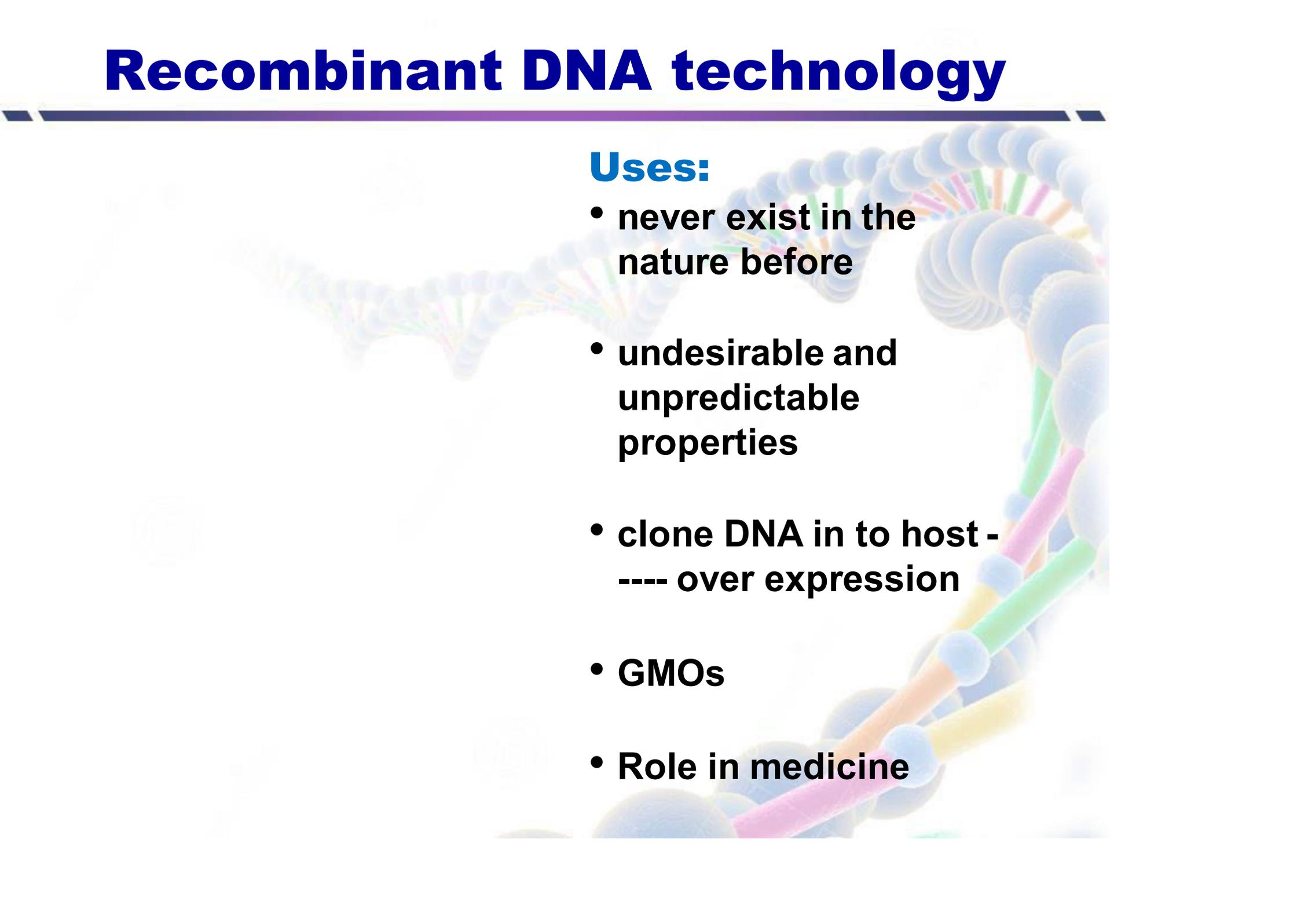
Lesson # 95

Biosafety



**Recombinant
DNA
technology**

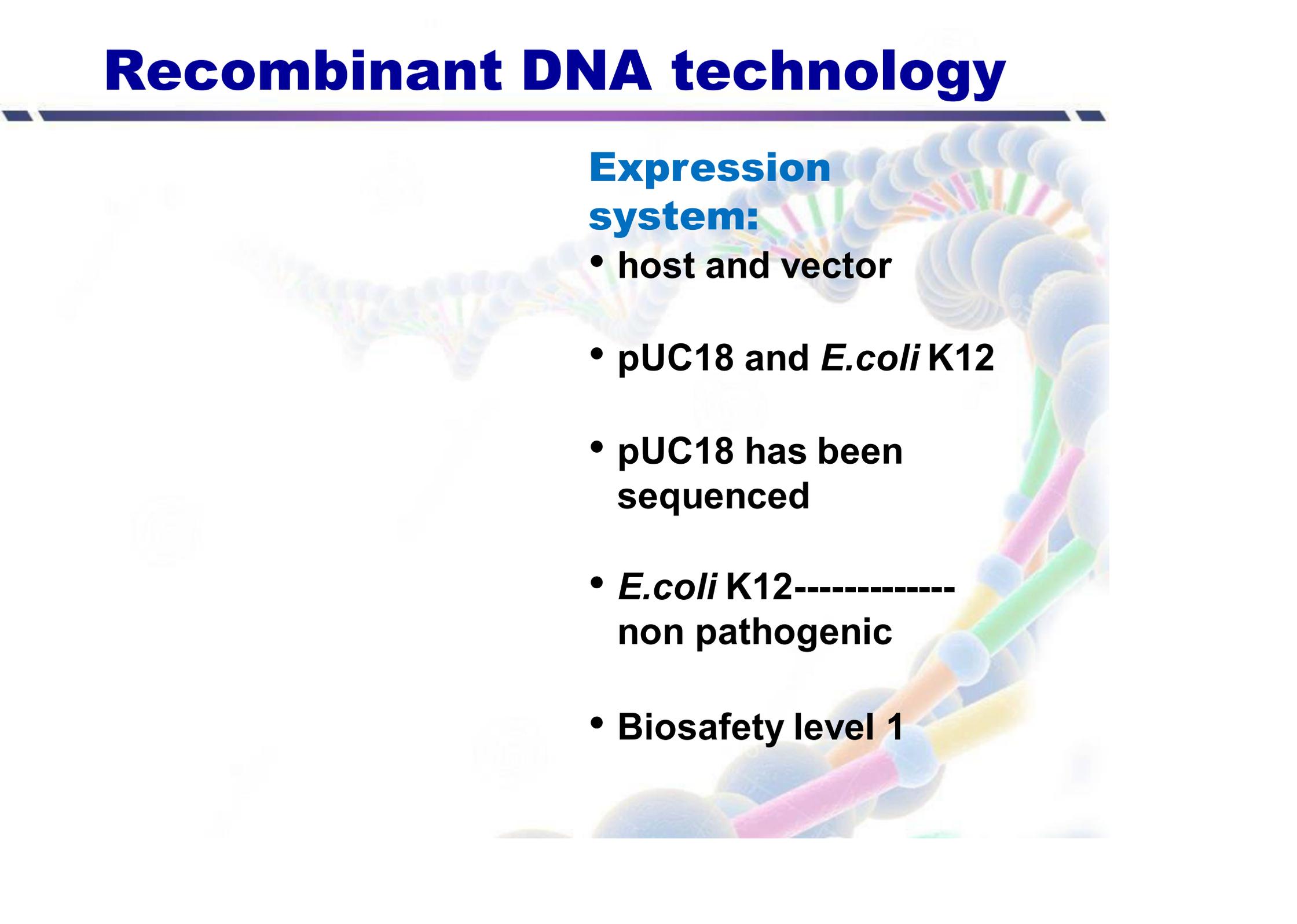
Recombinant DNA technology



Uses:

- never exist in the nature before
- undesirable and unpredictable properties
- clone DNA in to host -
---- over expression
- GMOs
- Role in medicine

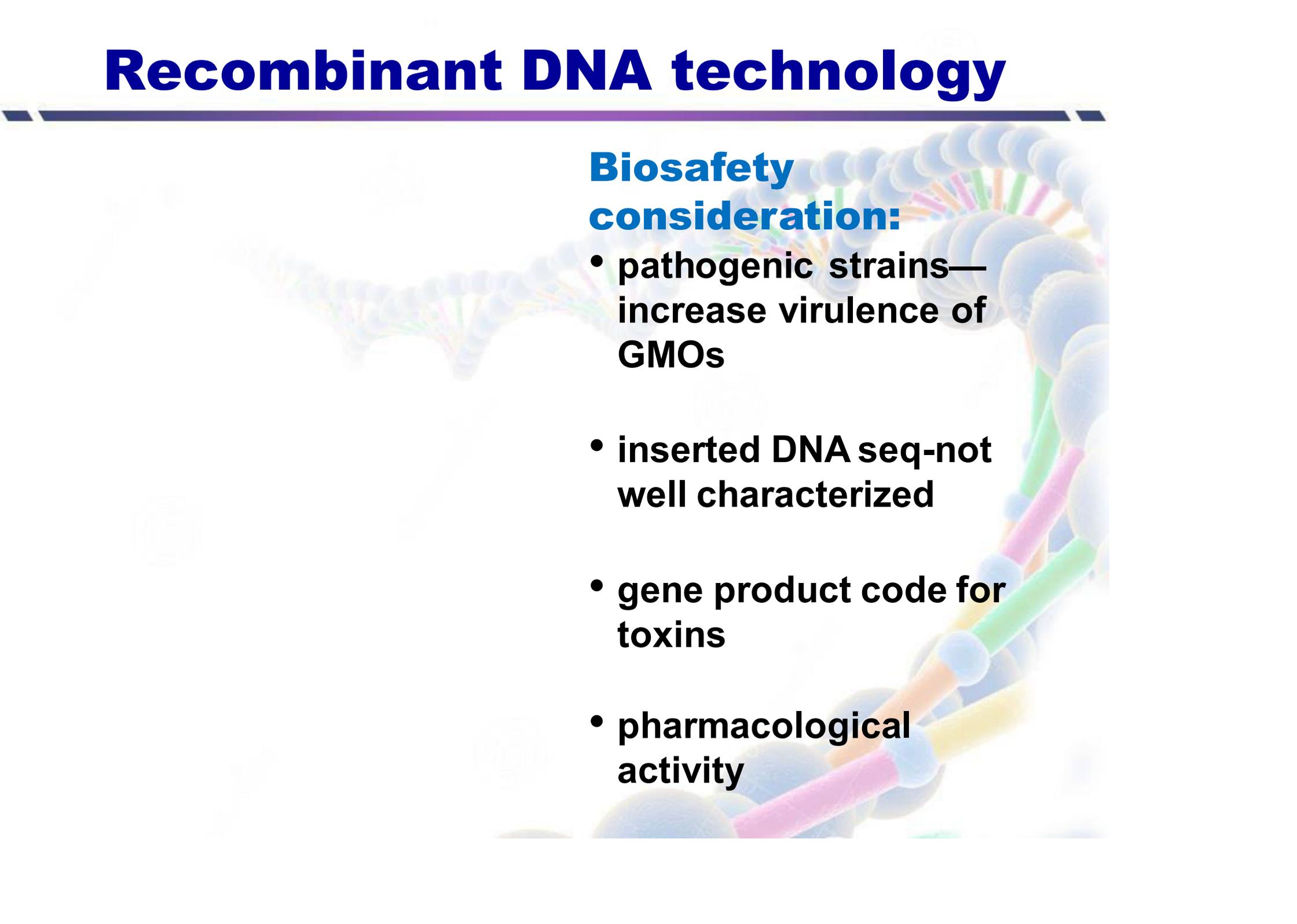
Recombinant DNA technology



Expression system:

- host and vector
- pUC18 and *E.coli* K12
- pUC18 has been sequenced
- *E.coli* K12-----
non pathogenic
- Biosafety level 1

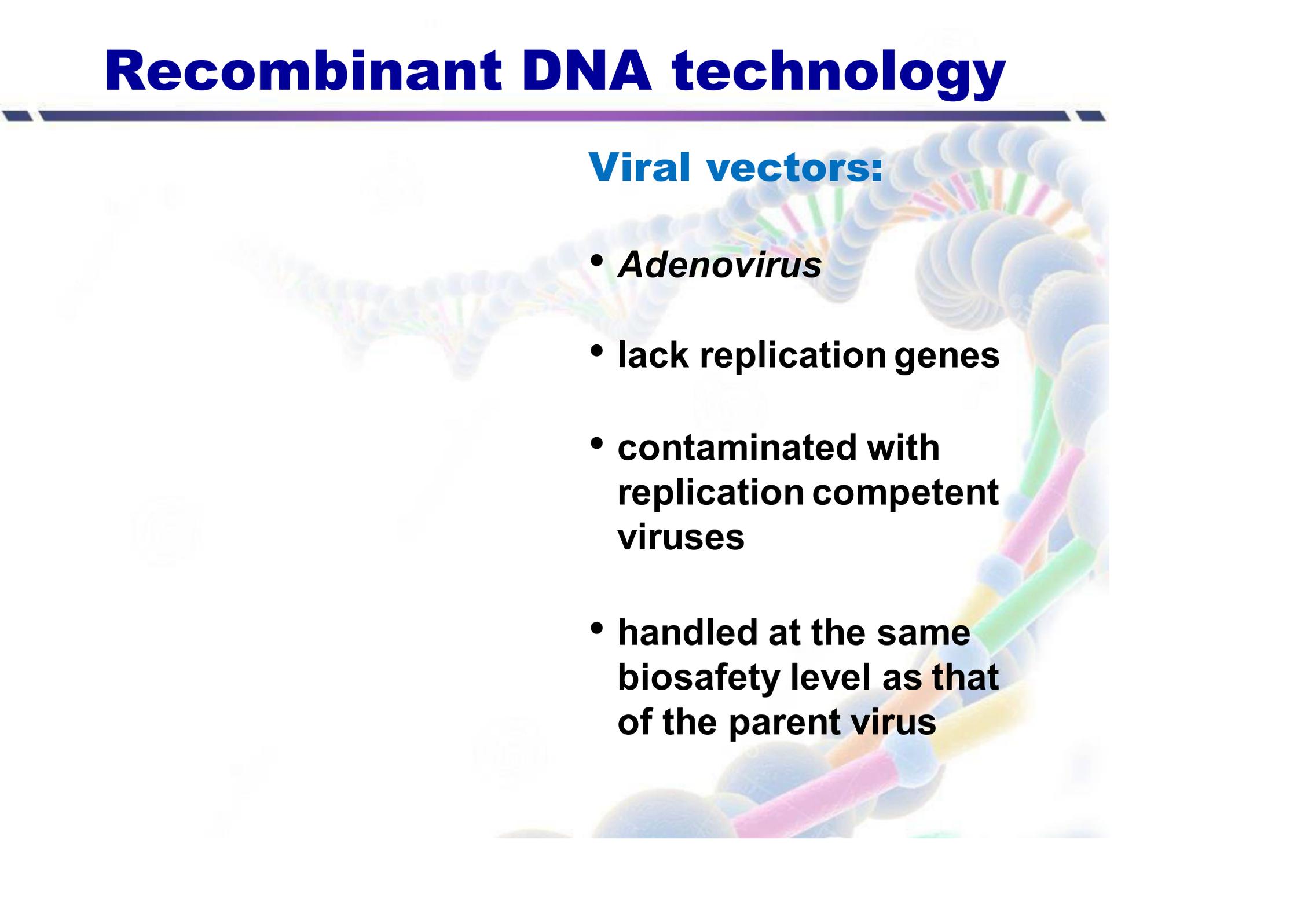
Recombinant DNA technology



Biosafety consideration:

- **pathogenic strains—
increase virulence of
GMOs**
- **inserted DNA seq-not
well characterized**
- **gene product code for
toxins**
- **pharmacological
activity**

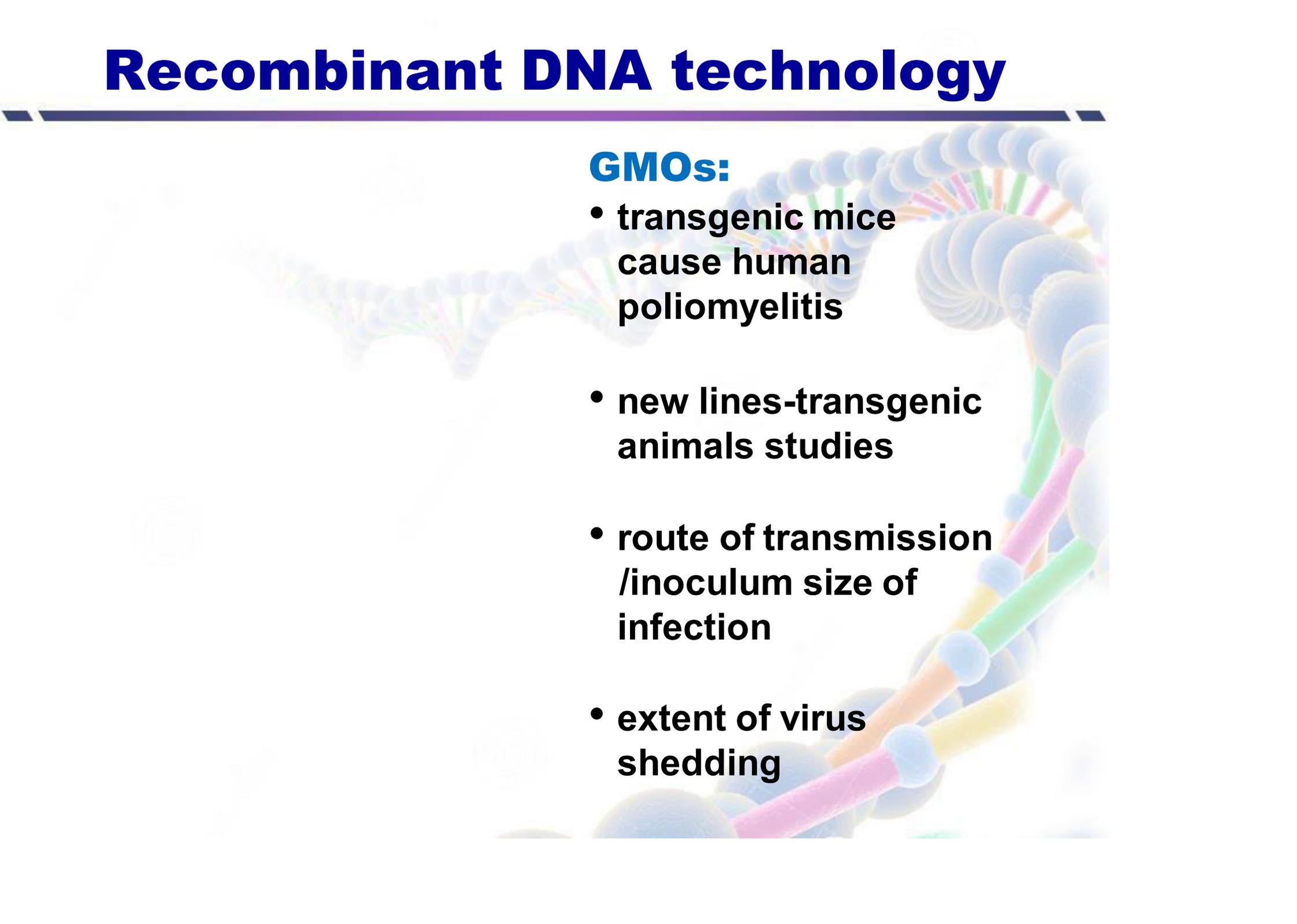
Recombinant DNA technology



Viral vectors:

- *Adenovirus*
- lack replication genes
- contaminated with replication competent viruses
- handled at the same biosafety level as that of the parent virus

Recombinant DNA technology



GMOs:

- **transgenic mice cause human poliomyelitis**
- **new lines-transgenic animals studies**
- **route of transmission /inoculum size of infection**
- **extent of virus shedding**

Recombinant DNA technology

Risk assessment:

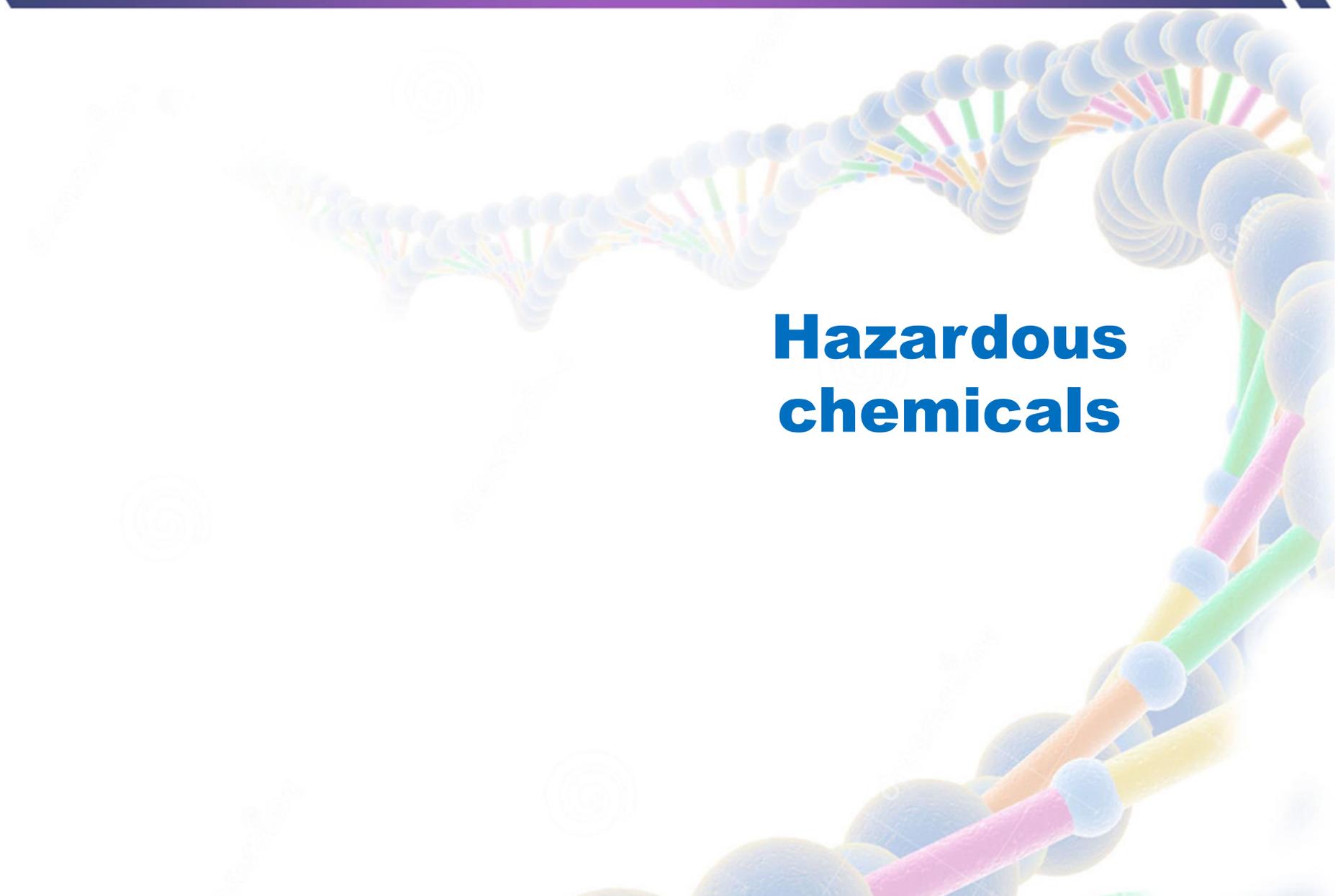
- **inserted gene with known properties**
- **toxins/cytokines/hormones/allergens**
- **gene expression regulators/enhancers**
- **oncogene sequence**
- **antibiotic resistance**

Biosafety



Lesson # 96

Biosafety



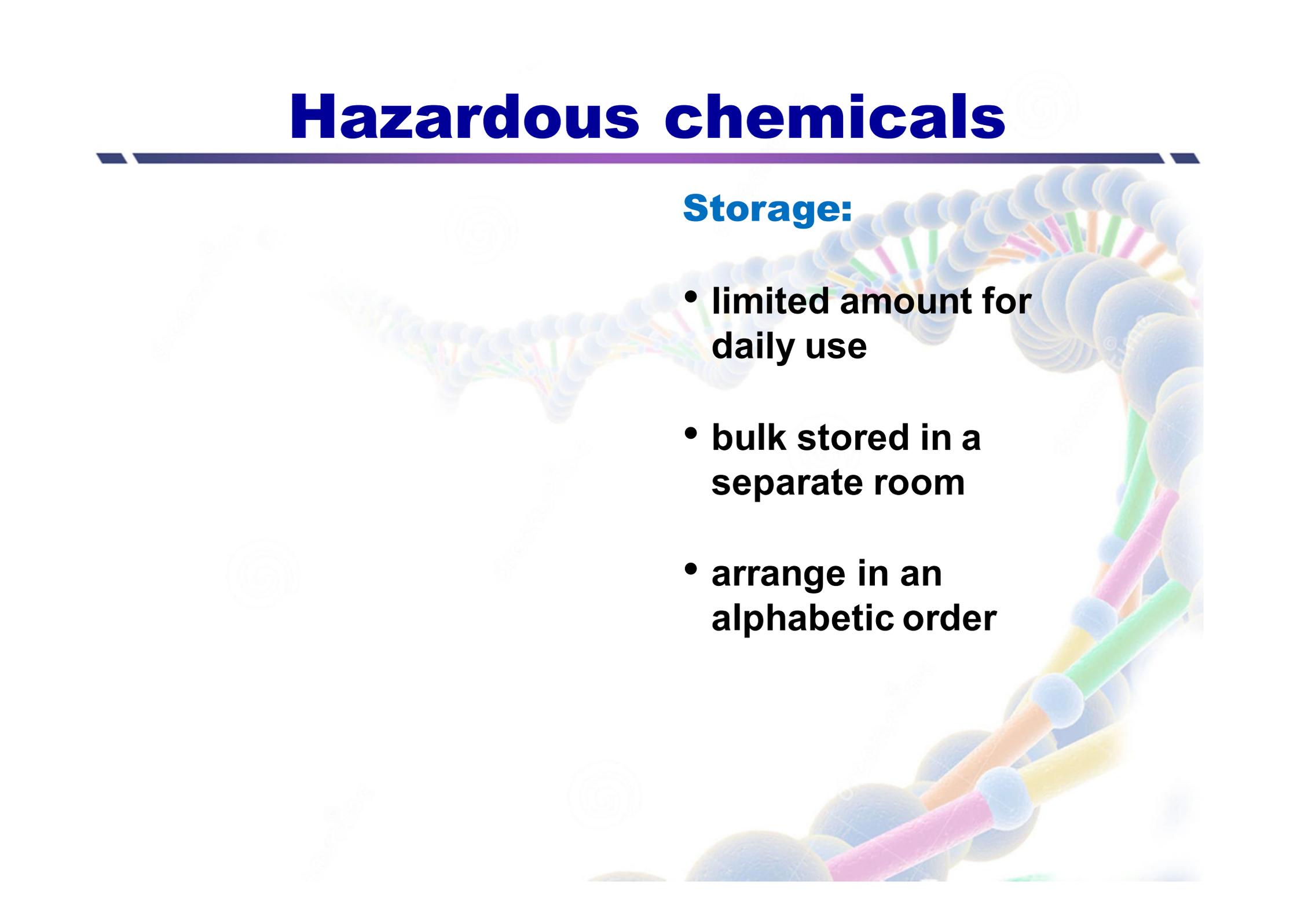
**Hazardous
chemicals**

Hazardous chemicals

Route of exposure:

- **inhalation**
 - **contact**
 - **ingestion**
 - **needle sticks**
 - **broken skin**
- 

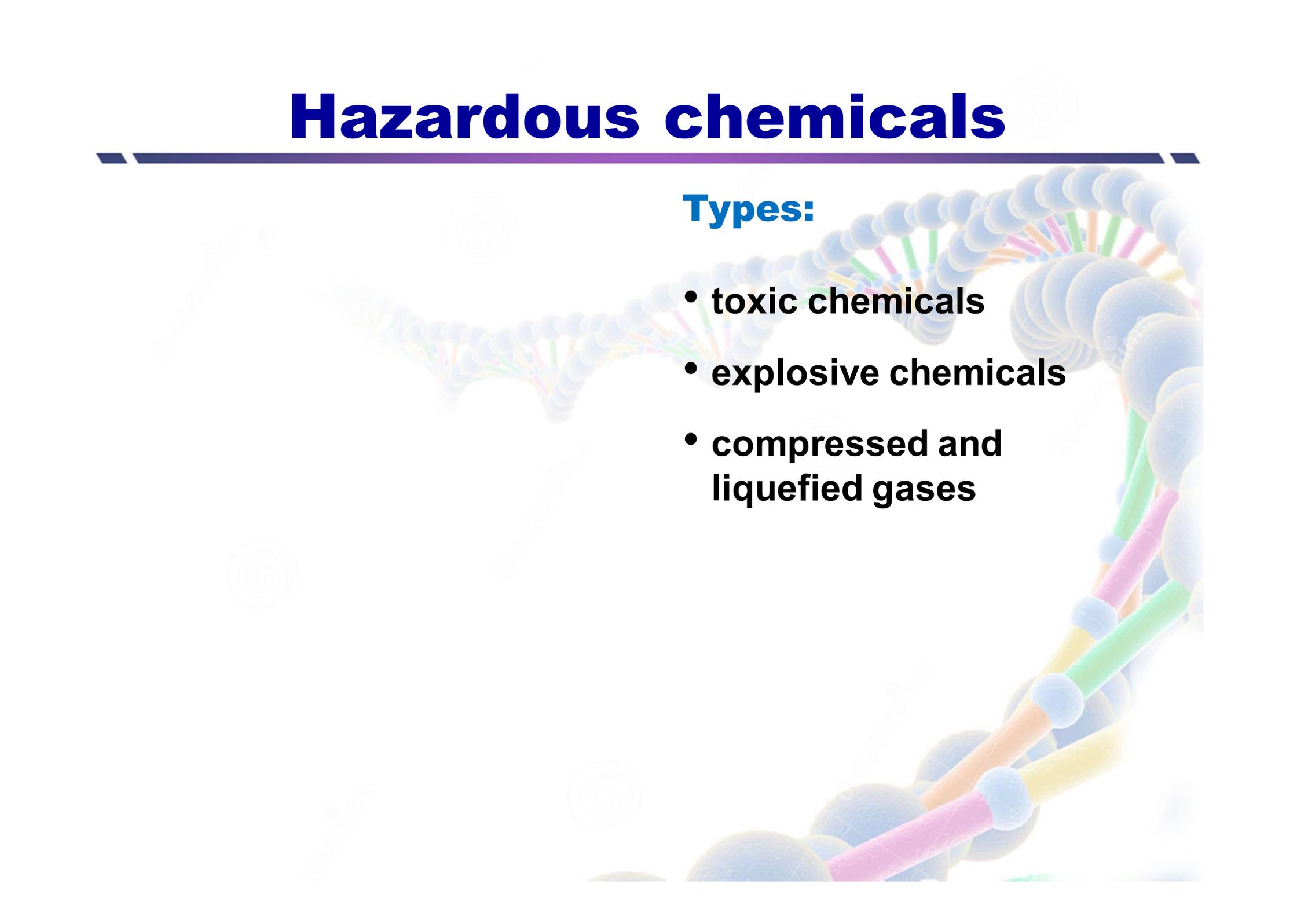
Hazardous chemicals



Storage:

- limited amount for daily use
- bulk stored in a separate room
- arrange in an alphabetic order

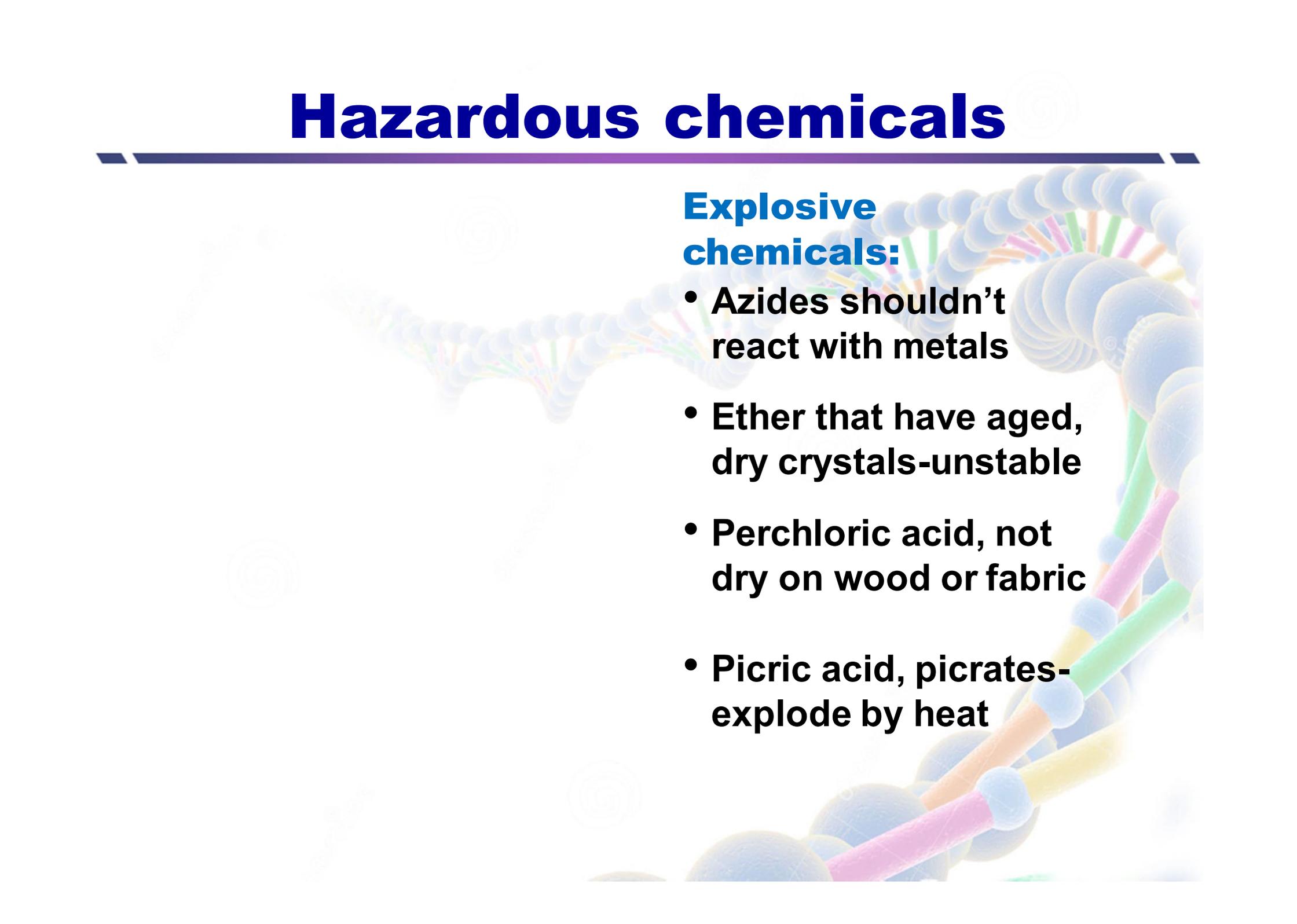
Hazardous chemicals



Types:

- toxic chemicals
- explosive chemicals
- compressed and liquefied gases

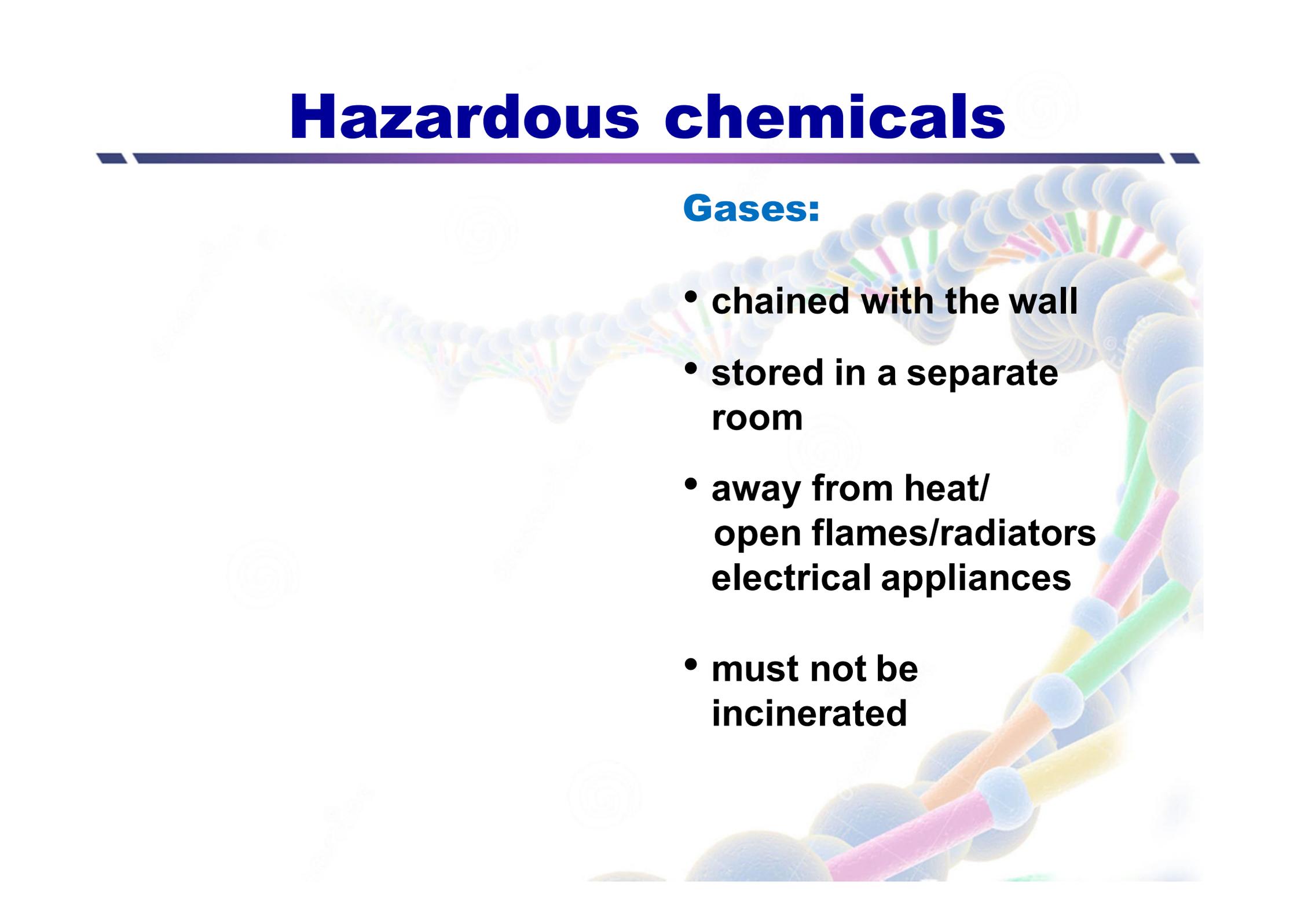
Hazardous chemicals



Explosive chemicals:

- **Azides shouldn't react with metals**
- **Ether that have aged, dry crystals-unstable**
- **Perchloric acid, not dry on wood or fabric**
- **Picric acid, picrates-explode by heat**

Hazardous chemicals



Gases:

- chained with the wall
- stored in a separate room
- away from heat/
open flames/radiators
electrical appliances
- must not be
incinerated

Biosafety



Lesson # 97

Biosafety



Fire Hazard

Fire hazard

Introduction:

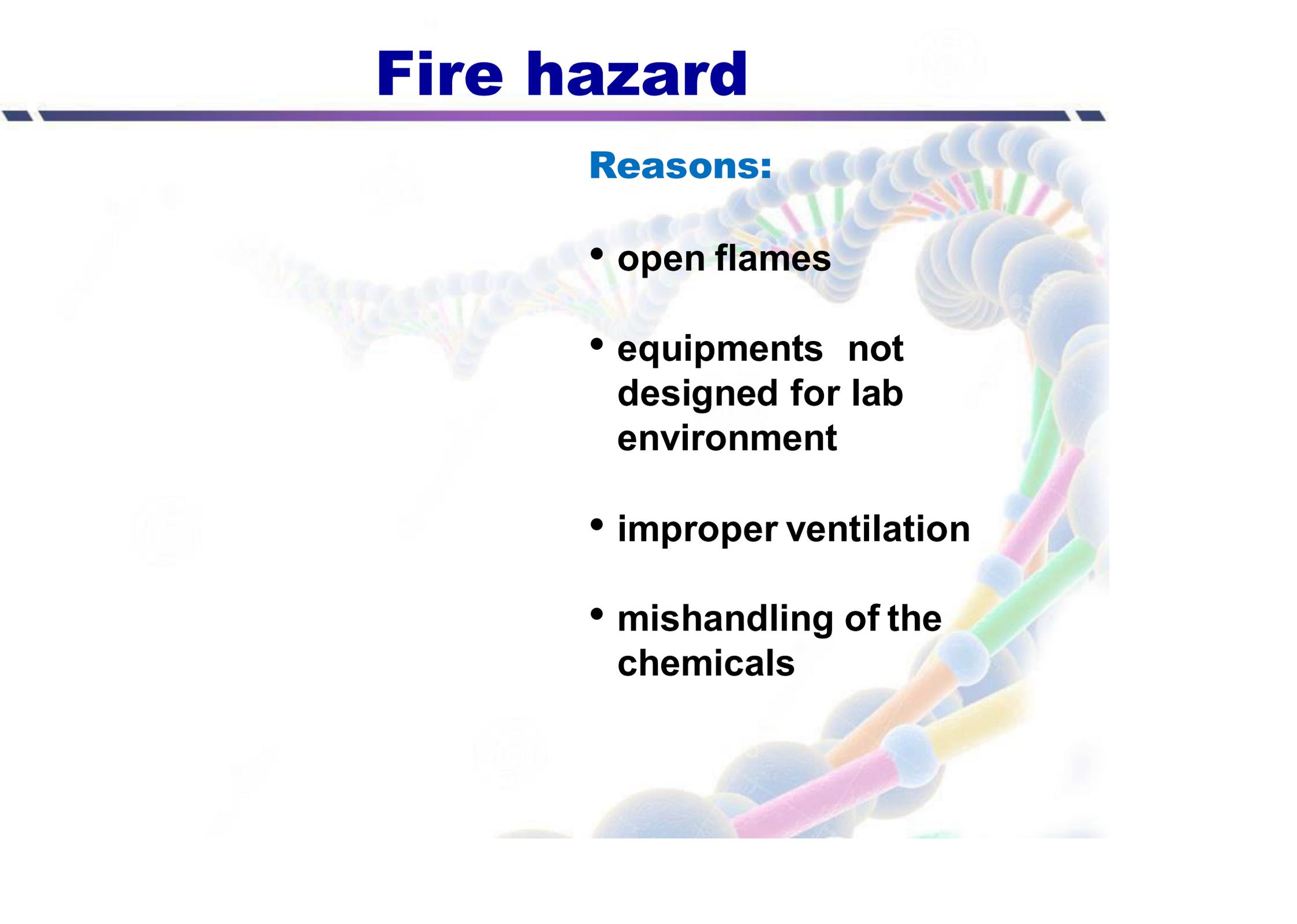
- **close cooperation between safety officer and fire prevention officer**
- **immediate action in case of fire**
- **determine-it is best to contain or extinguish fire**

Fire hazard

Reasons:

- **electric circuit overloading**
- **poor electrical maintenance**
- **long electrical leads**
- **equipment unnecessarily switched on**

Fire hazard



Reasons:

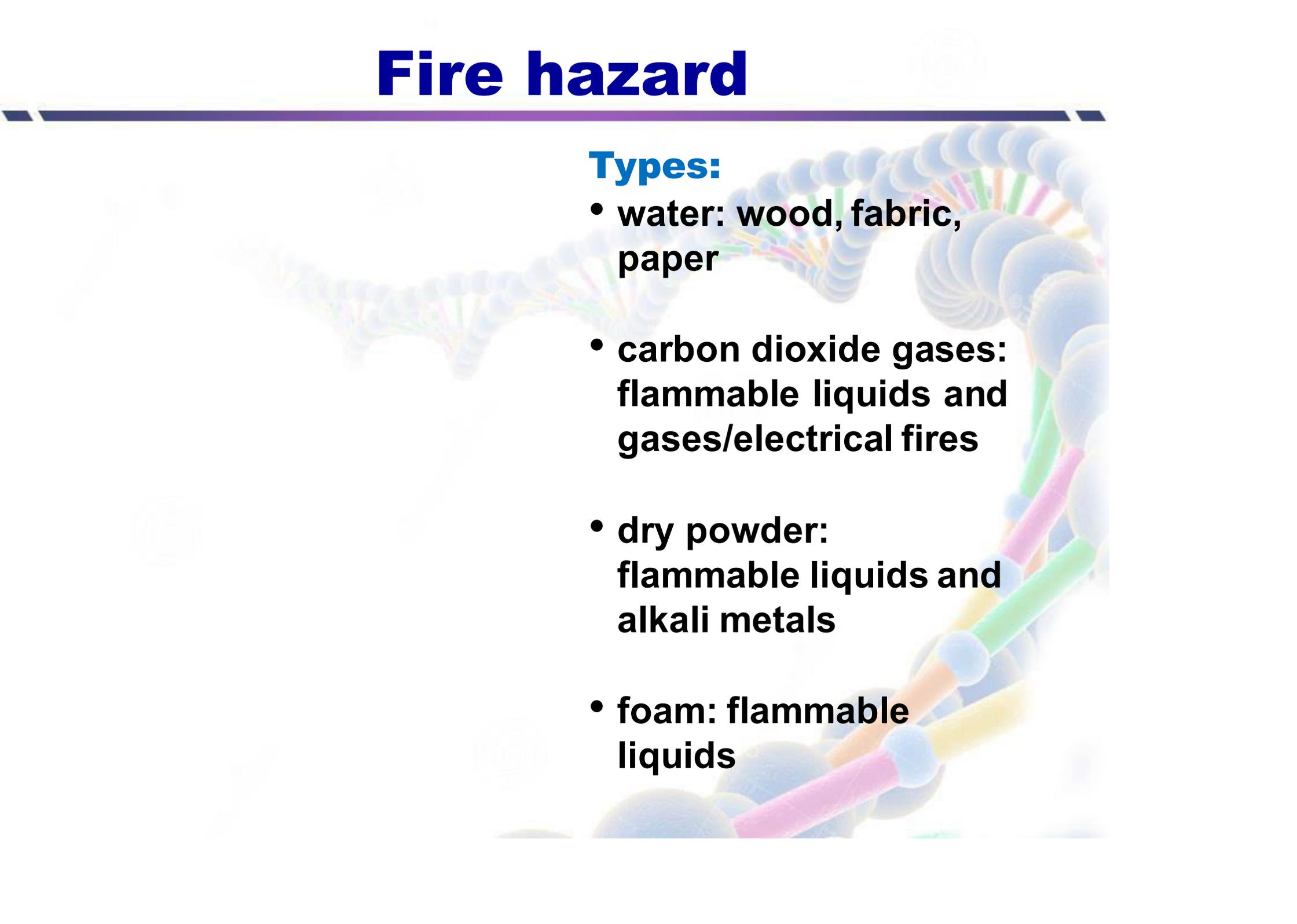
- open flames
- equipments not designed for lab environment
- improper ventilation
- mishandling of the chemicals

Fire hazard

Fire-fighting equipments:

- inspected, maintained shelf life
- near doors/ corridors
- hoses, buckets and fire extinguishers
- fire warnings/ instructions
- escape routes/ assembly point

Fire hazard

A decorative background featuring a series of colorful spheres (blue, green, yellow, pink) connected by thin lines, creating a molecular or network-like structure. The spheres are arranged in a curved path across the top and right side of the slide.

Types:

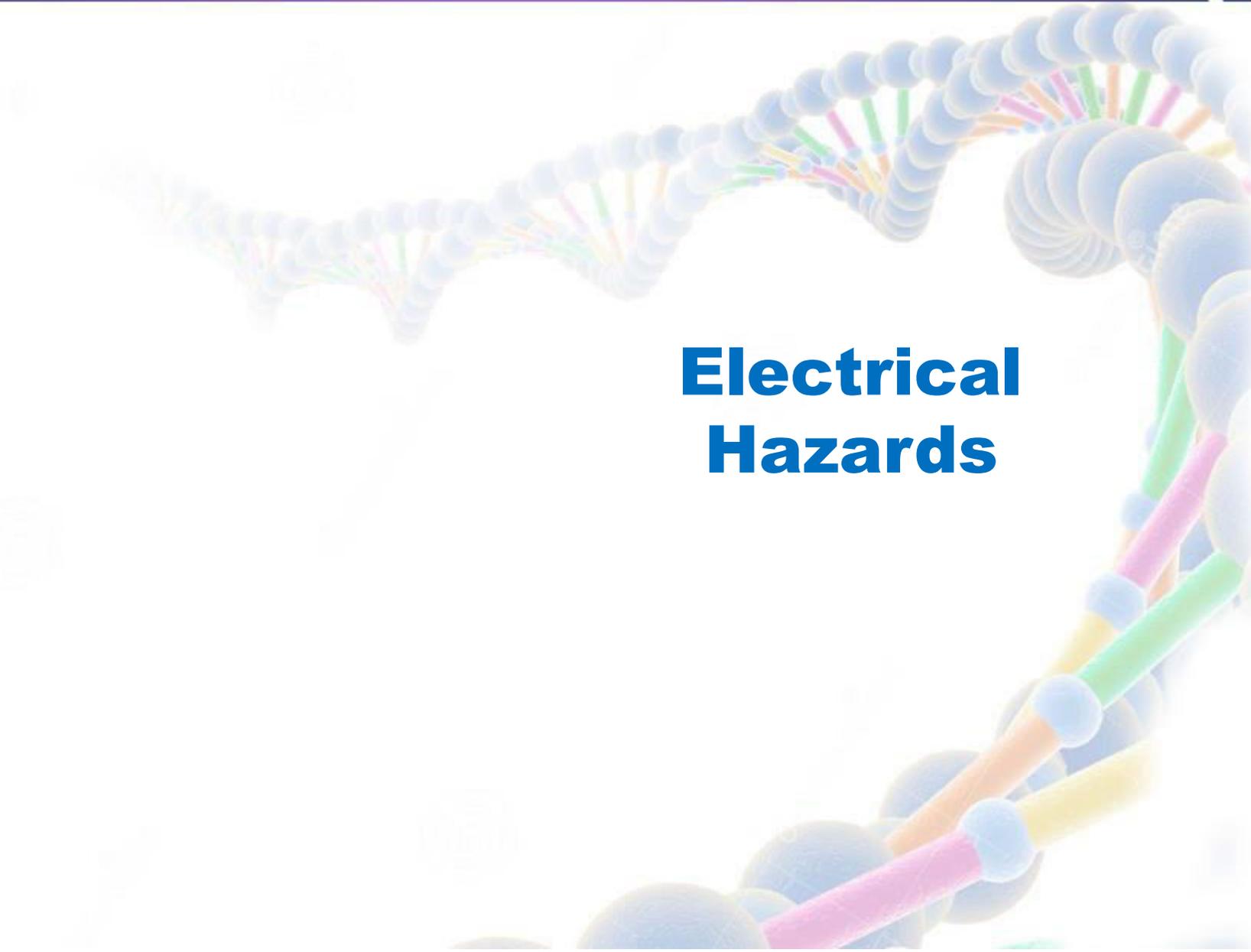
- **water:** wood, fabric, paper
- **carbon dioxide gases:** flammable liquids and gases/electrical fires
- **dry powder:** flammable liquids and alkali metals
- **foam:** flammable liquids

Biosafety



Lesson # 98

Biosafety



**Electrical
Hazards**

Electrical hazards

Introduction:

- **electrical appliances and equipments ----- tested and inspected**
- **electric- circuit protect wiring from being overloaded with electric current**
- **earth-fault- interrupters: protect people from electric shock**

Electrical hazards

Safety:

- National electrical standard and safety codes
- earth / grounding systems with three-prong plugs

Biosafety



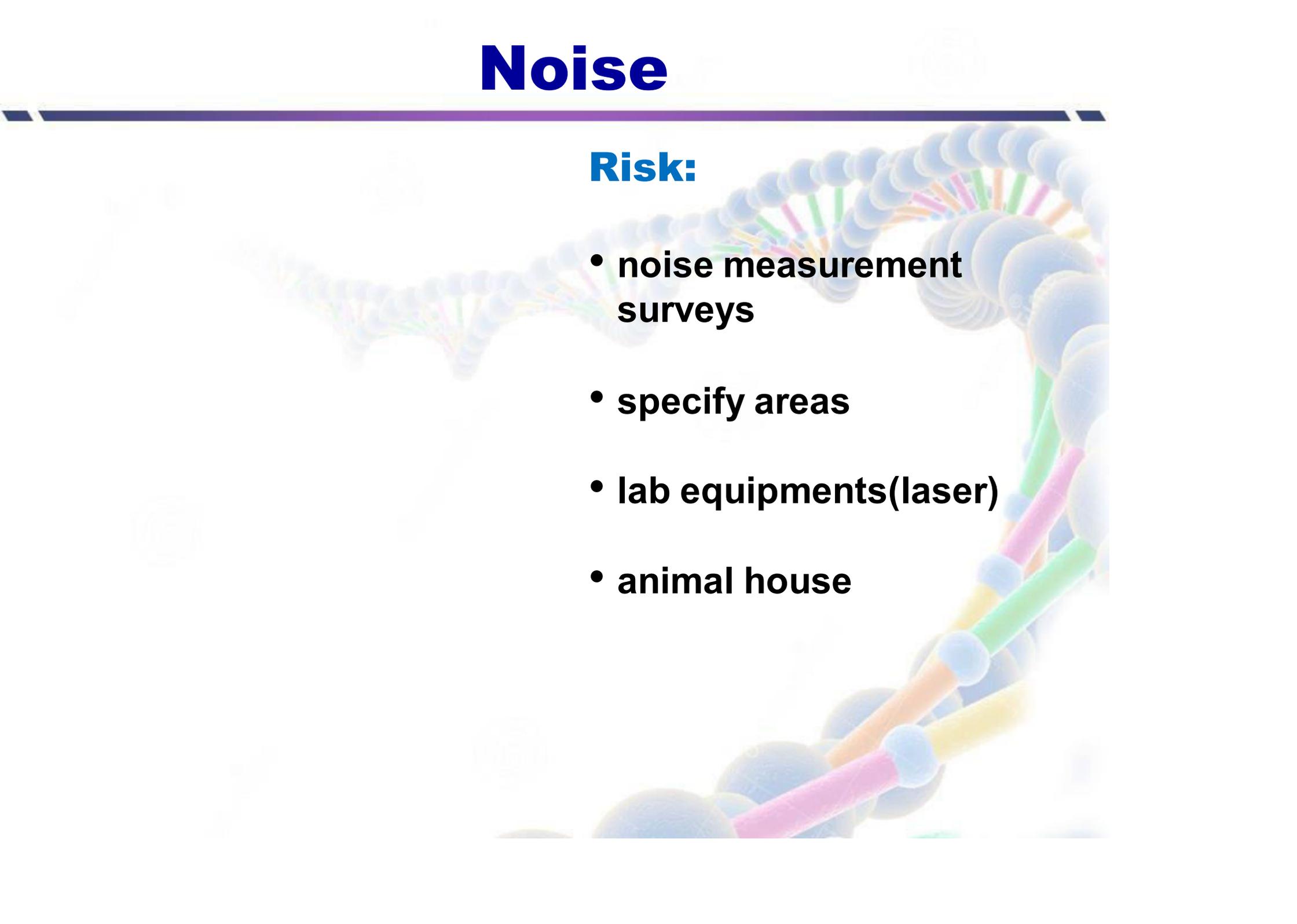
Lesson # 99

Biosafety



Noise

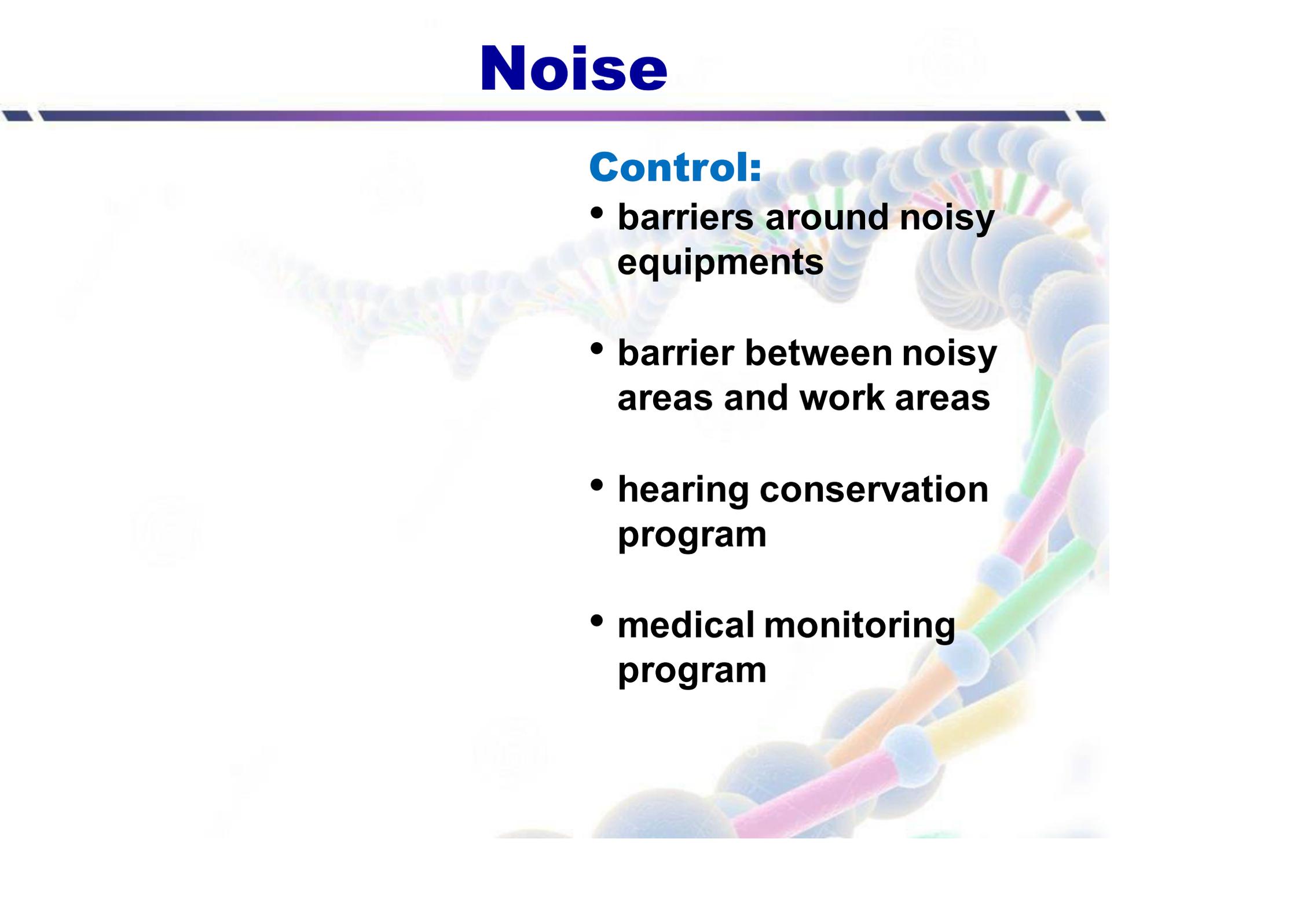
Noise



Risk:

- **noise measurement surveys**
- **specify areas**
- **lab equipments(laser)**
- **animal house**

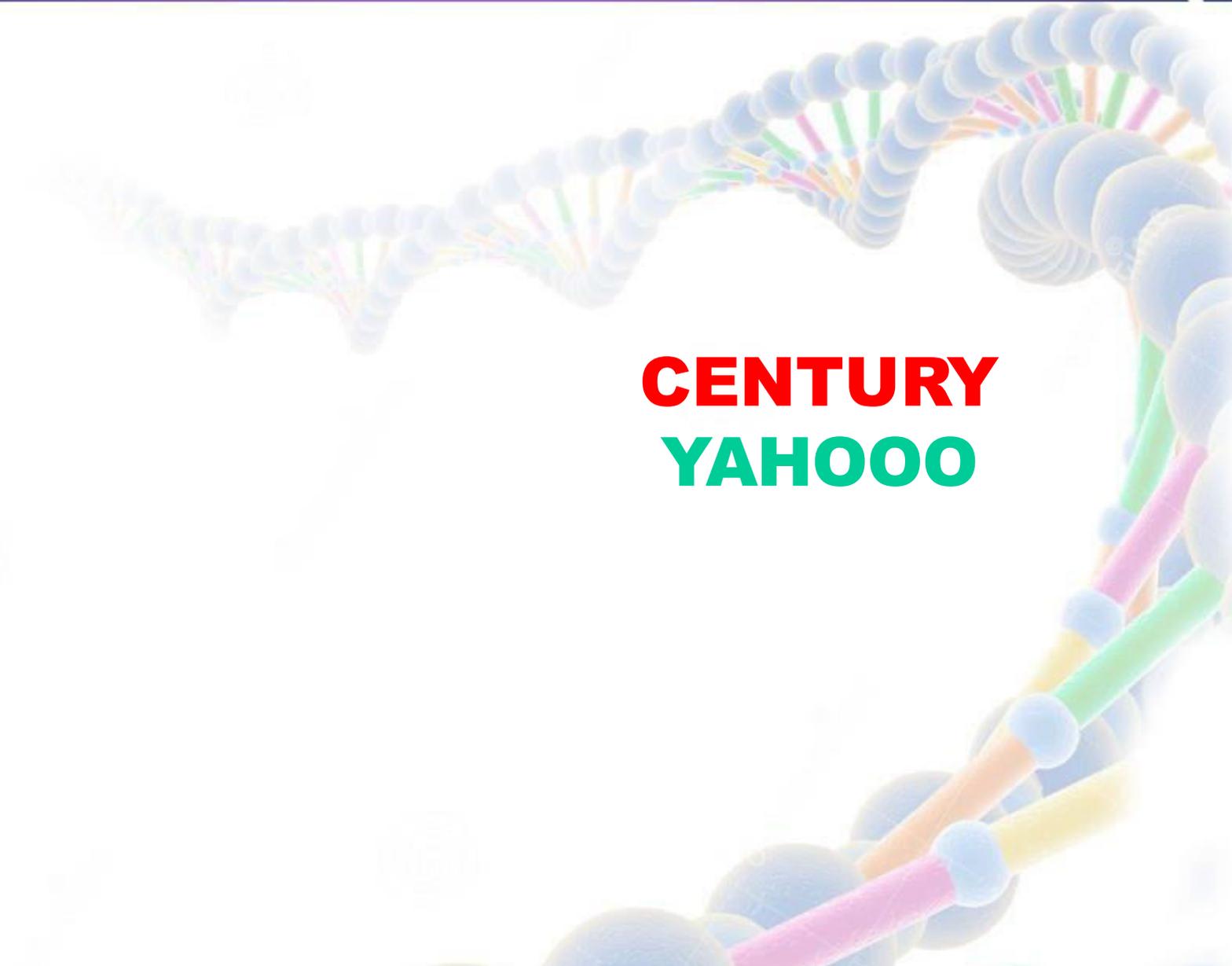
Noise



Control:

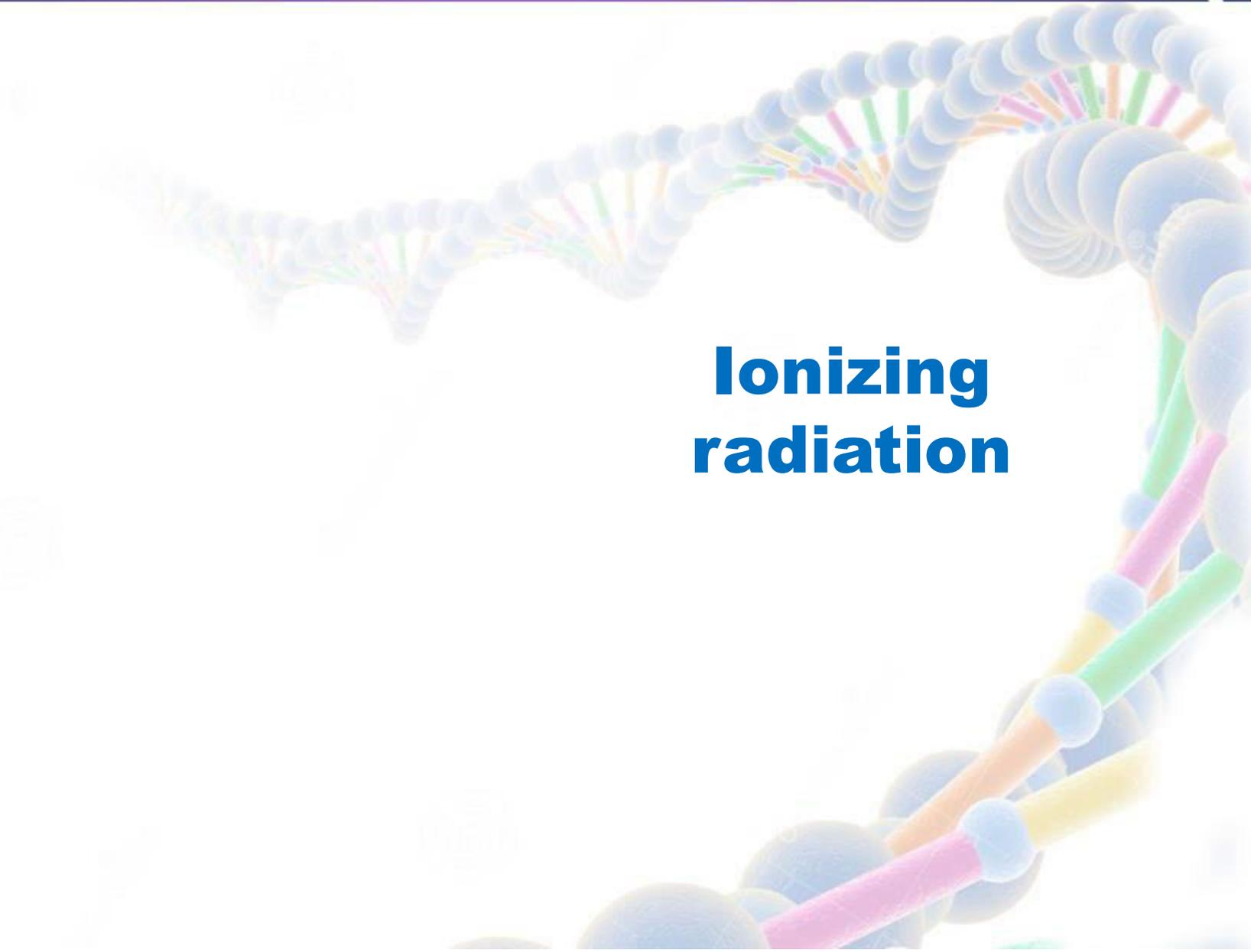
- **barriers around noisy equipments**
- **barrier between noisy areas and work areas**
- **hearing conservation program**
- **medical monitoring program**

Biosafety



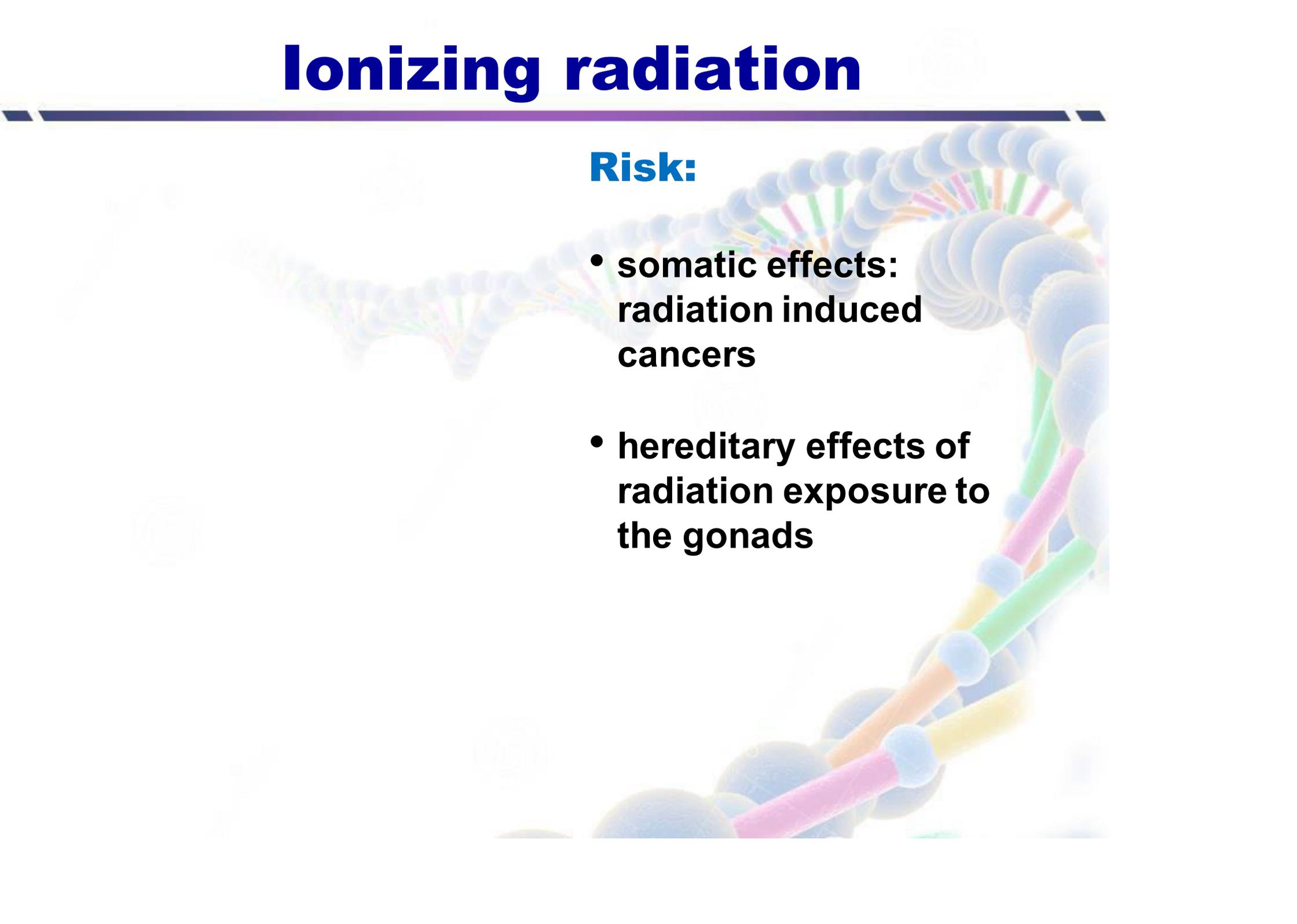
CENTURY
YAHOOO

Biosafety



**Ionizing
radiation**

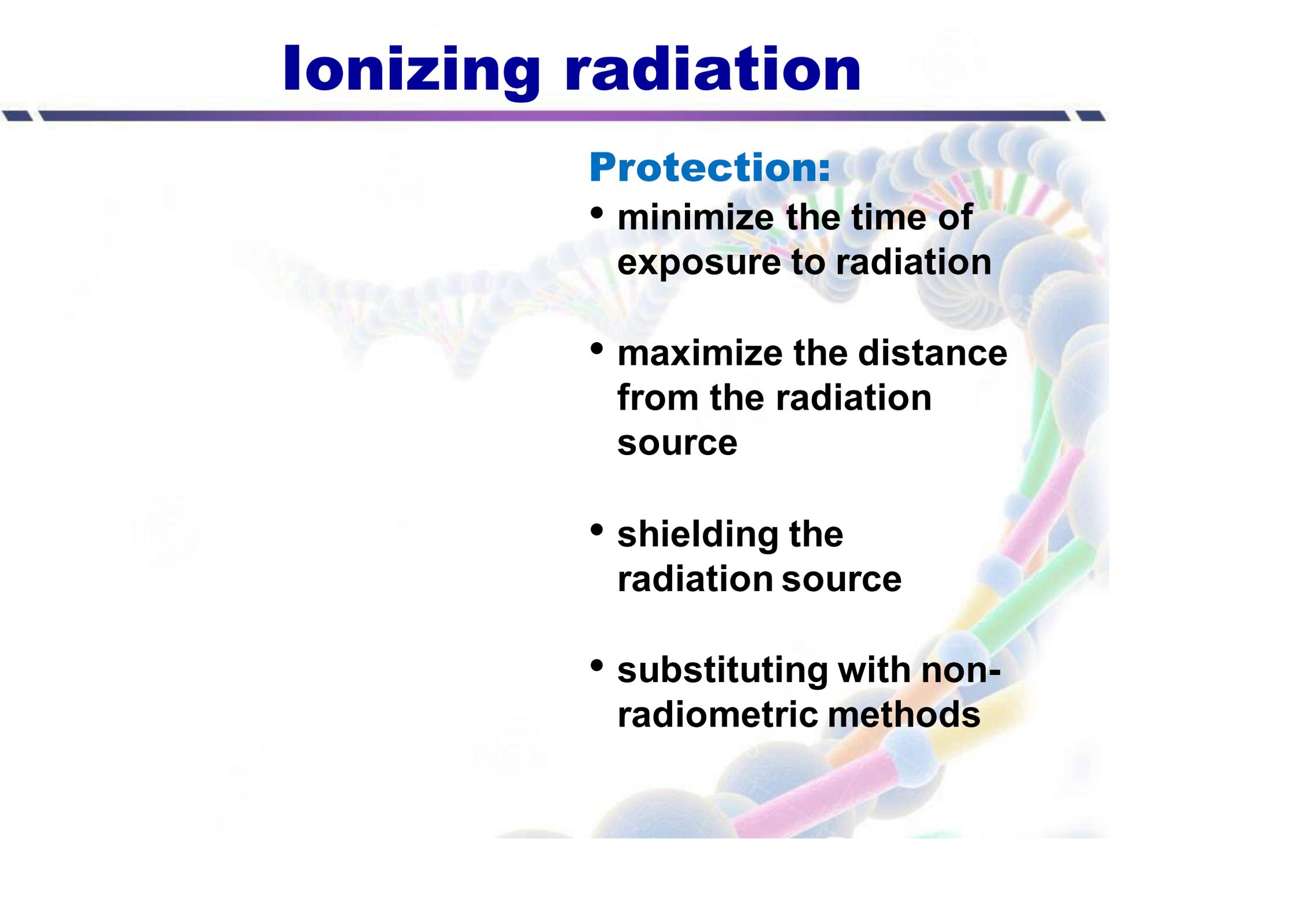
Ionizing radiation



Risk:

- **somatic effects:**
radiation induced
cancers
- **hereditary effects of
radiation exposure to
the gonads**

Ionizing radiation



Protection:

- minimize the time of exposure to radiation
- maximize the distance from the radiation source
- shielding the radiation source
- substituting with non-radiometric methods

Ionizing radiation

Rules:

- radiation area
- work-bench area
- radioactive waste area
- emergency response

Biosafety



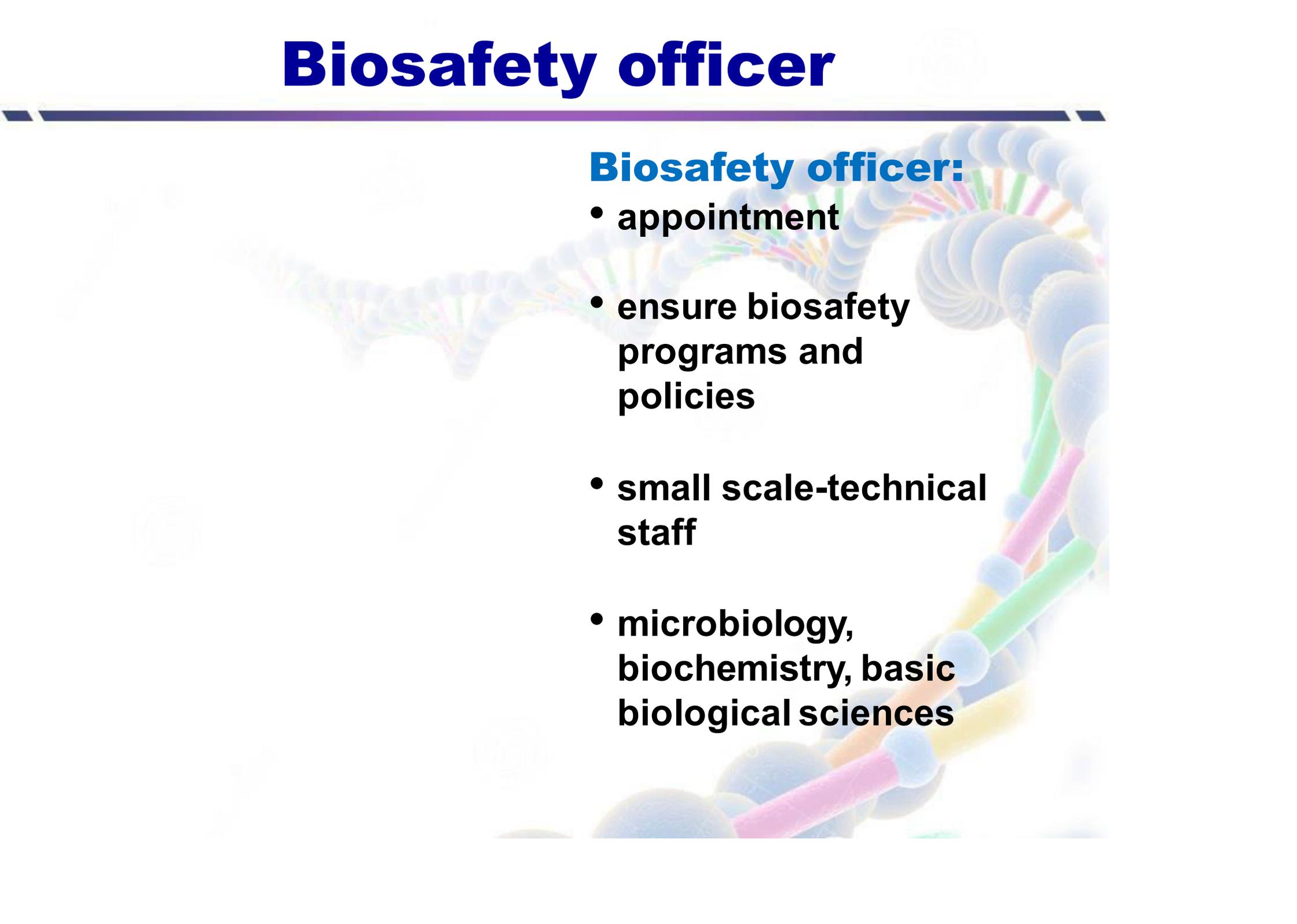
Lesson # 101

Biosafety



**Biosafety
officer**

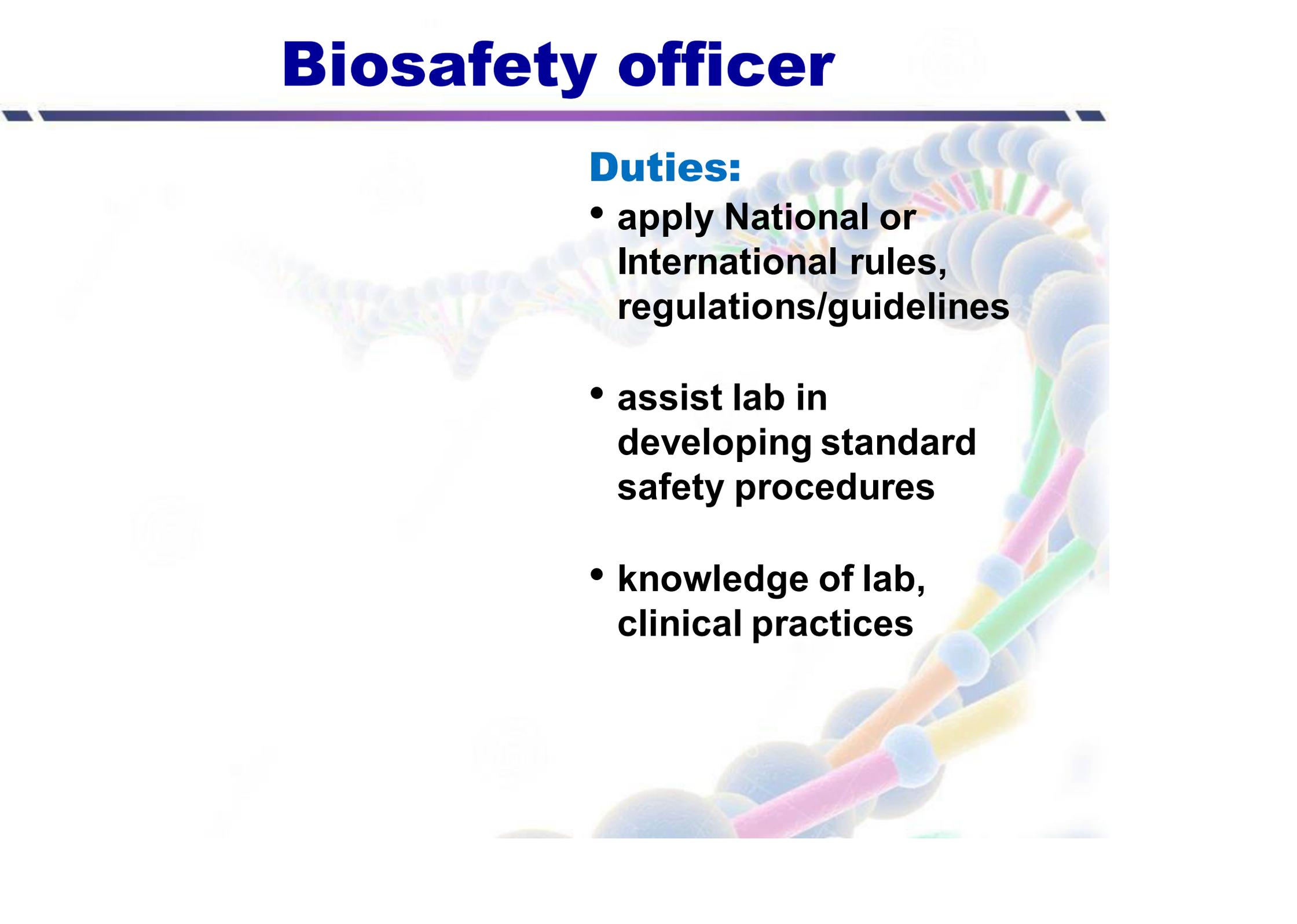
Biosafety officer



Biosafety officer:

- **appointment**
- **ensure biosafety programs and policies**
- **small scale-technical staff**
- **microbiology, biochemistry, basic biological sciences**

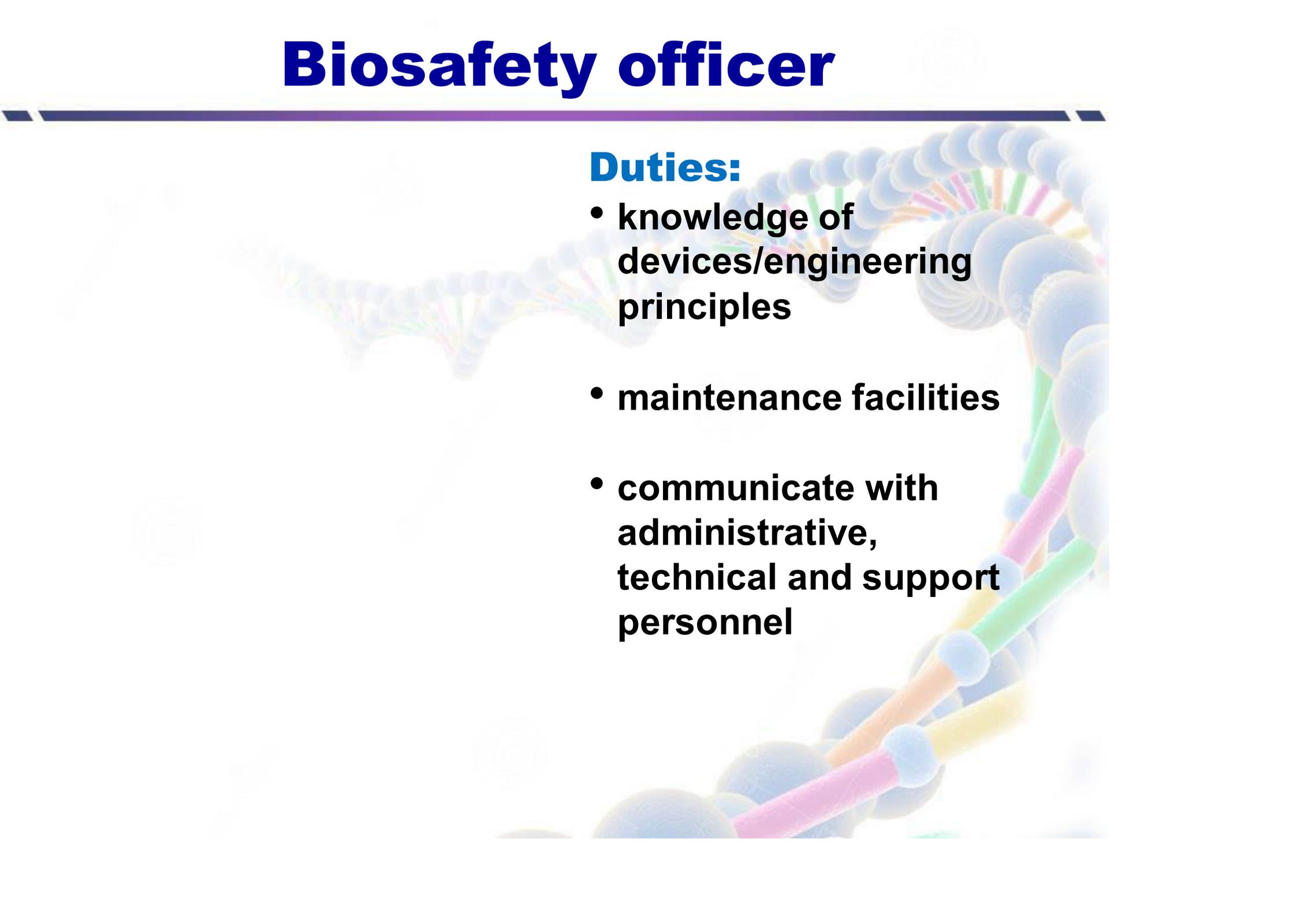
Biosafety officer



Duties:

- **apply National or International rules, regulations/guidelines**
- **assist lab in developing standard safety procedures**
- **knowledge of lab, clinical practices**

Biosafety officer

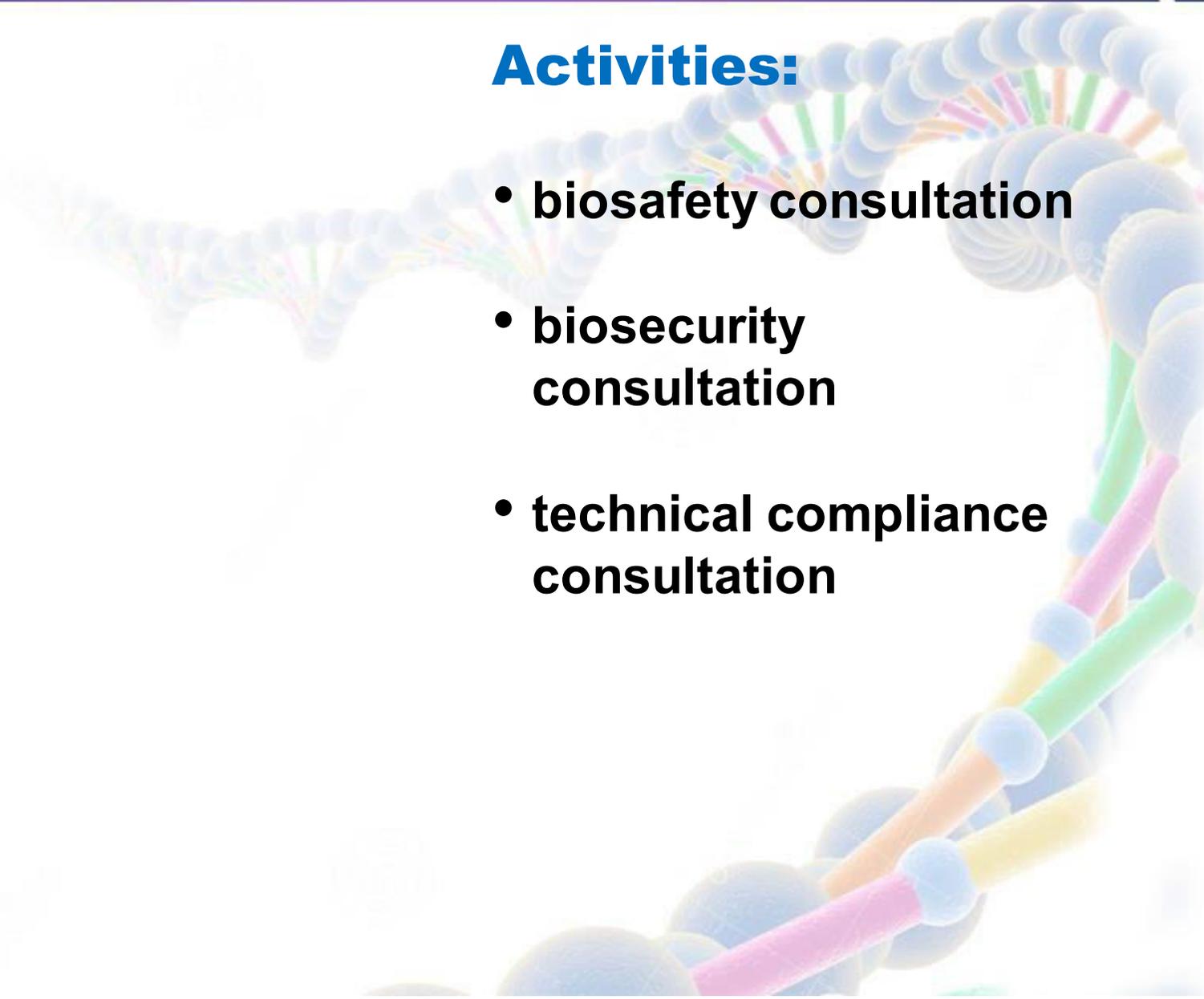


Duties:

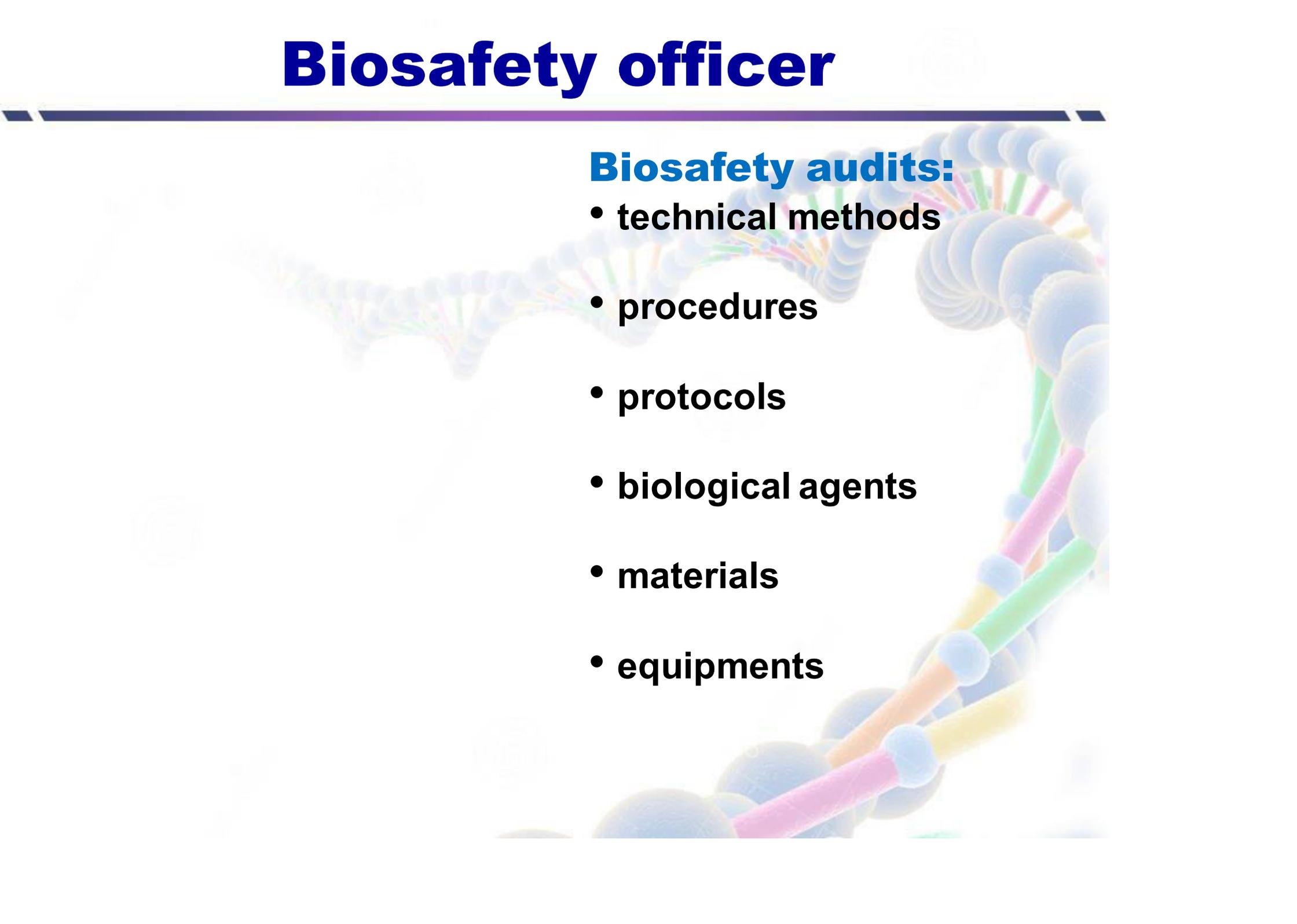
- **knowledge of devices/engineering principles**
- **maintenance facilities**
- **communicate with administrative, technical and support personnel**

Biosafety officer

Activities:

- biosafety consultation
 - biosecurity consultation
 - technical compliance consultation
- 

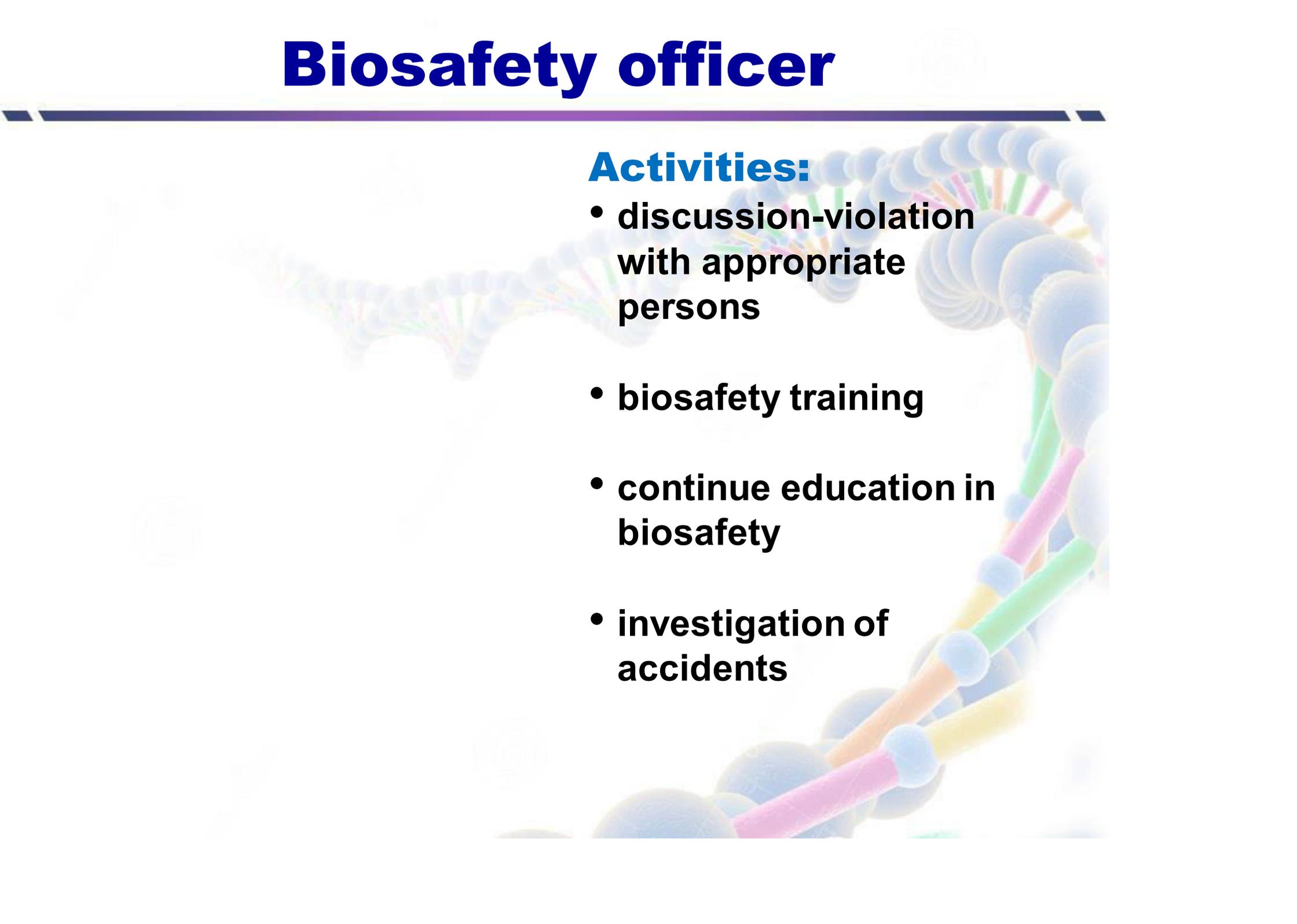
Biosafety officer



Biosafety audits:

- **technical methods**
- **procedures**
- **protocols**
- **biological agents**
- **materials**
- **equipments**

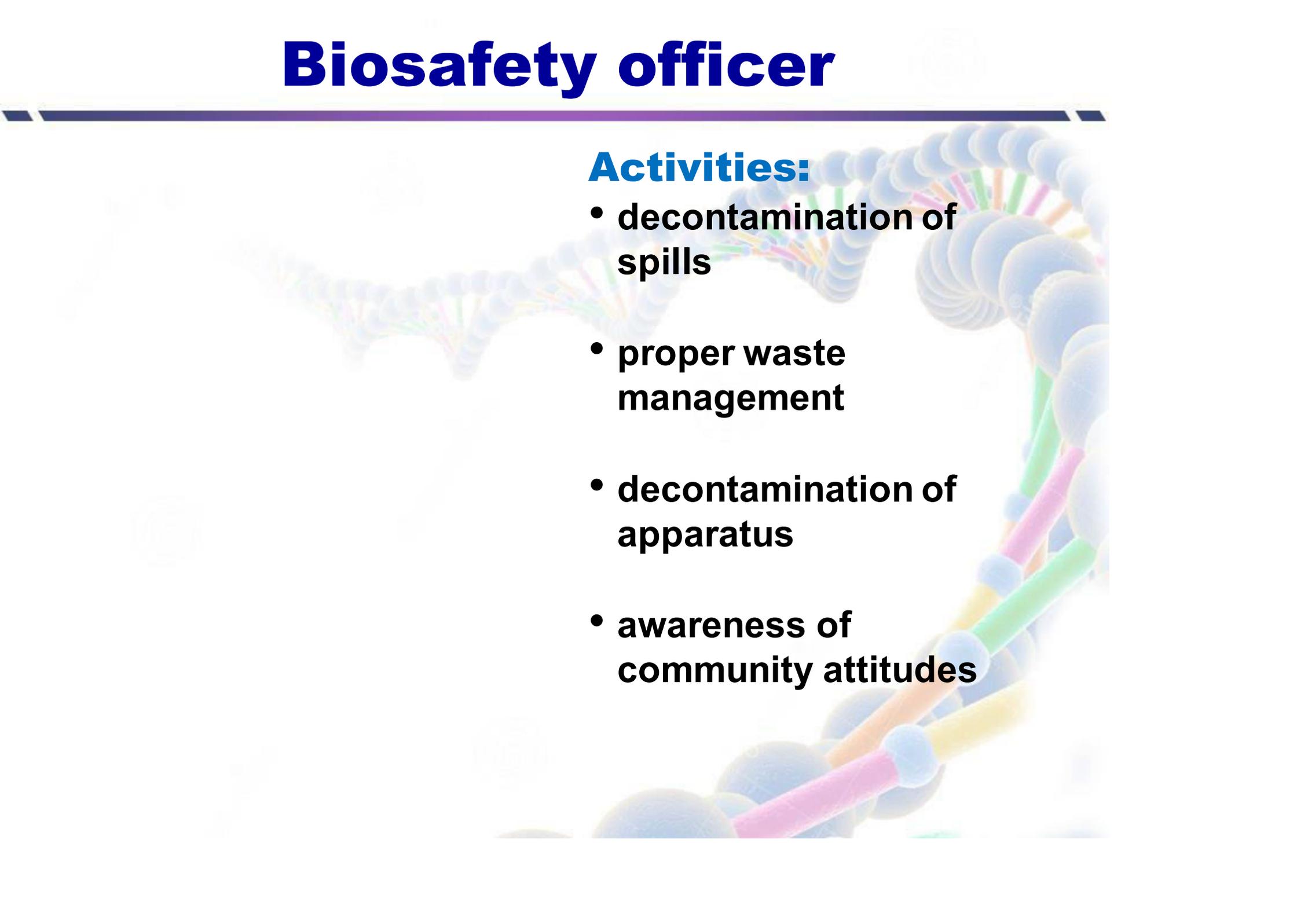
Biosafety officer



Activities:

- **discussion-violation with appropriate persons**
- **biosafety training**
- **continue education in biosafety**
- **investigation of accidents**

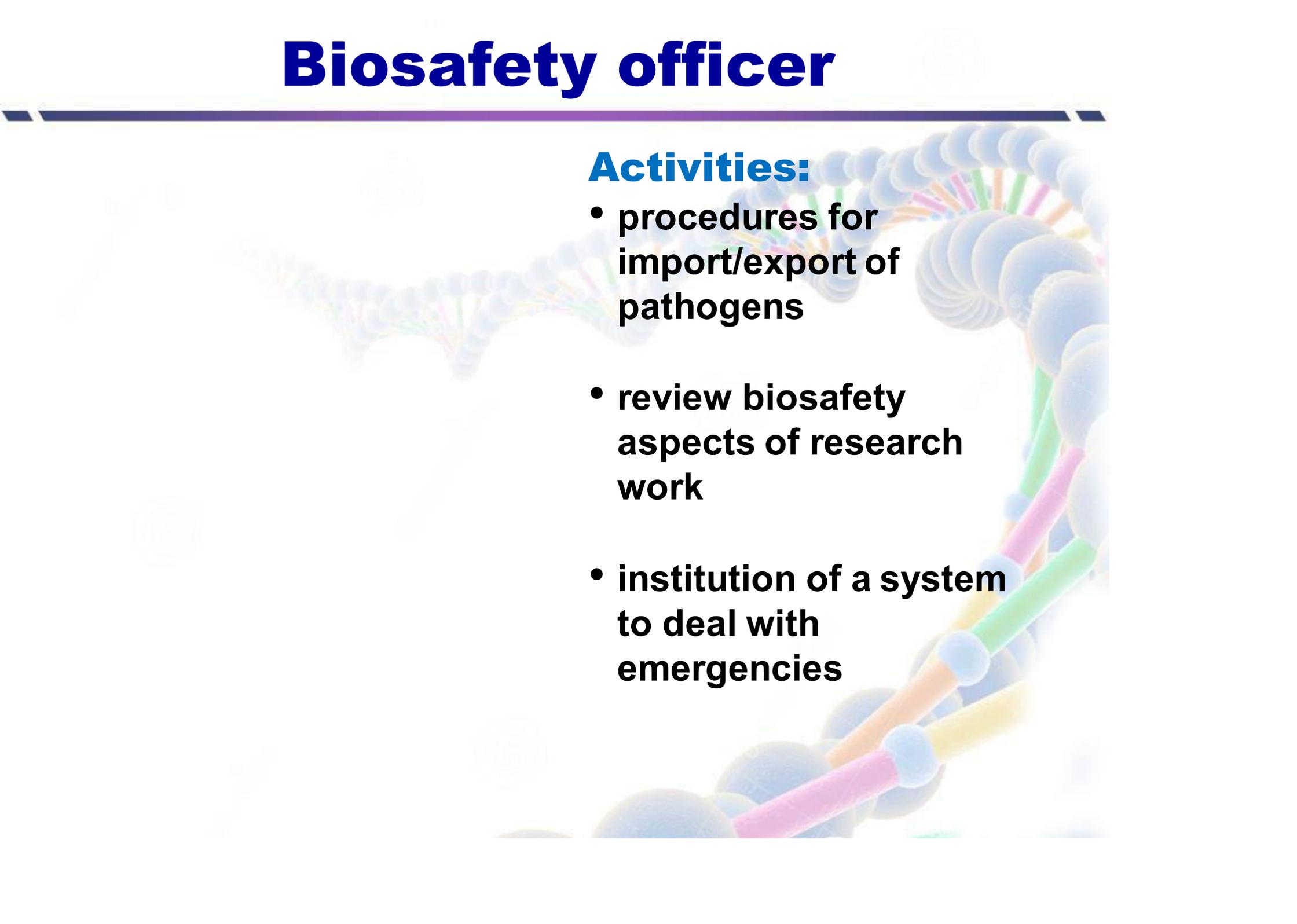
Biosafety officer



Activities:

- **decontamination of spills**
- **proper waste management**
- **decontamination of apparatus**
- **awareness of community attitudes**

Biosafety officer



Activities:

- **procedures for import/export of pathogens**
- **review biosafety aspects of research work**
- **institution of a system to deal with emergencies**

Biosafety



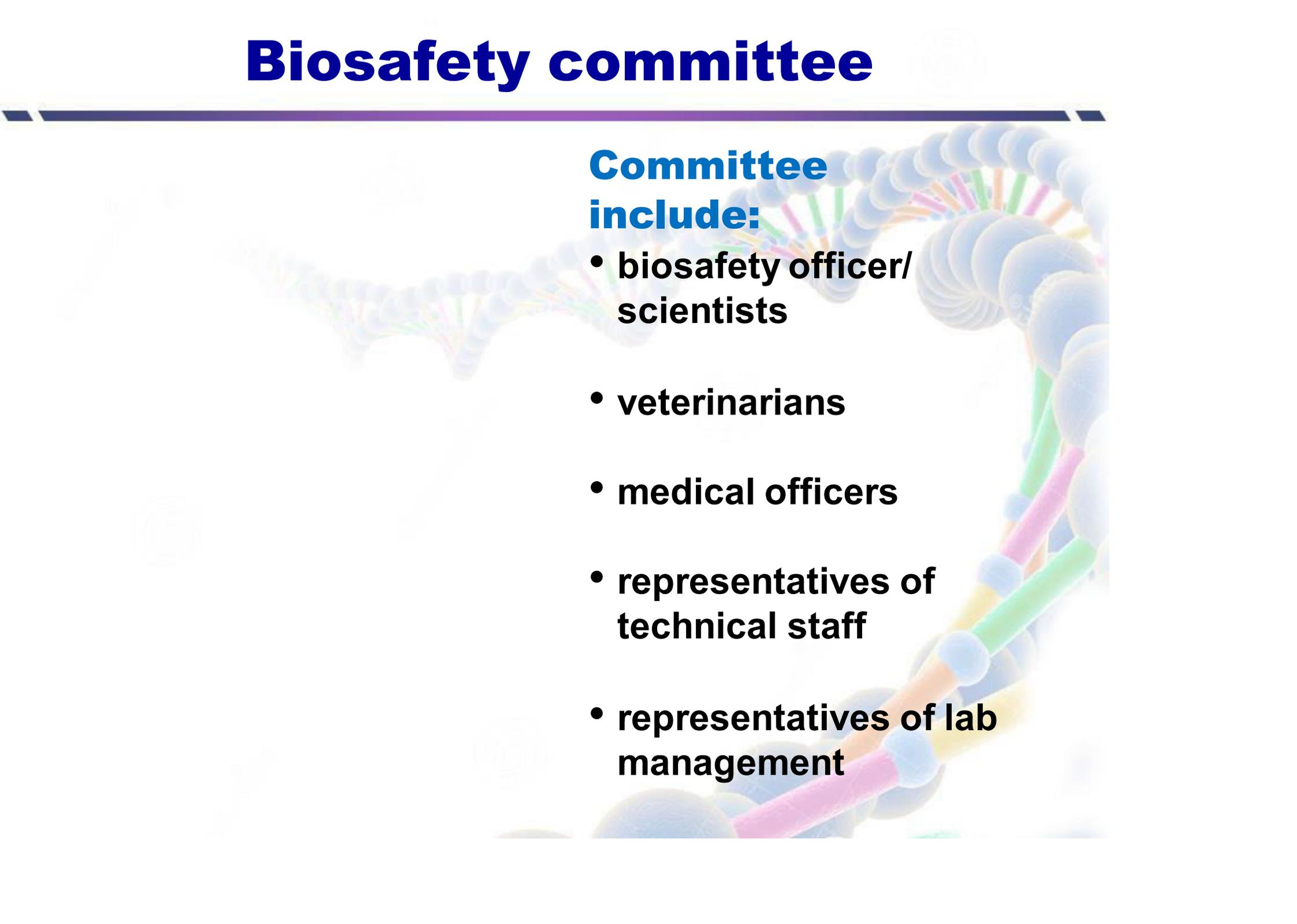
Lesson # 102

Biosafety



**Biosafety
committee**

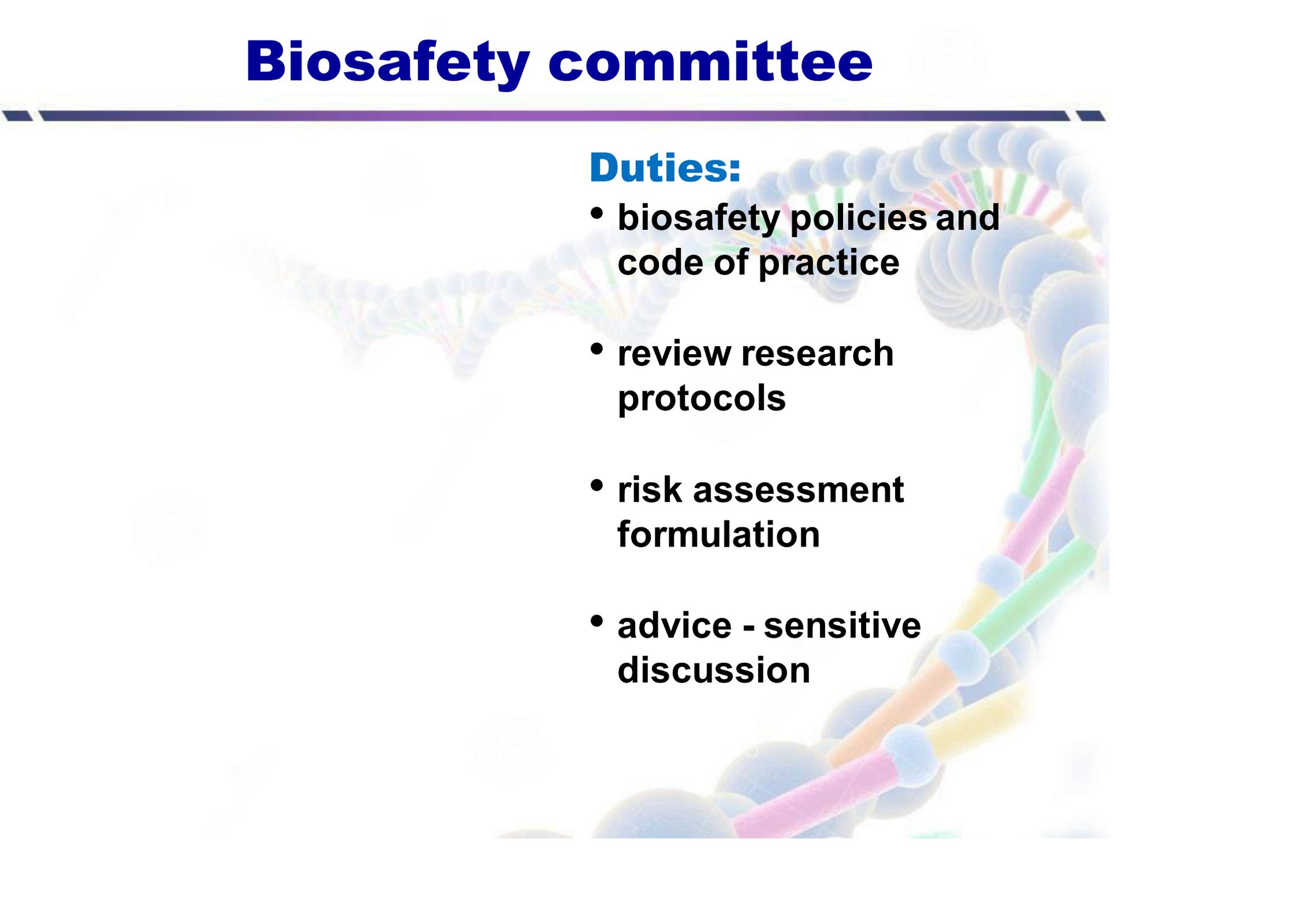
Biosafety committee



Committee include:

- biosafety officer/
scientists
- veterinarians
- medical officers
- representatives of
technical staff
- representatives of lab
management

Biosafety committee



Duties:

- **biosafety policies and code of practice**
- **review research protocols**
- **risk assessment formulation**
- **advice - sensitive discussion**

Biosafety



Lesson # 103

Biosafety



**Safety for
support
staff**

Safety for support staff

Introduction:

- safe and optimum operations of a lab
- dependent on support staff
- safety training

Safety for support staff

Engineering and maintenance services:

- institutional internal services
- good relationship with local services
- supervision of biosafety officer
- enter BSL-3 and BSL4 with clearance

Safety for support staff

Knowledge:

- maintain and repair the structure
- equipments
- nature of lab work
- safety regulations
- safety procedures

Biosafety



Lesson # 104

Biosafety



**Training
program
s**

Training programs

Effectiveness:

- **management commitment**
- **motivational factors**
- **initial job training**
- **good communication**
- **organization goals and objectives**

Training programs

Elements:

- needs assessment
- establishing training objectives
- specifying training contents and media
- accounting for individual learning differences

Training programs

Elements:

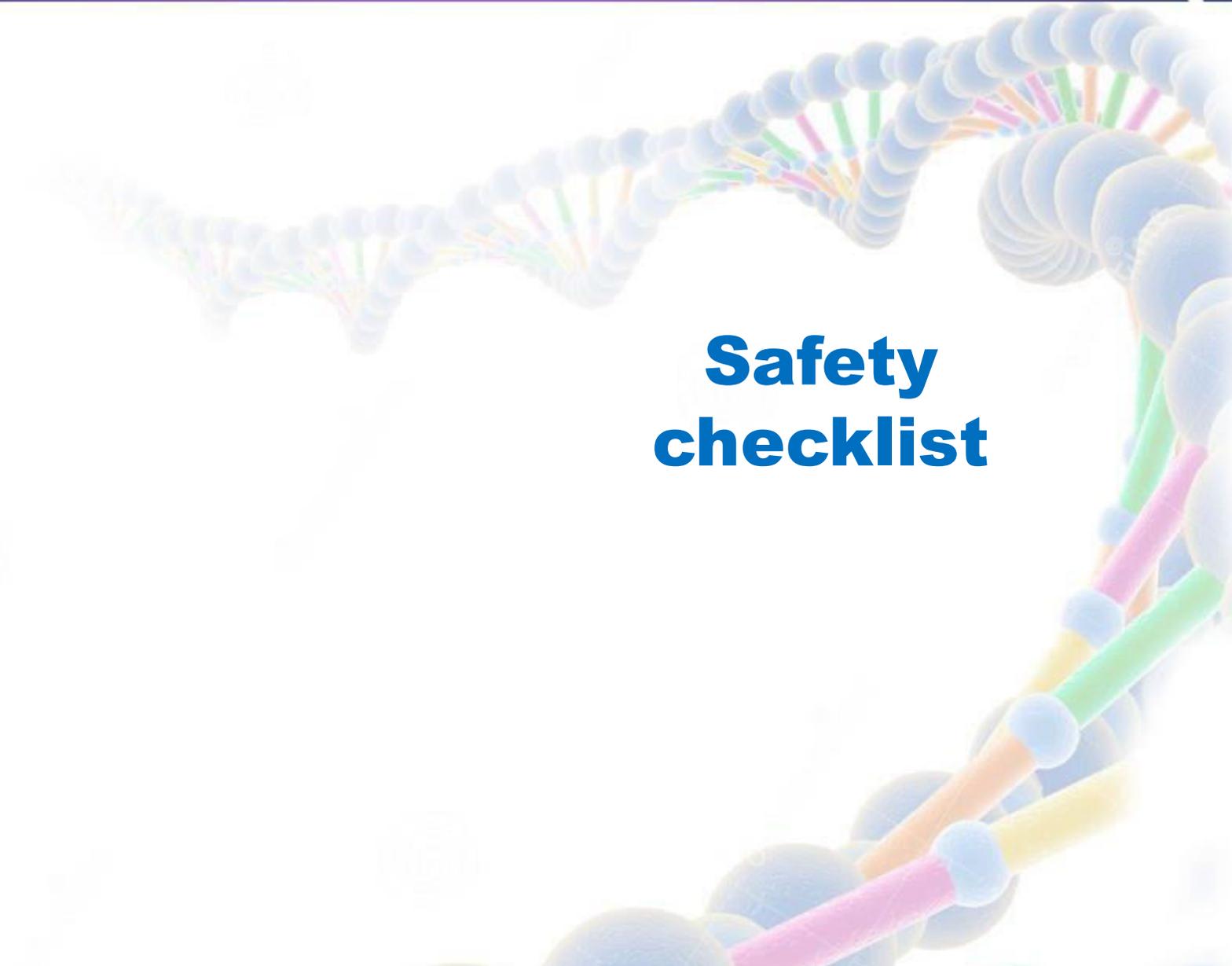
- specifying learning objectives
- training evaluation
- training revision

Biosafety



Lesson # 105

Biosafety



**Safety
checklist**

Safety checklist

Uses:

- intended to assist in assessment
- microbiological lab safety
- security status
- biomedical labs

Safety checklist

Checklist:

- lab premises
- storage facilities
- sanitation and staff facilities
- heating and ventilation
- lighting

Safety checklist

Checklist:

- **services**
- **lab biosecurity**
- **fire prevention and protection**
- **electrical hazards**
- **personal protection**

Safety checklist



Checklist:

- health and safety of staff
- chemicals/radioactive substances
- lab equipment
- infectious materials
- flammable liquid storage/compressed gases

Biosafety



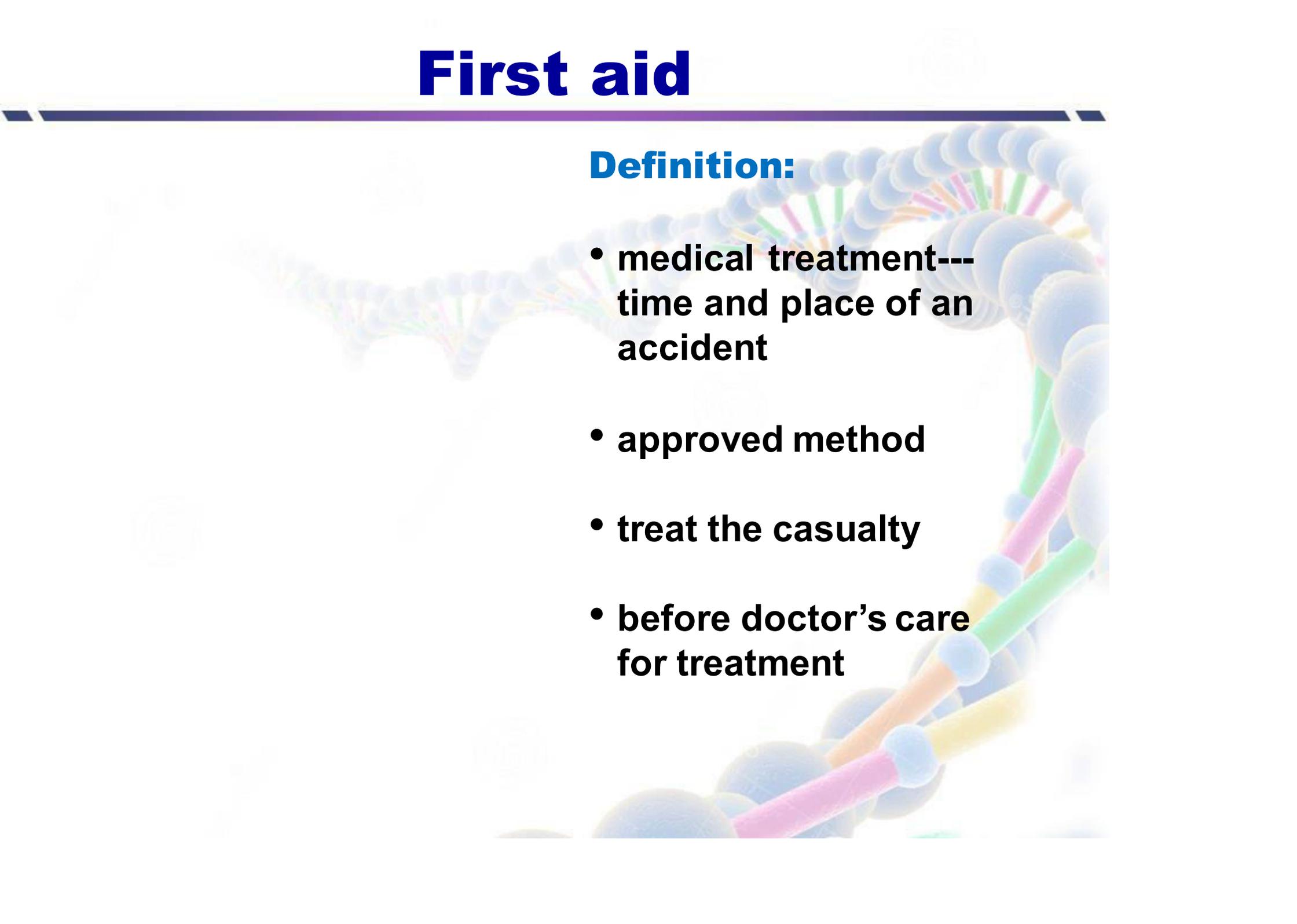
Lesson # 106

Biosafety



First aid

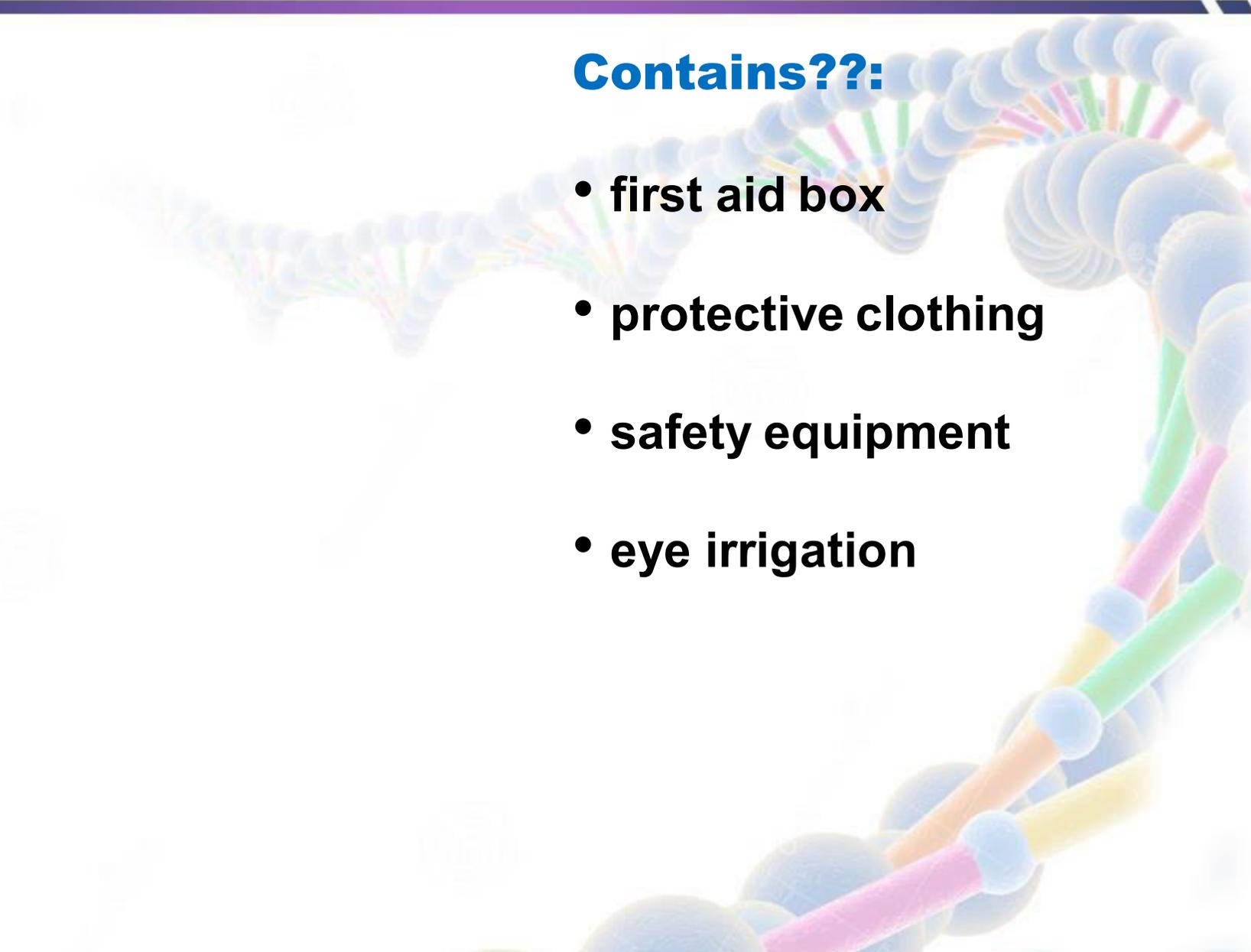
First aid



Definition:

- **medical treatment---**
time and place of an
accident
- **approved method**
- **treat the casualty**
- **before doctor's care**
for treatment

First aid



Contains??:

- first aid box
- protective clothing
- safety equipment
- eye irrigation

First aid

First aid box:

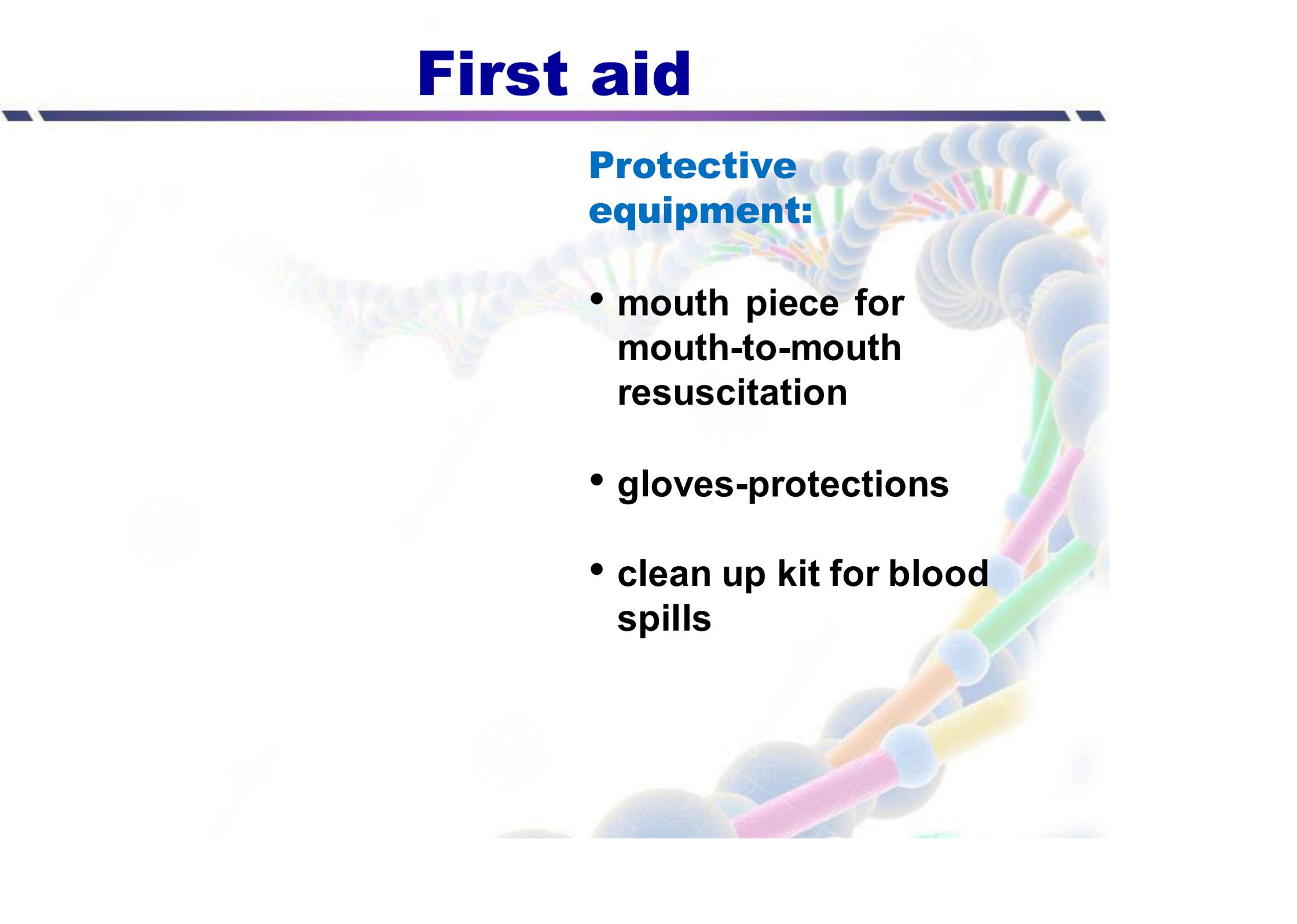
- made up of material-keep the content dust and damp free
- white cross with green box
- prominent position
- easily recognizable

First aid

Box contains??:

- first aid manual
- bandages
- sterile dressings
- safety pins

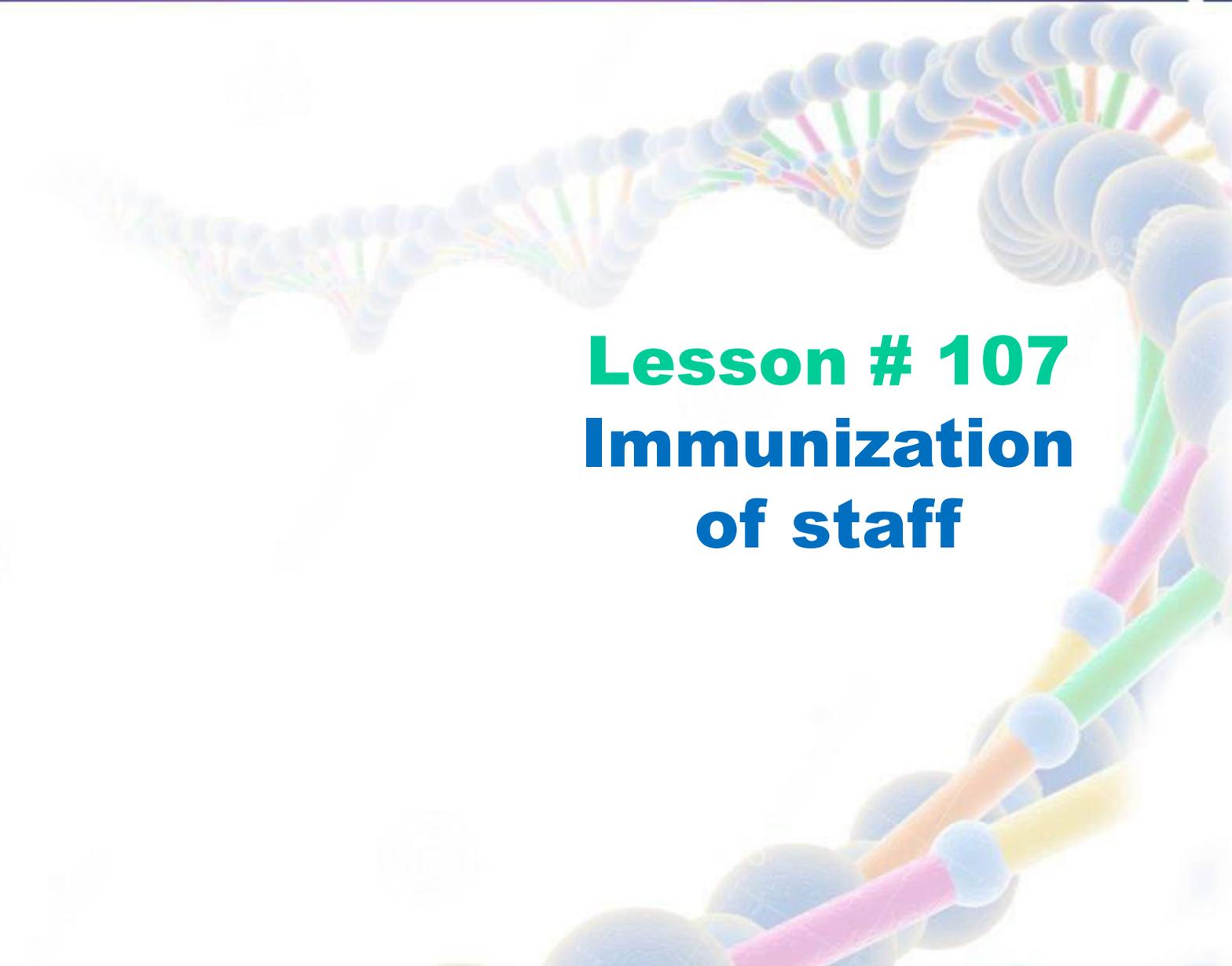
First aid



Protective equipment:

- mouth piece for mouth-to-mouth resuscitation
- gloves-protections
- clean up kit for blood spills

Biosafety



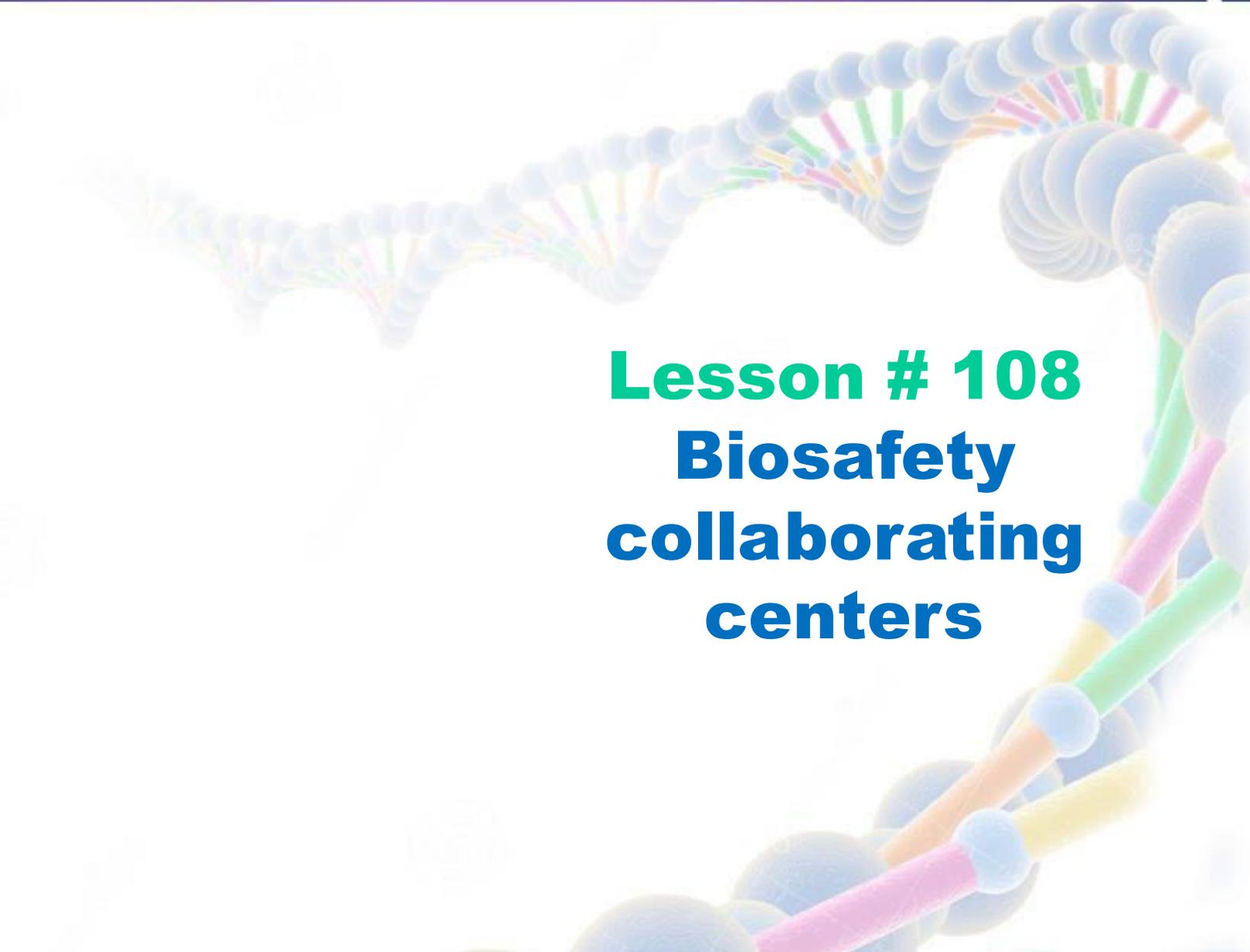
Lesson # 107
Immunization
of staff

Immunization of staff

Introduction:

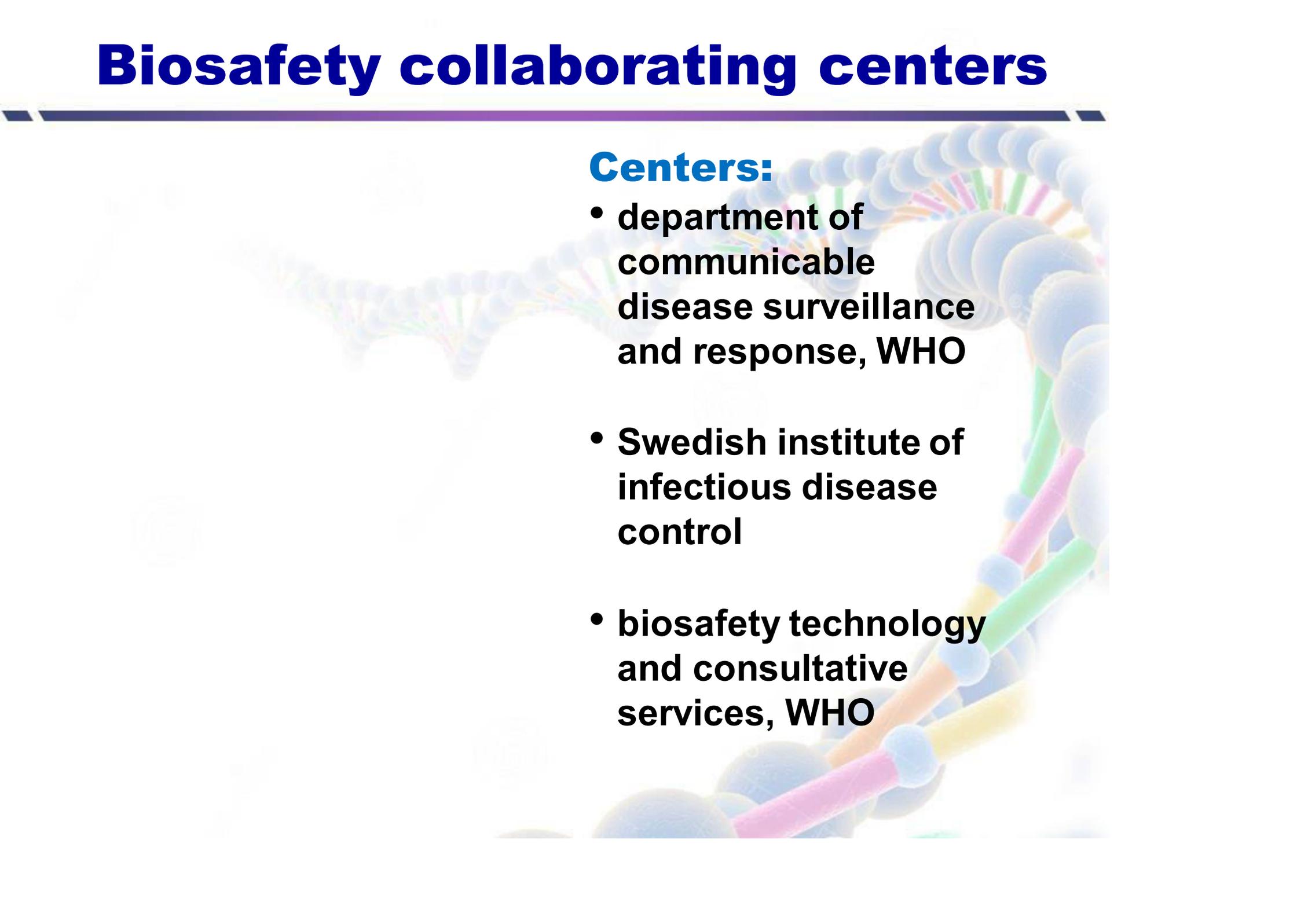
- discuss with workers
- vaccines
- therapeutic drugs-
after exposure

Biosafety



Lesson # 108
Biosafety
collaborating
centers

Biosafety collaborating centers



Centers:

- **department of communicable disease surveillance and response, WHO**
- **Swedish institute of infectious disease control**
- **biosafety technology and consultative services, WHO**

Biosafety collaborating centers



Centers:

- applied biosafety programs and training
- Victorian infectious diseases reference laboratory

Biosecurity



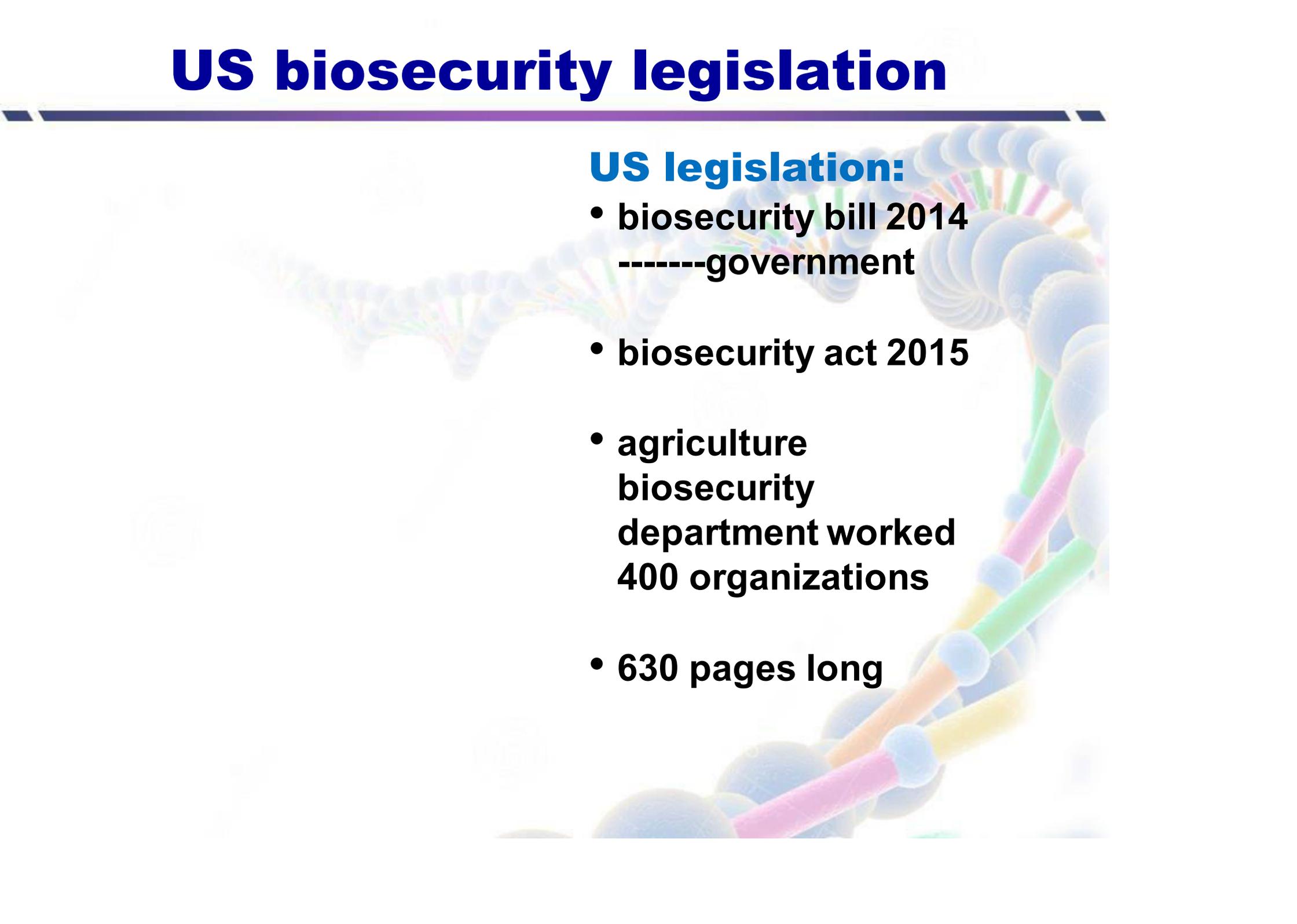
Lesson # 109

Biosecurity



US biosecurity legislation

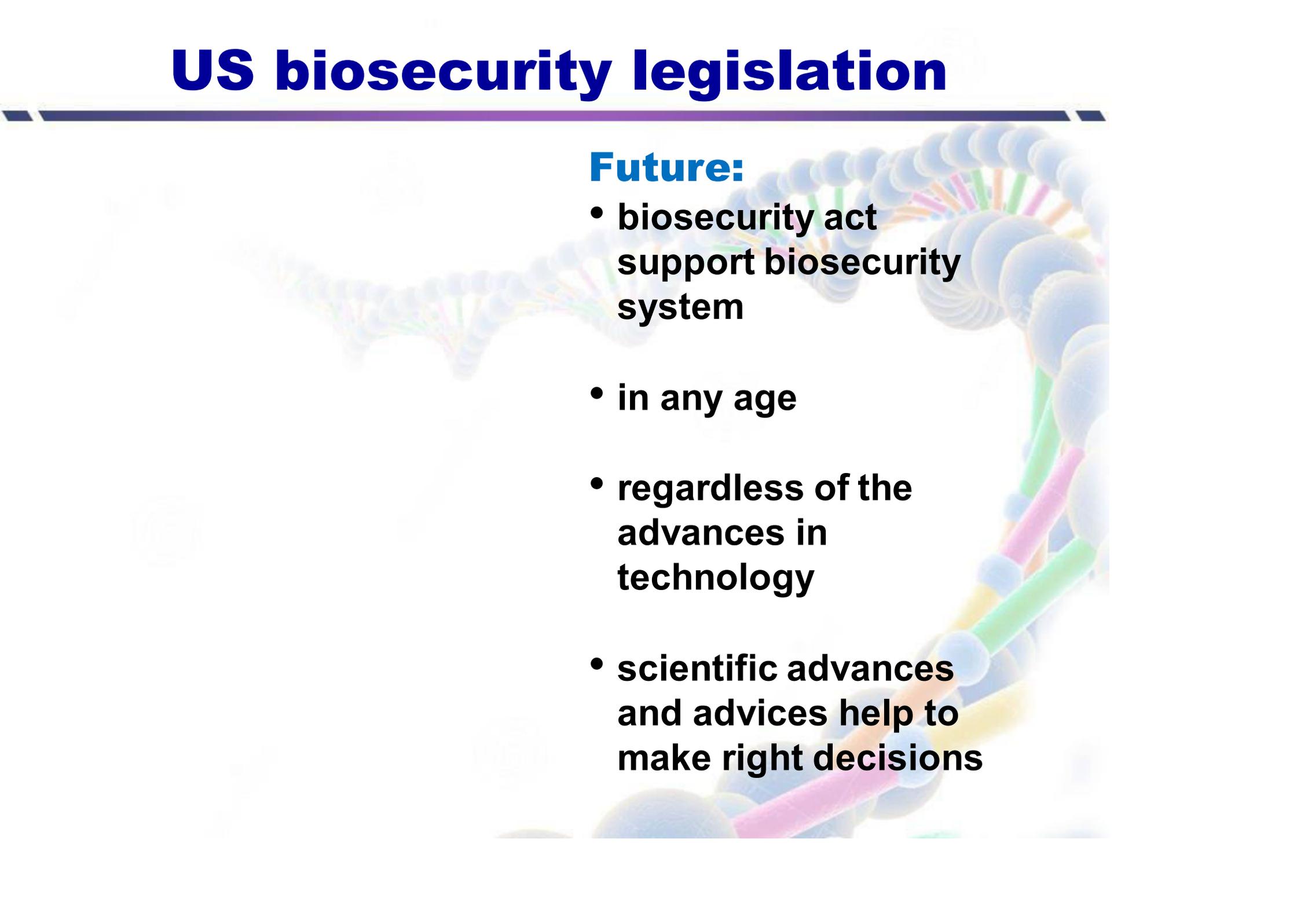
US biosecurity legislation



US legislation:

- biosecurity bill 2014
-----government
- biosecurity act 2015
- agriculture
biosecurity
department worked
400 organizations
- 630 pages long

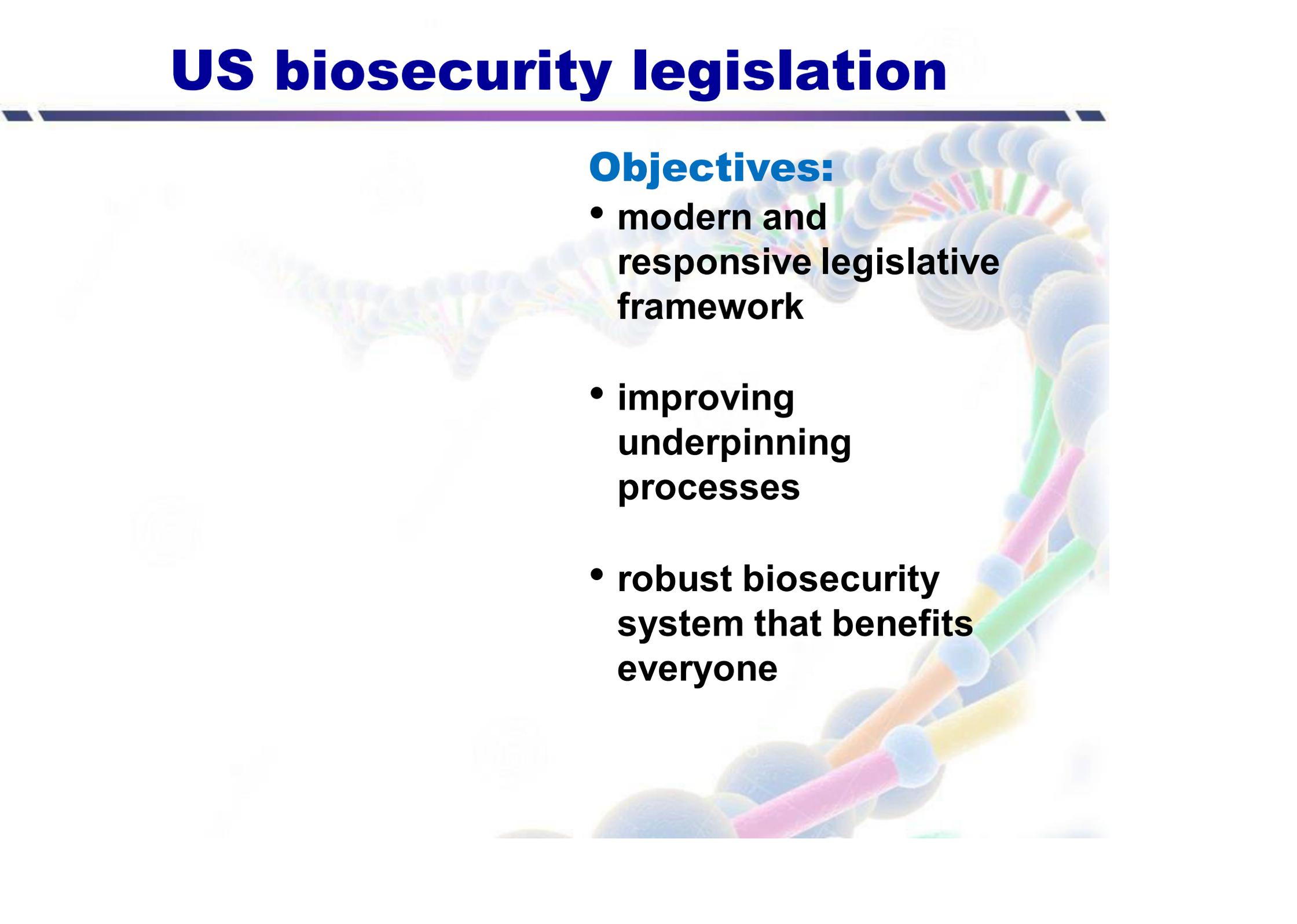
US biosecurity legislation



Future:

- **biosecurity act support biosecurity system**
- **in any age**
- **regardless of the advances in technology**
- **scientific advances and advices help to make right decisions**

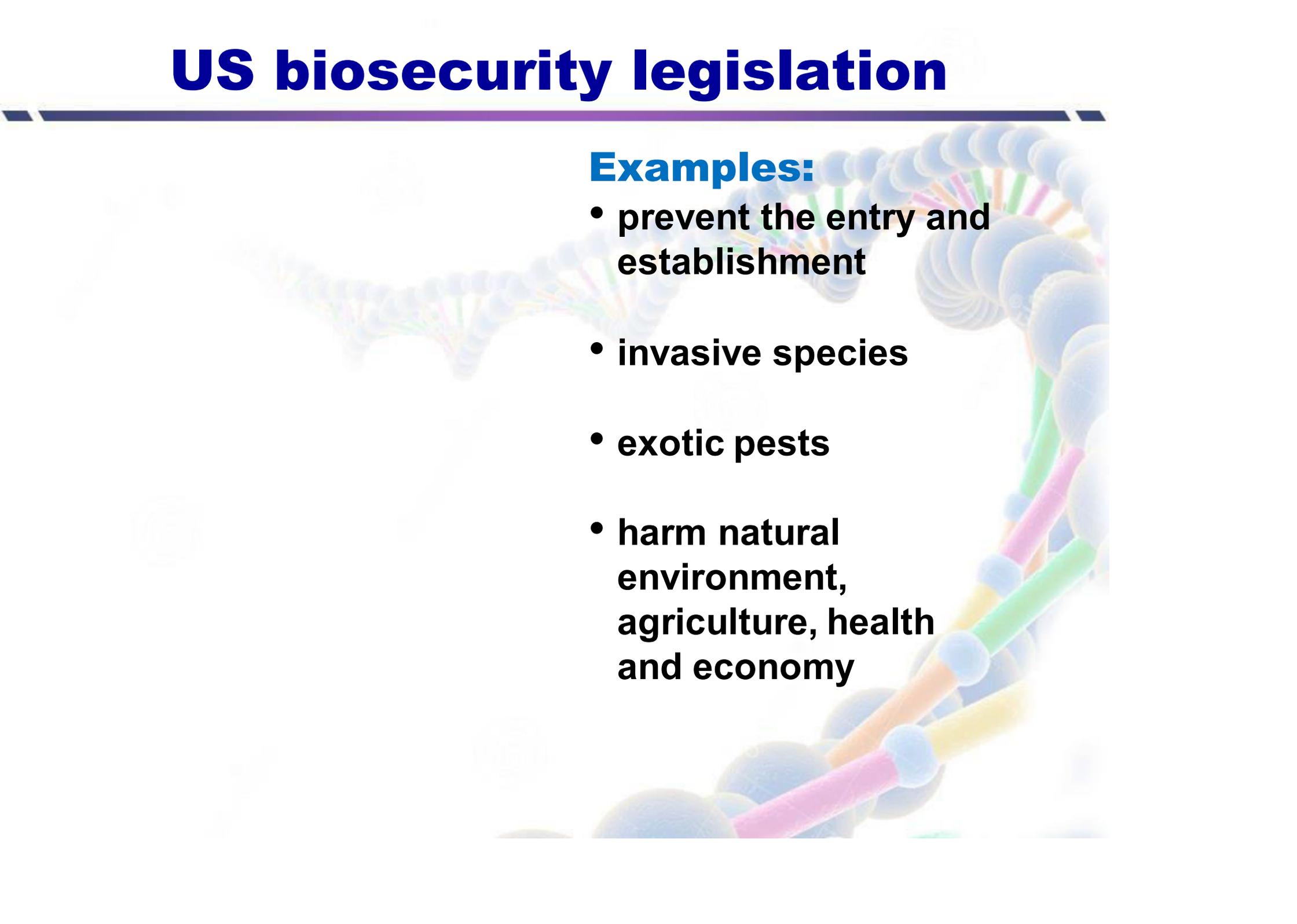
US biosecurity legislation



Objectives:

- **modern and responsive legislative framework**
- **improving underpinning processes**
- **robust biosecurity system that benefits everyone**

US biosecurity legislation



Examples:

- prevent the entry and establishment
- invasive species
- exotic pests
- harm natural environment, agriculture, health and economy

Biosecurity



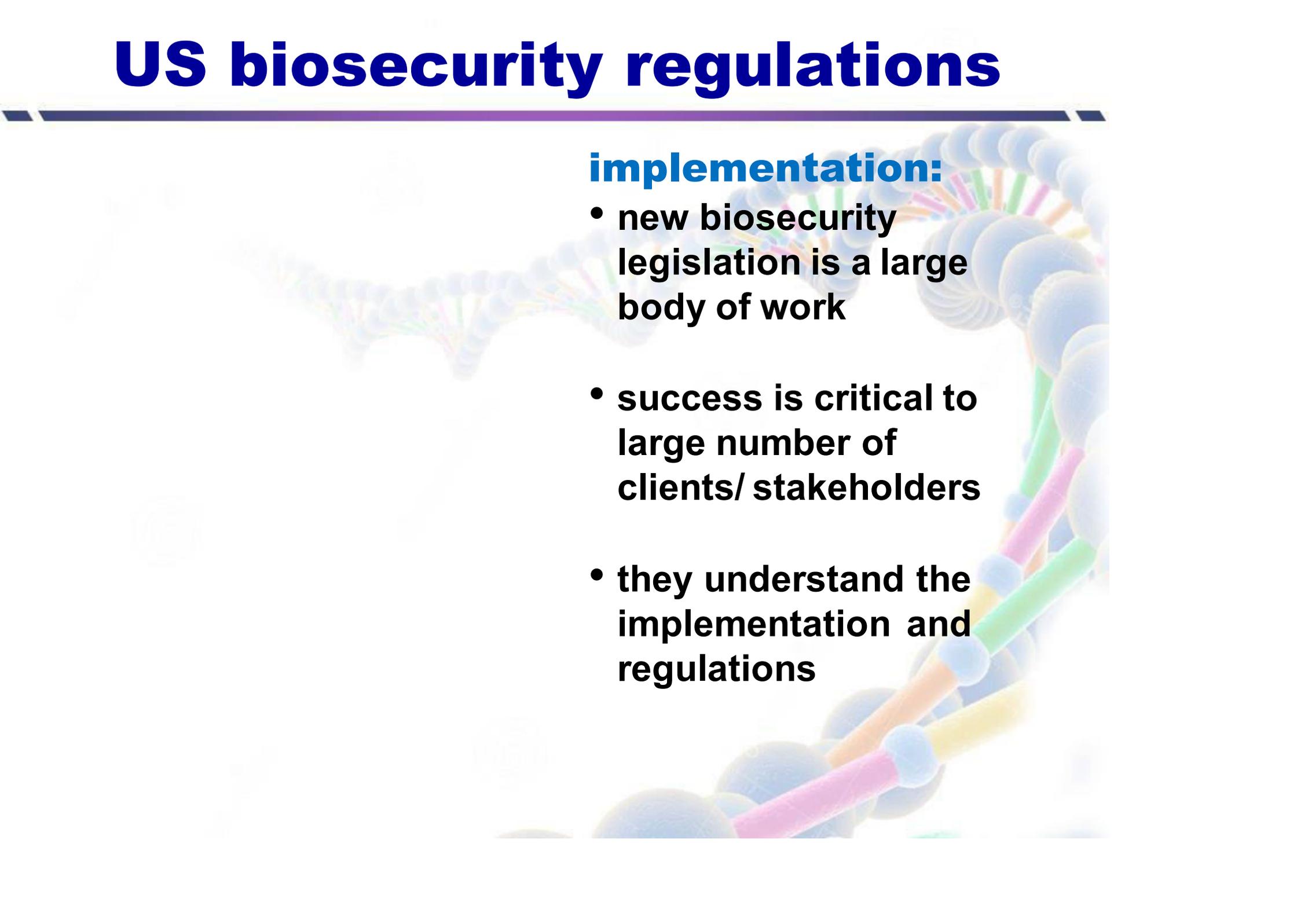
Lesson # 110

Biosecurity



US biosecurity regulations

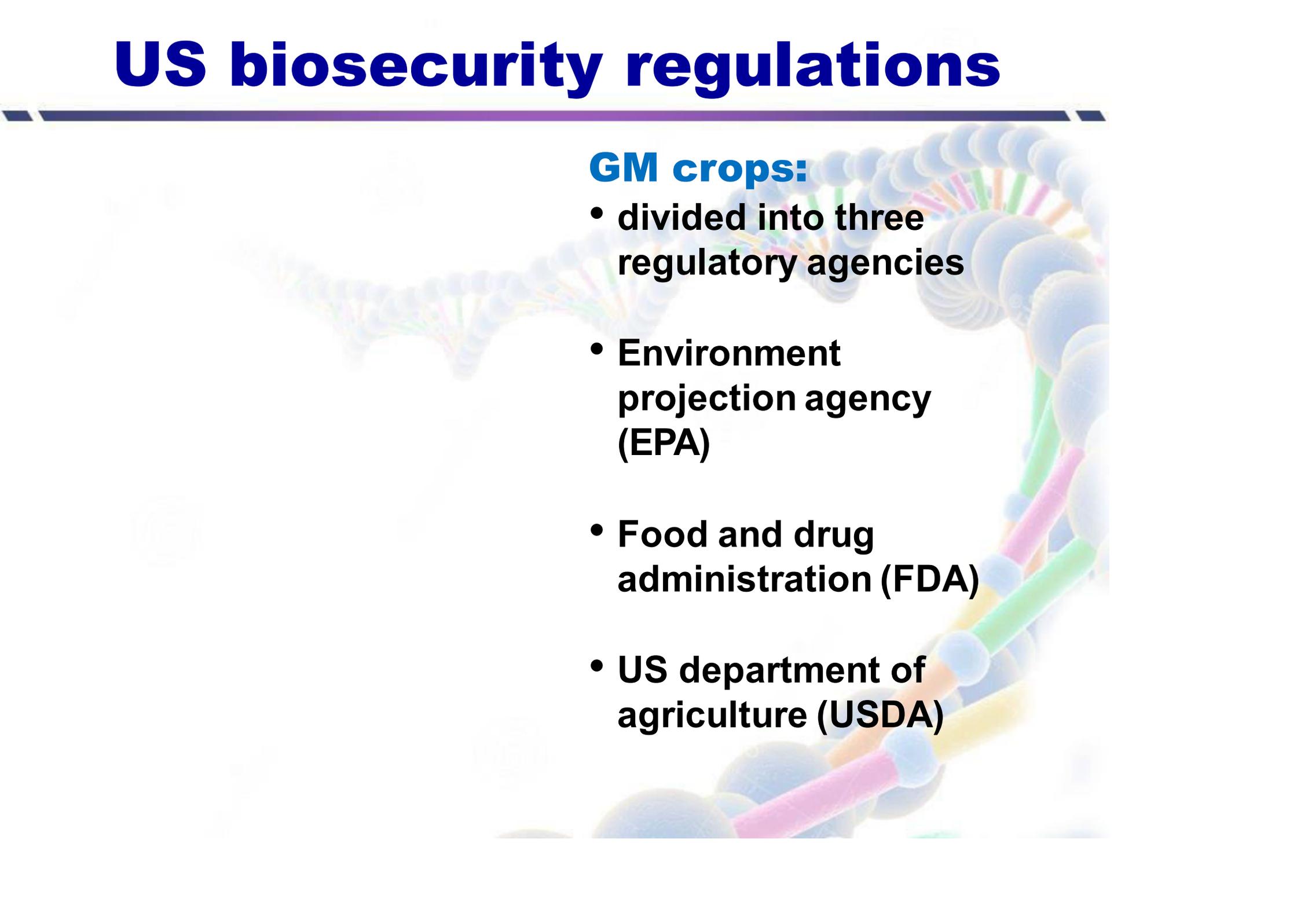
US biosecurity regulations



implementation:

- **new biosecurity legislation is a large body of work**
- **success is critical to large number of clients/ stakeholders**
- **they understand the implementation and regulations**

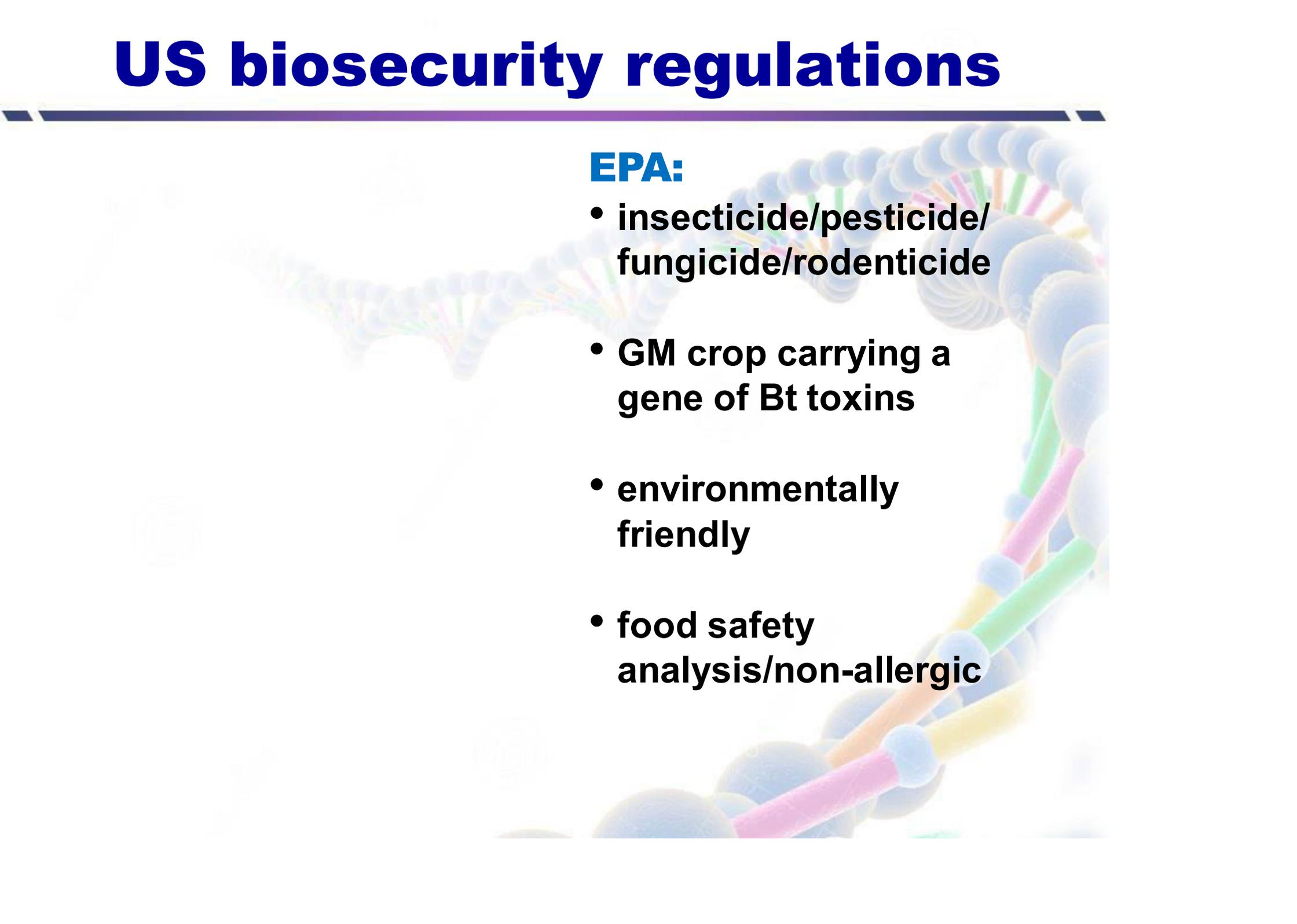
US biosecurity regulations



GM crops:

- **divided into three regulatory agencies**
- **Environment protection agency (EPA)**
- **Food and drug administration (FDA)**
- **US department of agriculture (USDA)**

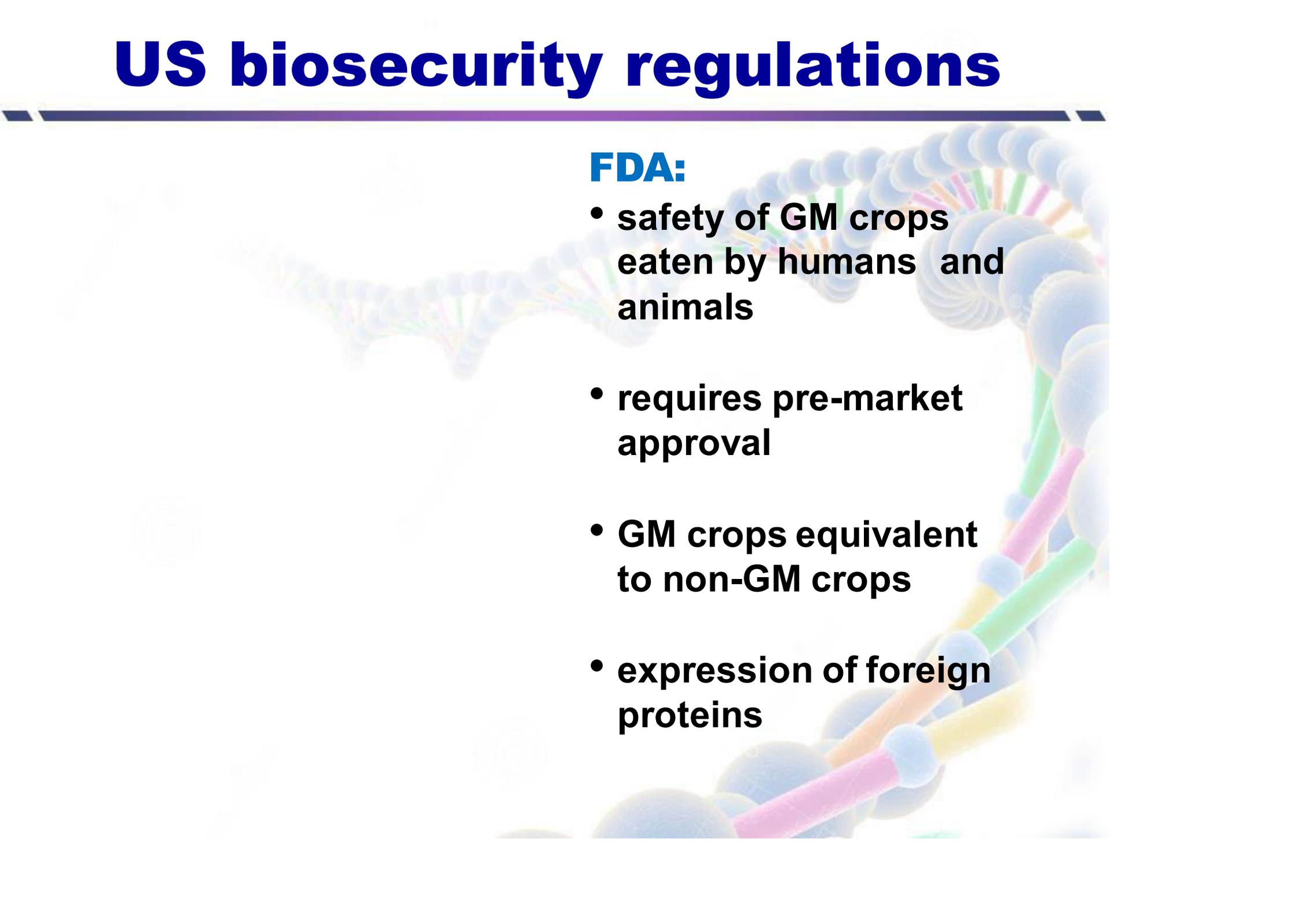
US biosecurity regulations



EPA:

- **insecticide/pesticide/
fungicide/rodenticide**
- **GM crop carrying a
gene of Bt toxins**
- **environmentally
friendly**
- **food safety
analysis/non-allergic**

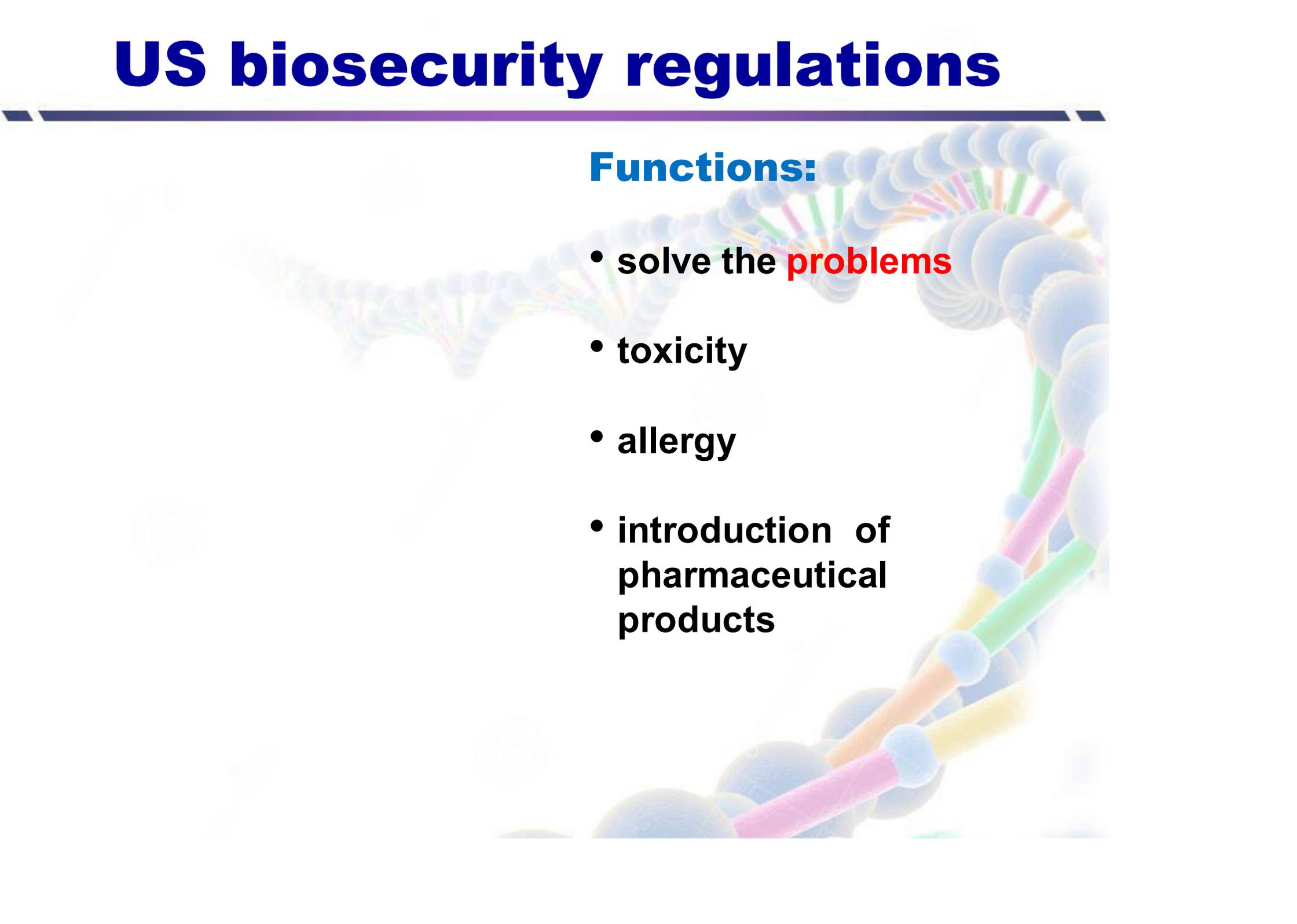
US biosecurity regulations



FDA:

- **safety of GM crops eaten by humans and animals**
- **requires pre-market approval**
- **GM crops equivalent to non-GM crops**
- **expression of foreign proteins**

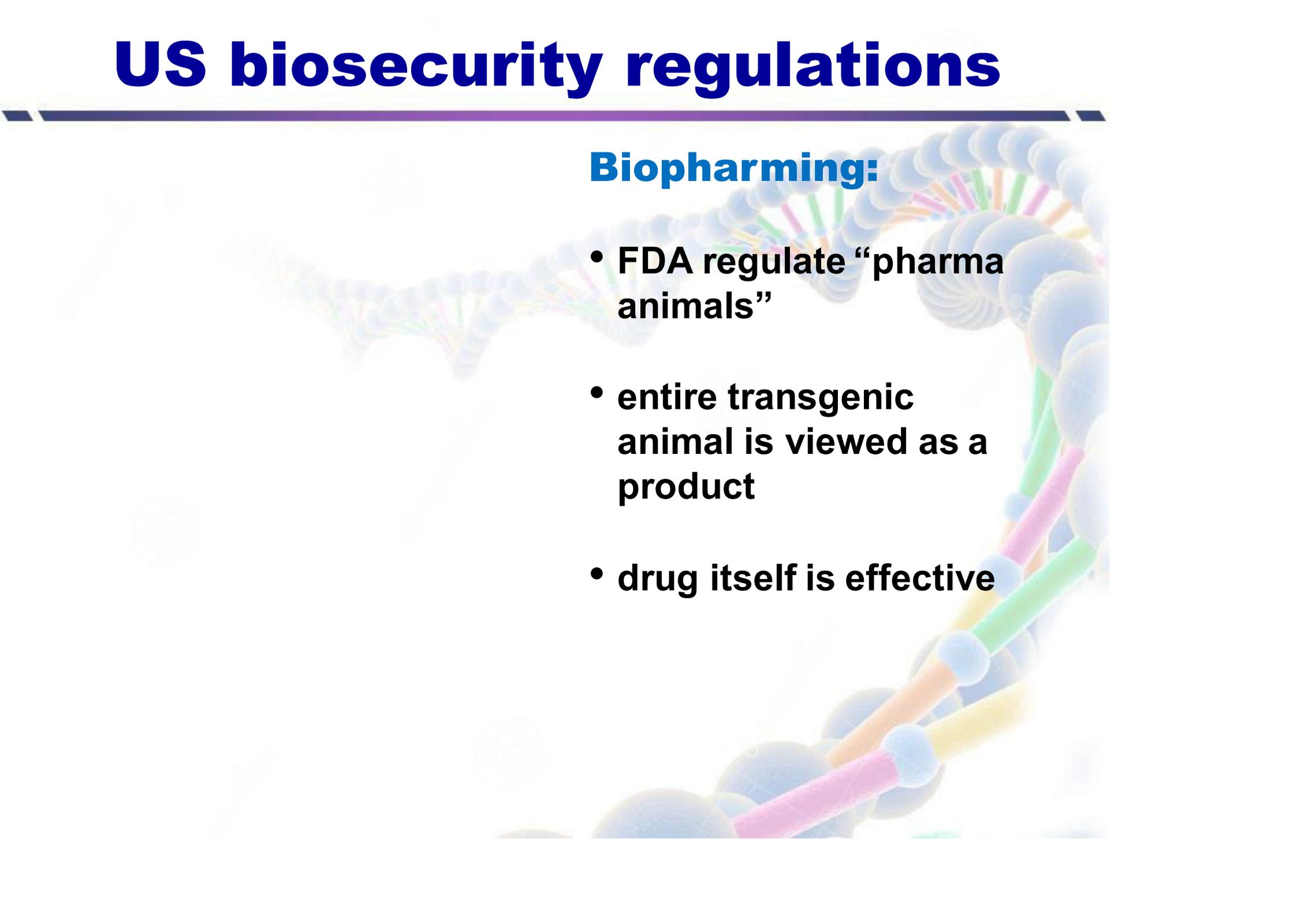
US biosecurity regulations



Functions:

- solve the **problems**
- toxicity
- allergy
- introduction of pharmaceutical products

US biosecurity regulations



Biopharming:

- FDA regulate “pharma animals”
- entire transgenic animal is viewed as a product
- drug itself is effective

Biosecurity



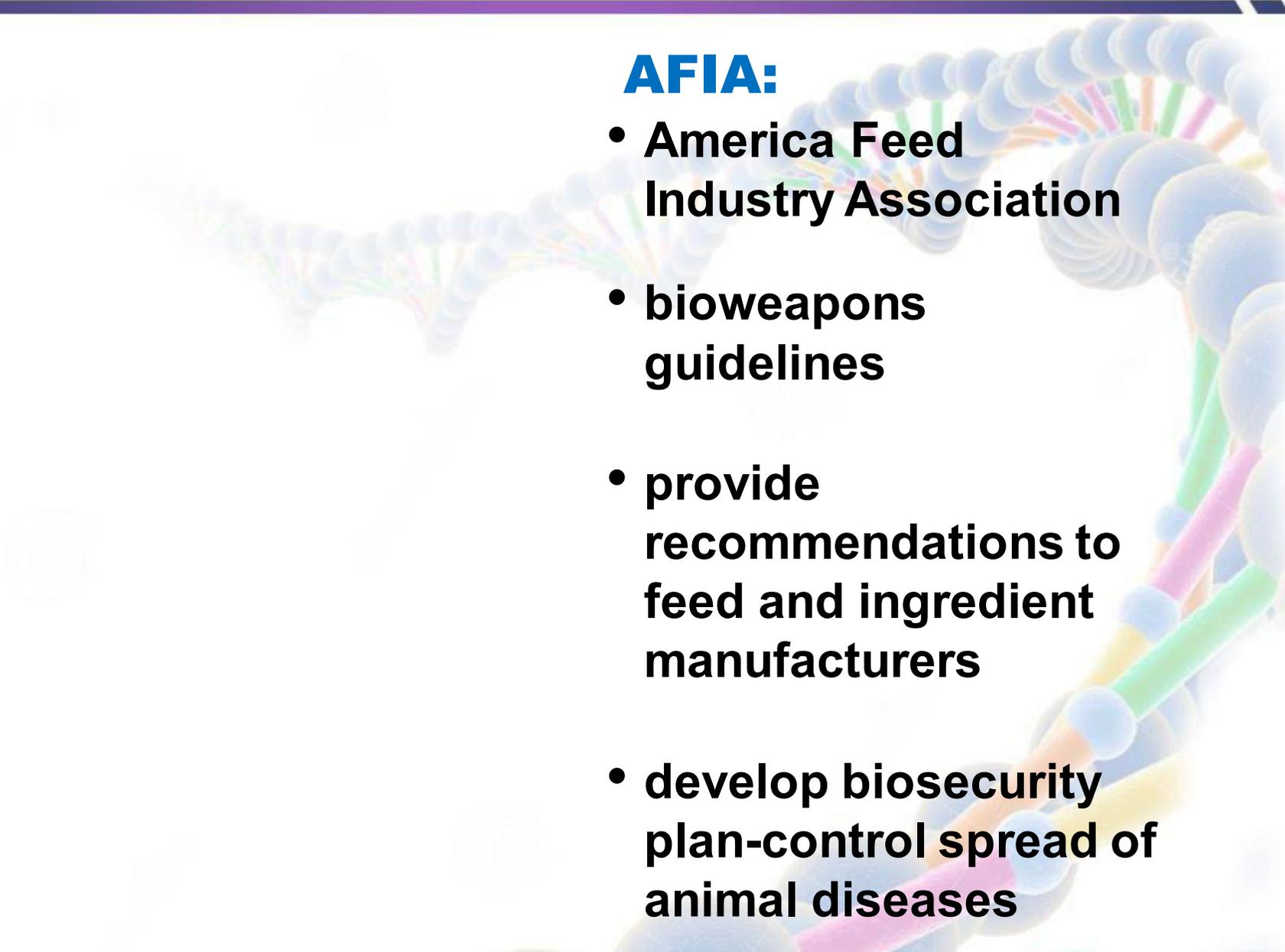
Lesson # 111

Biosecurity



**US biosecurity
guidance**

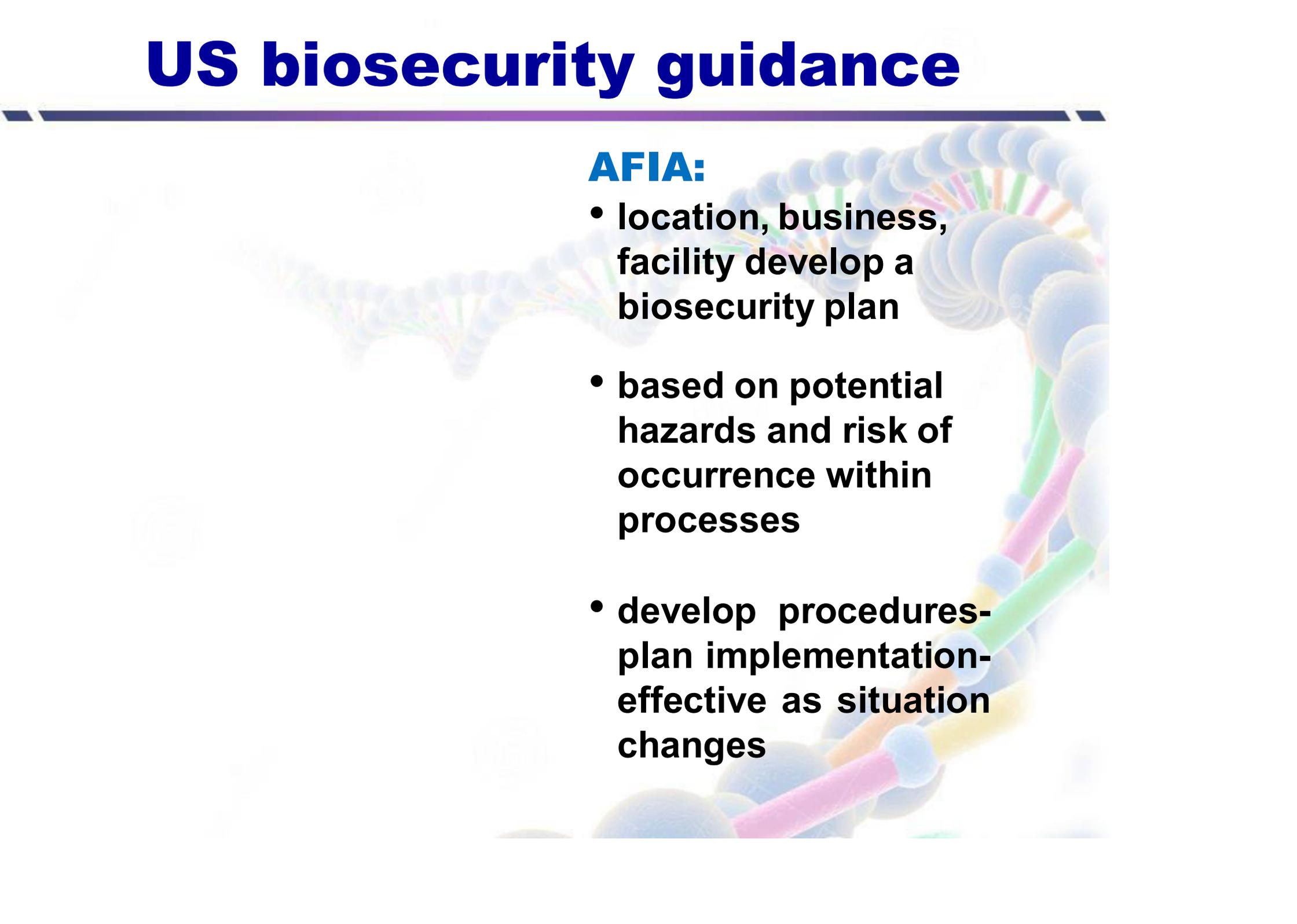
US biosecurity guidance



AFIA:

- **America Feed Industry Association**
- **bioweapons guidelines**
- **provide recommendations to feed and ingredient manufacturers**
- **develop biosecurity plan-control spread of animal diseases**

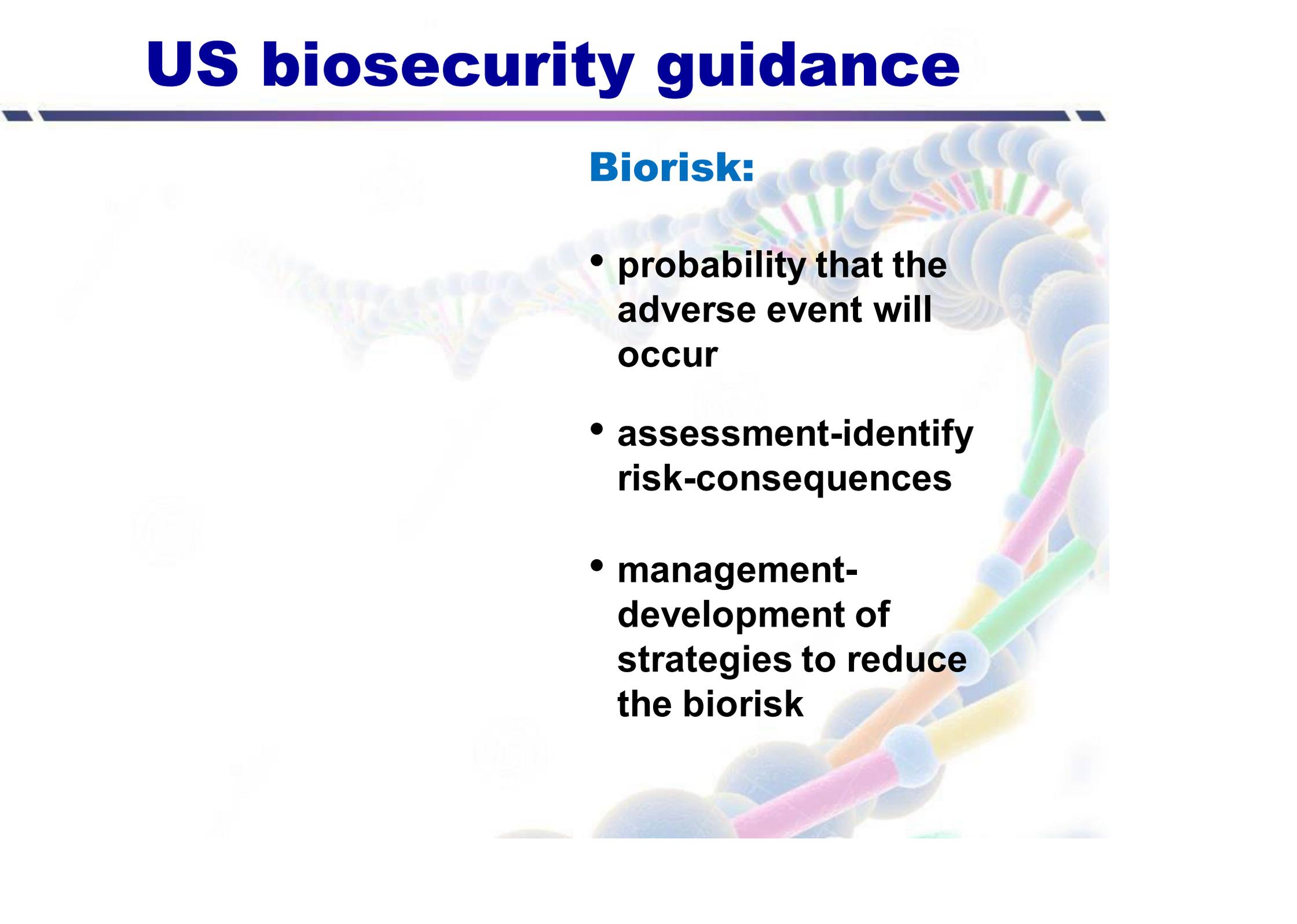
US biosecurity guidance



AFIA:

- **location, business, facility develop a biosecurity plan**
- **based on potential hazards and risk of occurrence within processes**
- **develop procedures-plan implementation-effective as situation changes**

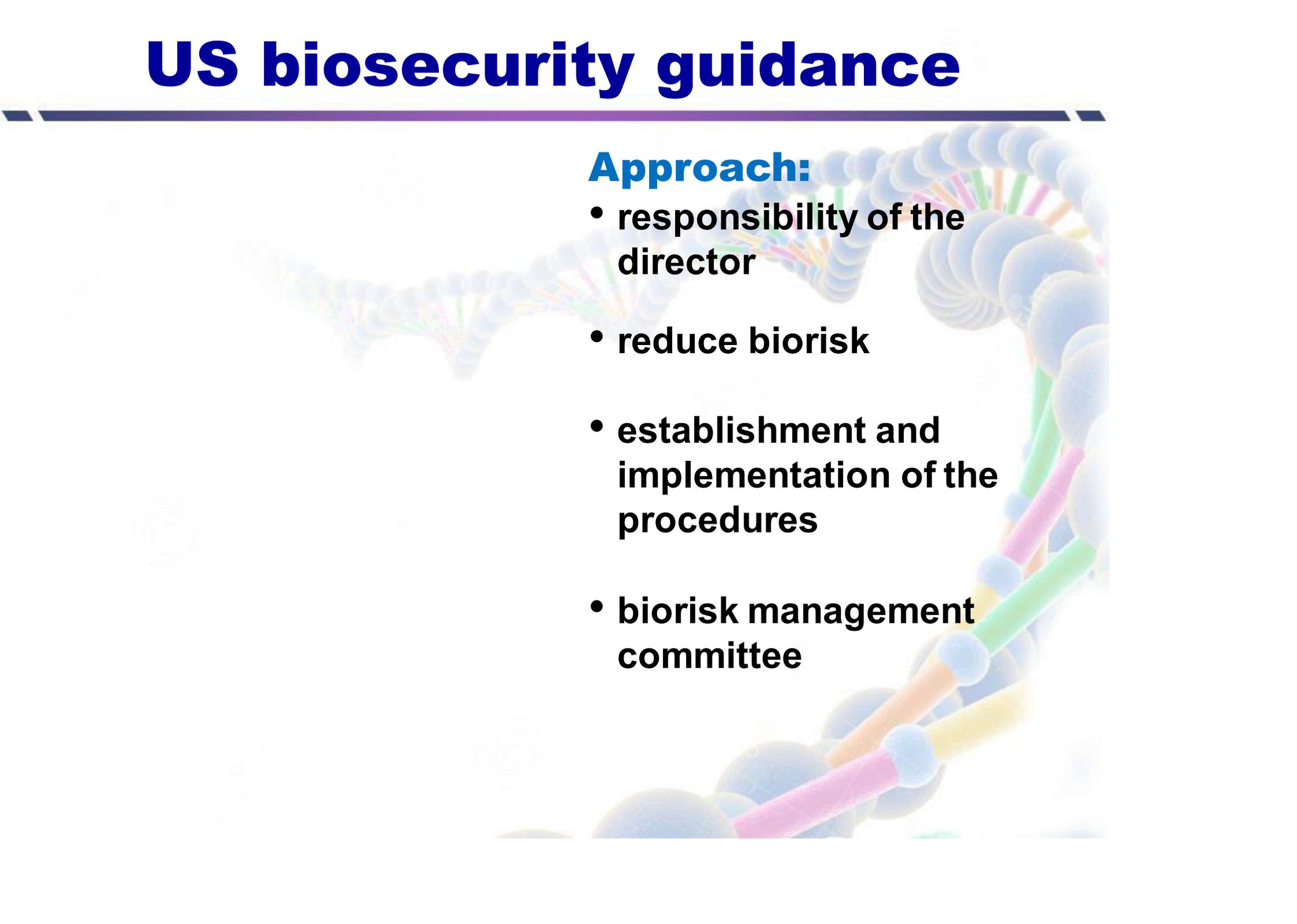
US biosecurity guidance



Biorisk:

- **probability that the adverse event will occur**
- **assessment-identify risk-consequences**
- **management-development of strategies to reduce the biorisk**

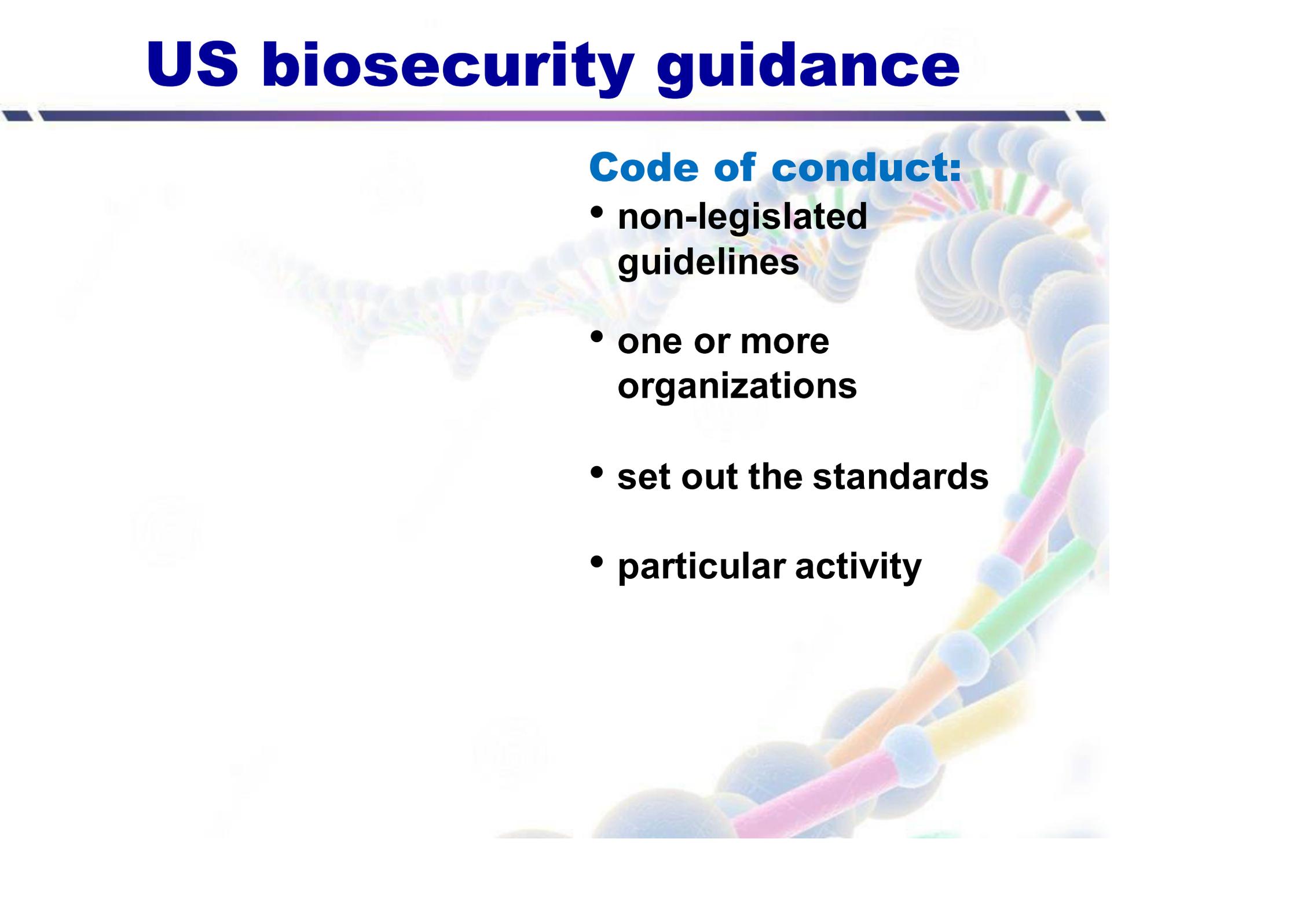
US biosecurity guidance



Approach:

- **responsibility of the director**
- **reduce biorisk**
- **establishment and implementation of the procedures**
- **biorisk management committee**

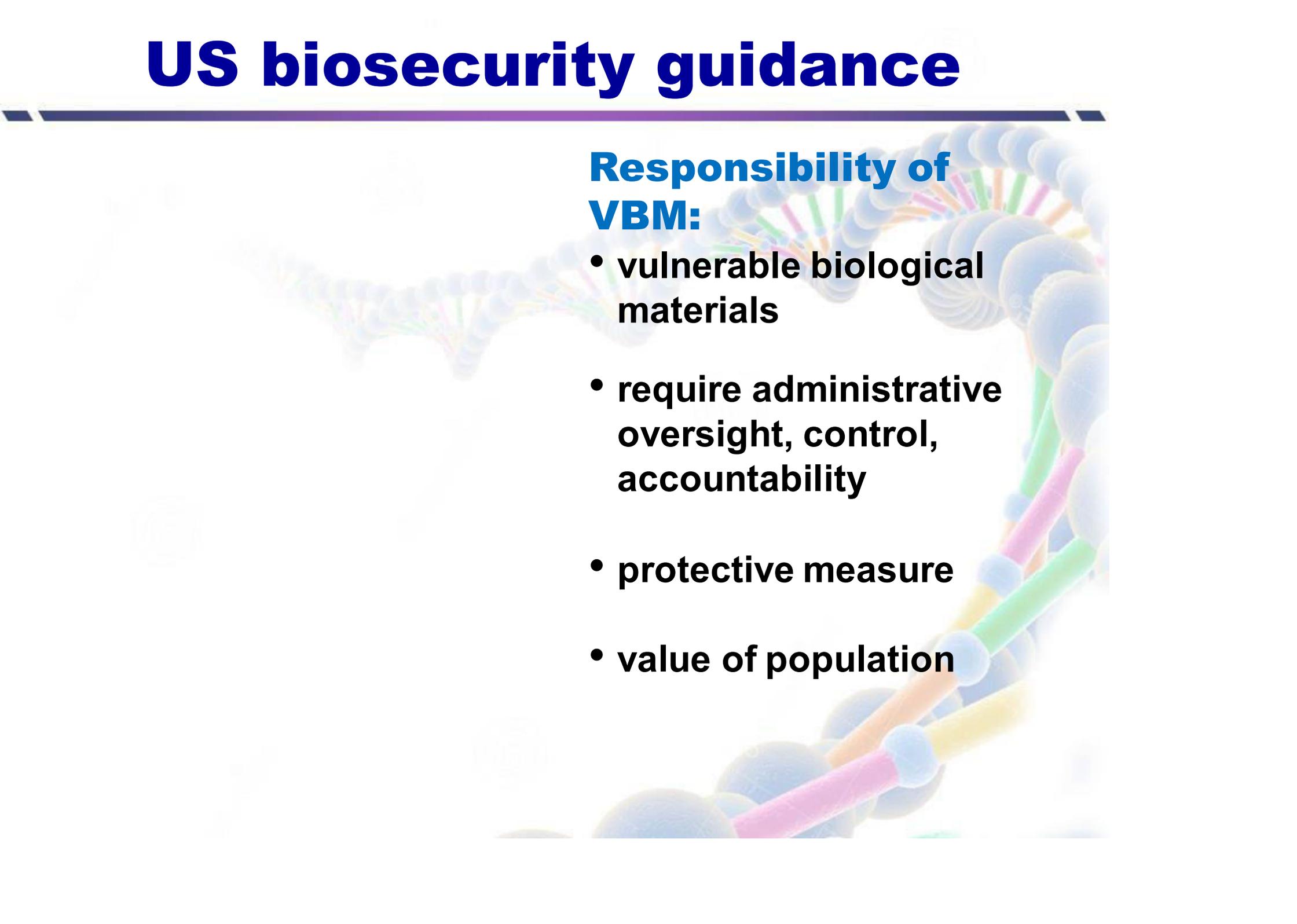
US biosecurity guidance



Code of conduct:

- **non-legislated guidelines**
- **one or more organizations**
- **set out the standards**
- **particular activity**

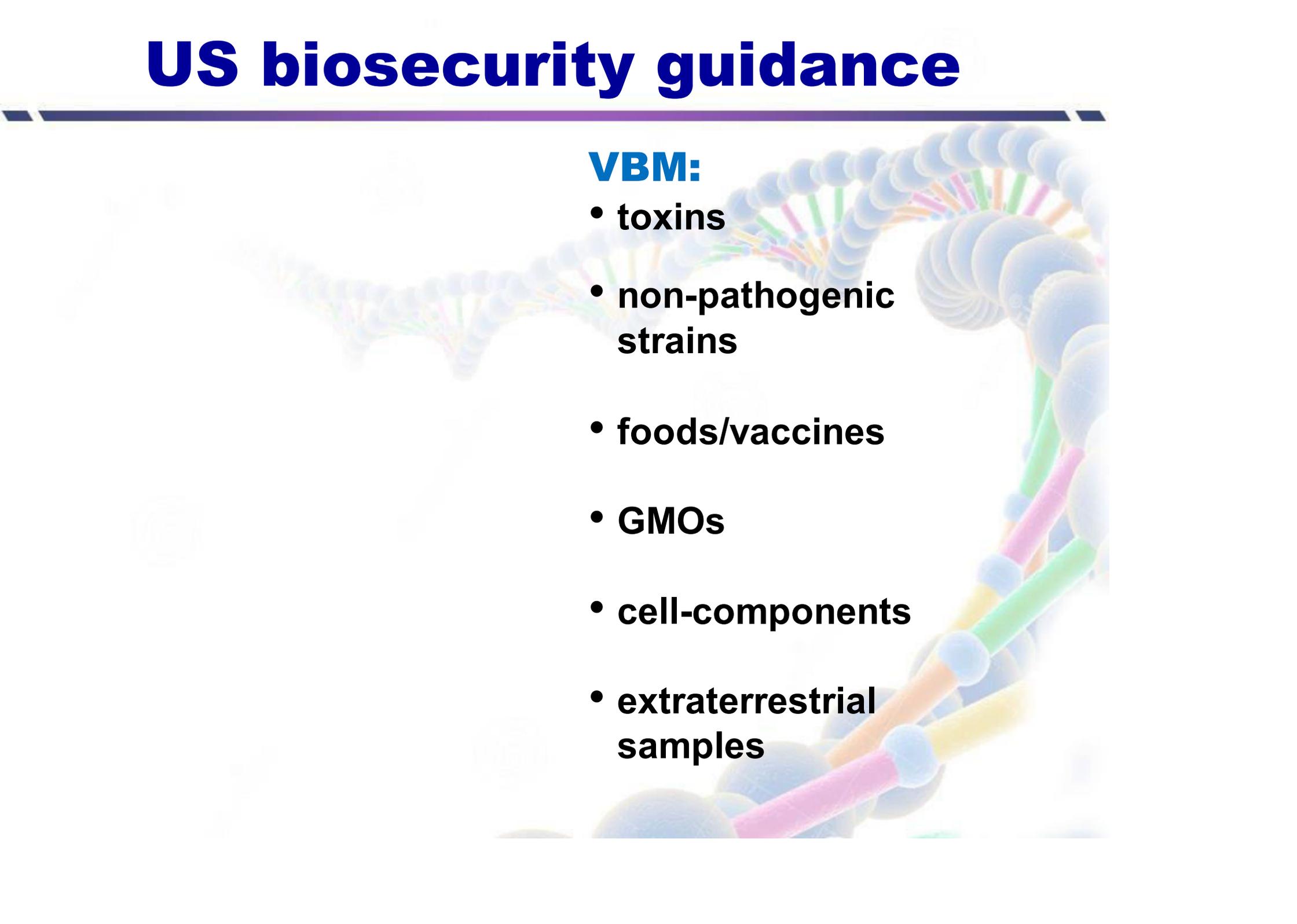
US biosecurity guidance



Responsibility of VBM:

- **vulnerable biological materials**
- **require administrative oversight, control, accountability**
- **protective measure**
- **value of population**

US biosecurity guidance



VBM:

- toxins
- non-pathogenic strains
- foods/vaccines
- GMOs
- cell-components
- extraterrestrial samples

Biosecurity



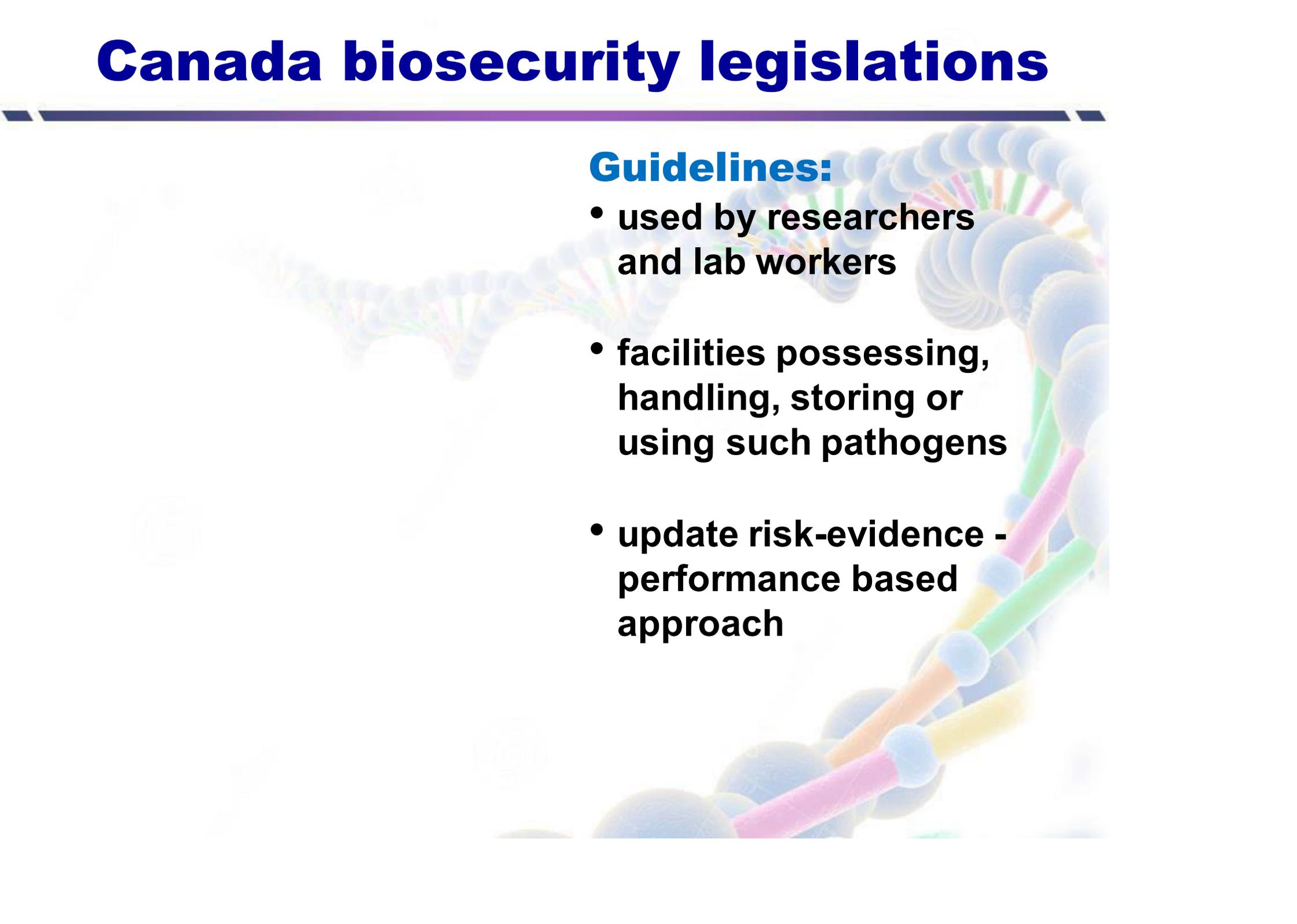
Lesson # 112
Canada
biosecurity
legislations

Canada biosecurity legislations

Development:

- **public health agency of Canada**
- **Canadian food inspection agency**
- **guidelines for human and animal pathogens and toxins**

Canada biosecurity legislations



Guidelines:

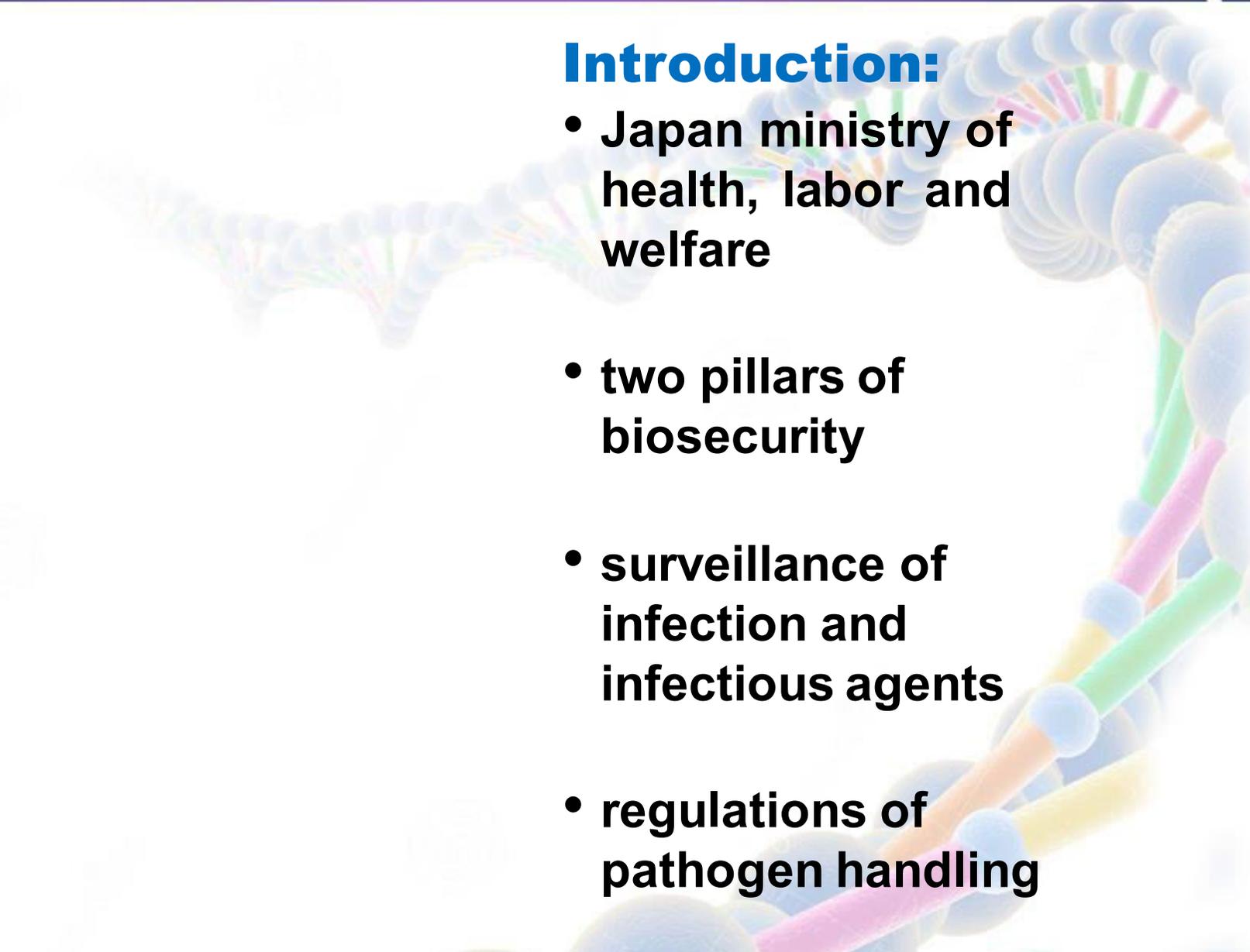
- **used by researchers and lab workers**
- **facilities possessing, handling, storing or using such pathogens**
- **update risk-evidence - performance based approach**

Biosecurity



Lesson # 113
Japan
biosecurity
legislations

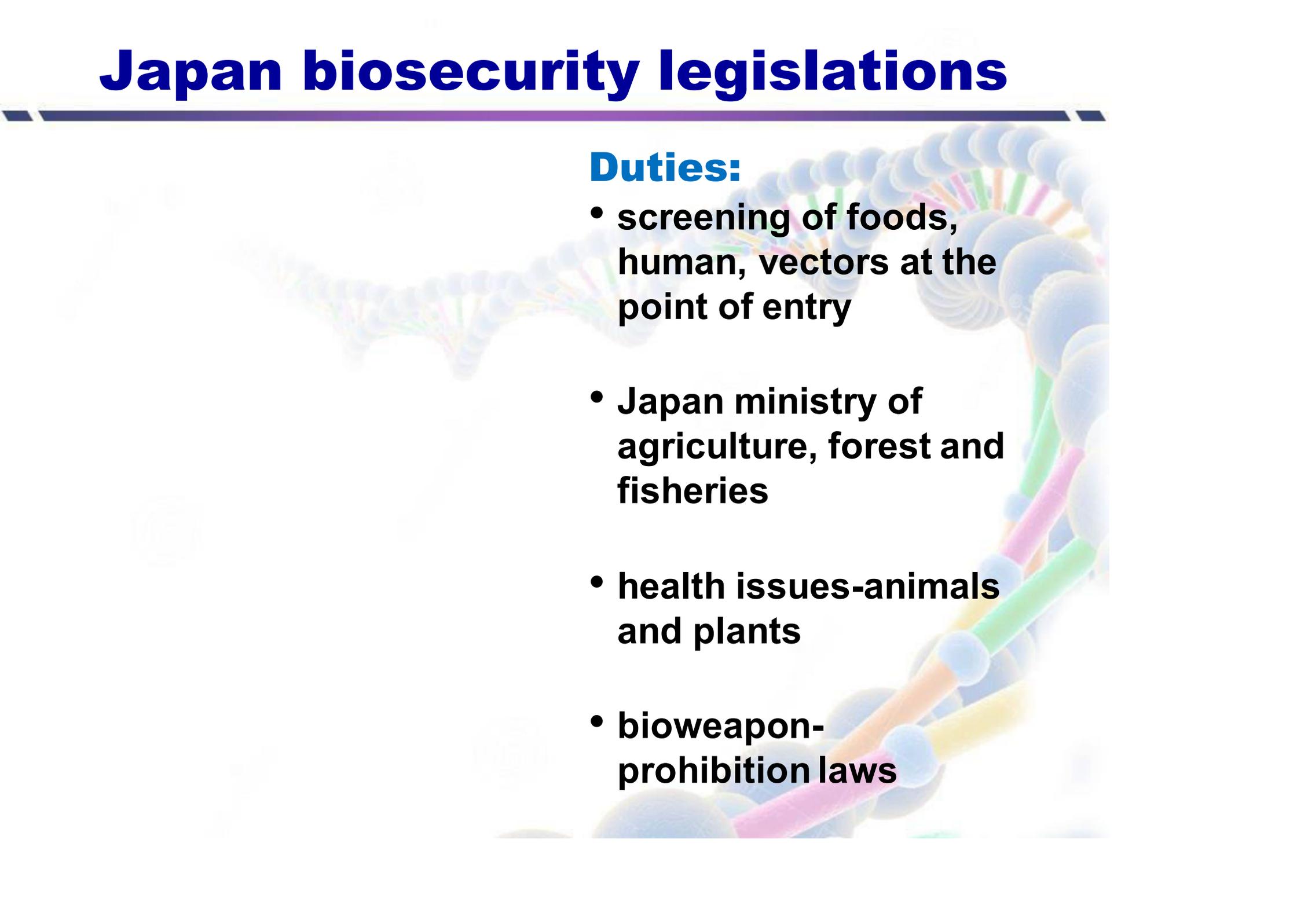
Japan biosecurity legislations



Introduction:

- **Japan ministry of health, labor and welfare**
- **two pillars of biosecurity**
- **surveillance of infection and infectious agents**
- **regulations of pathogen handling**

Japan biosecurity legislations



Duties:

- screening of foods, human, vectors at the point of entry
- Japan ministry of agriculture, forest and fisheries
- health issues-animals and plants
- bioweapon-prohibition laws

Biosecurity



Lesson # 114

Biosecurity



**Other
countries
biosecurity**

Other countries biosecurity



New Zealand:

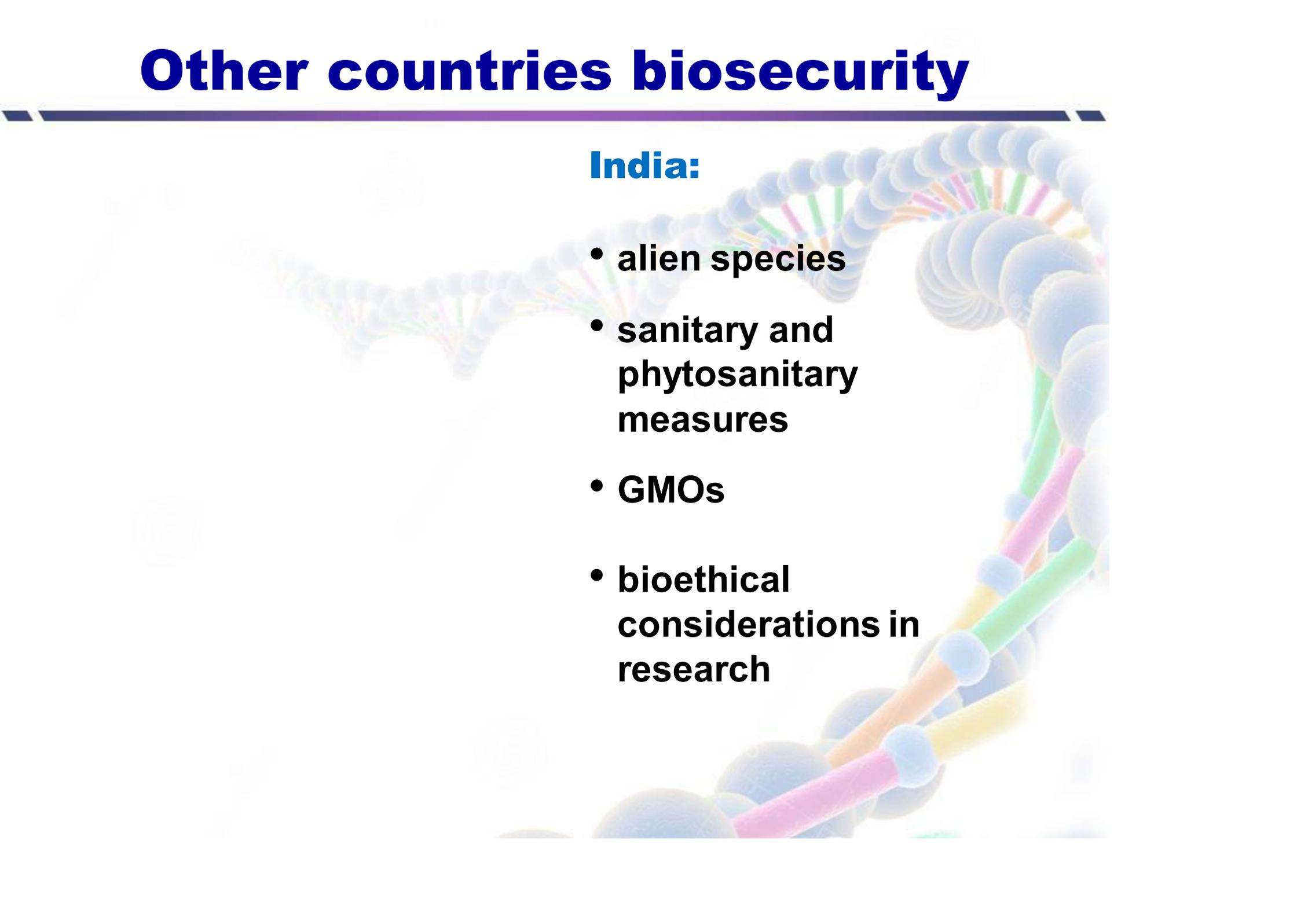
- **work with other organizations**
- **hazardous substance and new organism act**
- **not in 1993-develop 1996**
- **environment safety**
- **human health**

Other countries biosecurity

Queensland biosecurity act 2014:

- facilitates responding -impact of biosecurity consideration
- safety and quality of animal field
- agriculture inputs
- requirement at national level

Other countries biosecurity



India:

- alien species
- sanitary and phytosanitary measures
- GMOs
- bioethical considerations in research

Biosecurity



Lesson # 115

3/1/2018

Amaan Khan

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Biosecurity



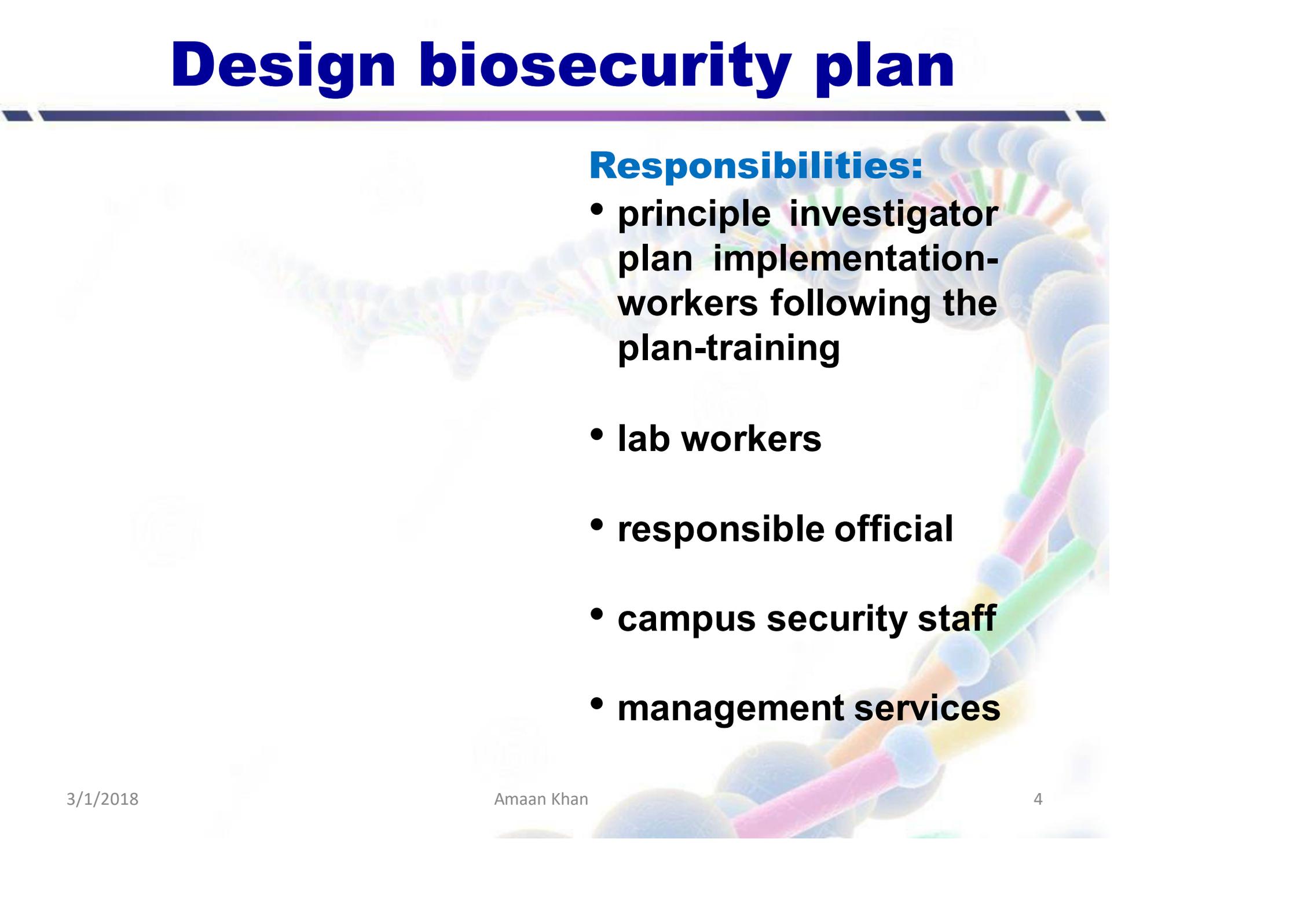
Design biosecurity plan

Design biosecurity plan

Biosecurity plan:

- **written plan-prevent the introduction and spread of disease to farm**
- **daily operation procedures**
- **disinfecting procedures-part of the plan**

Design biosecurity plan



Responsibilities:

- **principle investigator
plan implementation-
workers following the
plan-training**
- **lab workers**
- **responsible official**
- **campus security staff**
- **management services**

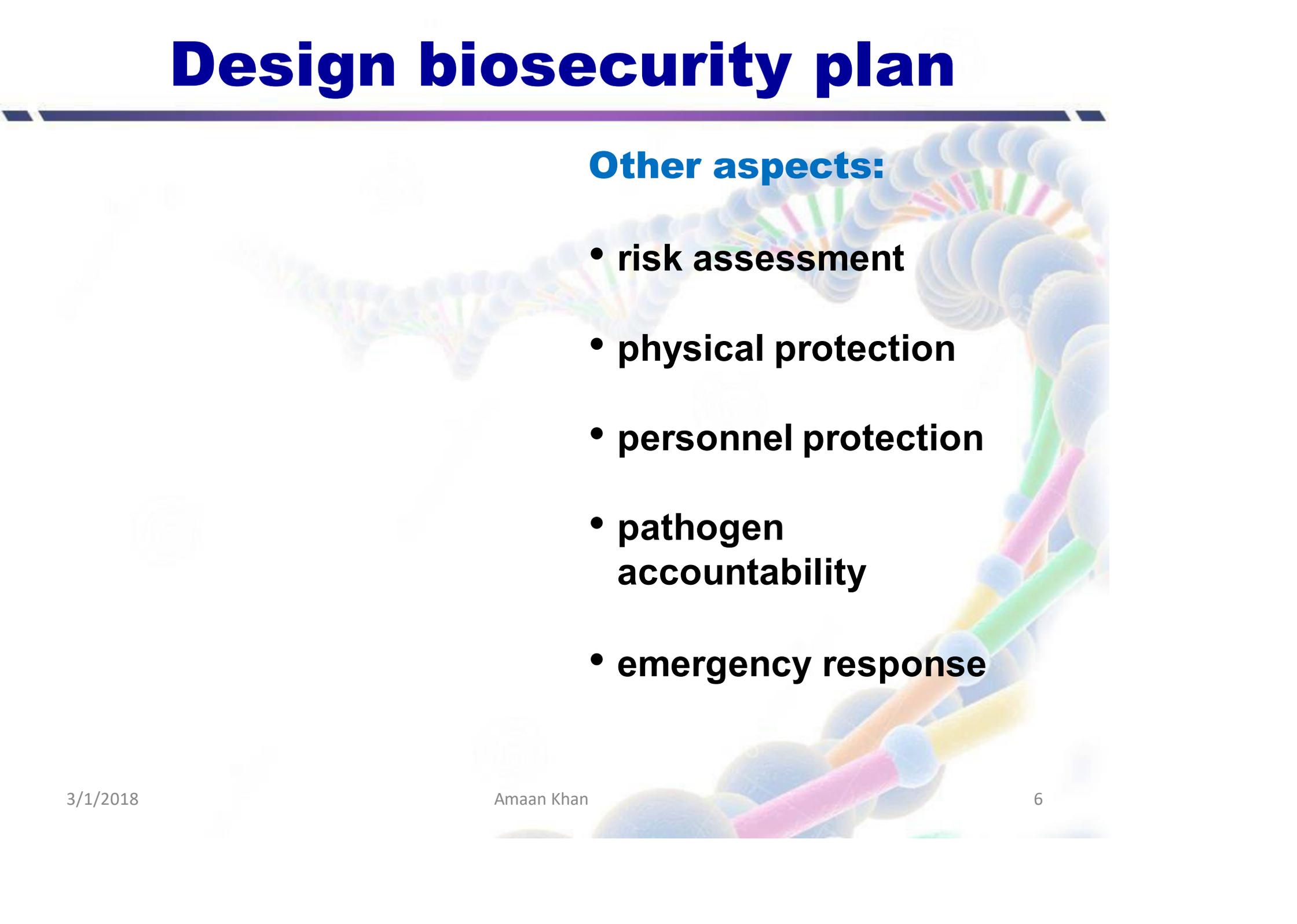
Design biosecurity plan



RO:

- **contacted if biological agent is theft or lost**
- **contacted agencies if there is threat or spill**
- **training**

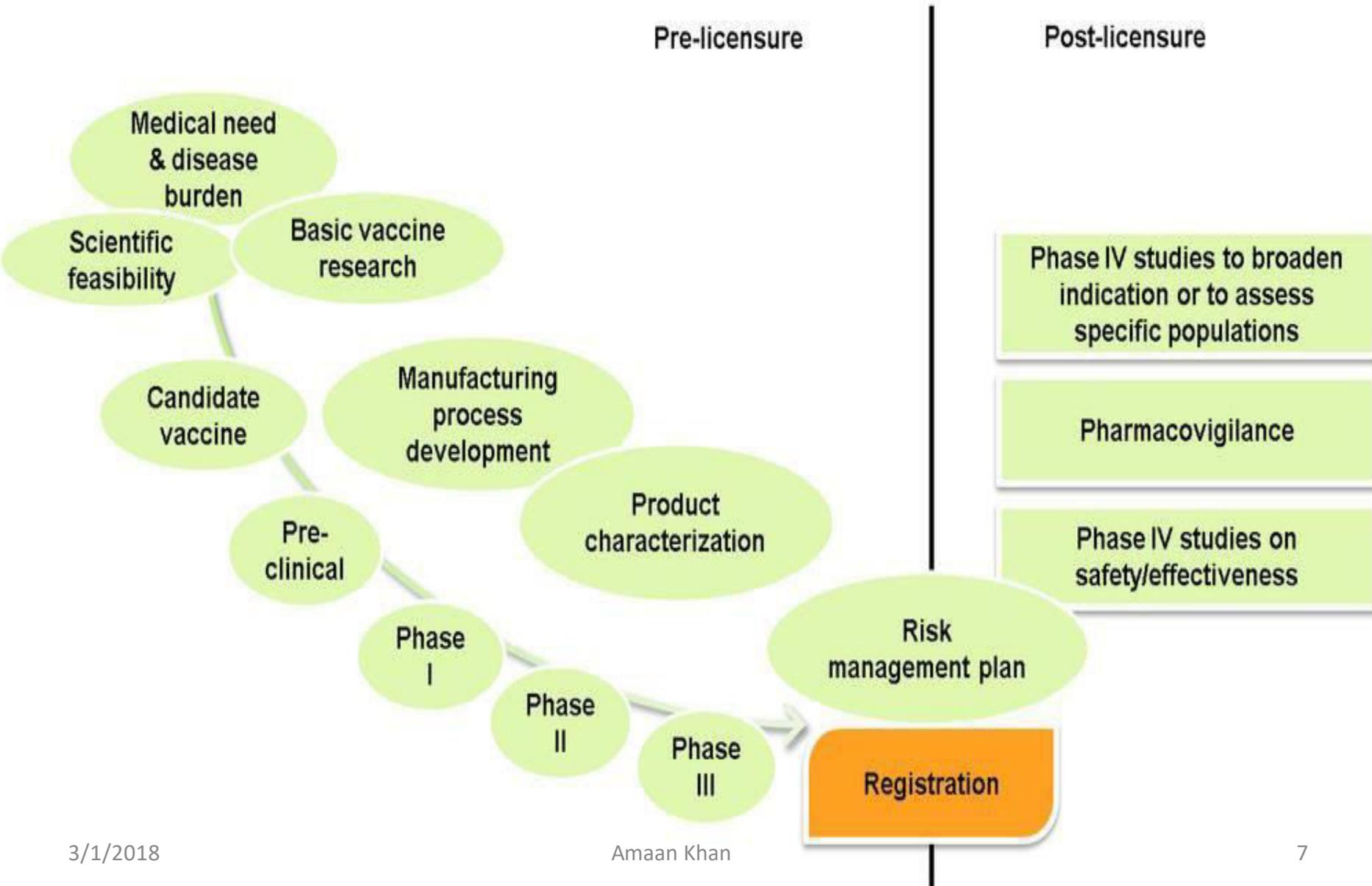
Design biosecurity plan



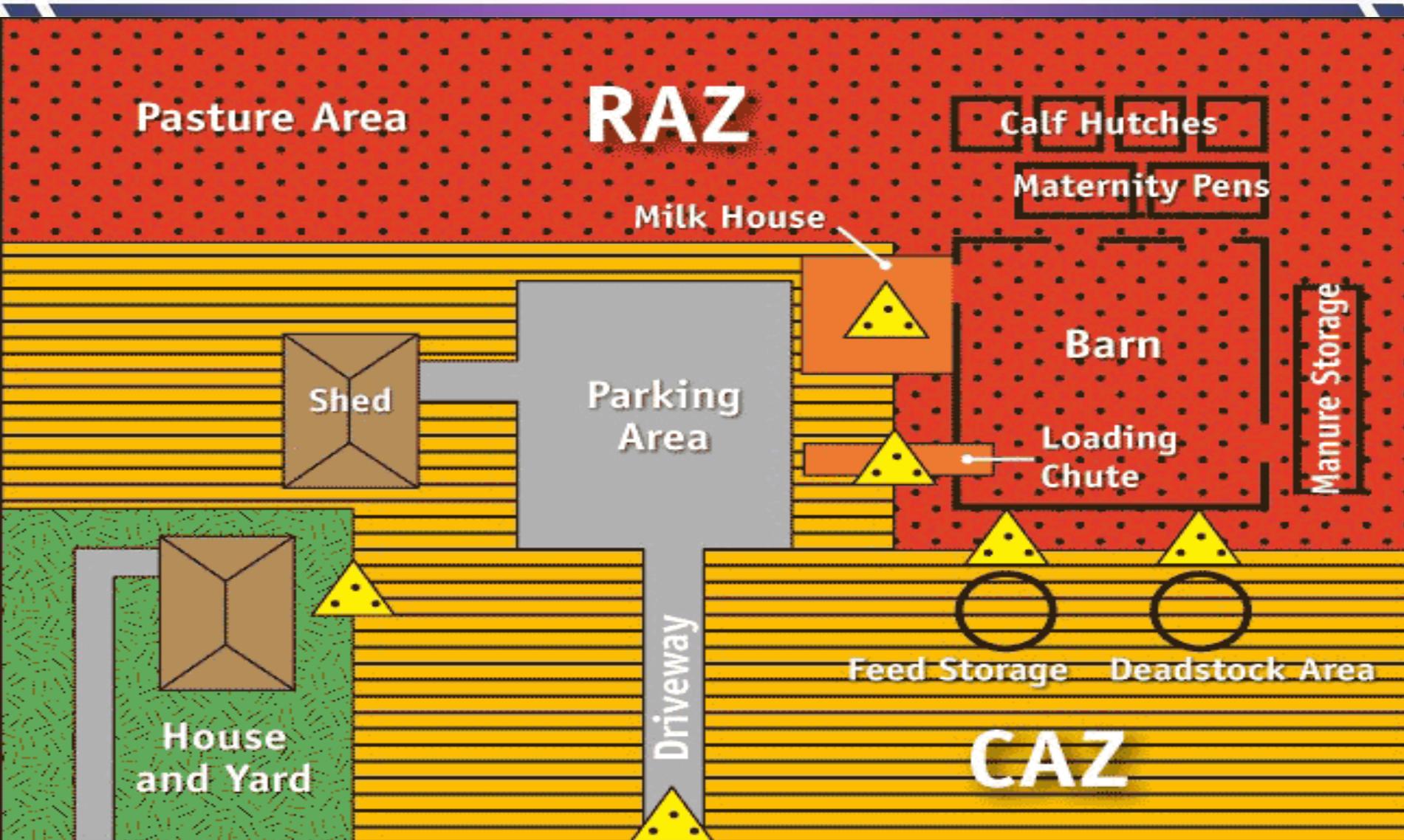
Other aspects:

- risk assessment
- physical protection
- personnel protection
- pathogen accountability
- emergency response

Design biosecurity plan



Design biosecurity plan



3/1/2018

Amaan Khan

8

Biosecurity



Lesson # 116
Objectives of
lab biosecurity

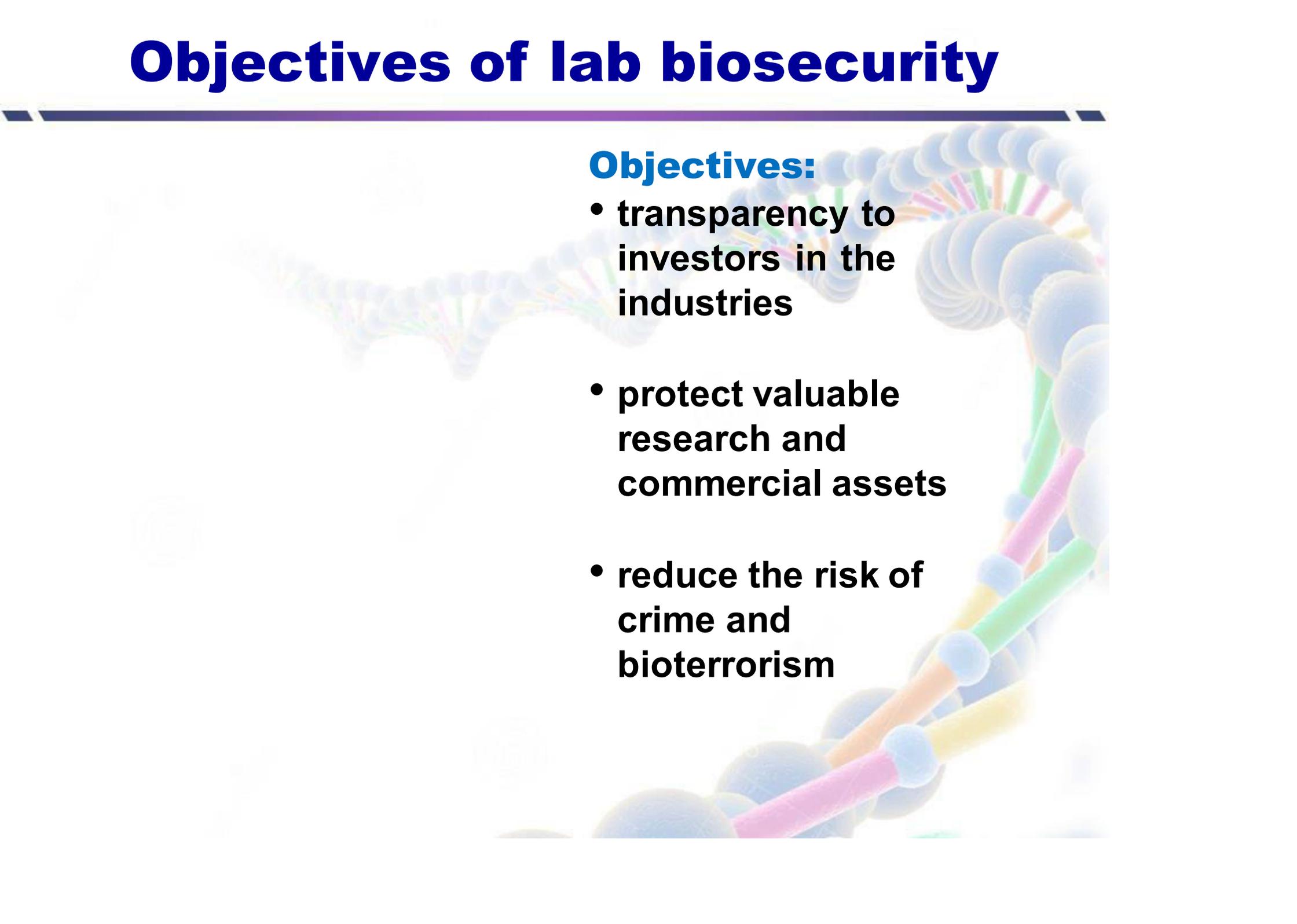
Objectives of lab biosecurity



Objectives:

- **this supports lab safety agenda to prevent diseases**
- **ensure containment of infectious materials**
- **maintain citizen confidence of bioscience research community**

Objectives of lab biosecurity



Objectives:

- **transparency to investors in the industries**
- **protect valuable research and commercial assets**
- **reduce the risk of crime and bioterrorism**

Biosecurity



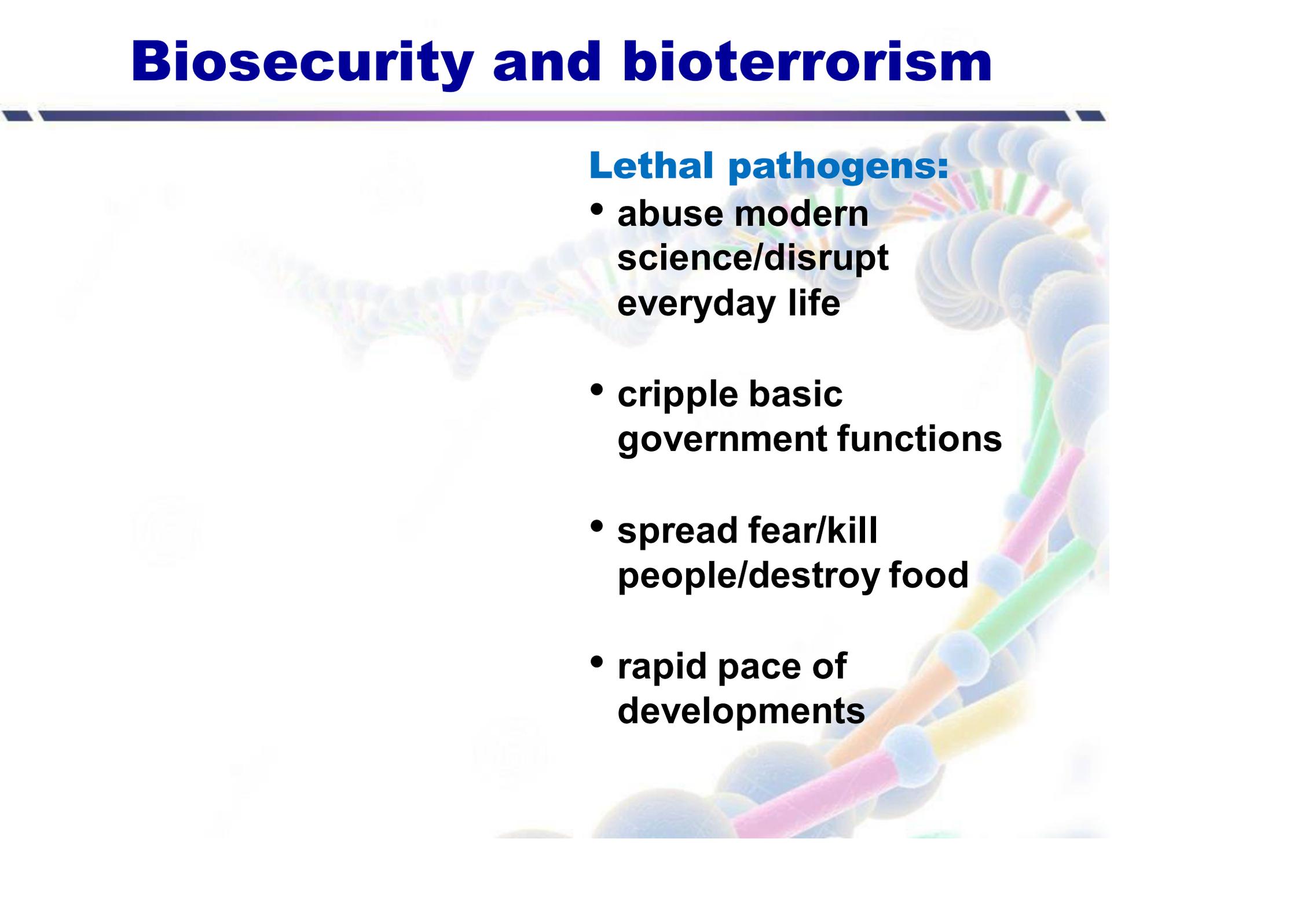
Lesson # 117

Biosecurity



**Biosecurity
and
bioterroris
m**

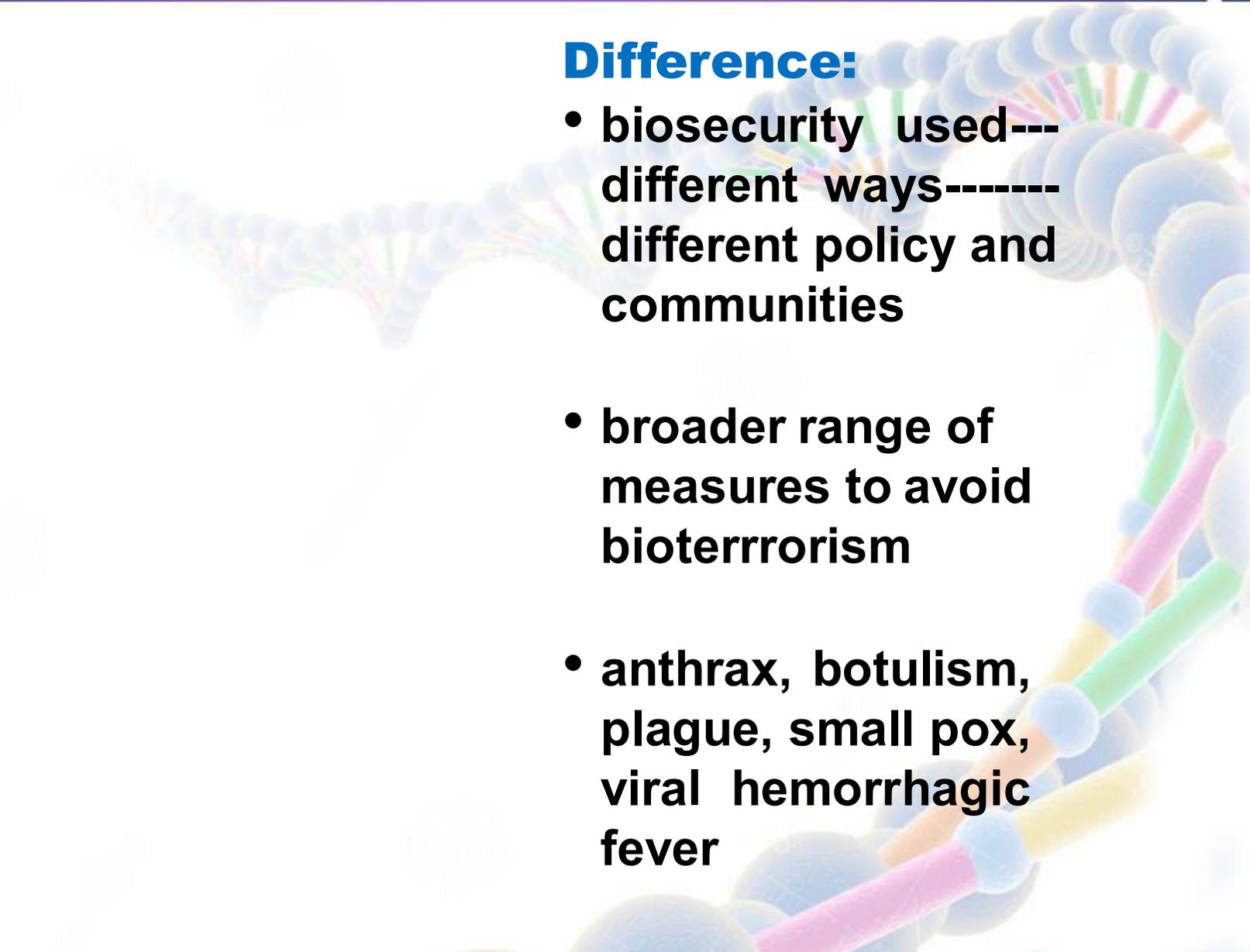
Biosecurity and bioterrorism



Lethal pathogens:

- **abuse modern science/disrupt everyday life**
- **cripple basic government functions**
- **spread fear/kill people/destroy food**
- **rapid pace of developments**

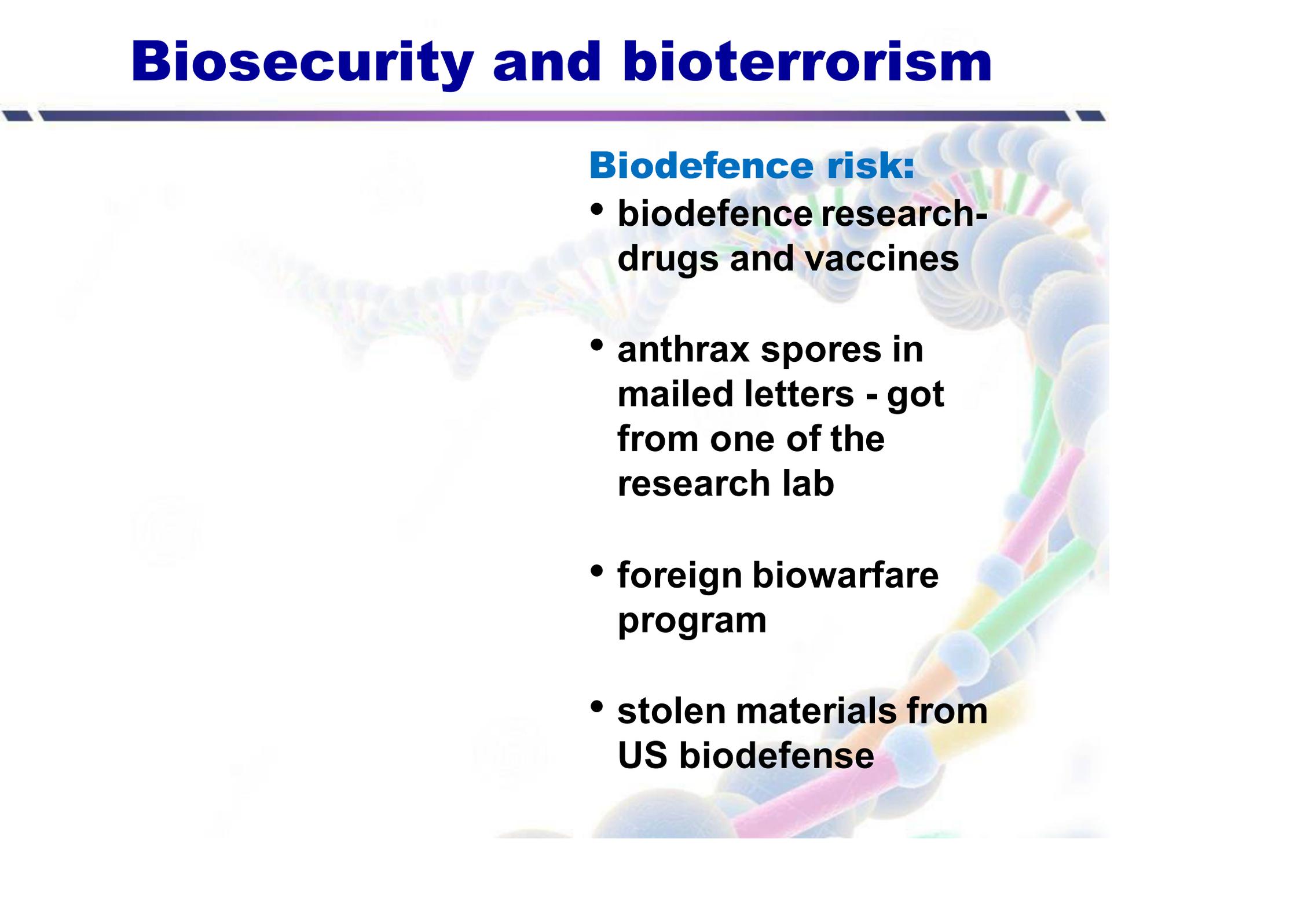
Biosecurity and bioterrorism



Difference:

- **biosecurity used---
different ways-----
different policy and
communities**
- **broader range of
measures to avoid
bioterrorism**
- **anthrax, botulism,
plague, small pox,
viral hemorrhagic
fever**

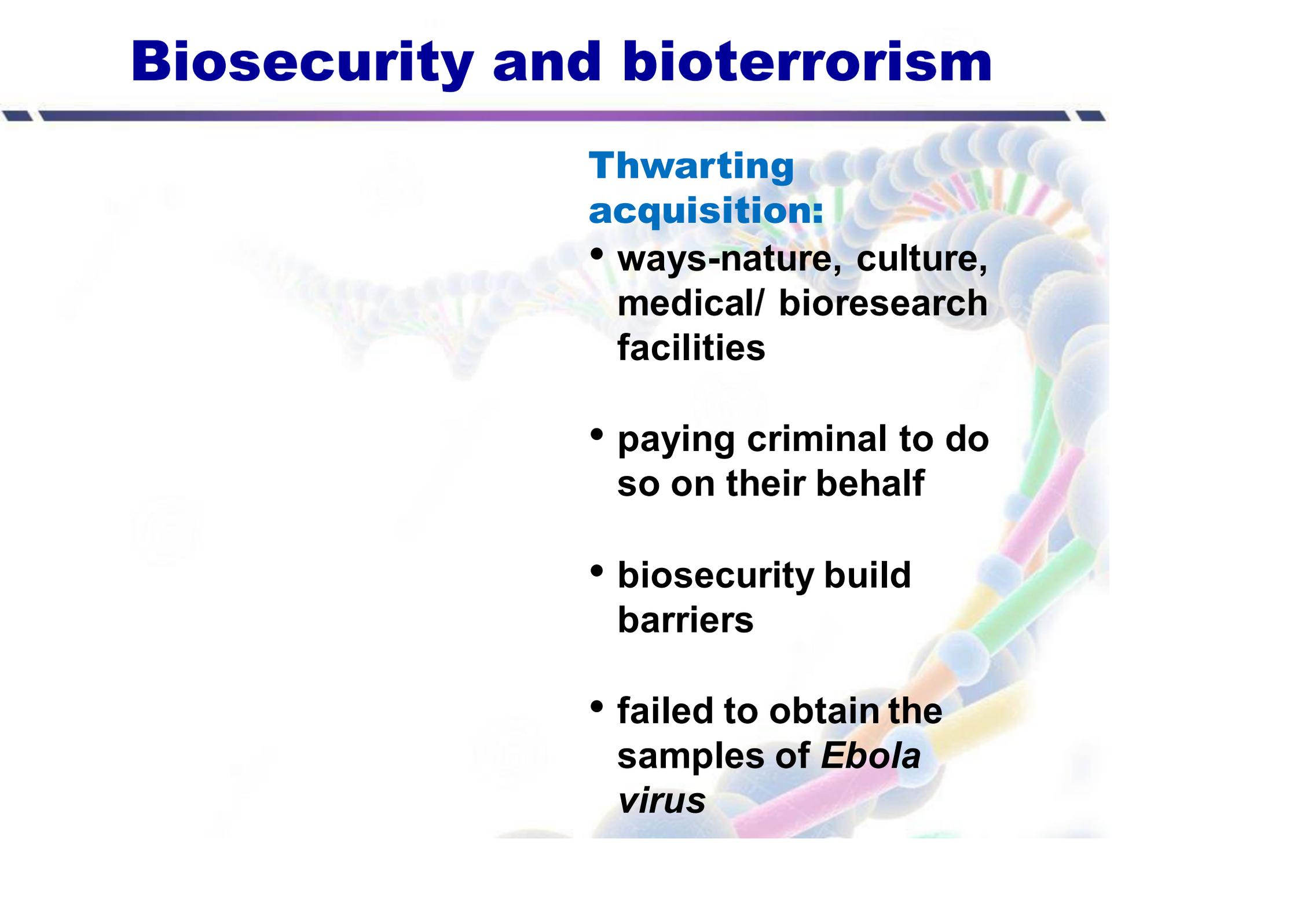
Biosecurity and bioterrorism



Biodefence risk:

- **biodefence research-
drugs and vaccines**
- **anthrax spores in
mailed letters - got
from one of the
research lab**
- **foreign biowarfare
program**
- **stolen materials from
US biodefense**

Biosecurity and bioterrorism



Thwarting acquisition:

- ways-nature, culture, medical/ bioresearch facilities
- paying criminal to do so on their behalf
- biosecurity build barriers
- failed to obtain the samples of *Ebola virus*

Biosecurity



Lesson # 118
International
obligations

International obligations

Introduction:

- **international community - set of international obligations on lab biosecurity**
- **state implement legislations**
- **control misuse of bioweapons**

International obligations

Other aspects:

- **protect the public and environment**
- **transportation biosecurity**
- **enforce legal barriers**
- **rules to manufacture, store and use biological materials**

Biosecurity



Lesson # 119

Biosecurity



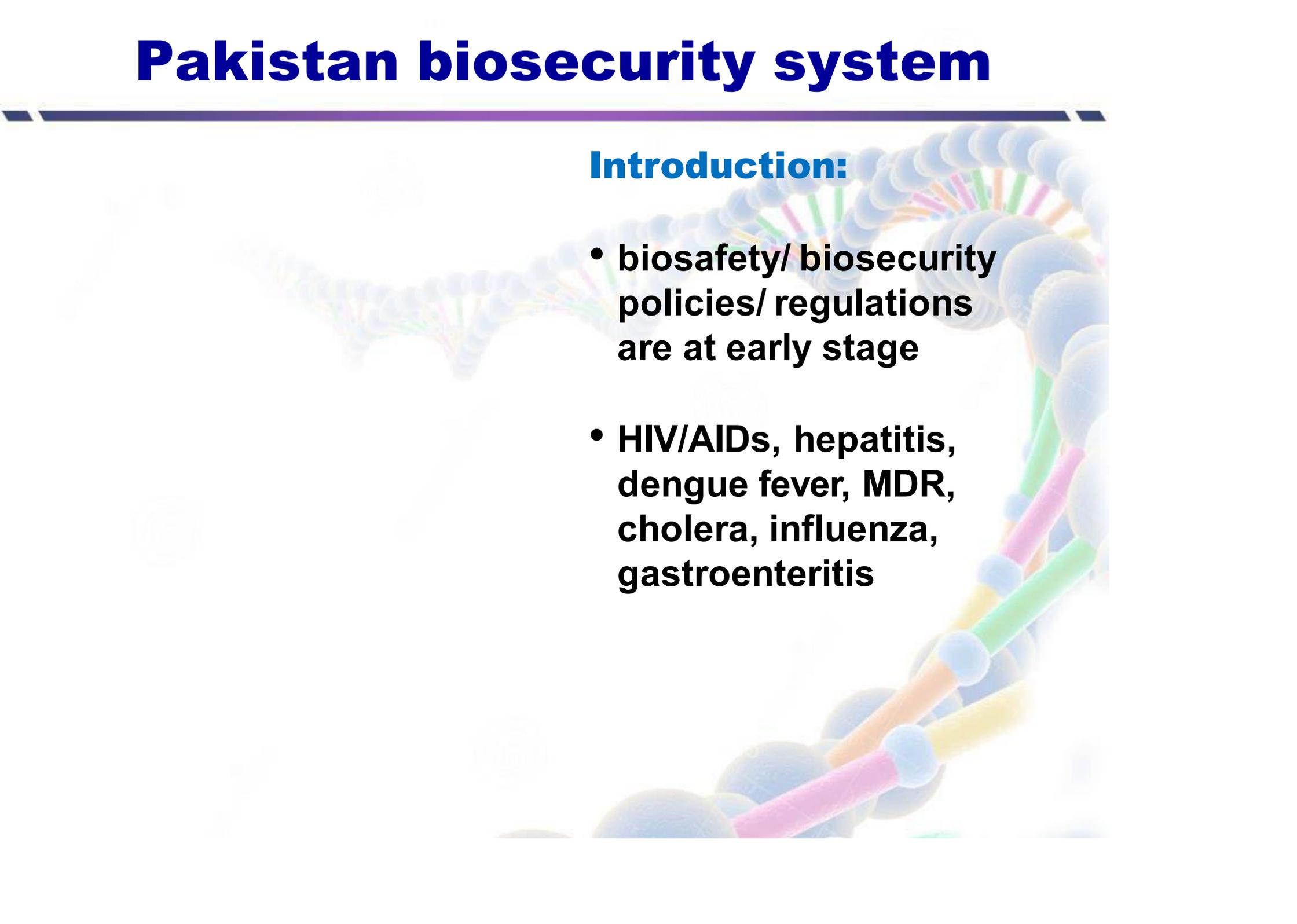
**Pakistan
biosecurity
system**

Pakistan biosecurity system

Introduction:

- **developing country-
enjoys fewer benefits**
- **recent advances in
biomedical research**
- **stress given by the
public/private sector
to control infection
diseases**

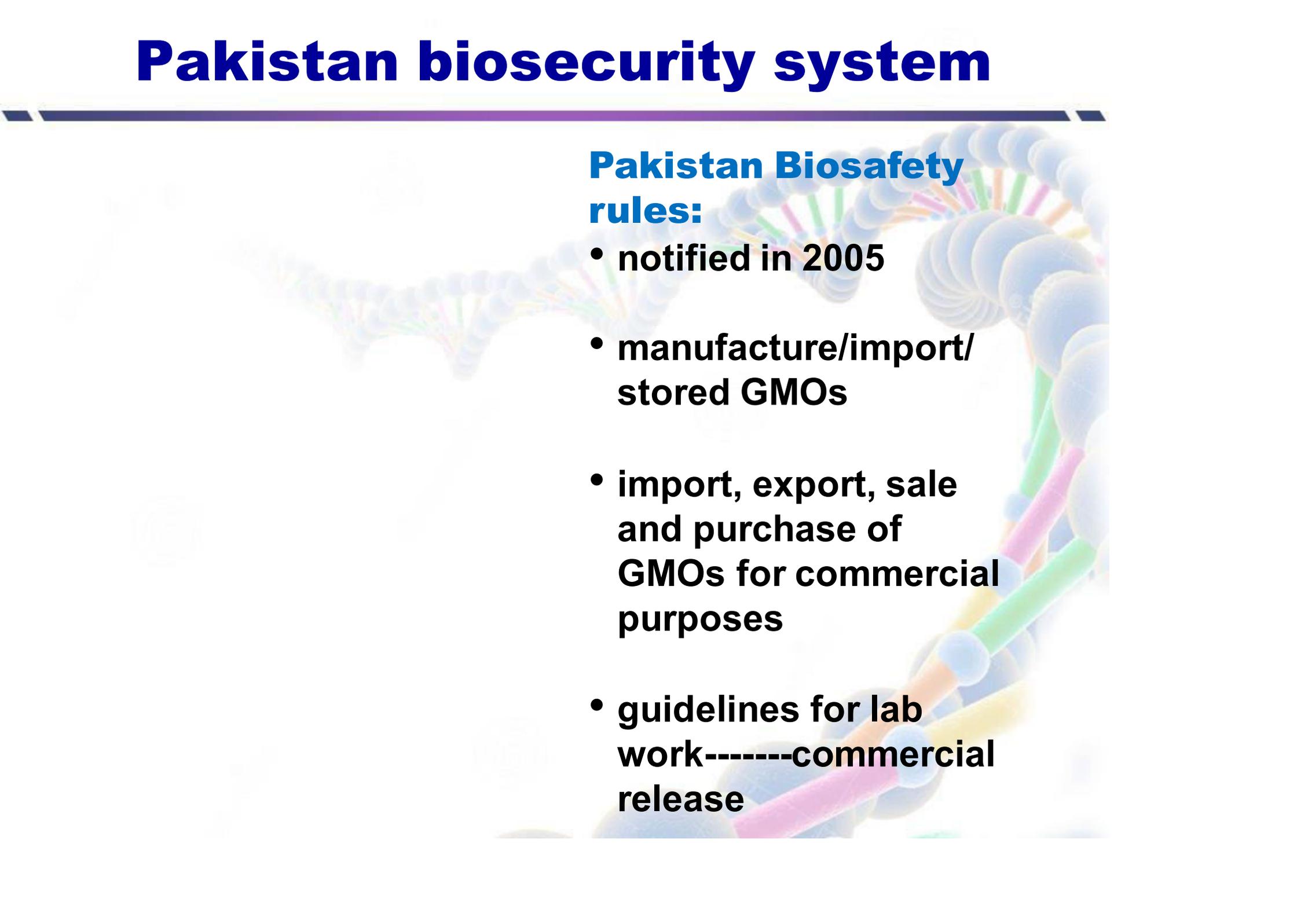
Pakistan biosecurity system



Introduction:

- **biosafety/ biosecurity policies/ regulations are at early stage**
- **HIV/AIDs, hepatitis, dengue fever, MDR, cholera, influenza, gastroenteritis**

Pakistan biosecurity system



Pakistan Biosafety rules:

- notified in 2005
- manufacture/import/
stored GMOs
- import, export, sale
and purchase of
GMOs for commercial
purposes
- guidelines for lab
work-----commercial
release

Pakistan biosecurity system

Pakistan Biosafety rules:

- **guidelines for the establishment of proper procedures**
- **National Biosafety Committee (NBC)**
- **Institutional Biosafety Committee (IBC)**
- **Technical Advisory Committee (TAC)**

Biosecurity



Lesson # 120

Biosecurity



**Risk
assessment**

Risk assessment

Introduction:

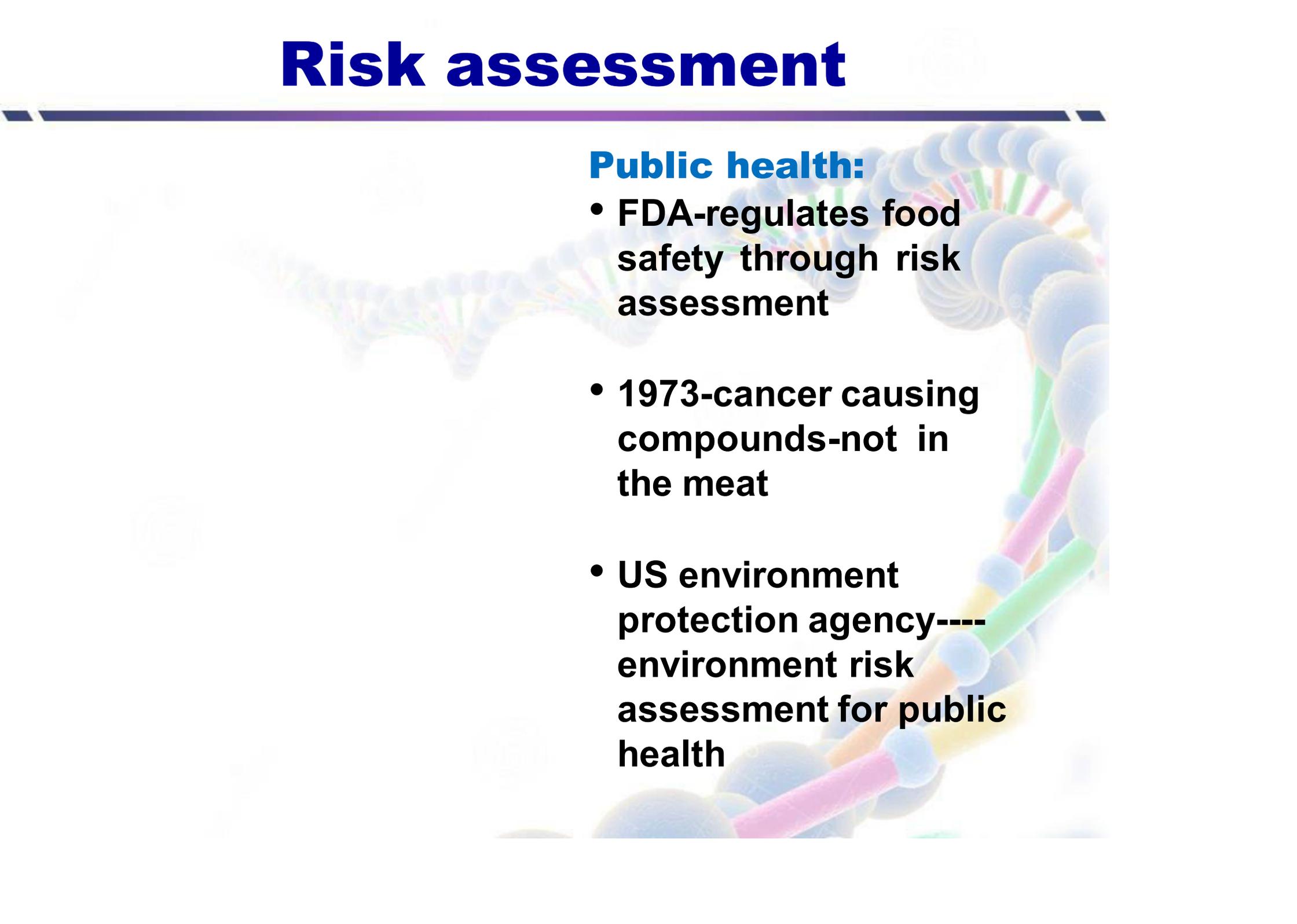
- **qualitative and quantitative approach**
- **identify hazards**
- **quantitative: two components**
- **magnitude of the potential loss**
- **probability that the loss will occur**

Risk assessment

Fields:

- **medical/hospital services**
- **nuclear/aerospace/oil/military industries**
- **food industry**
- **methods of risk assessment may differ**

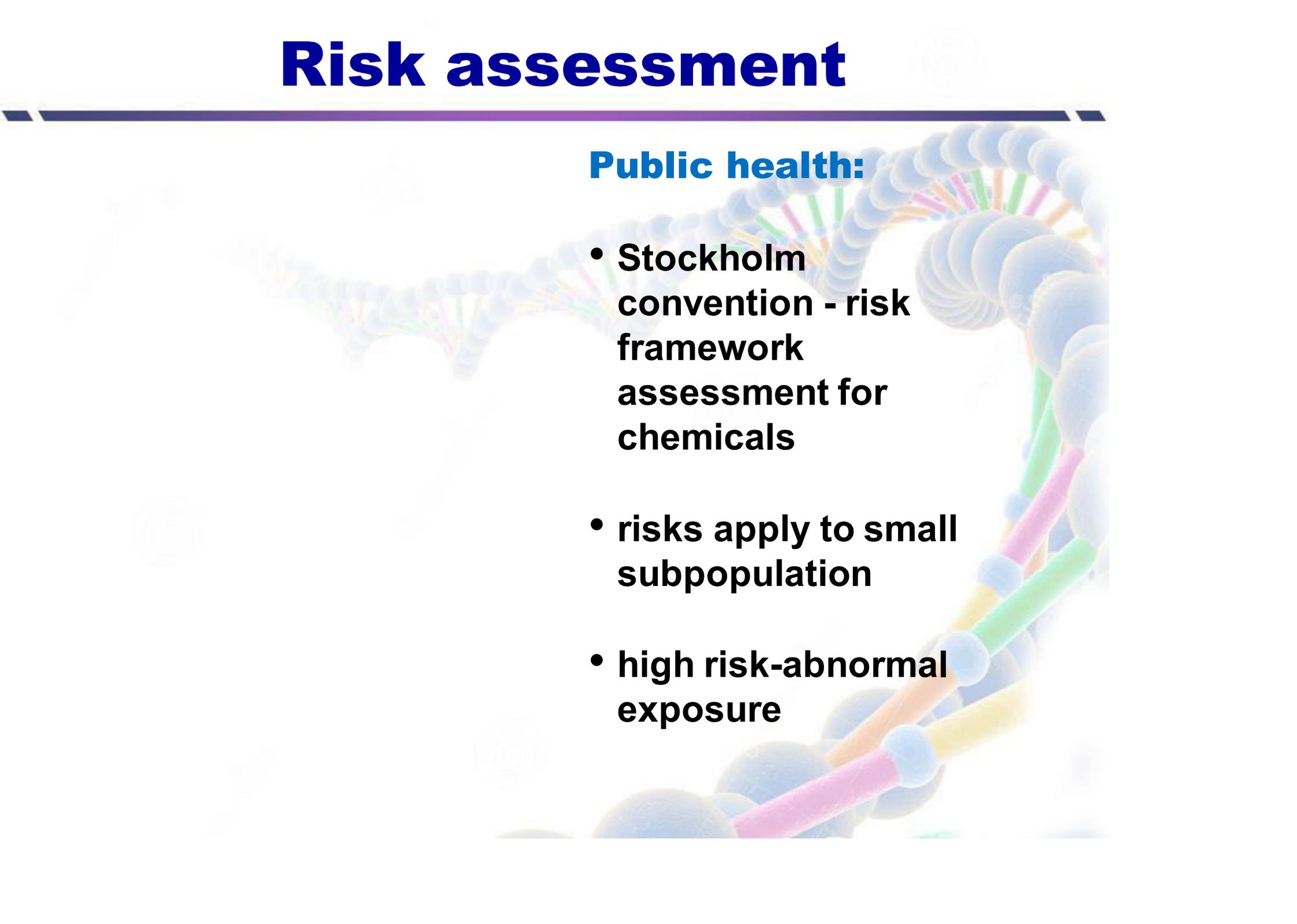
Risk assessment



Public health:

- **FDA-regulates food safety through risk assessment**
- **1973-cancer causing compounds-not in the meat**
- **US environment protection agency----environment risk assessment for public health**

Risk assessment



Public health:

- **Stockholm convention - risk framework assessment for chemicals**
- **risks apply to small subpopulation**
- **high risk-abnormal exposure**

Risk assessment

Risk < 1%:

- **all infants younger than X days**
- **recreational users of a particular product**

Biosecurity



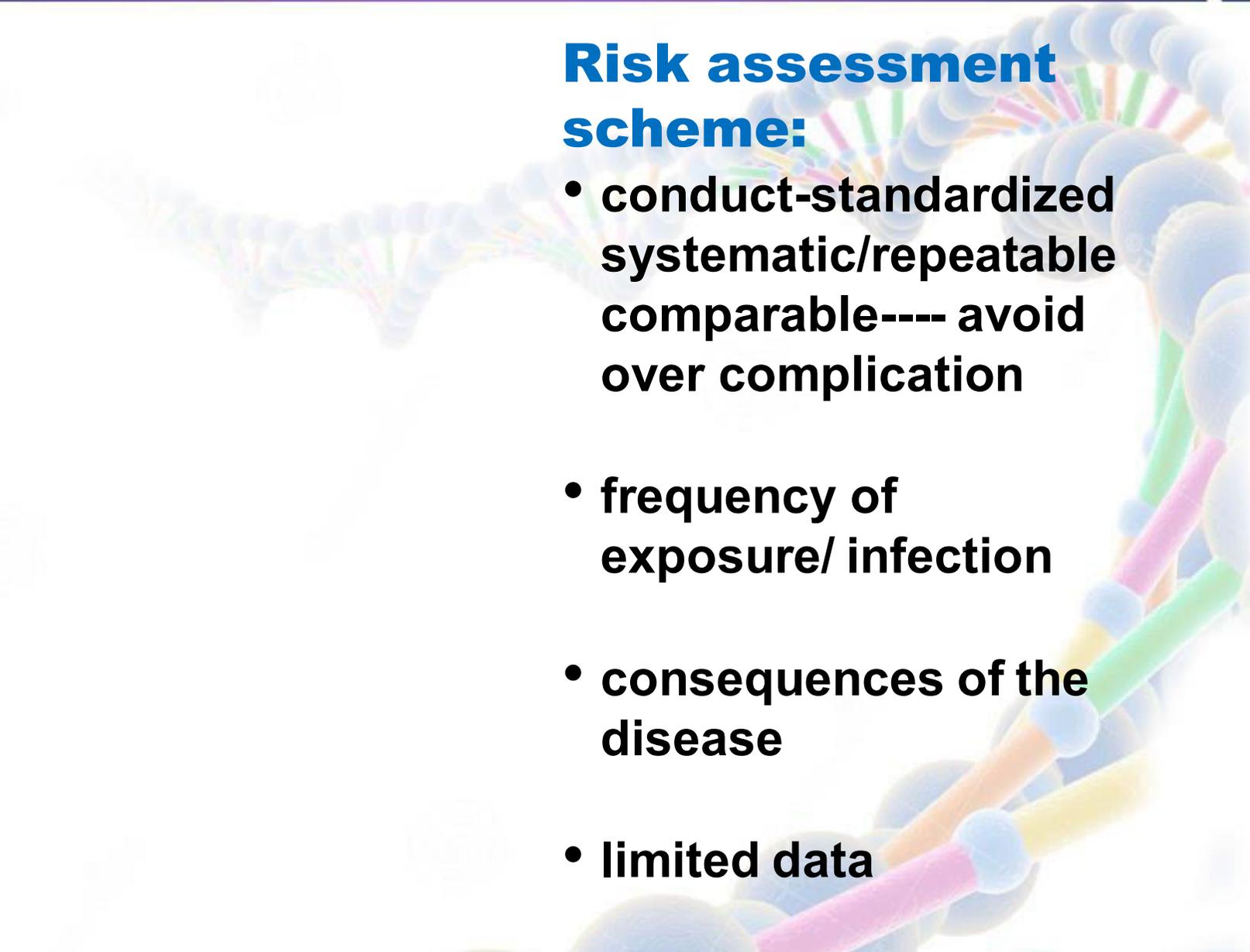
Lesson # 121

Biosecurity



**Risk
assessment
methodology**

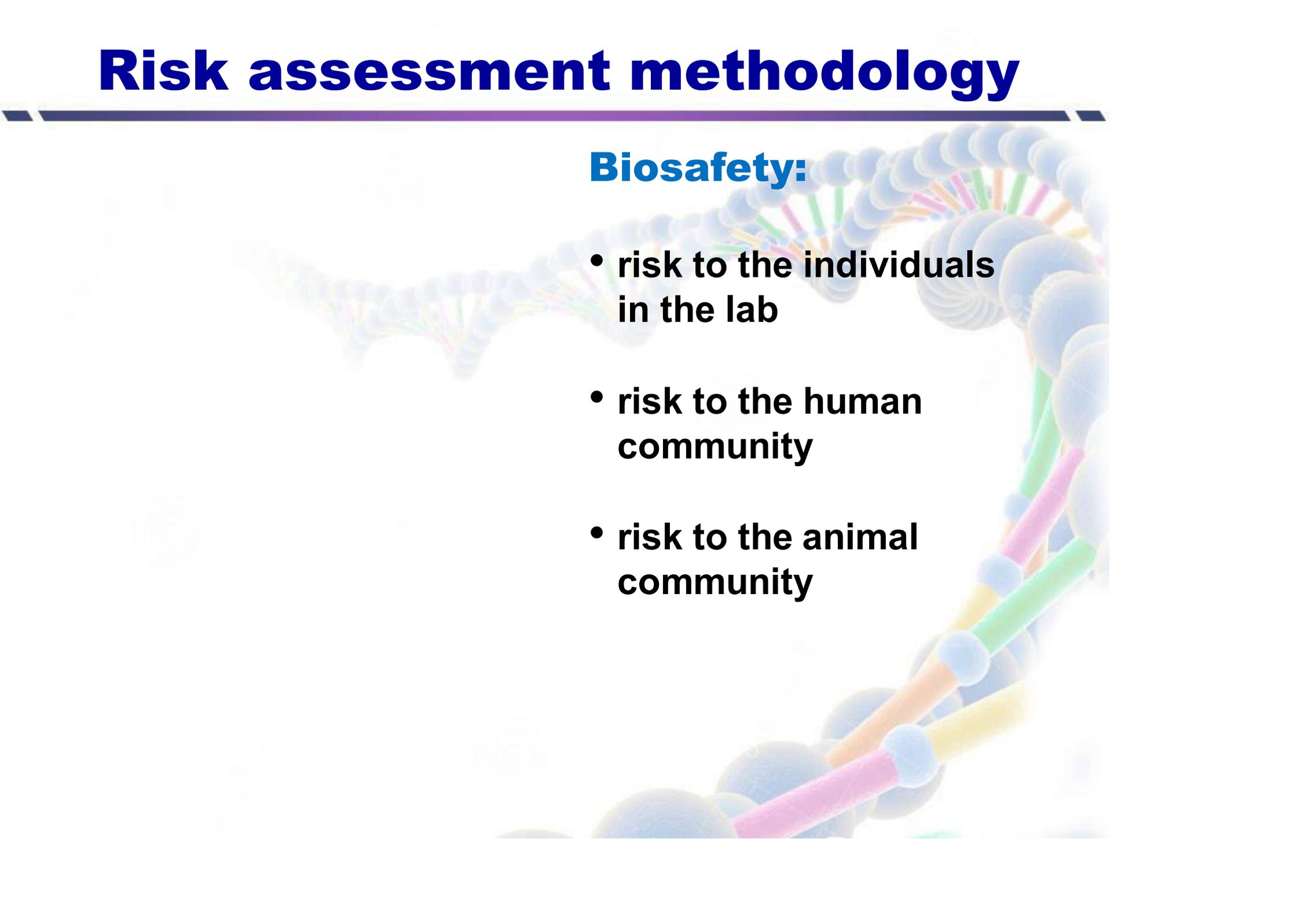
Risk assessment methodology



Risk assessment scheme:

- **conduct-standardized systematic/repeatable comparable---- avoid over complication**
- **frequency of exposure/ infection**
- **consequences of the disease**
- **limited data**

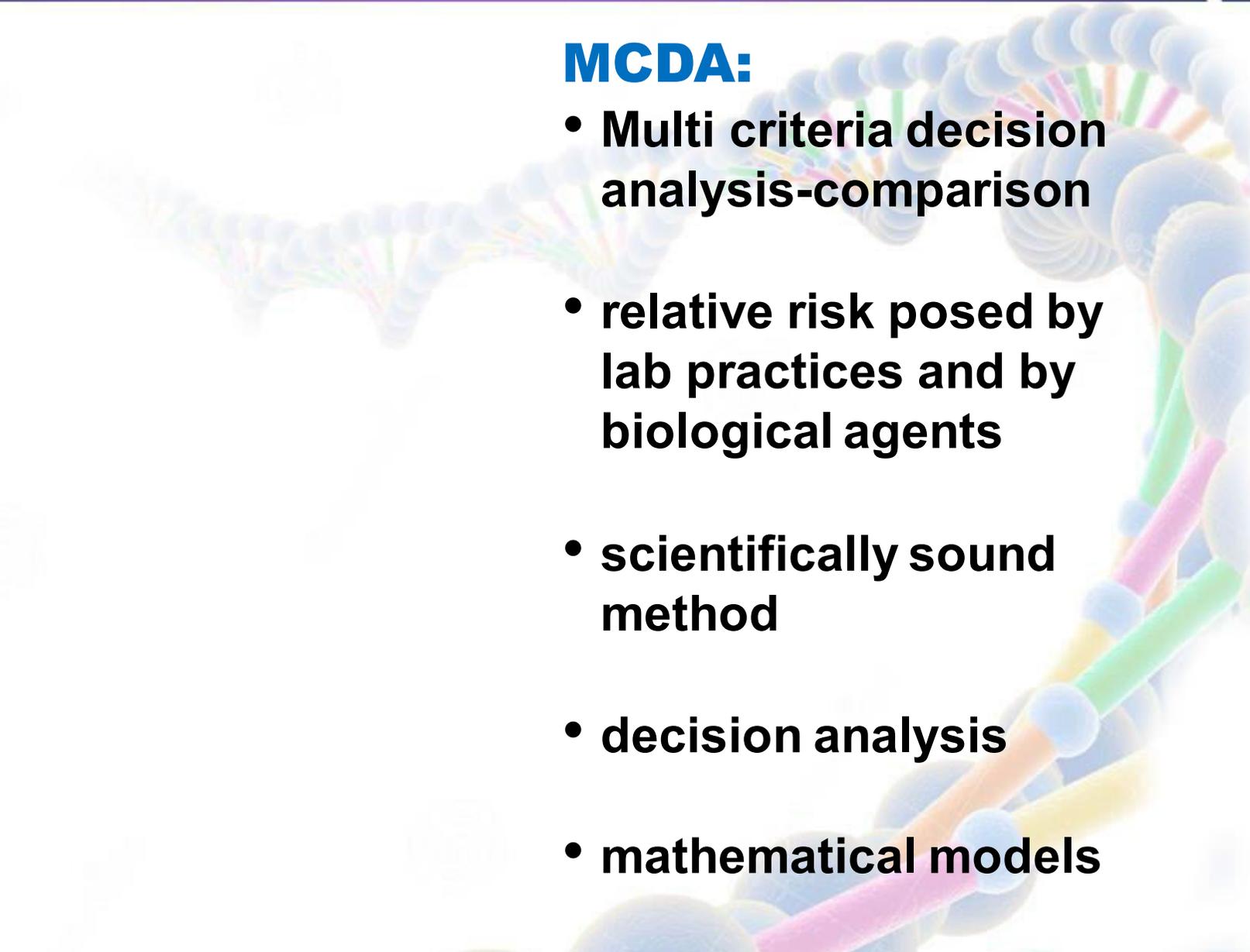
Risk assessment methodology



Biosafety:

- risk to the individuals in the lab
- risk to the human community
- risk to the animal community

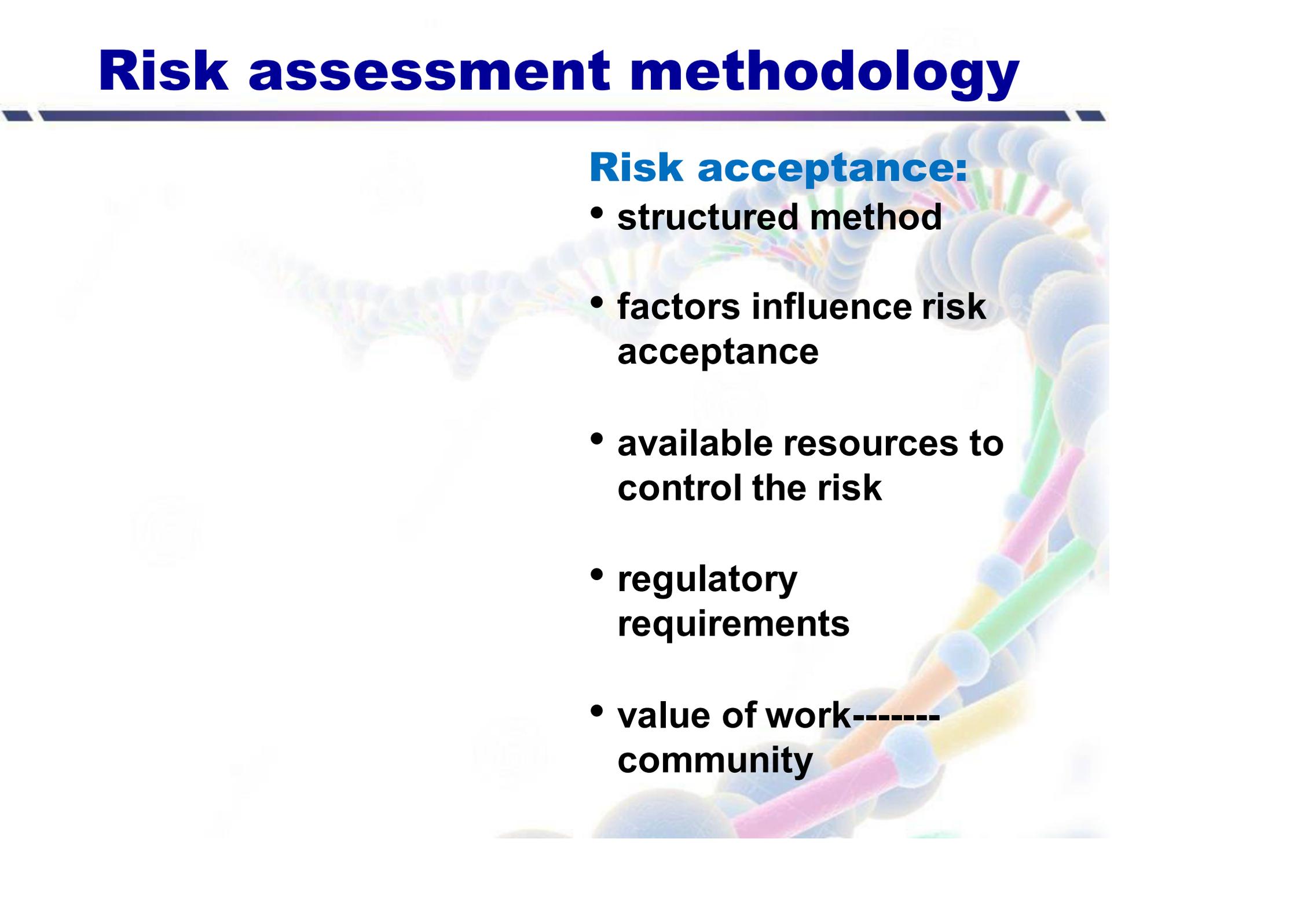
Risk assessment methodology



MCDA:

- **Multi criteria decision analysis-comparison**
- **relative risk posed by lab practices and by biological agents**
- **scientifically sound method**
- **decision analysis**
- **mathematical models**

Risk assessment methodology

A decorative background featuring a series of colorful spheres (blue, green, yellow, pink) connected by thin lines, creating a network-like structure that curves across the slide.

Risk acceptance:

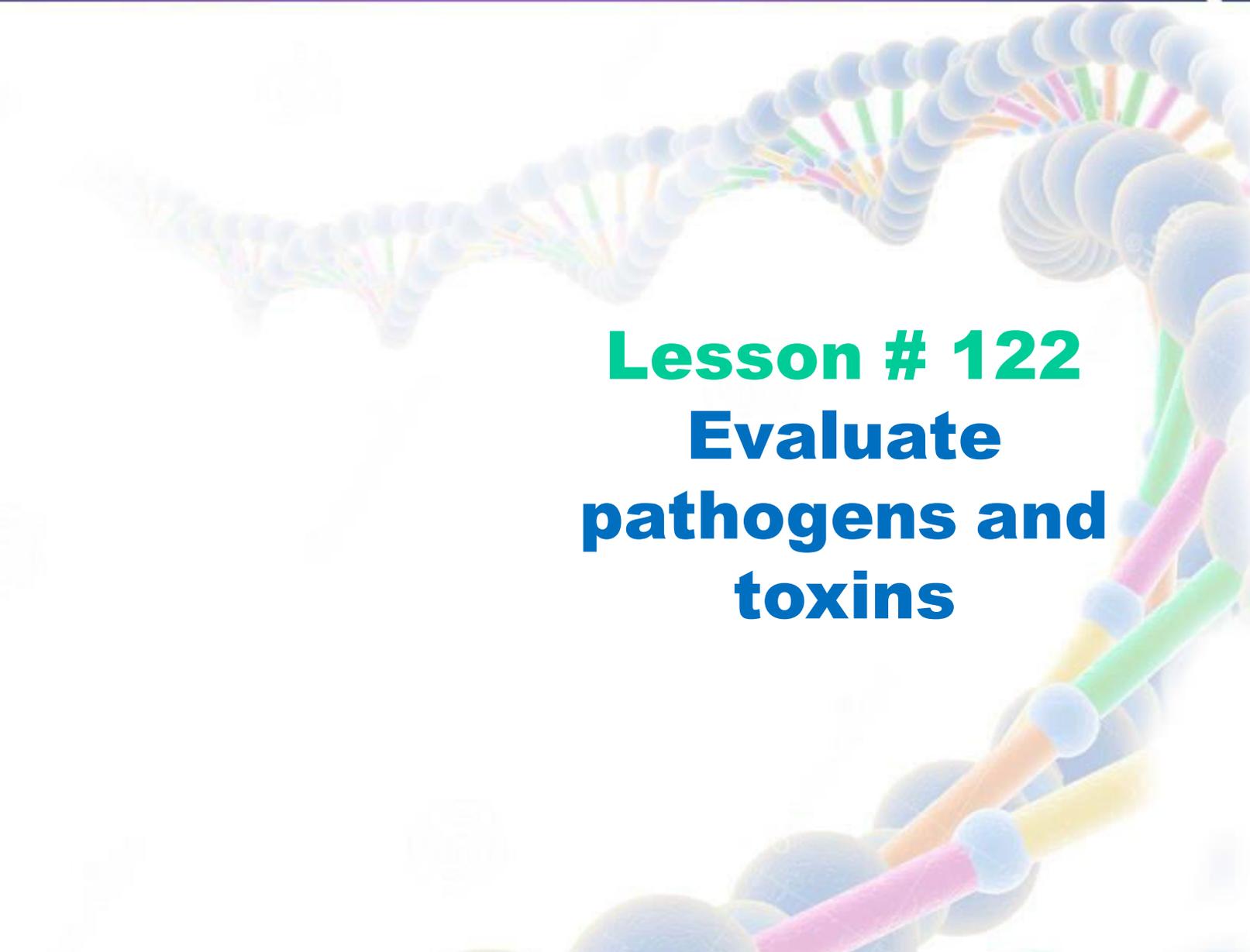
- structured method
- factors influence risk acceptance
- available resources to control the risk
- regulatory requirements
- value of work-----
community

Risk assessment methodology

Technical assessment scheme:

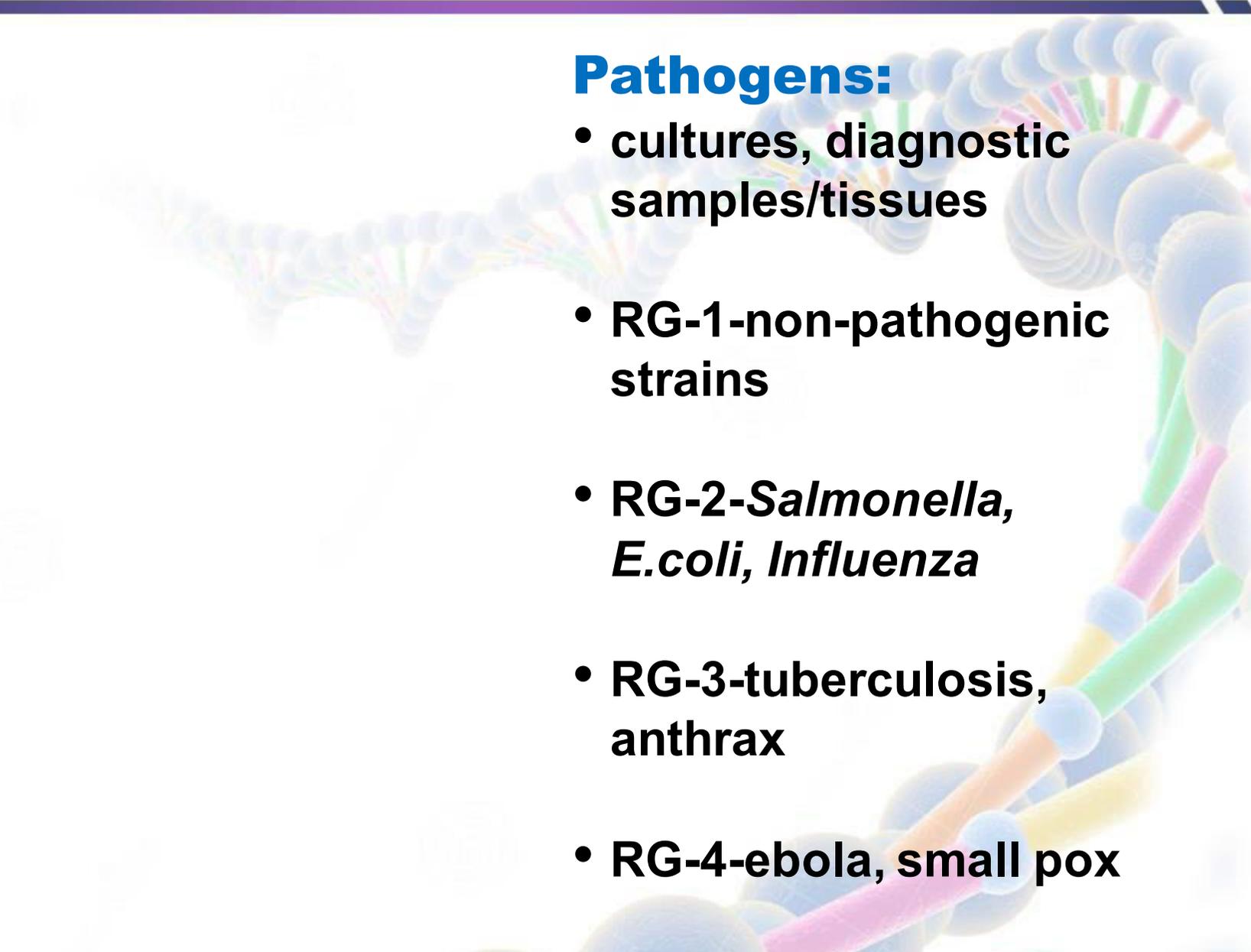
- define accepted criteria
- scoring system
- calculation
- development of equation

Biosecurity



Lesson # 122
Evaluate
pathogens and
toxins

Evaluate pathogens and toxins



Pathogens:

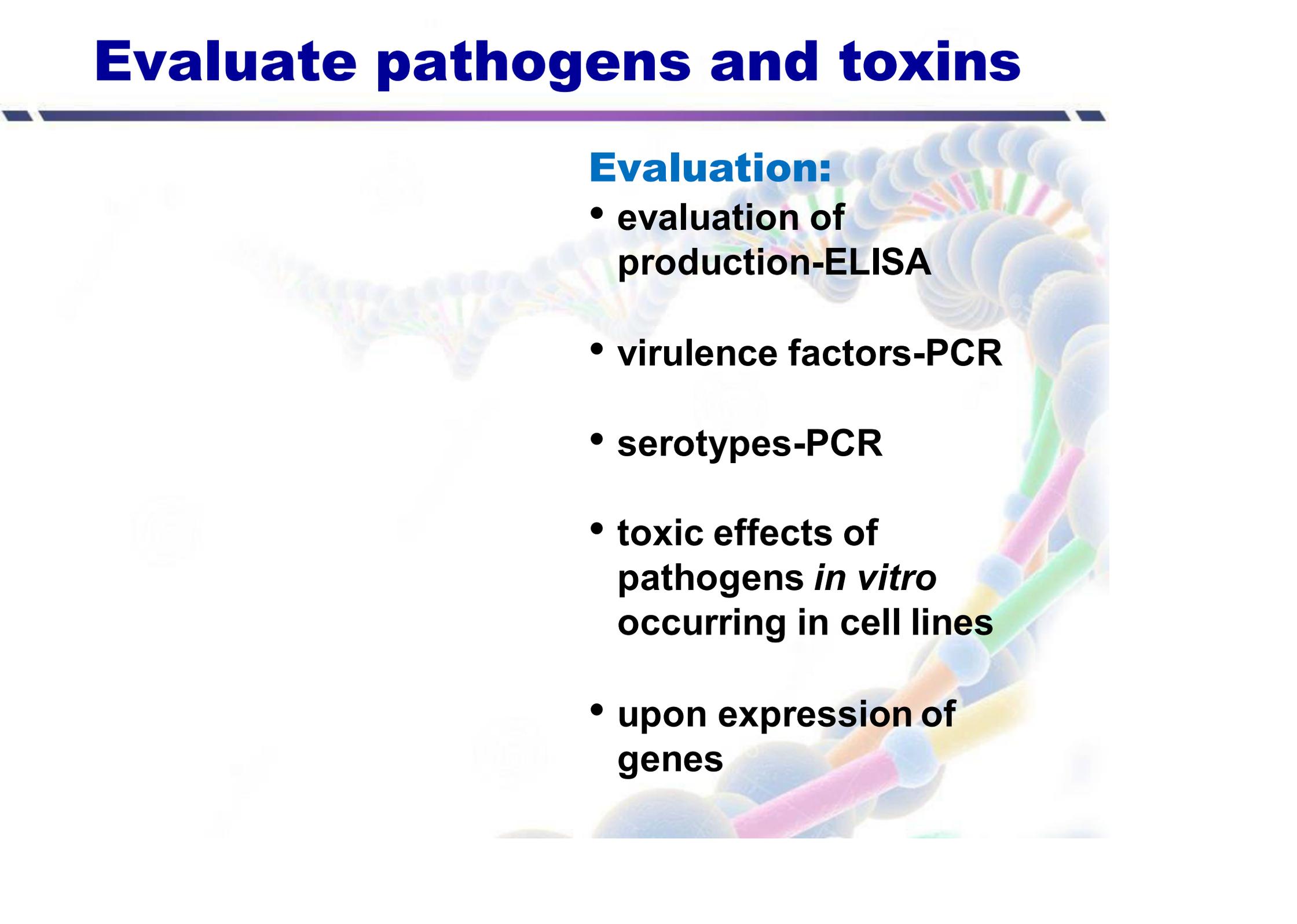
- **cultures, diagnostic samples/tissues**
- **RG-1-non-pathogenic strains**
- **RG-2-Salmonella, E.coli, Influenza**
- **RG-3-tuberculosis, anthrax**
- **RG-4-ebola, small pox**

Evaluate pathogens and toxins

Toxins:

- **bacterial toxins-
exotoxin and
endotoxin**
- **exo-actively secreted**
- **endo-part of bacteria-
not released-unless
killed**
- **toxinoses-botulinum
neurotoxin/ tetanus
toxin**

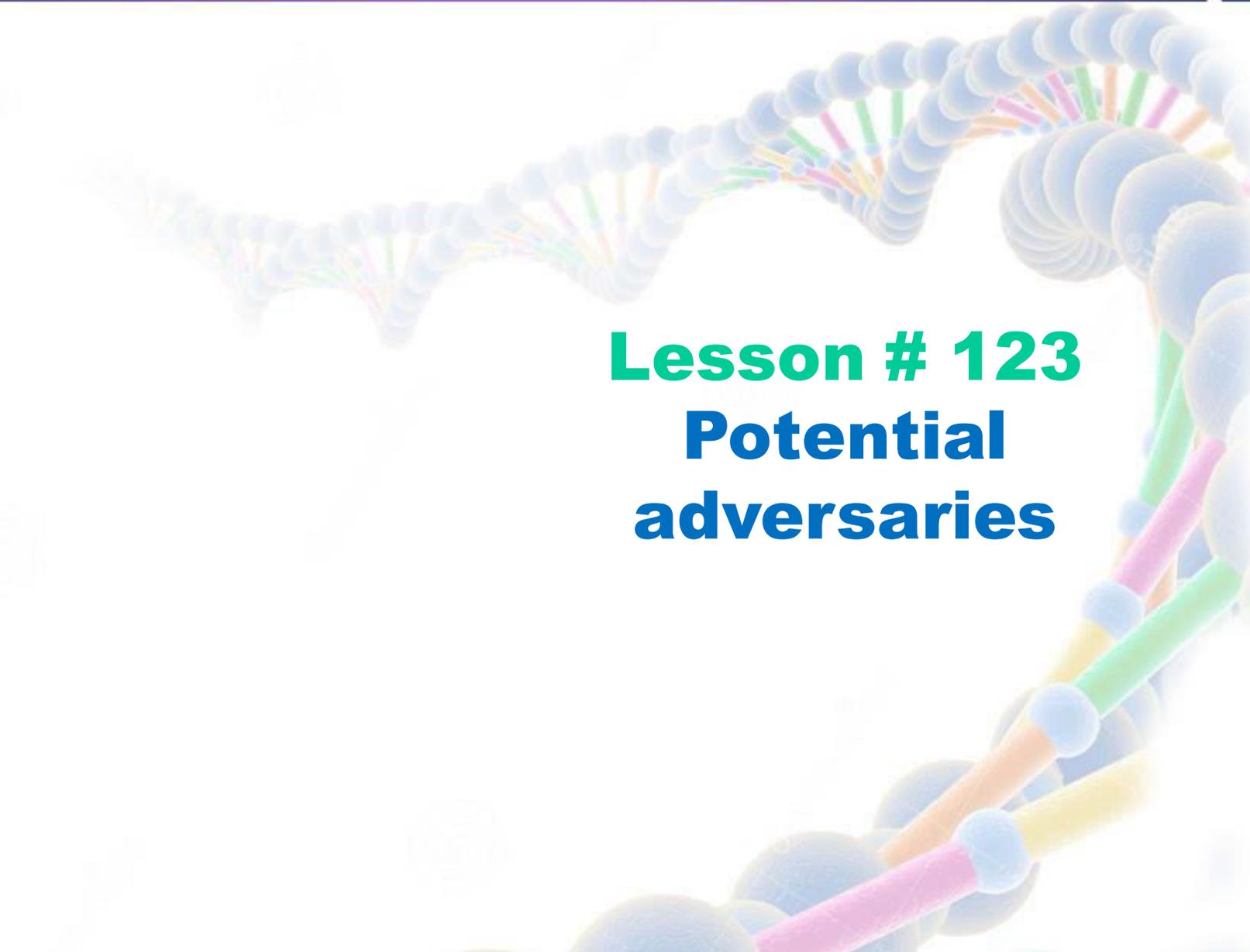
Evaluate pathogens and toxins



Evaluation:

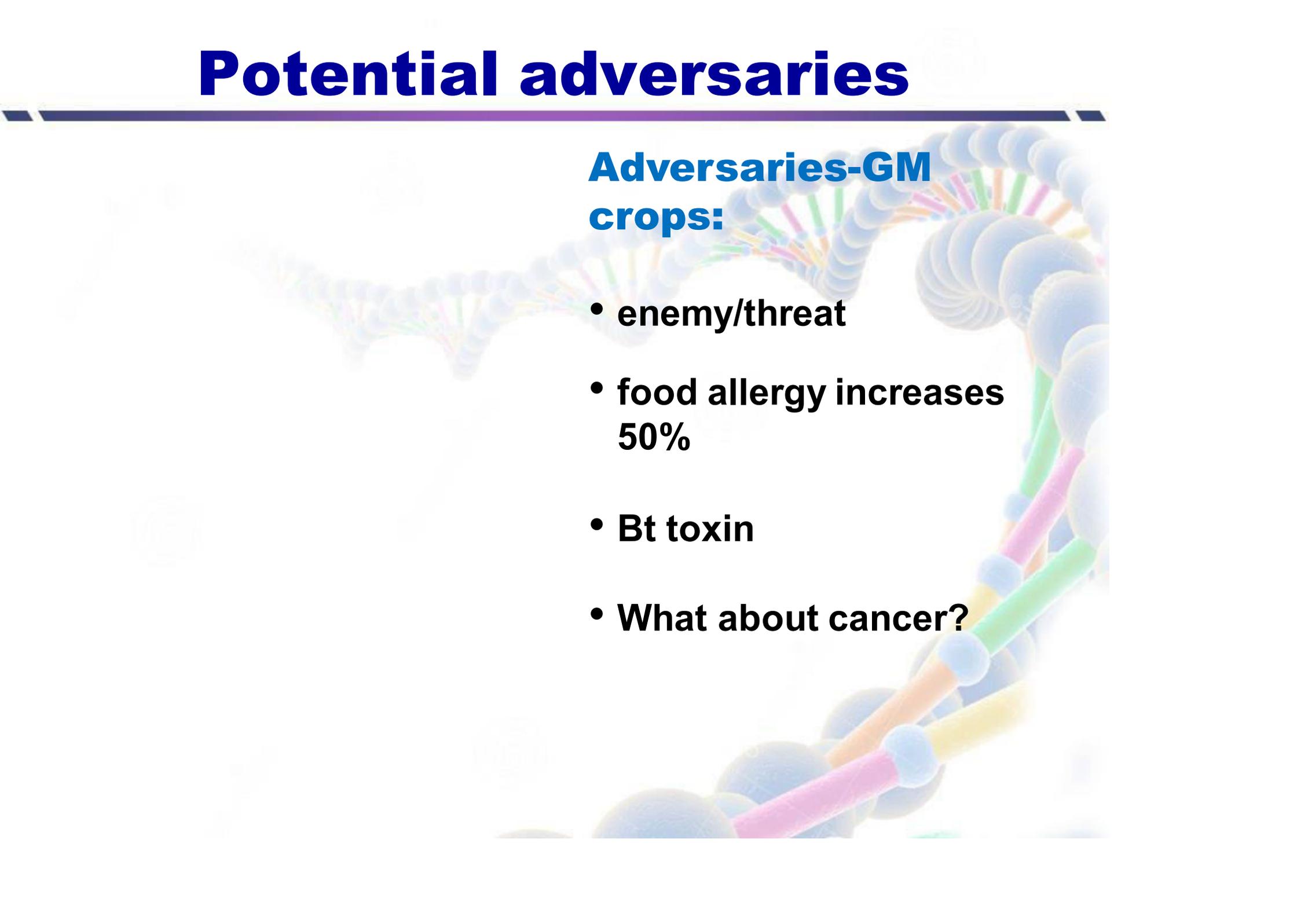
- evaluation of production-ELISA
- virulence factors-PCR
- serotypes-PCR
- toxic effects of pathogens *in vitro* occurring in cell lines
- upon expression of genes

Biosecurity



Lesson # 123
Potential
adversaries

Potential adversaries



Adversaries-GM crops:

- enemy/threat
- food allergy increases 50%
- Bt toxin
- What about cancer?

Potential adversaries

Adversaries-GM fish:

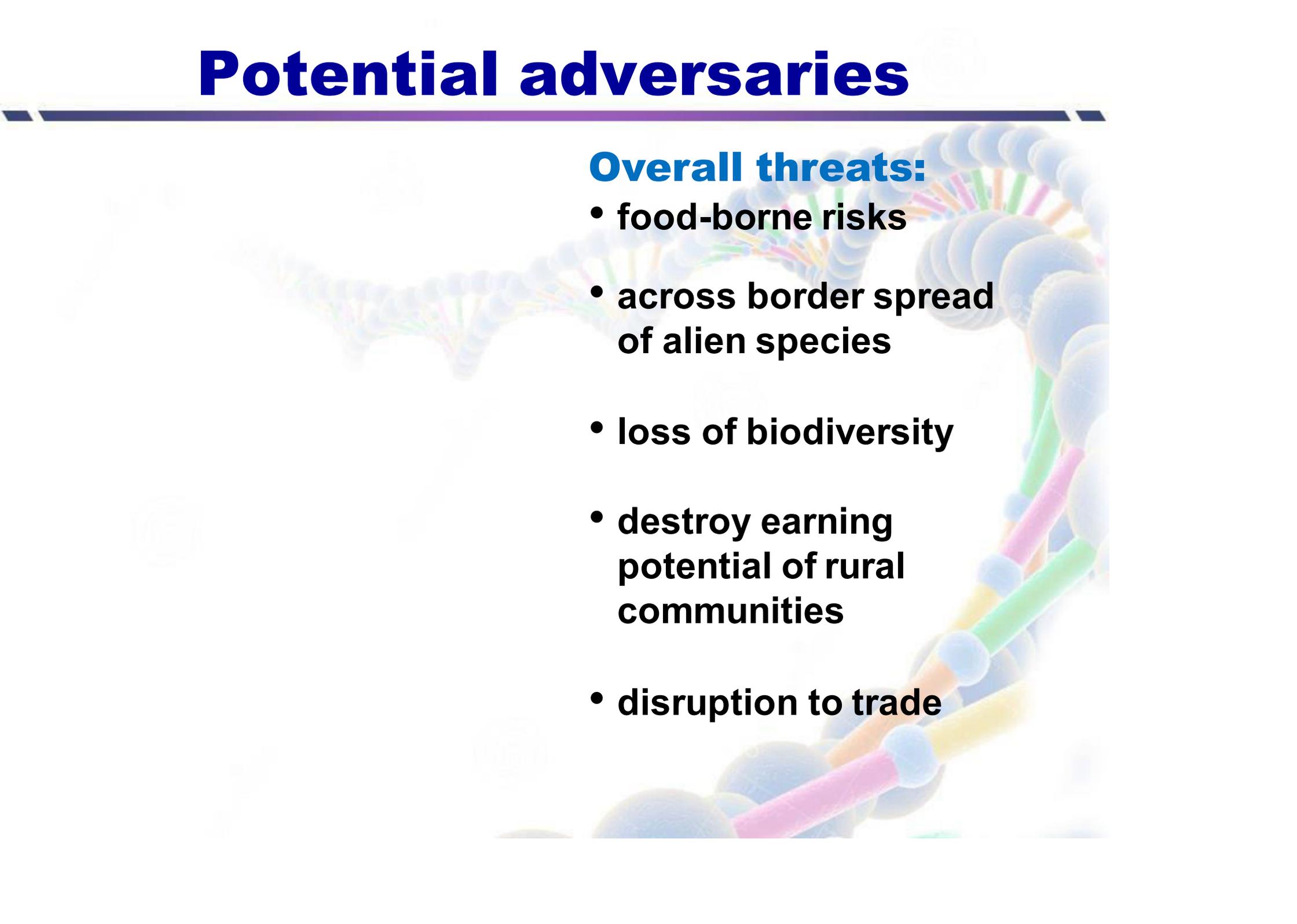
- environmental impact on wild life
- invade the population
- evaluate transgene itself

Potential adversaries

Examples:

- **Salmon with growth hormone gene**
- **gene for better anti-bacterial resistance**
- **genes for good nutritional product**
- **transgenic fish not commercial except zebrafish**

Potential adversaries



Overall threats:

- **food-borne risks**
- **across border spread of alien species**
- **loss of biodiversity**
- **destroy earning potential of rural communities**
- **disruption to trade**

Biosecurity



Lesson # 124
Evaluate
scenarios

Evaluate scenarios

Introduction:

- **risk is identified**
- **management committee-decide**
- **which scenarios protect against high risk**
- **which scenarios protect though incident response planning**

Evaluate scenarios

Description:

- design and implement protective measures
- risk assessment-rank scenarios

Evaluate scenarios

Create scenarios:

- **pathogen/toxin**
- **individual or group wish to steal pathogens**
- **theft of pathogen or toxin**
- **terrorist included in scenarios of high and extreme risk**

Biosecurity



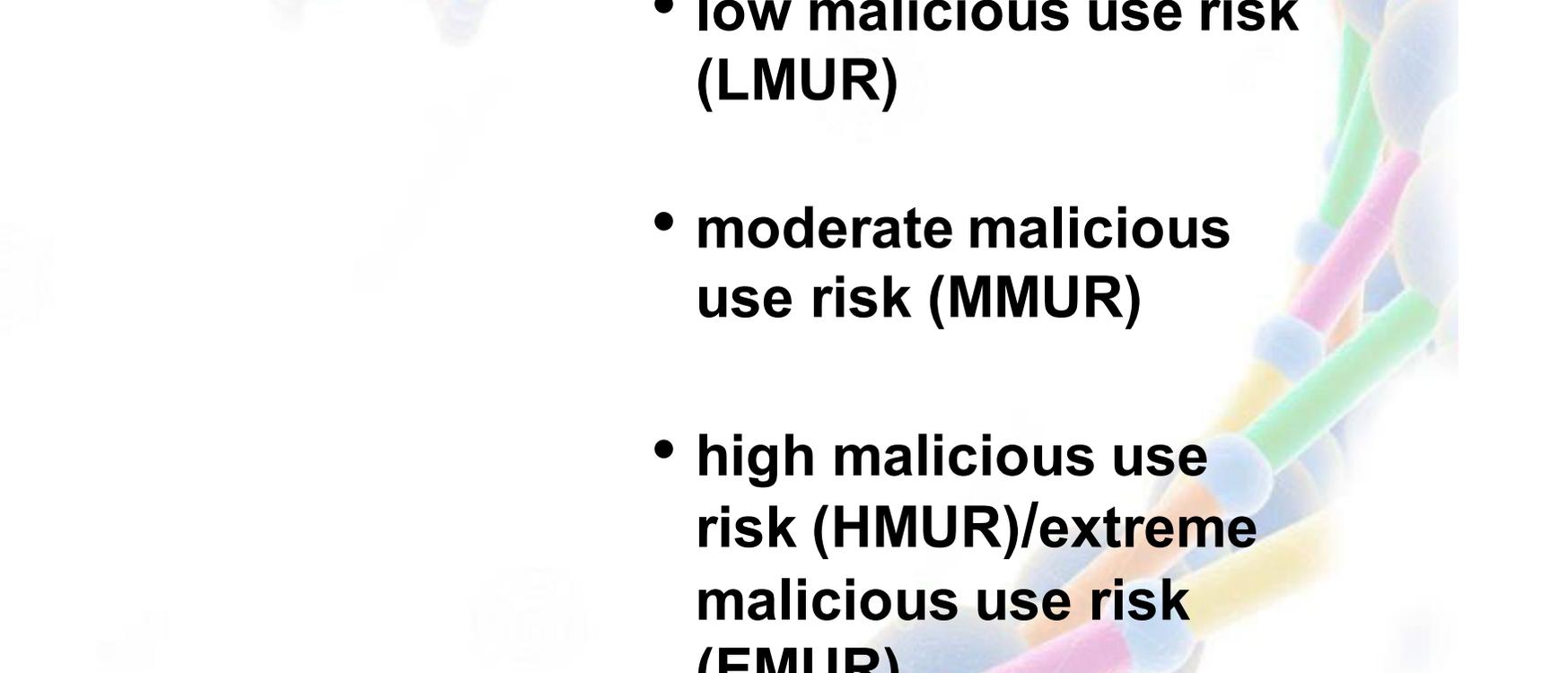
Lesson # 125

Biosecurity



**Characterize
risk**

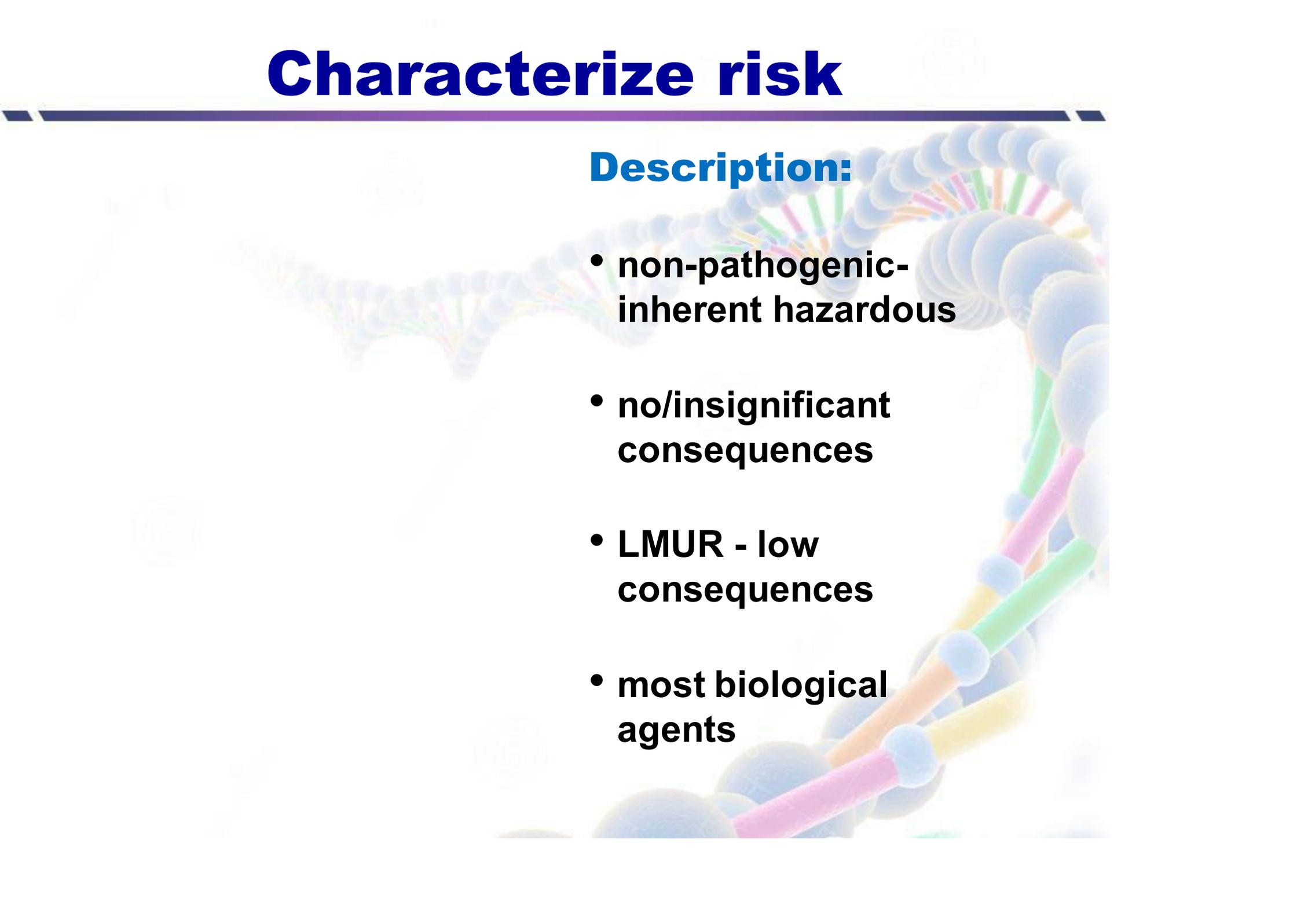
Characterize risk



Malicious risk groups:

- **non-pathogenic**
- **low malicious use risk (LMUR)**
- **moderate malicious use risk (MMUR)**
- **high malicious use risk (HMUR)/extreme malicious use risk (EMUR)**

Characterize risk



Description:

- non-pathogenic-inherent hazardous
- no/insignificant consequences
- LMUR - low consequences
- most biological agents

Characterize risk

Example:

- *Mycobacterium leprae*
- gram positive rods/
non-spore formers
- organism grow
slowly-generation
time 30 days
- not highly virulent
(LMUR)

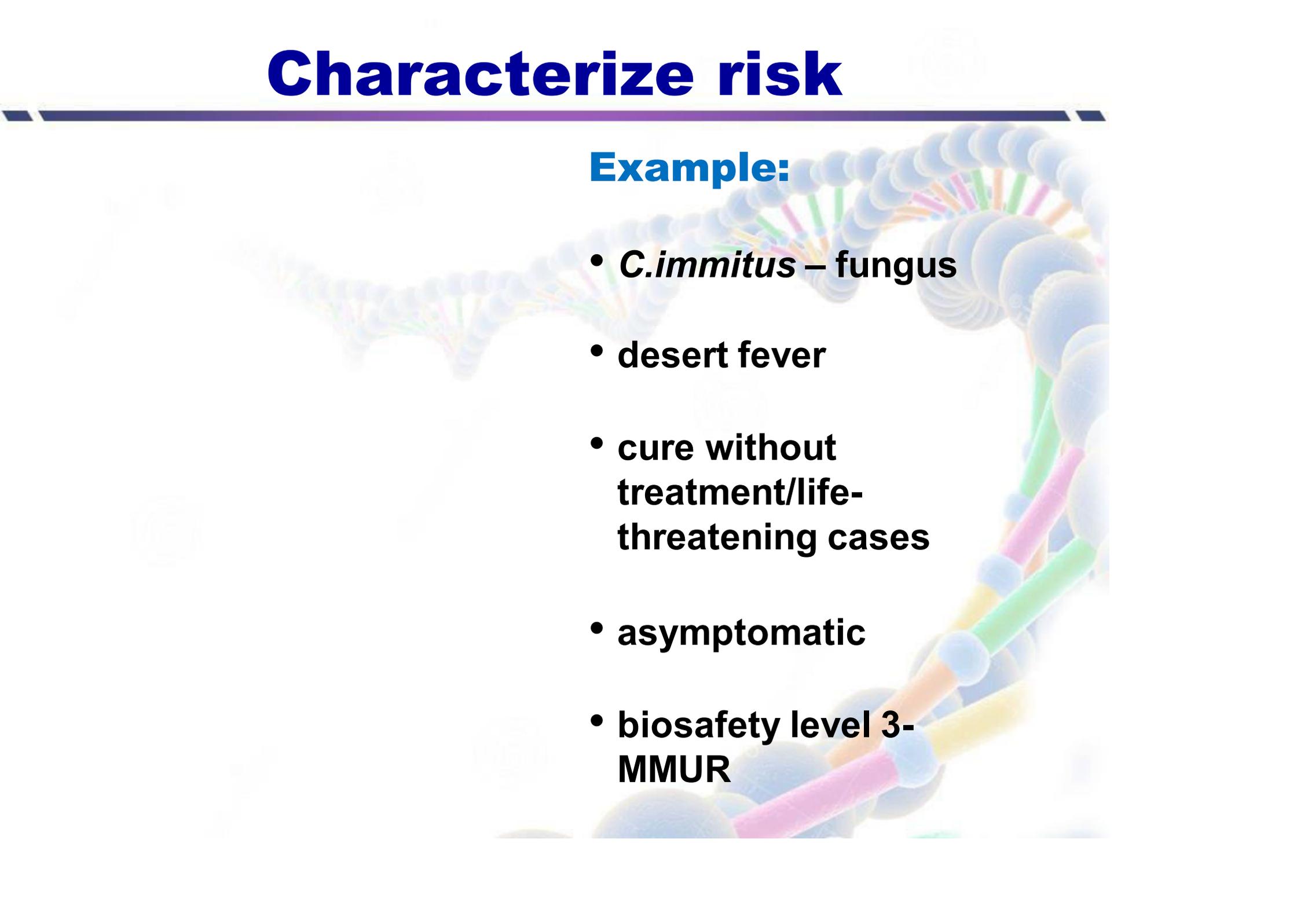
Characterize risk



Description:

- **MMUR-can't deploy as biological weapons**
- **low / moderate consequences**
- **low / moderate economic impact**
- **many current agents evaluated as MMUR**

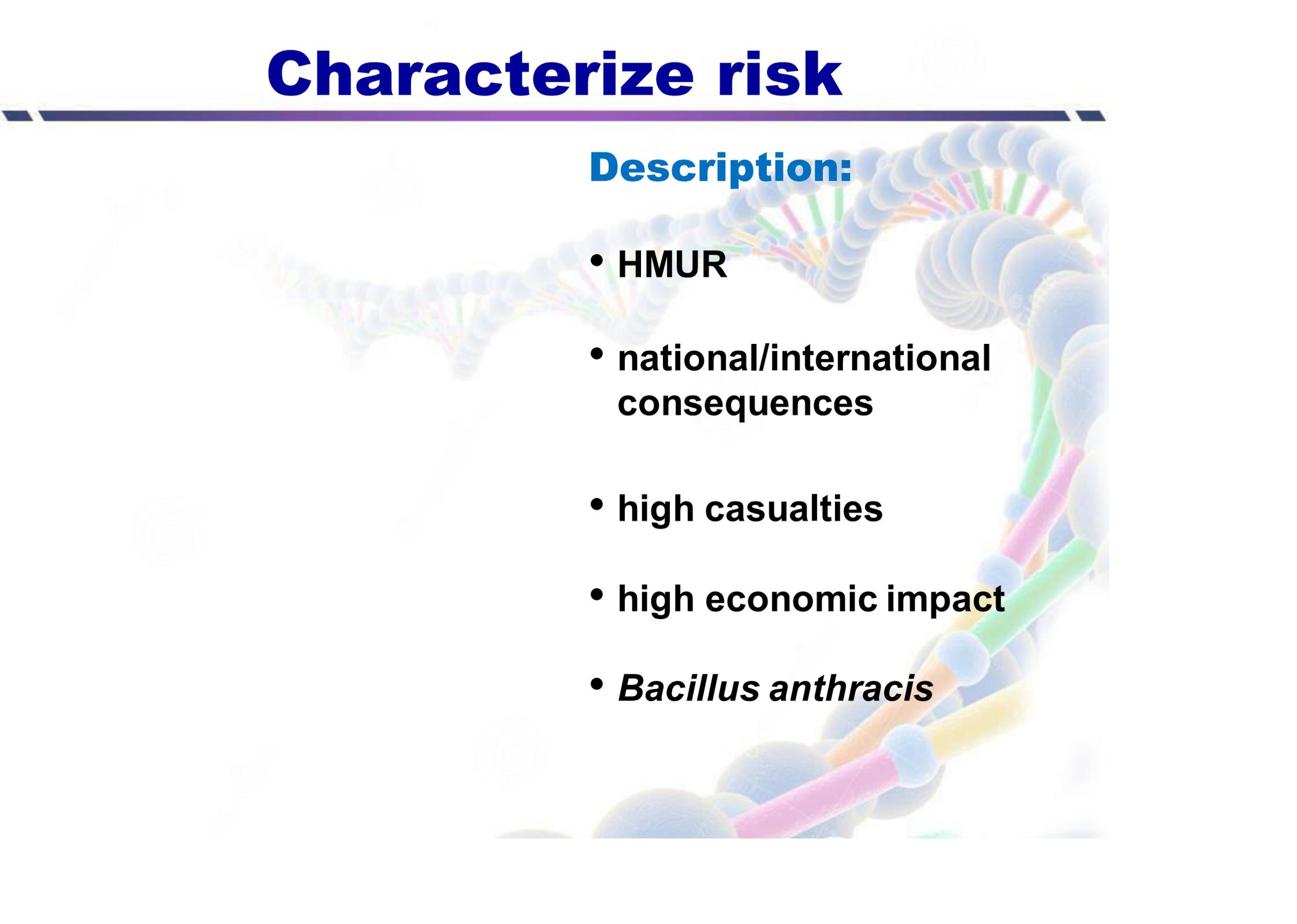
Characterize risk



Example:

- *C.immitus* – fungus
- desert fever
- cure without treatment/life-threatening cases
- asymptomatic
- biosafety level 3-MMUR

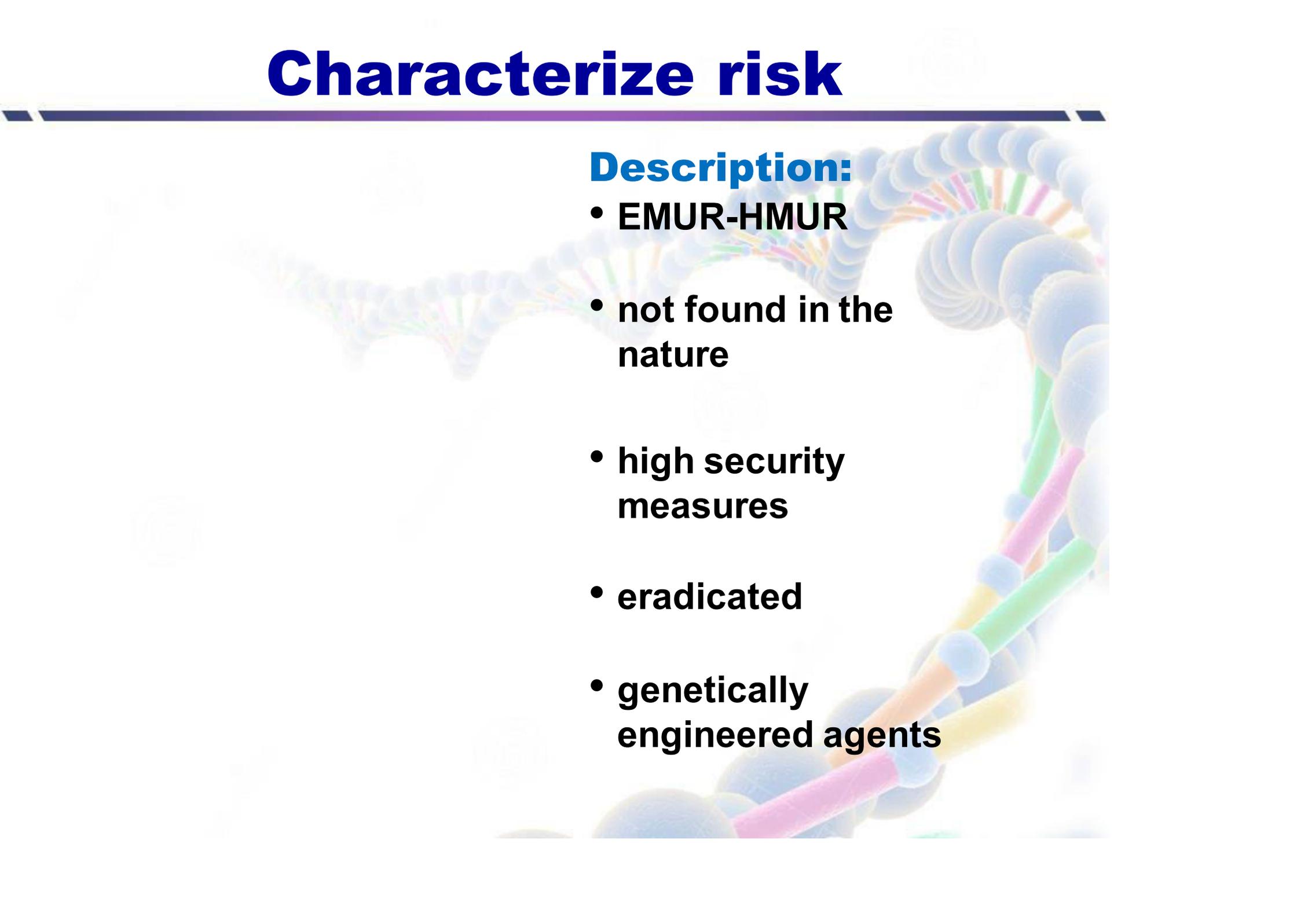
Characterize risk



Description:

- **HMUR**
- **national/international consequences**
- **high casualties**
- **high economic impact**
- ***Bacillus anthracis***

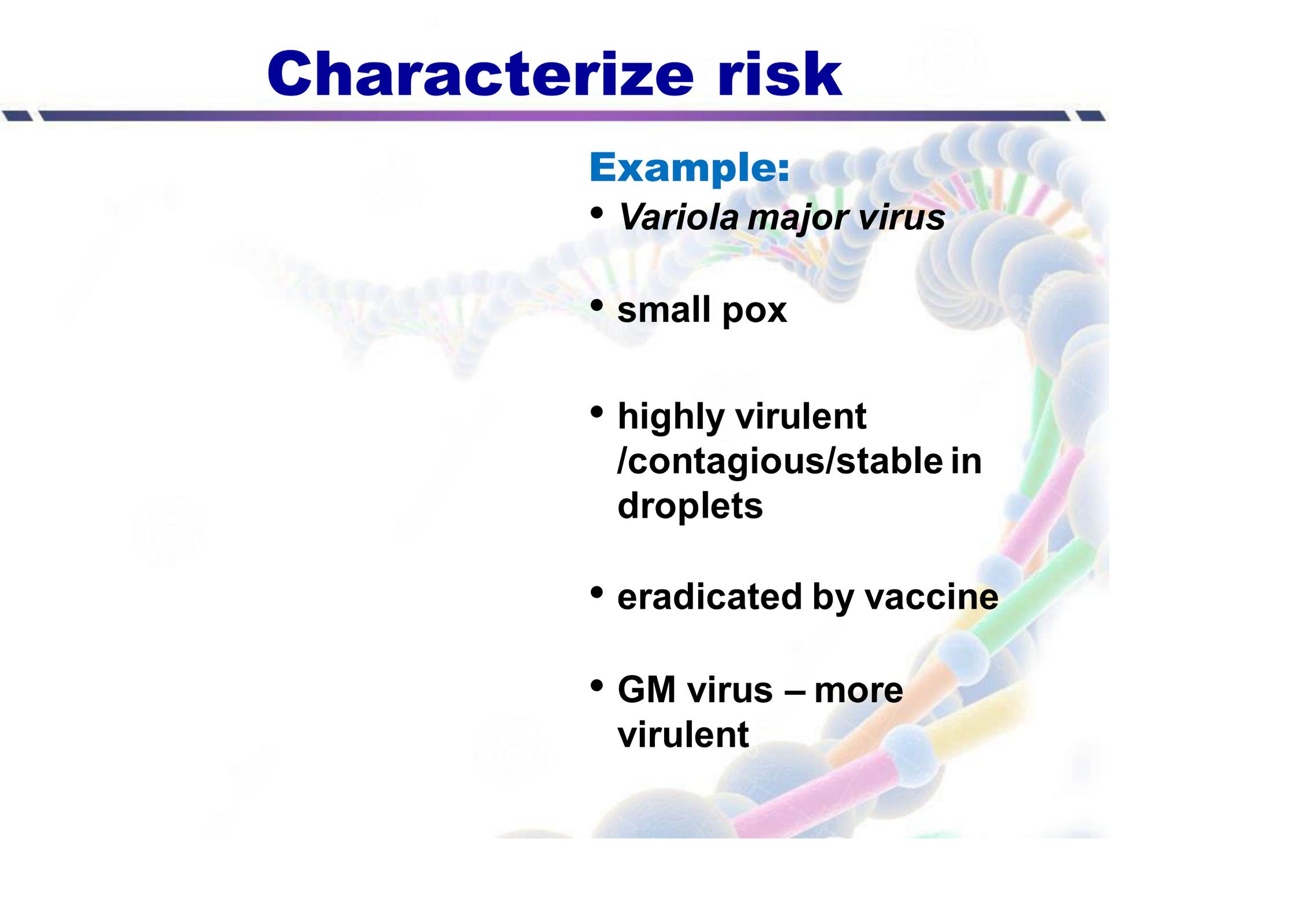
Characterize risk



Description:

- **EMUR-HMUR**
- **not found in the nature**
- **high security measures**
- **eradicated**
- **genetically engineered agents**

Characterize risk



Example:

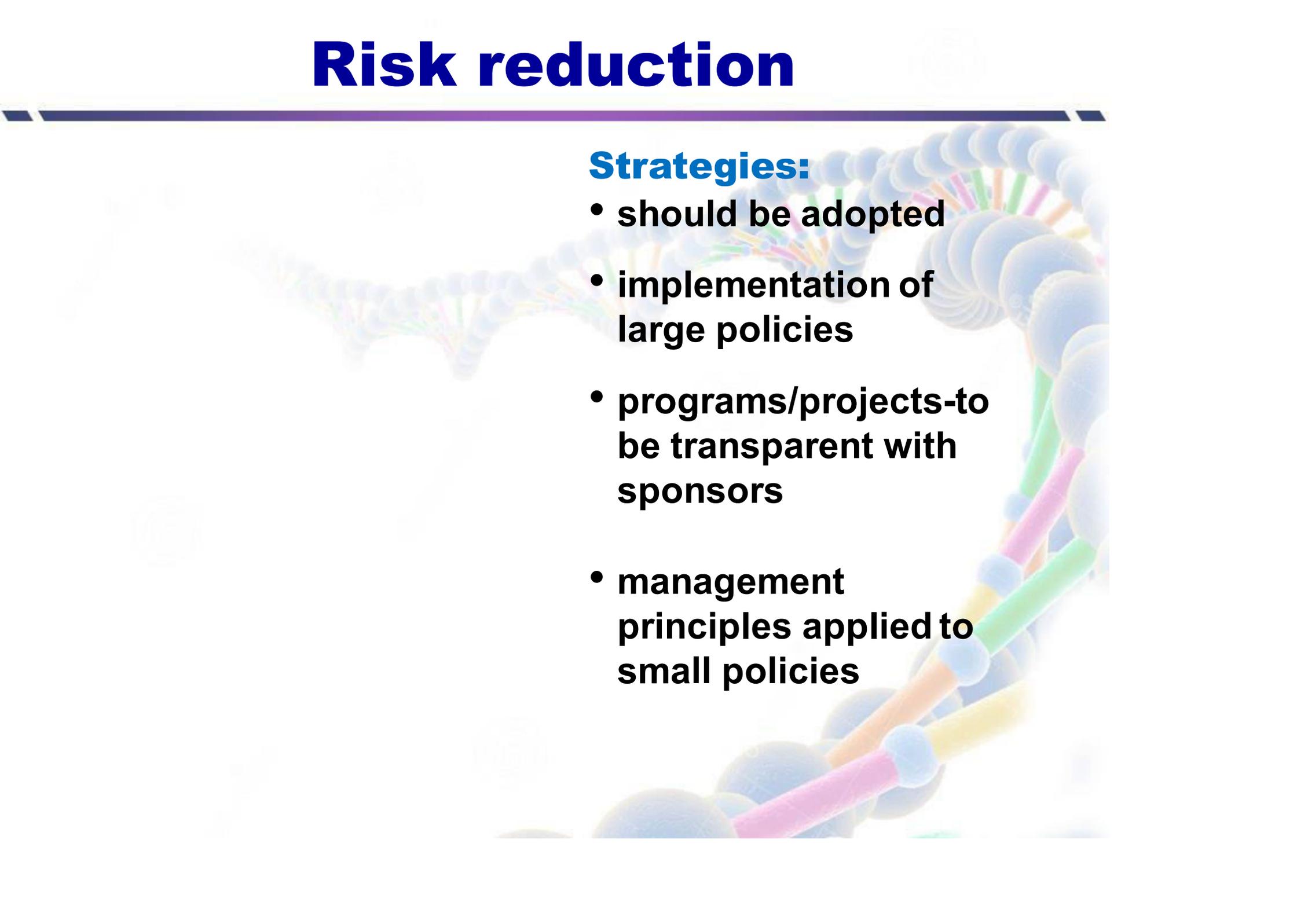
- *Variola major virus*
- small pox
- highly virulent
/contagious/stable in droplets
- eradicated by vaccine
- GM virus – more virulent

Biosecurity



Lesson # 126
Risk reduction

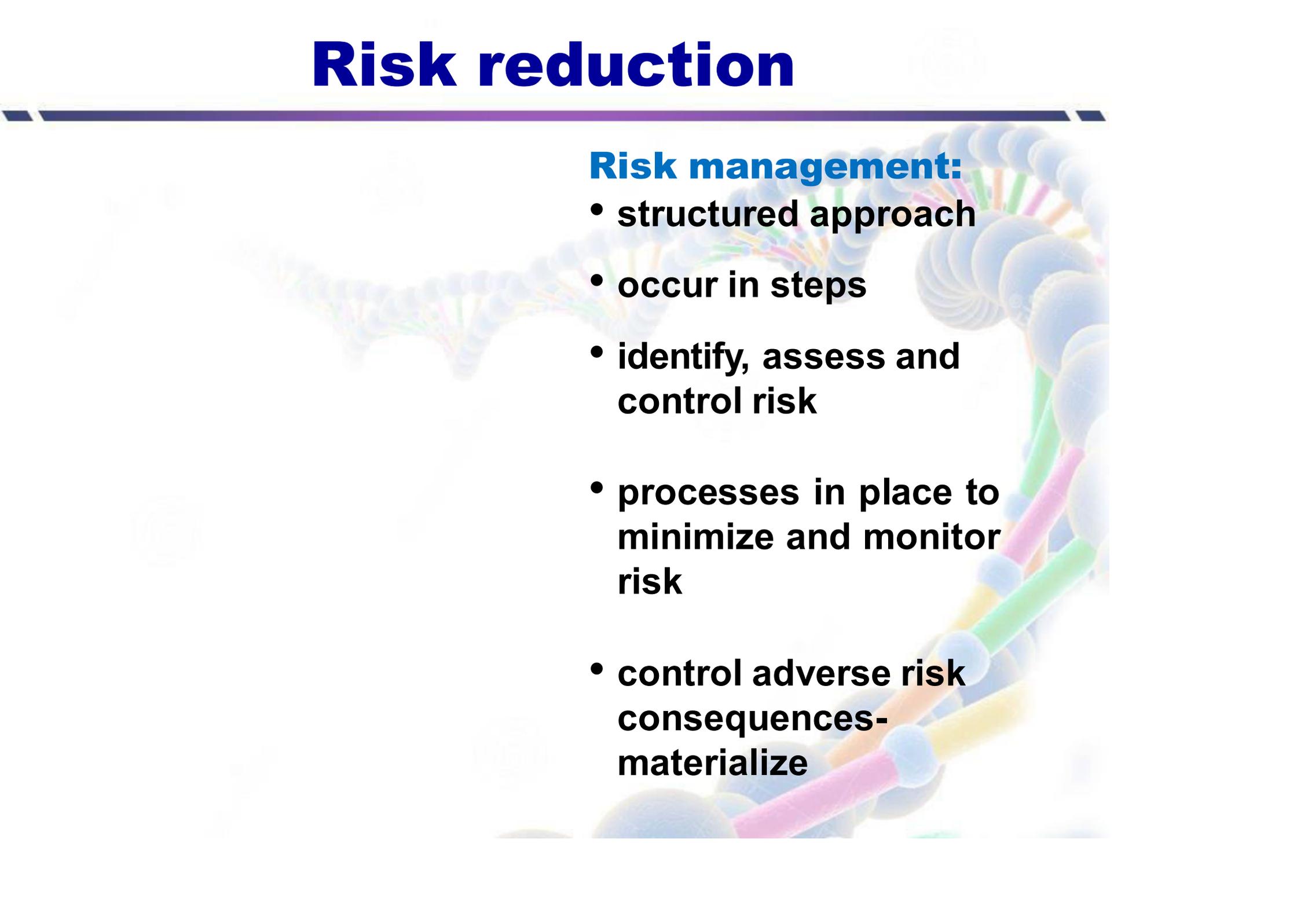
Risk reduction



Strategies:

- **should be adopted**
- **implementation of large policies**
- **programs/projects-to be transparent with sponsors**
- **management principles applied to small policies**

Risk reduction



Risk management:

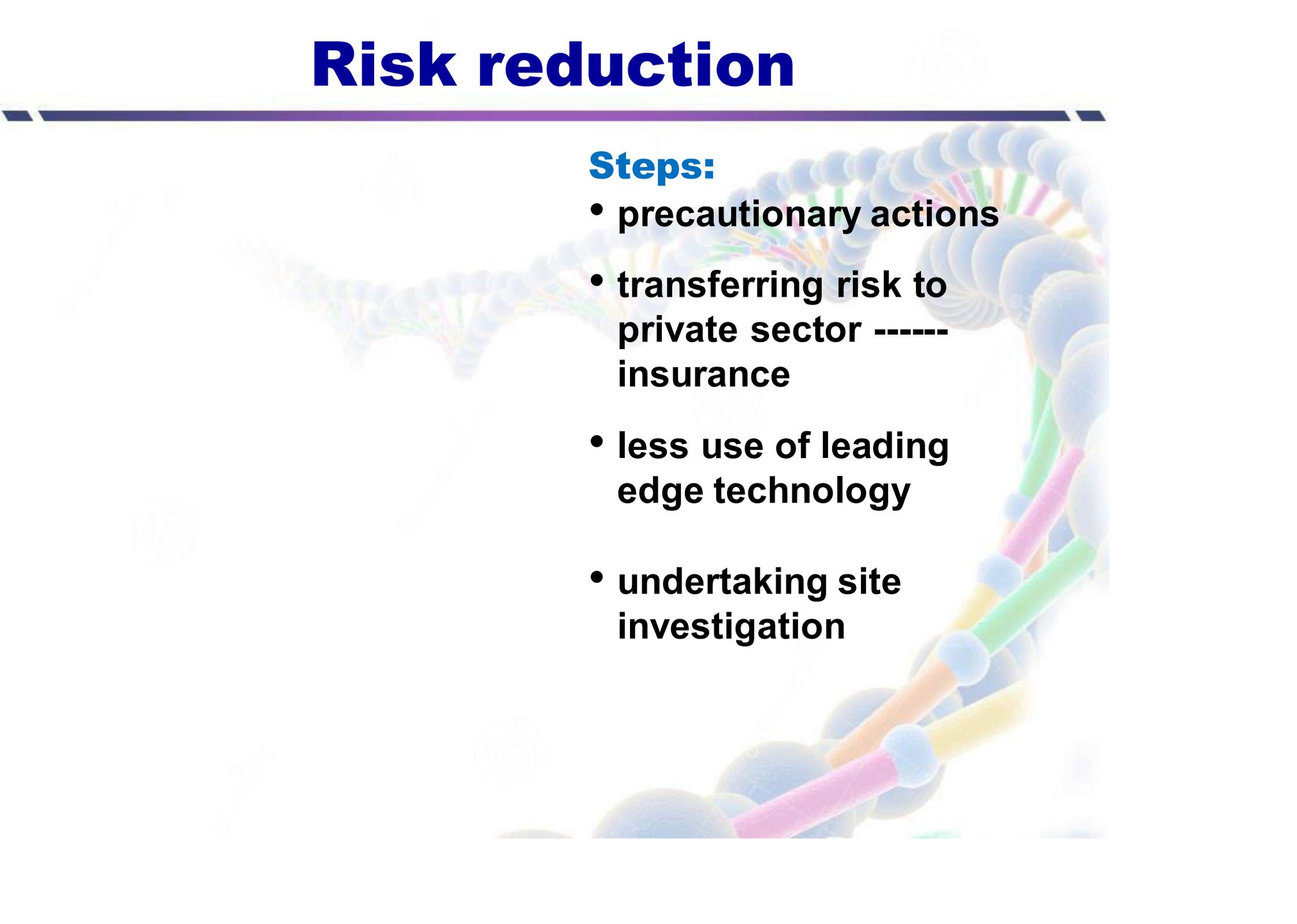
- **structured approach**
- **occur in steps**
- **identify, assess and control risk**
- **processes in place to minimize and monitor risk**
- **control adverse risk consequences-materialize**

Risk reduction

Steps:

- **early consultation-
identify needs and
cost**
- **deferring irreversible
decisions-need more
time to achieve
objectives**
- **pilot studies - more
information about risk**
- **design flexibility-
modify-future needs**

Risk reduction



Steps:

- precautionary actions
- transferring risk to private sector ----- insurance
- less use of leading edge technology
- undertaking site investigation

Risk reduction

Steps:

- staging the project-
review at different
steps
- abandoning the
project - too risky

Biosecurity



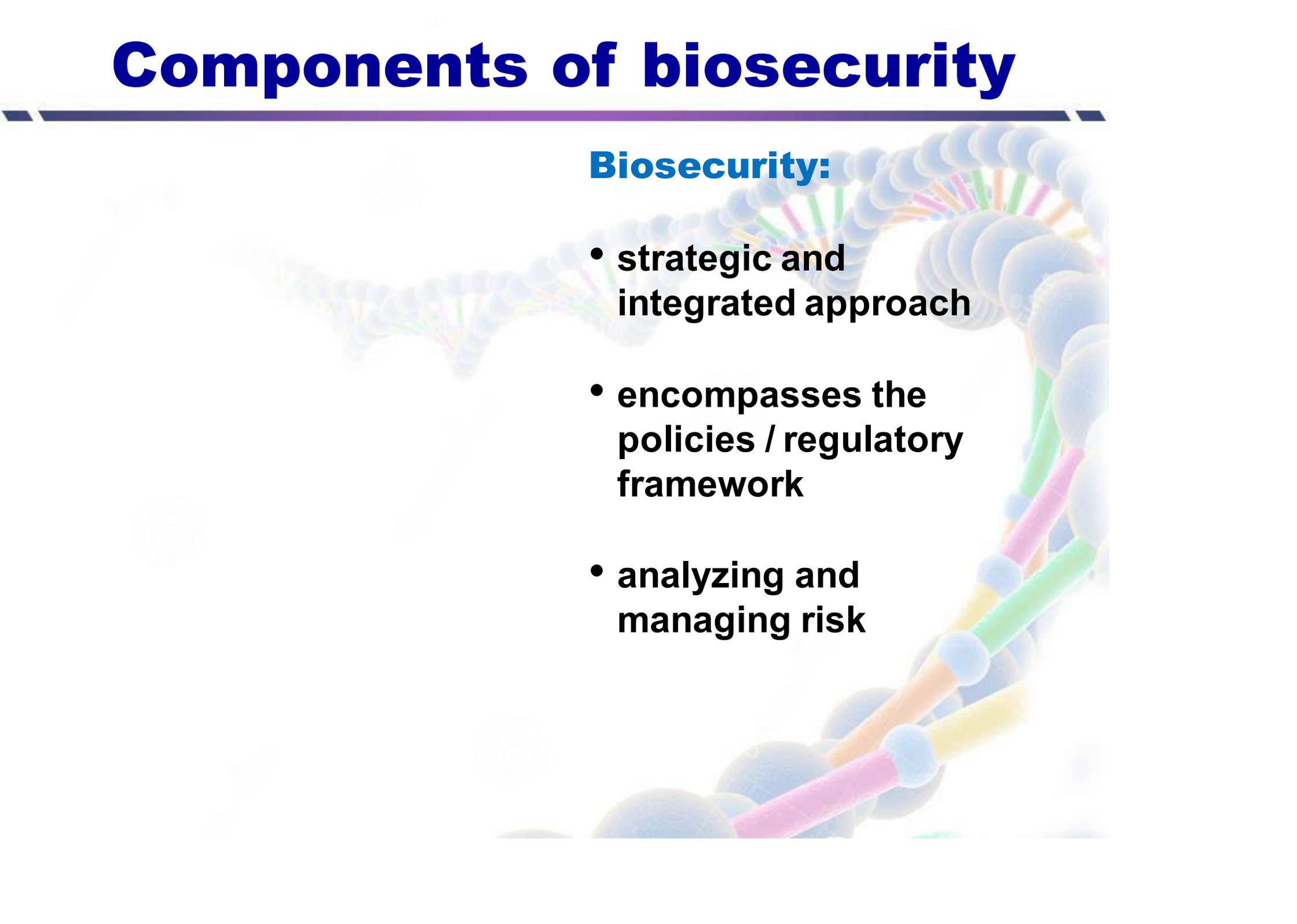
Lesson # 127

Biosecurity



**Components
of
biosecurity**

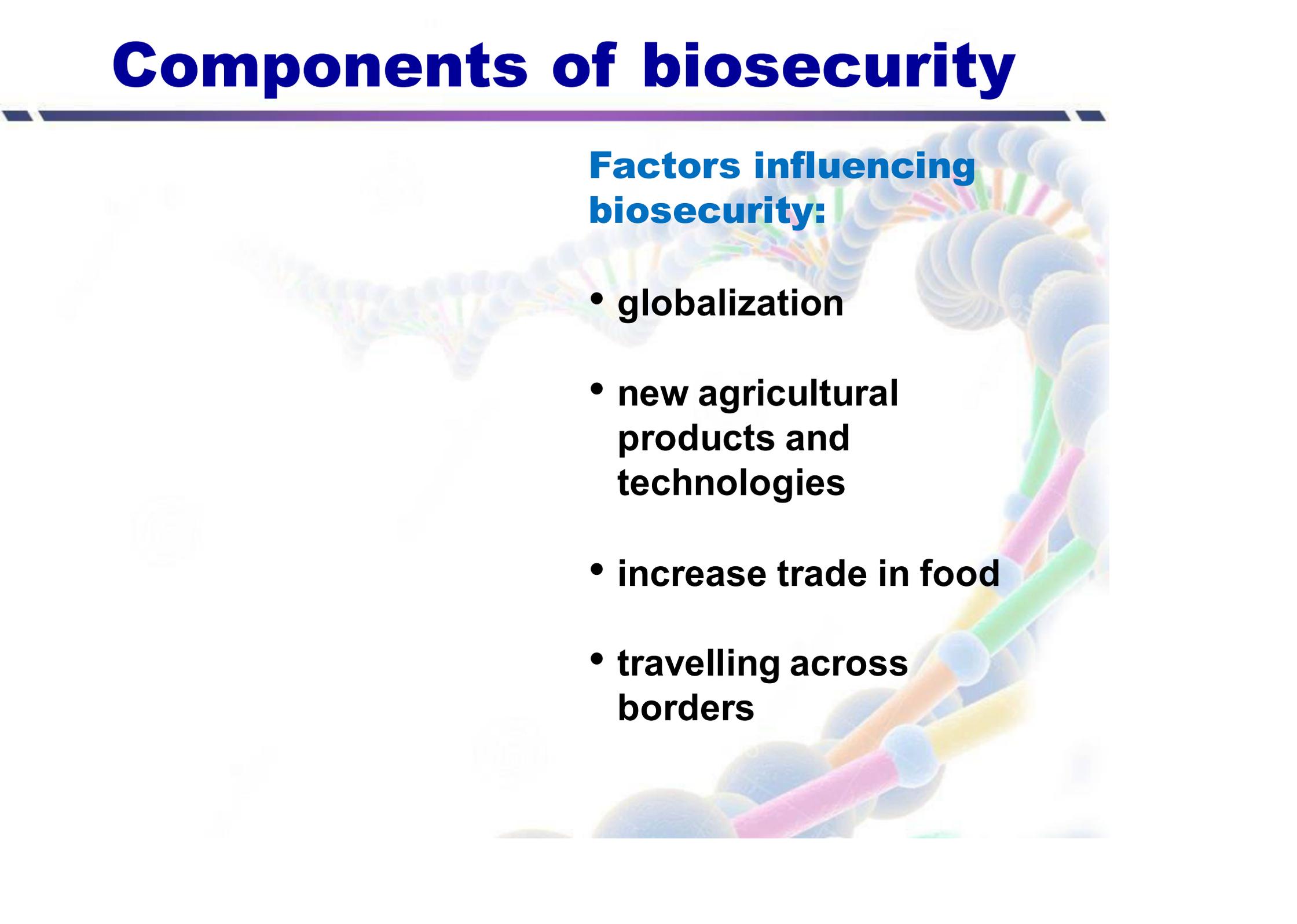
Components of biosecurity



Biosecurity:

- **strategic and integrated approach**
- **encompasses the policies / regulatory framework**
- **analyzing and managing risk**

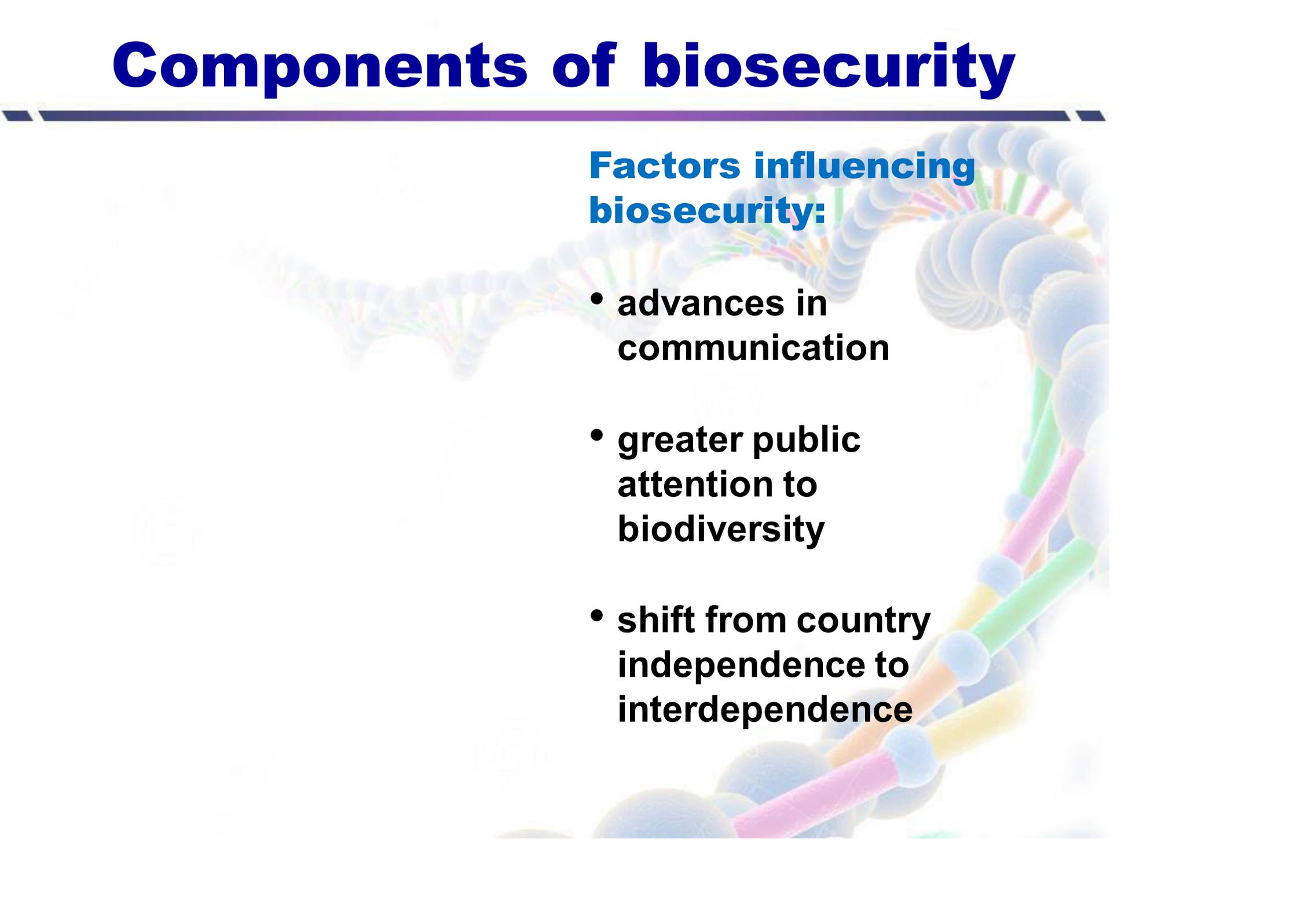
Components of biosecurity



Factors influencing biosecurity:

- globalization
- new agricultural products and technologies
- increase trade in food
- travelling across borders

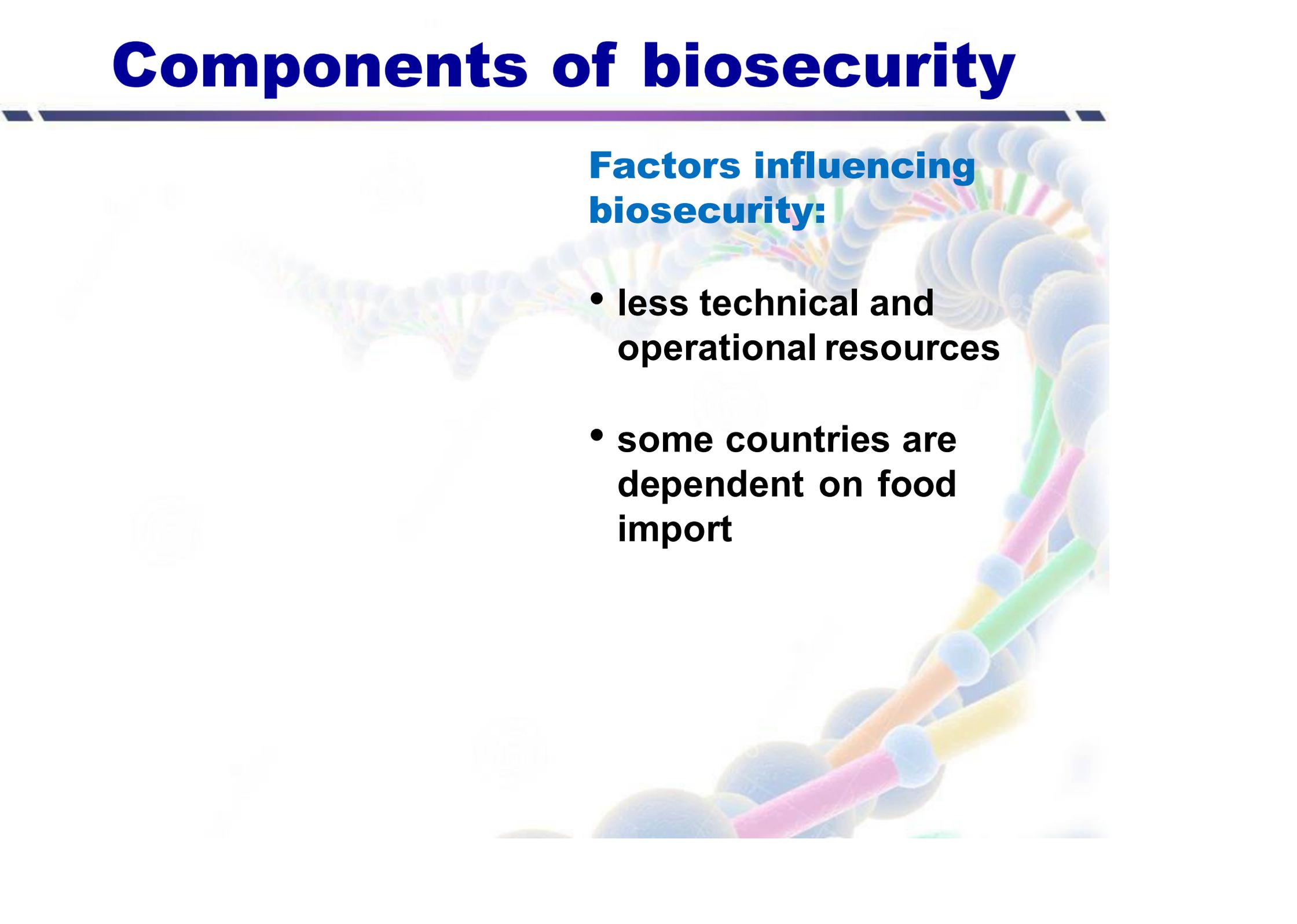
Components of biosecurity



Factors influencing biosecurity:

- **advances in communication**
- **greater public attention to biodiversity**
- **shift from country independence to interdependence**

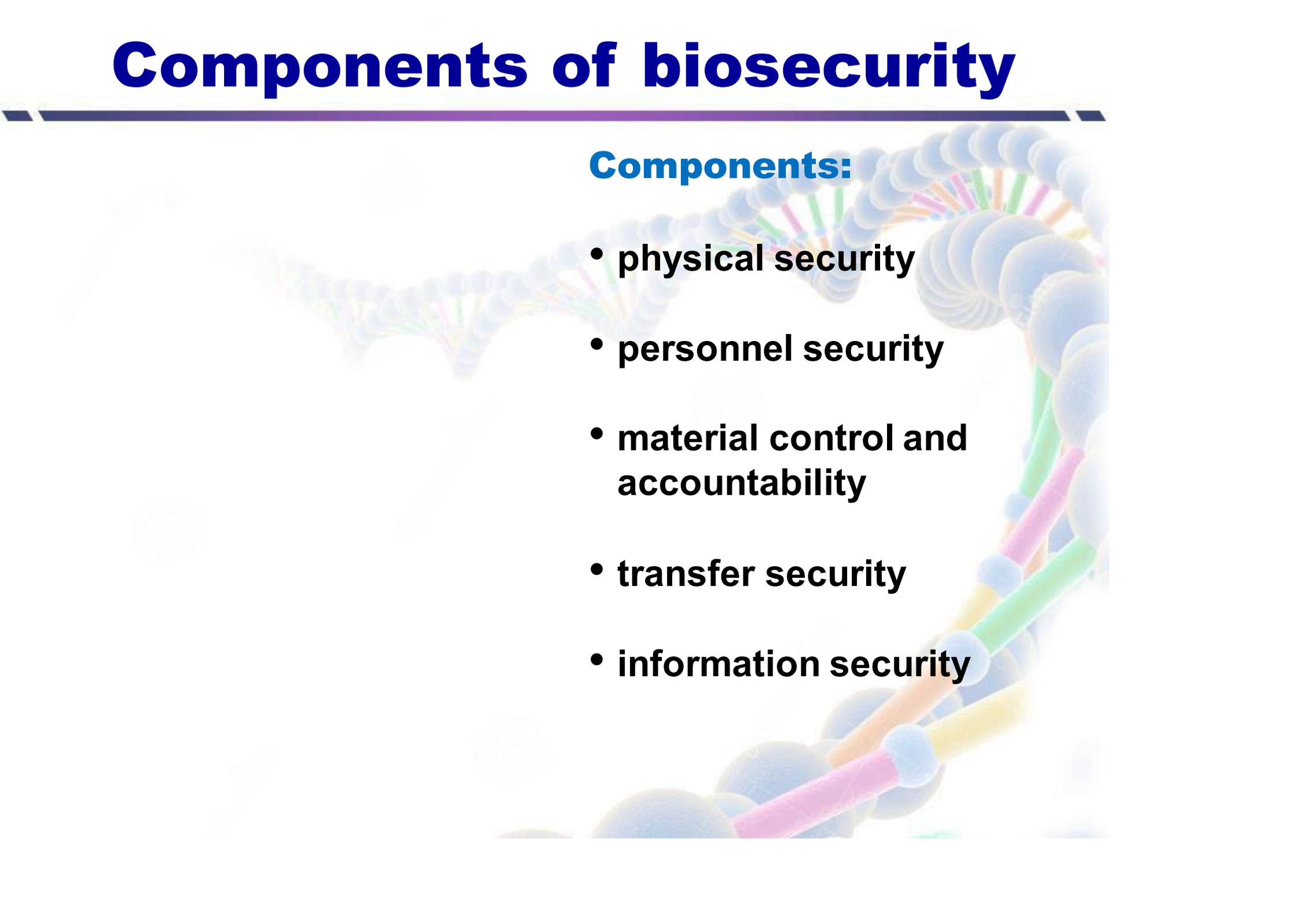
Components of biosecurity



Factors influencing biosecurity:

- less technical and operational resources
- some countries are dependent on food import

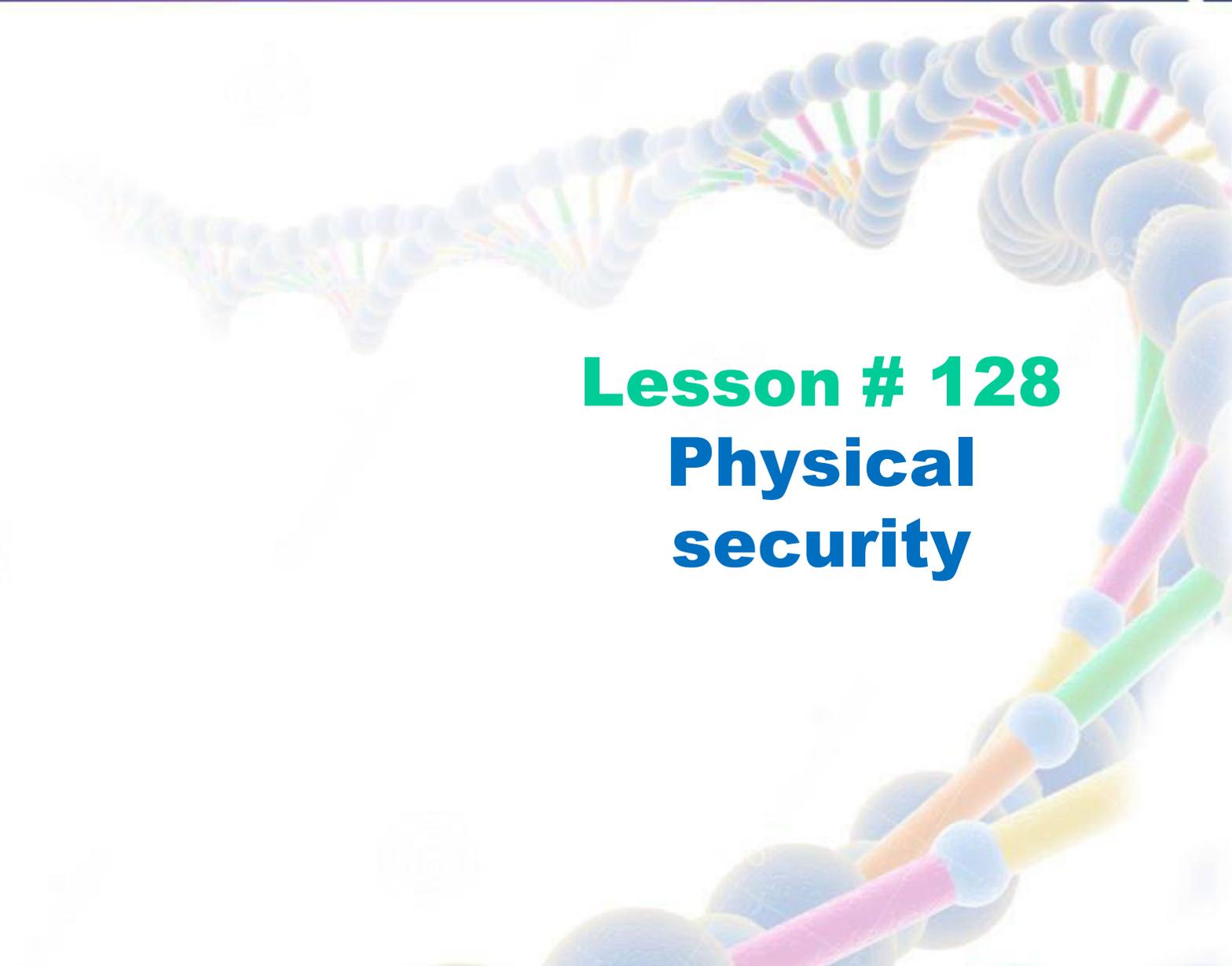
Components of biosecurity



Components:

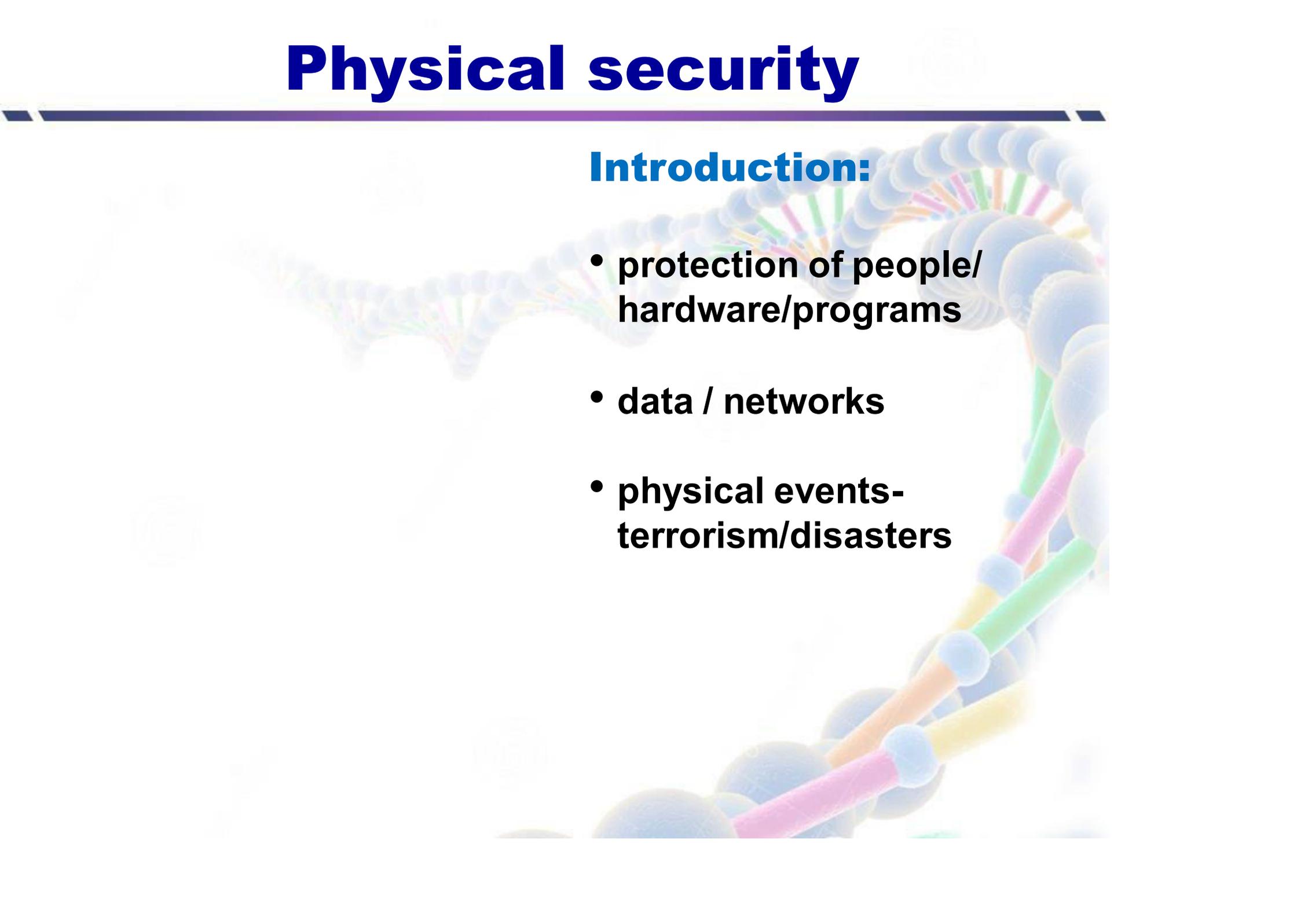
- physical security
- personnel security
- material control and accountability
- transfer security
- information security

Biosecurity



Lesson # 128
Physical security

Physical security



Introduction:

- protection of people/
hardware/programs
- data / networks
- physical events-
terrorism/disasters

Biosecurity



Lesson # 129

Biosecurity



**Physical
security
elements**

Physical security elements

Elements:

- obstacles placed in the way of attackers
- surveillance and notification system
- methods to recover quickly from disaster

Physical security elements

Obstacles:

- fencing
- wall
- multiple locks
- fireproof safes
- water sprinkles

Physical security elements

Surveillance/notification system:

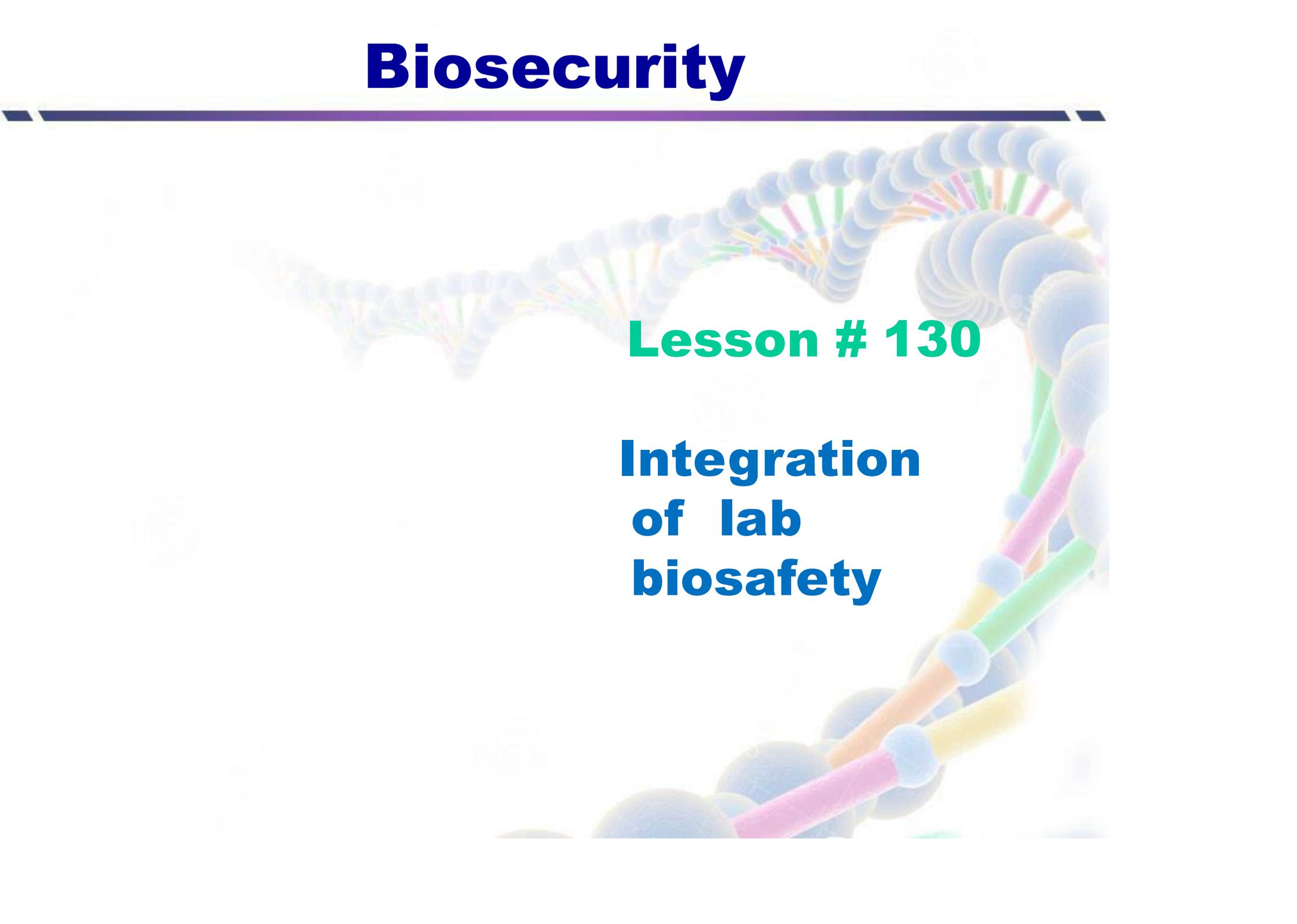
- heat detector
- smoke detector
- lighting
- alarms
- cameras

Physical security elements

Recovery:

- repairment
- hiring additional security
- cameras

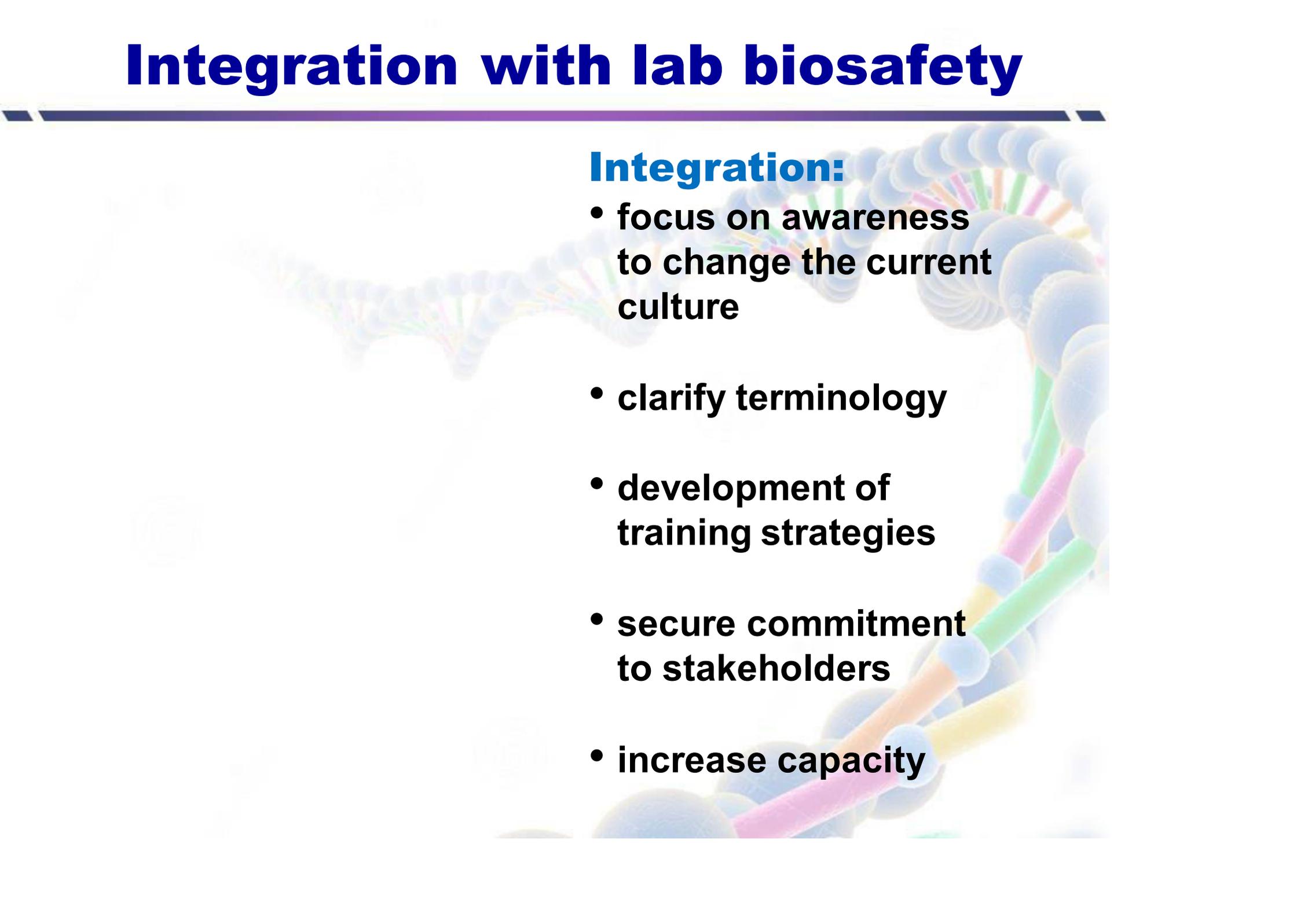
Biosecurity



Lesson # 130

Integration of lab biosafety

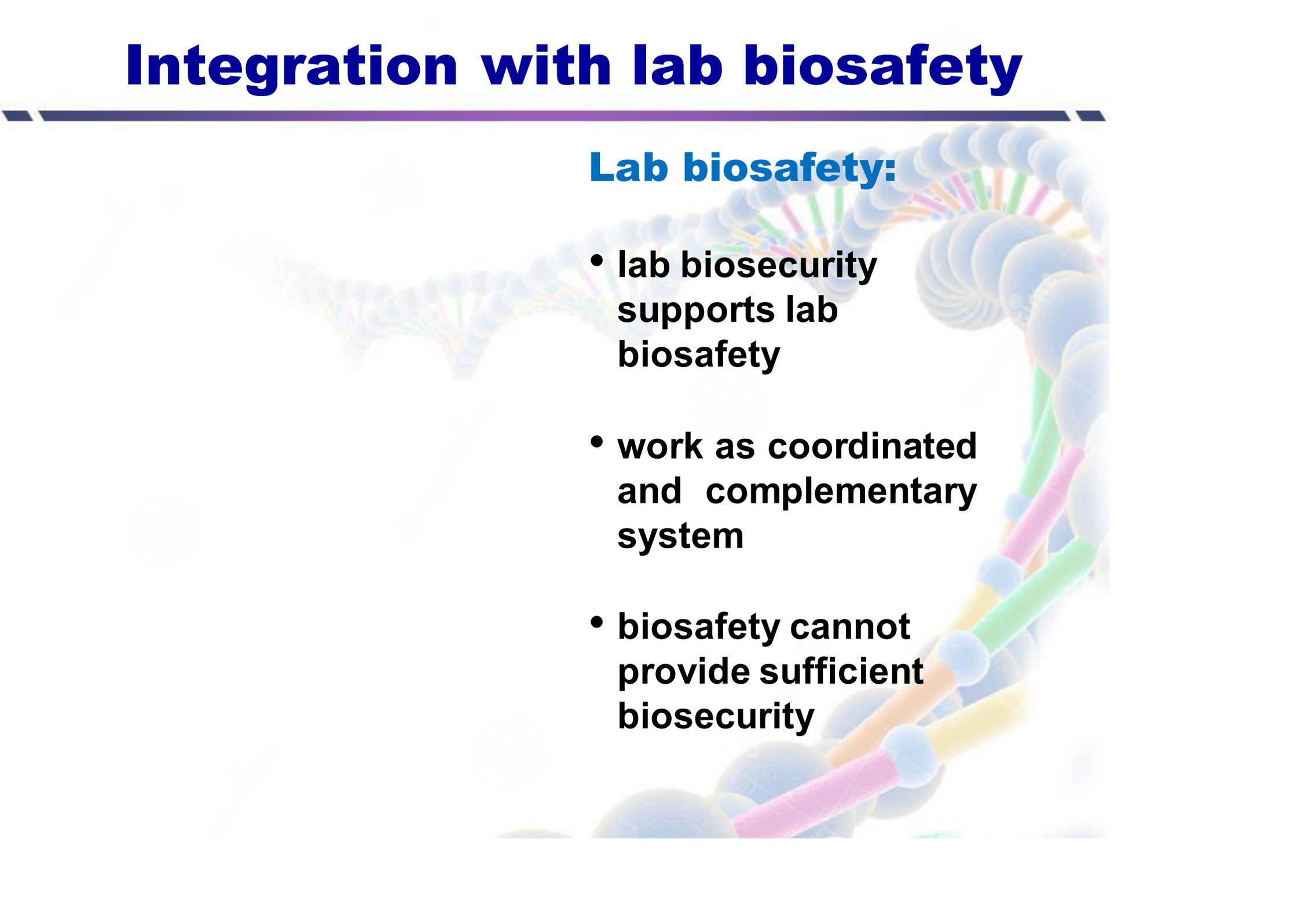
Integration with lab biosafety



Integration:

- **focus on awareness to change the current culture**
- **clarify terminology**
- **development of training strategies**
- **secure commitment to stakeholders**
- **increase capacity**

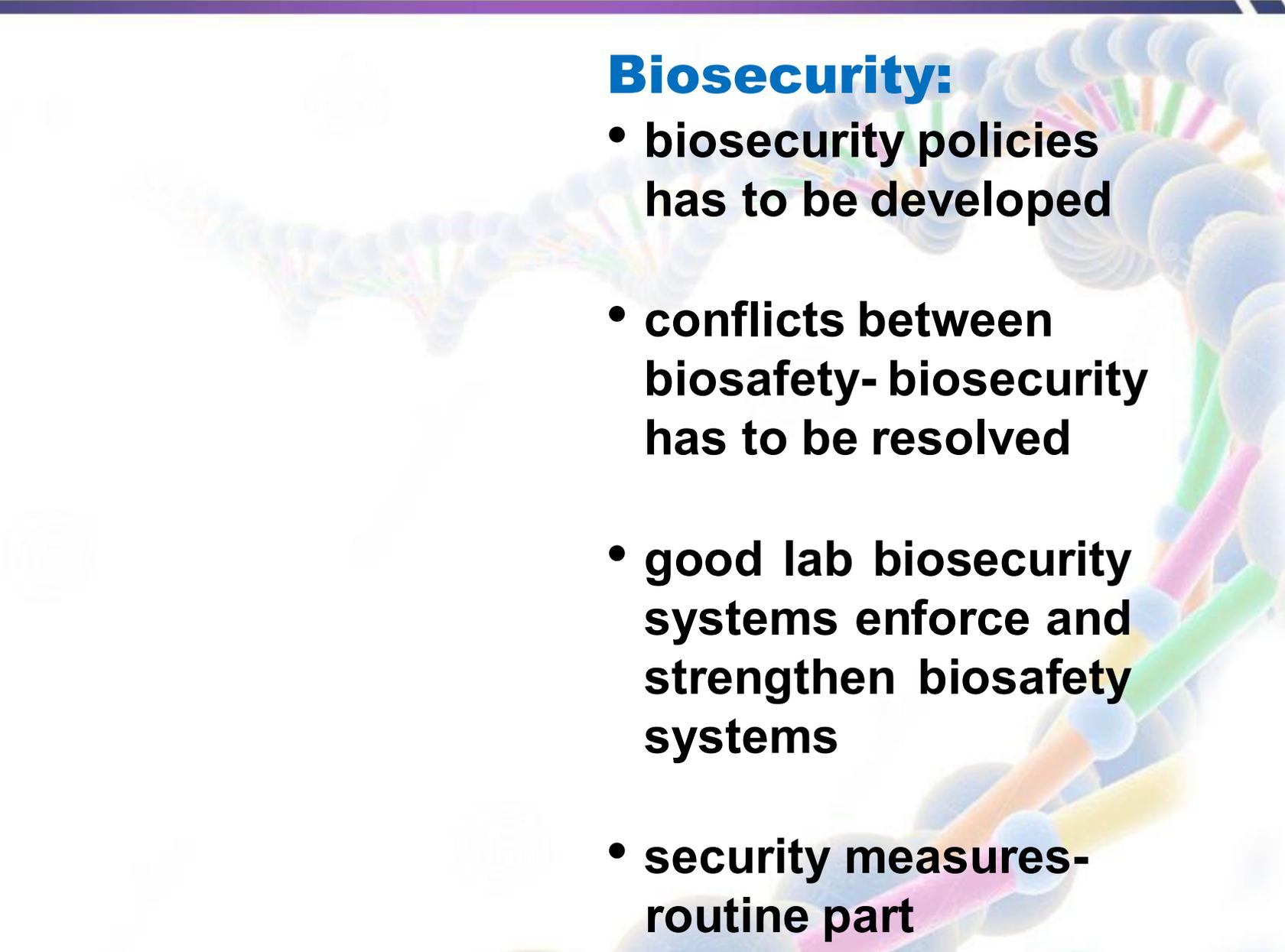
Integration with lab biosafety



Lab biosafety:

- **lab biosecurity supports lab biosafety**
- **work as coordinated and complementary system**
- **biosafety cannot provide sufficient biosecurity**

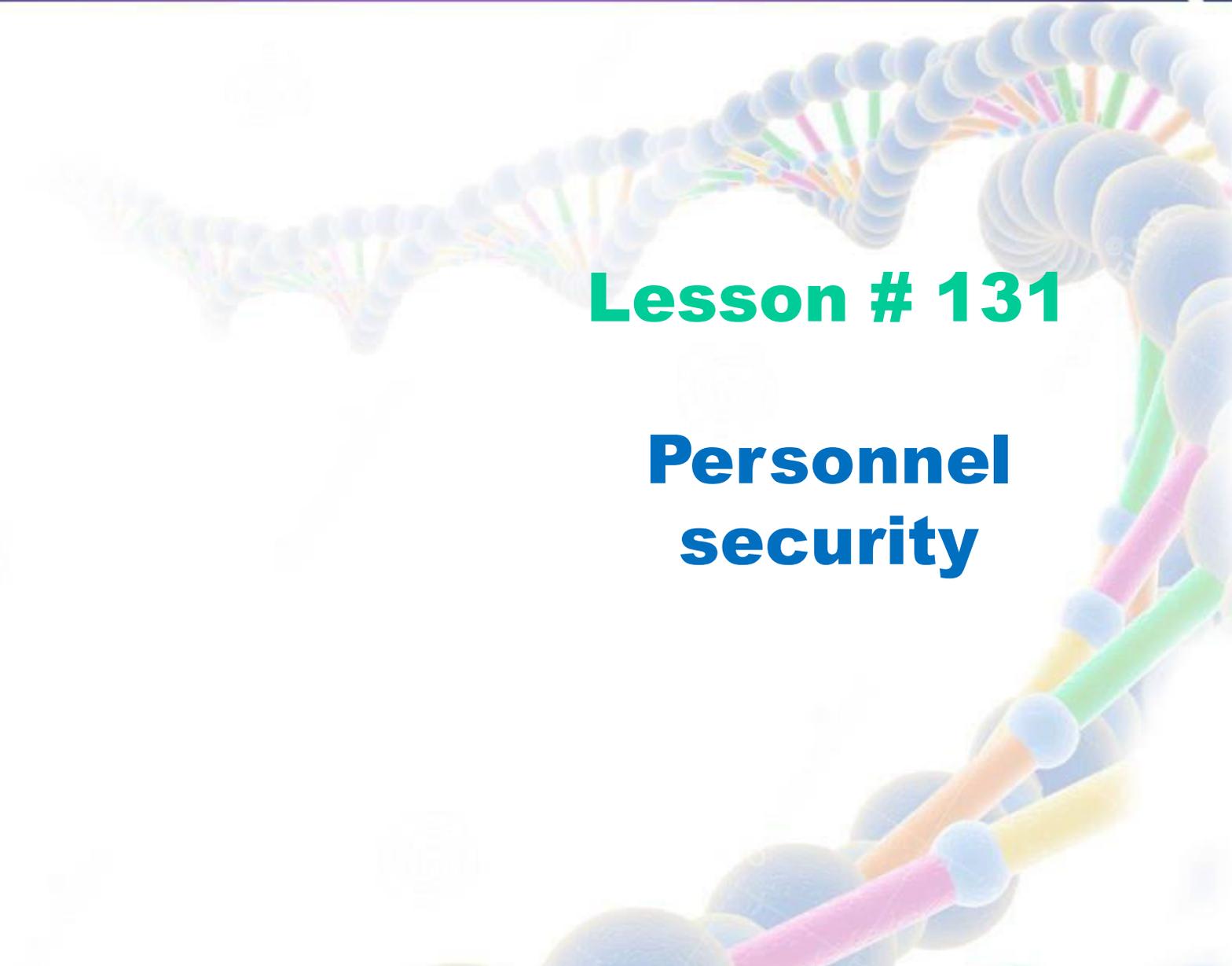
Integration with lab biosafety



Biosecurity:

- **biosecurity policies has to be developed**
- **conflicts between biosafety- biosecurity has to be resolved**
- **good lab biosecurity systems enforce and strengthen biosafety systems**
- **security measures- routine part**

Biosecurity



Lesson # 131

**Personnel
security**

Personnel security

Introduction:

- increases the level of assurance
- honesty, trustworthy, loyalty with government resources
- reduces the risk of loss and damage

Personnel security

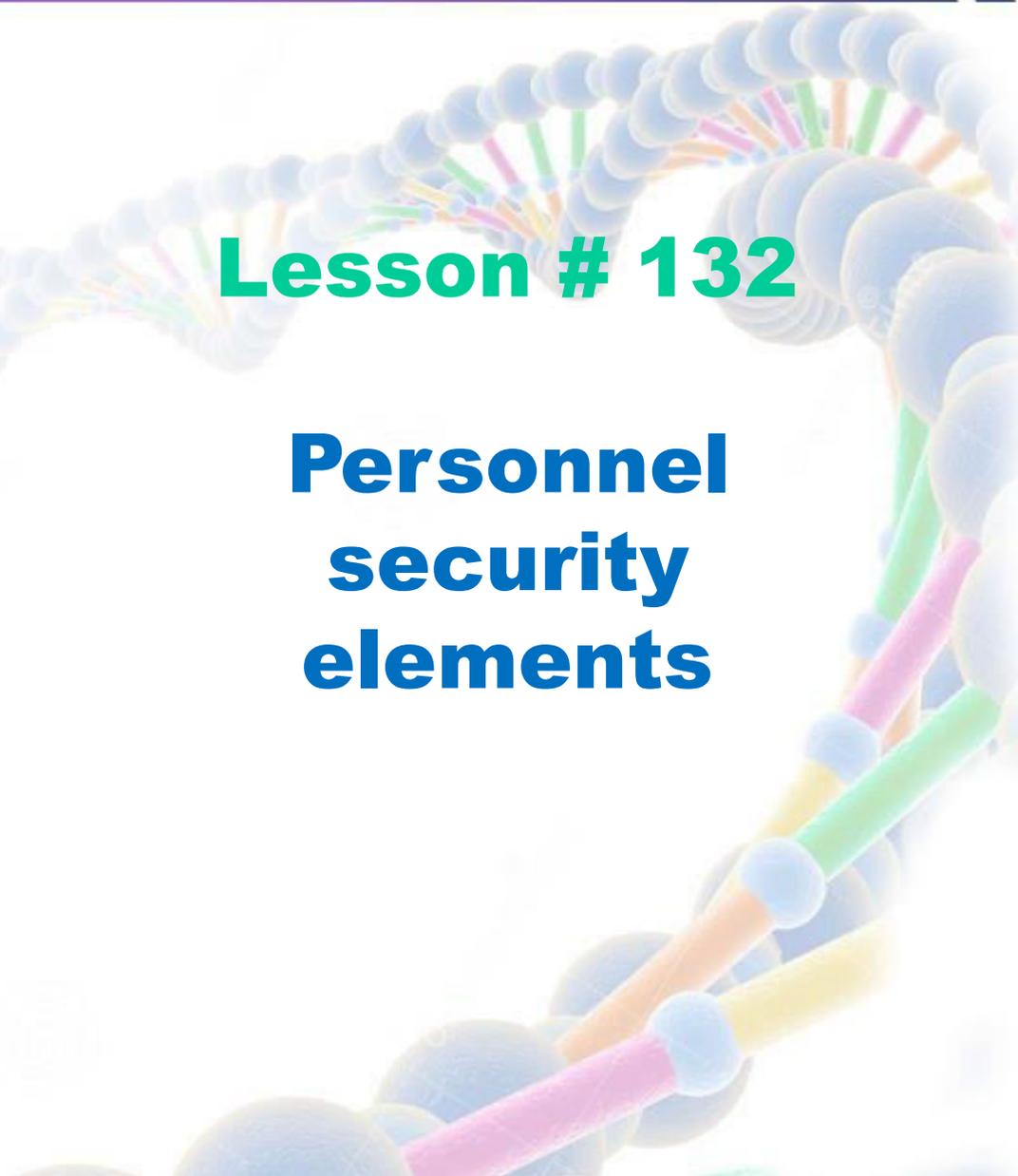
Requirement:

- robust pre-employment screening
- effective line management
- employee welfare /clear lines of communication
- strong security culture

Biosecurity

Lesson # 132

Personnel security elements



Personnel security elements

Elements:

- personnel screening
- badges
- visitors control
- training

Personnel security elements

Elements:

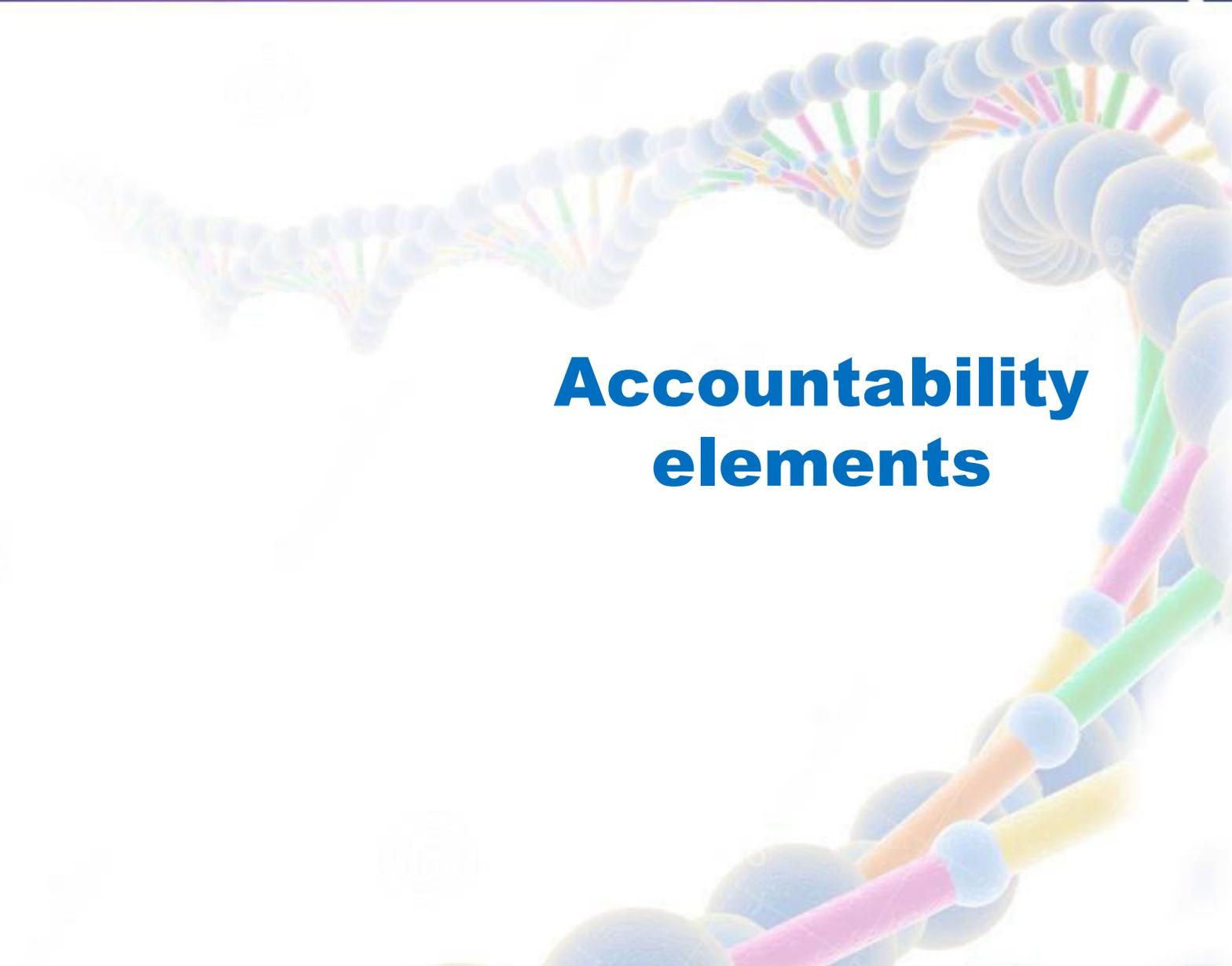
- all positions must be defined and trained
- security issues must be addressed
- divide responsibilities
- security officers----
personnel security policies

Biosecurity



Lesson # 133

Biosecurity



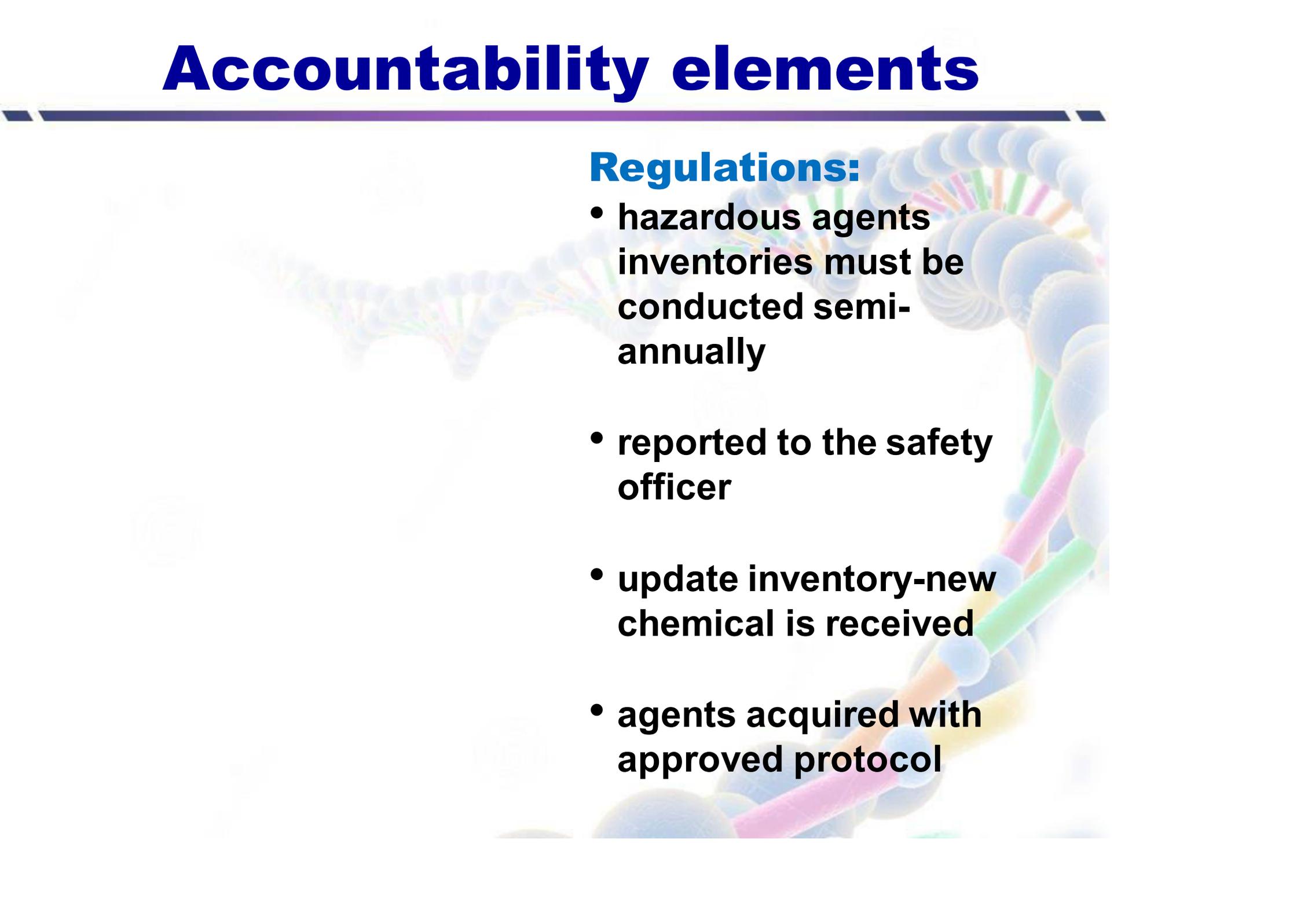
**Accountability
elements**

Accountability elements

Material control:

- **defining material is complicated**
- **agent/strain: name and description**
- **quantity in units-not the number of microbes**
- **procedural and physical measures**

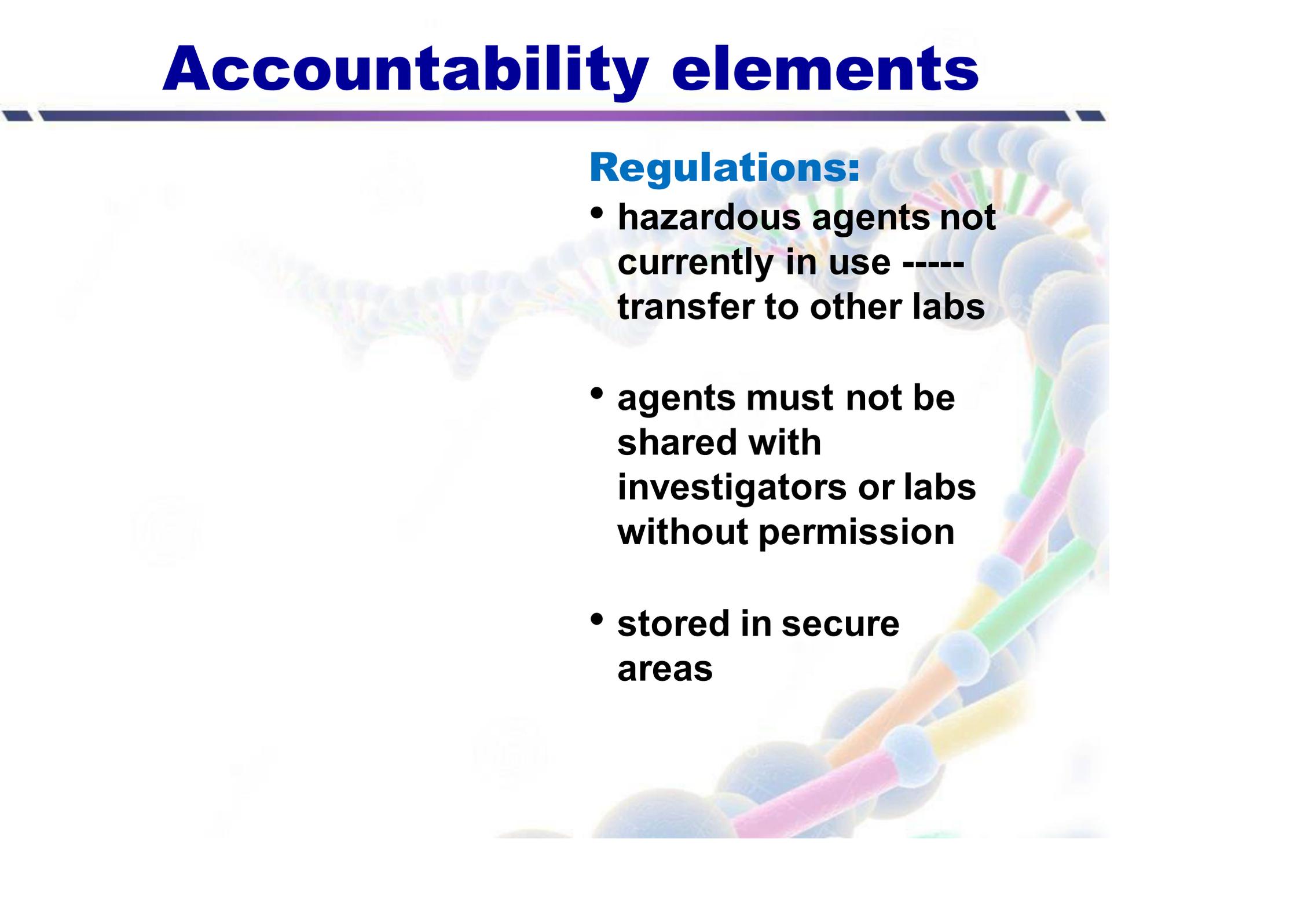
Accountability elements



Regulations:

- hazardous agents inventories must be conducted semi-annually
- reported to the safety officer
- update inventory-new chemical is received
- agents acquired with approved protocol

Accountability elements



Regulations:

- hazardous agents not currently in use -----
transfer to other labs
- agents must not be shared with investigators or labs without permission
- stored in secure areas

Accountability elements

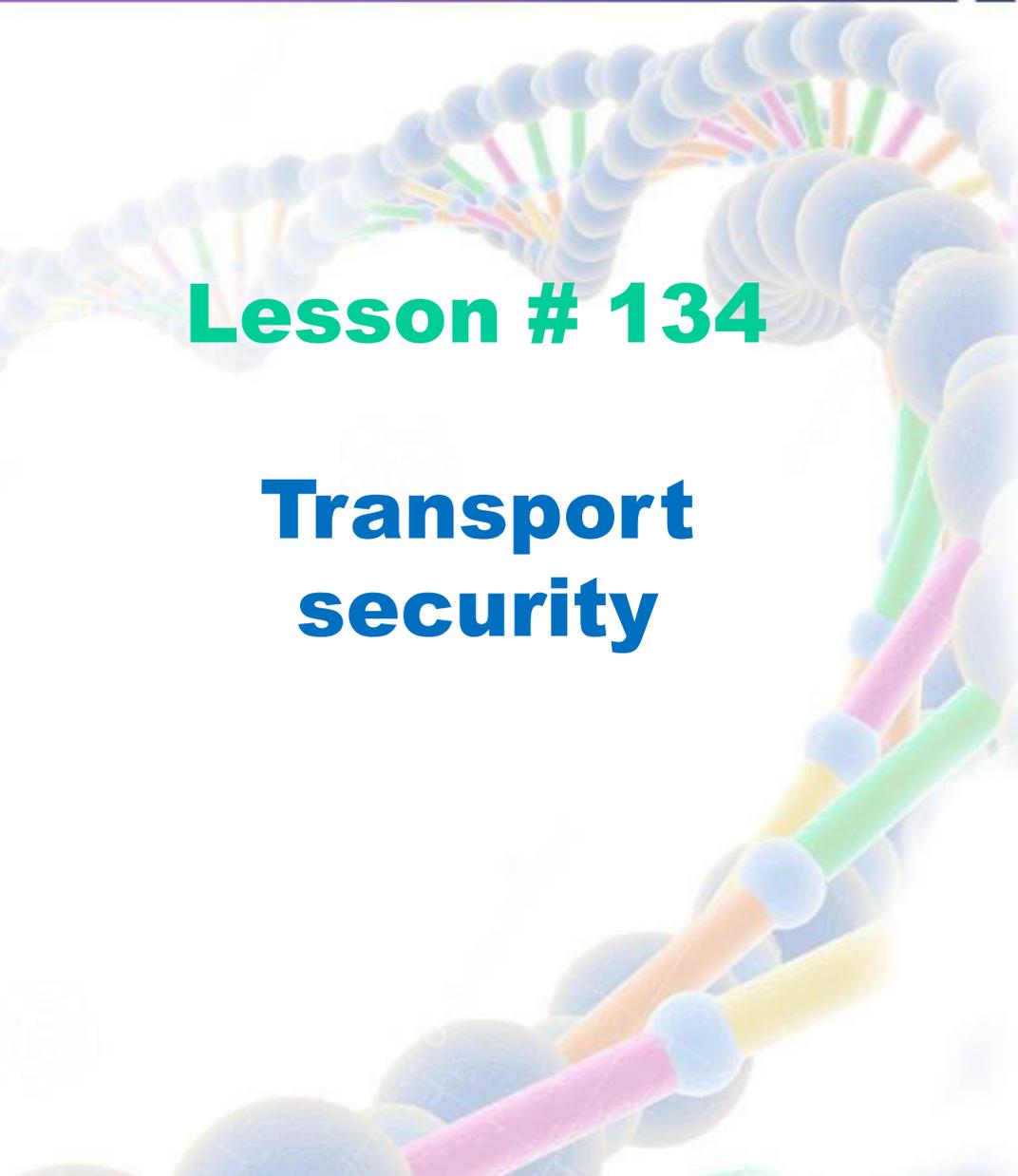
Accountability:

- **person who work with pathogens/toxins**
- **one-to-one correspondence between material and people**
- **system of records, reporting and audit**

Biosecurity

Lesson # 134

Transport security



Transport security

Introduction:

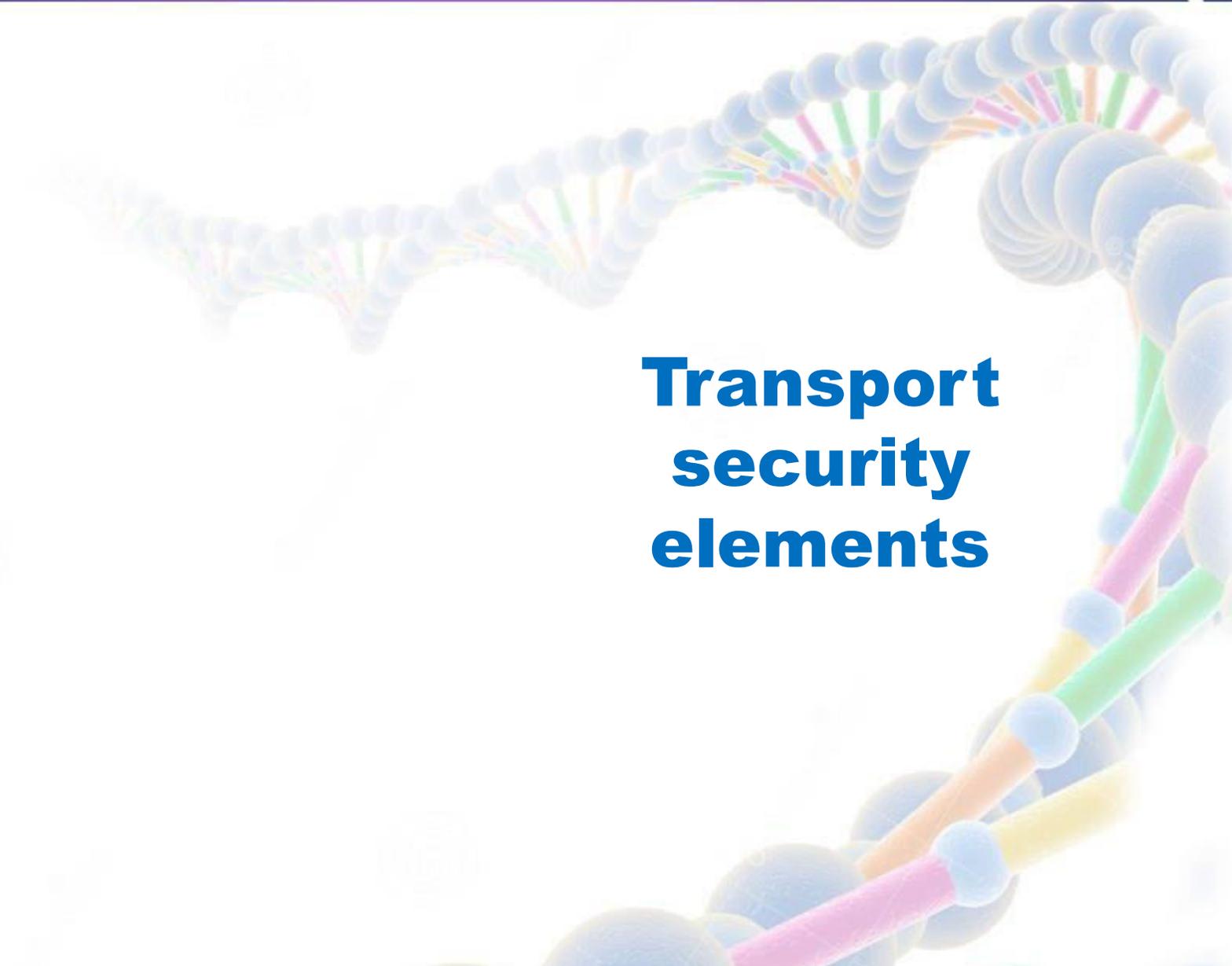
- **movement of biological materials from restricted areas**
- **occur within the country/even across borders**

Biosecurity



Lesson # 135

Biosecurity

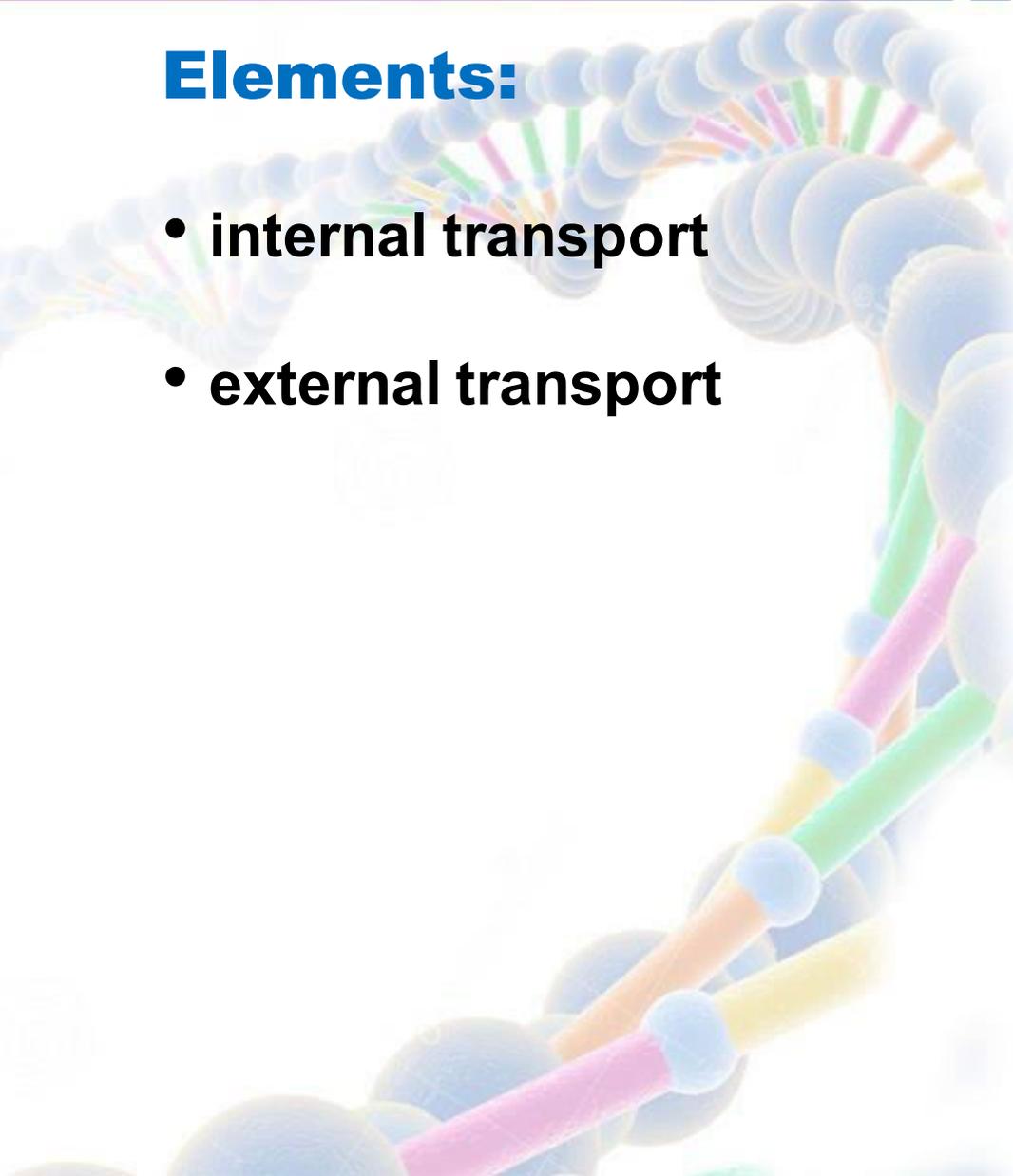


**Transport
security
elements**

Transport security elements

Elements:

- internal transport
- external transport



Transport security elements

Internal transport:

- movement from / to restricted area
- within facility
- involve personnel from labs
- shipping, receiving, disposal areas

Transport security elements

External transport:

- **movement of material from one facility to another**
- **involve commercial carriers**
- **able to move frozen materials**
- **need to be cost-effective**

Transport security elements

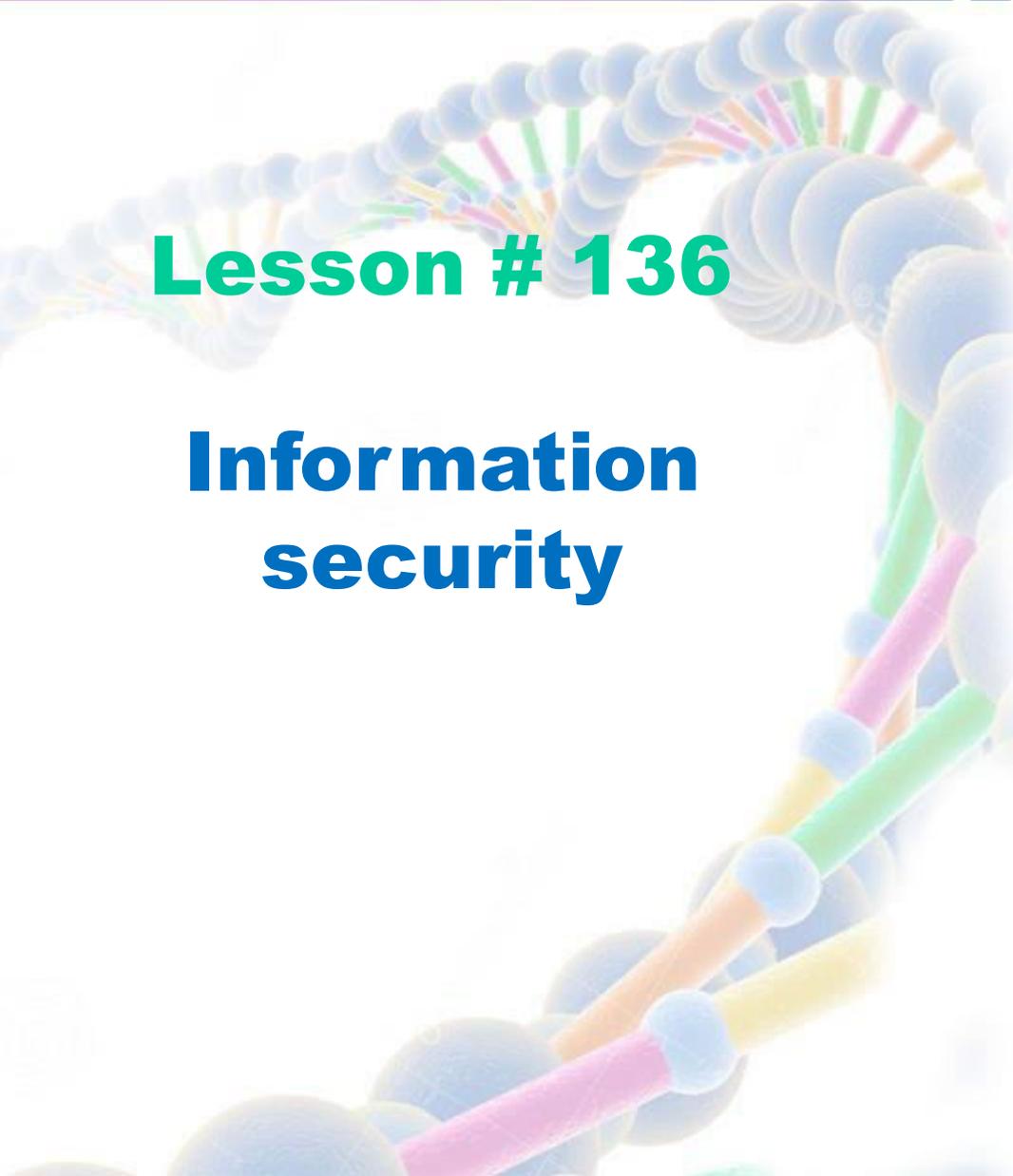
External transport:

- infectious materials are included in category B
- cultures
- triple packaging system

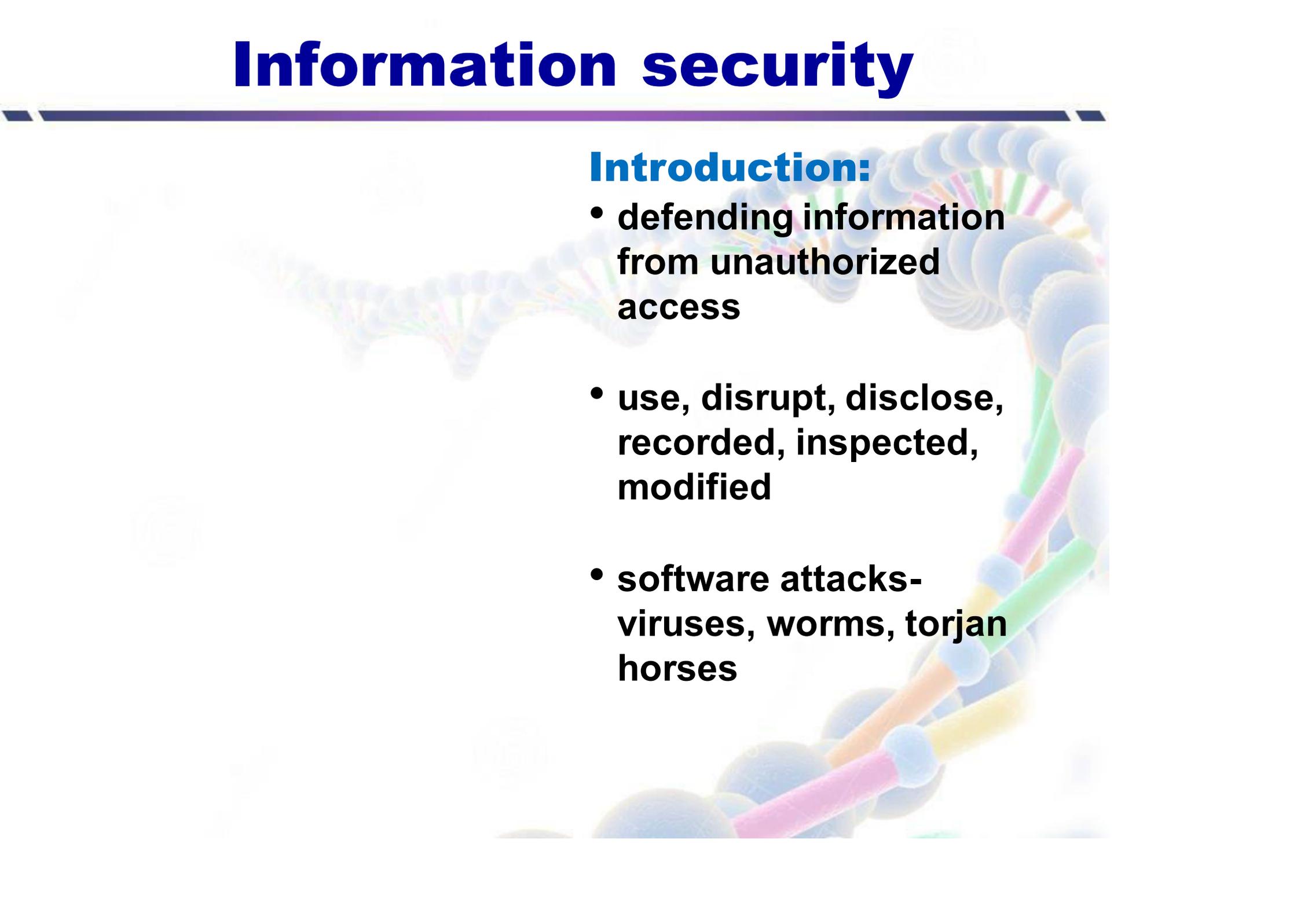
Biosecurity

Lesson # 136

Information security



Information security



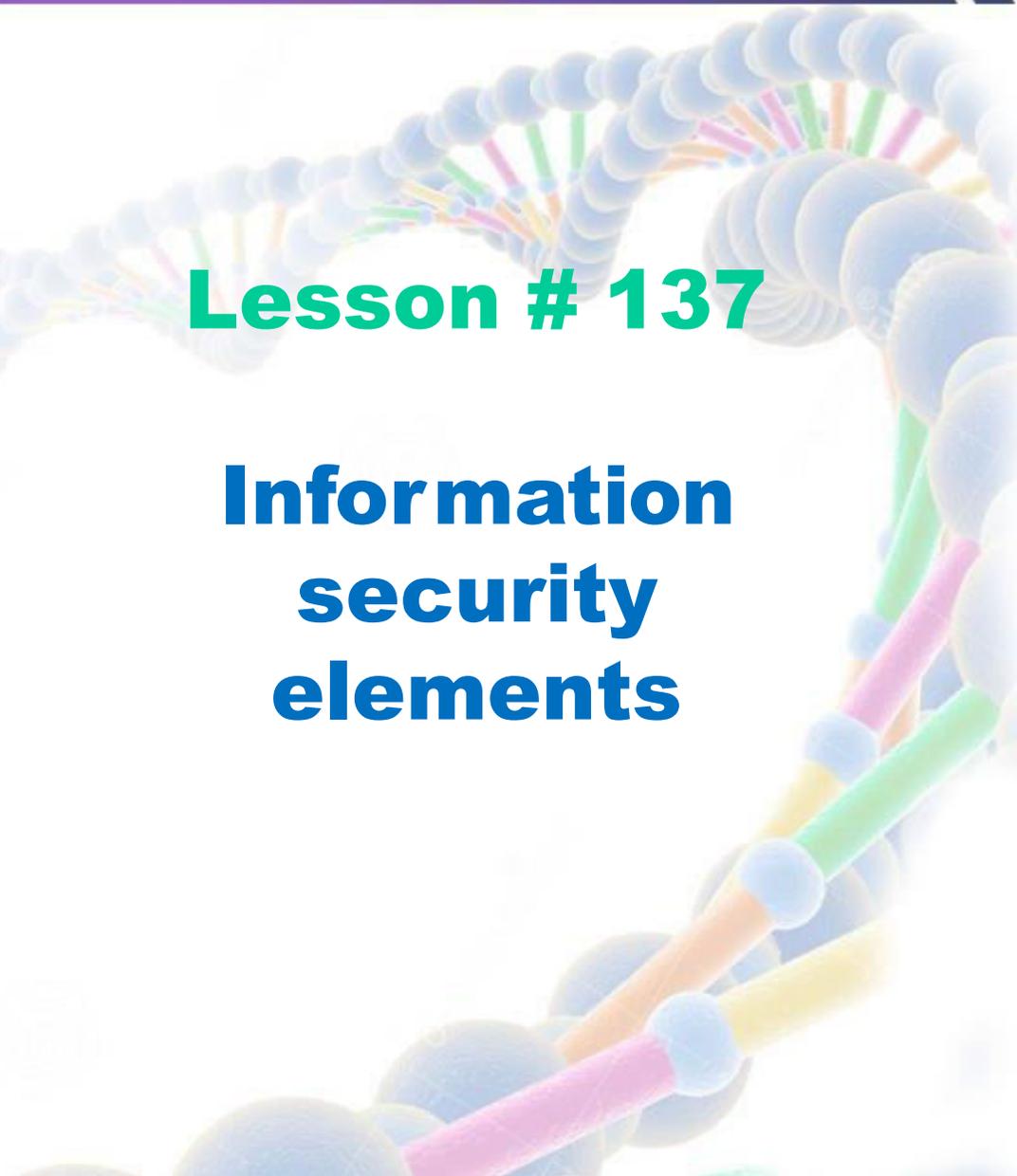
Introduction:

- **defending information from unauthorized access**
- **use, disrupt, disclose, recorded, inspected, modified**
- **software attacks- viruses, worms, torjan horses**

Biosecurity

Lesson # 137

Information security elements



Information security elements

Elements:

- **confidentiality**
“property” not disclosed to unauthorized persons
- **integrity-maintaining and assuring the accuracy and completeness of data**
- **availability**

Biosafety



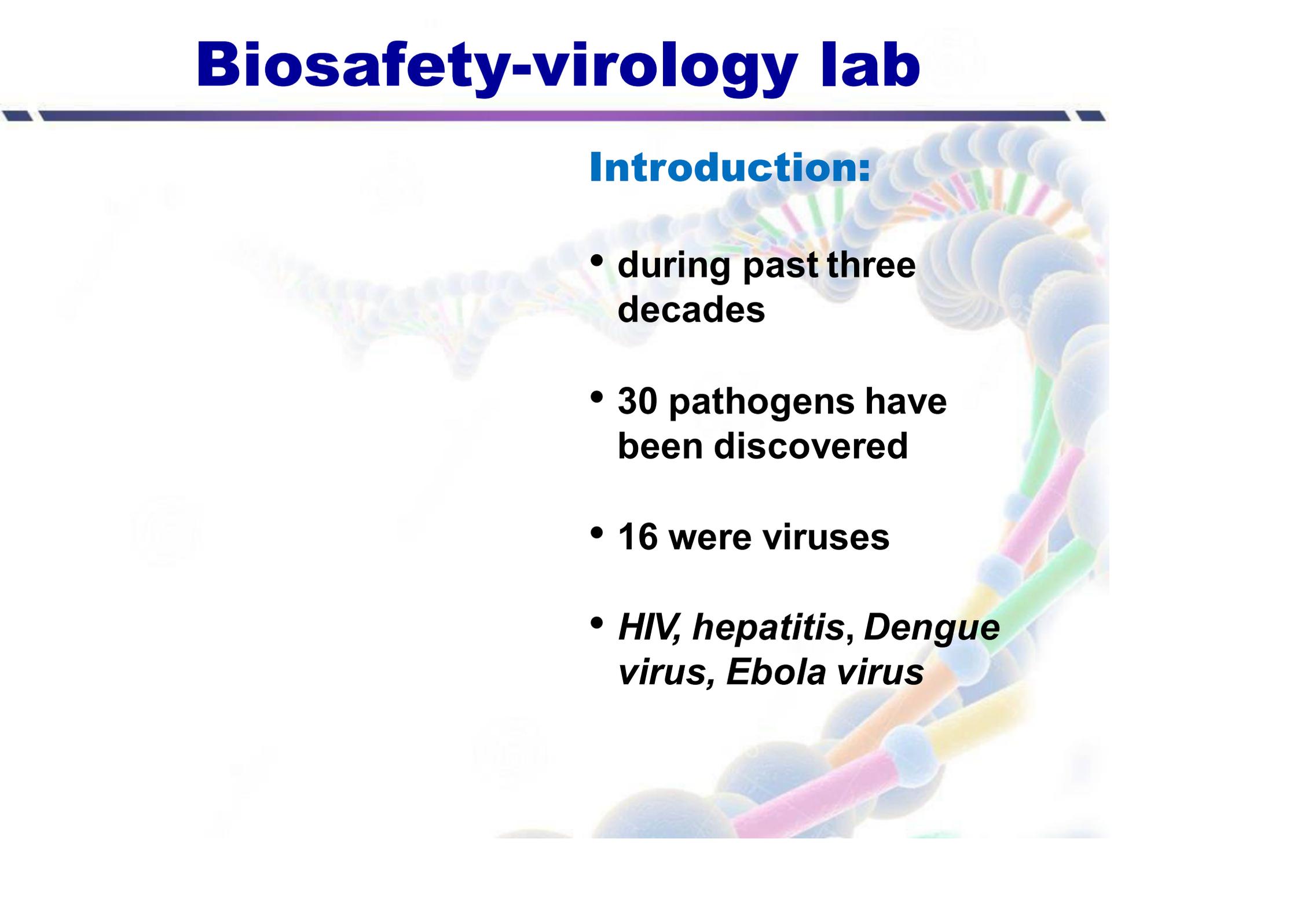
Lesson # 138
UFF 2 LONG

Biosafety



**Biosafety-
virology lab**

Biosafety-virology lab



Introduction:

- during past three decades
- 30 pathogens have been discovered
- 16 were viruses
- *HIV, hepatitis, Dengue virus, Ebola virus*

Biosafety-virology lab

Key elements:

- physical infrastructure
- human resources
- equipment and supplies



Biosafety-virology lab

Physical infrastructure

- viral isolation, detection of antigens/ antibodies
- separate, multistoried building / end of the corridor
- restrict-visitors, stop contamination, biosafety standards

Biosafety-virology lab



Biosafety:

- RG-1: open bench work -----AAV
- RG-2: bench work / BSC---*Herpes Viruses, Foot And Mouth Disease Virus*
- RG-3: *BSC-HIV, HBV, rabies*
- RG-4: BSC II/III—*smallpox, Nipah virus,*

Biosafety-virology lab

Biosafety level 3 lab:

- separated from traffic flow
- double-door entry
- autoclave within facility
- decontaminate waste prior to disposal

Biosafety-virology lab

Biosafety level 3 lab:

- inward directional air flow
- adequate space
- Illumination must be adequate
- walls, ceilings, floors-resistant to chemicals

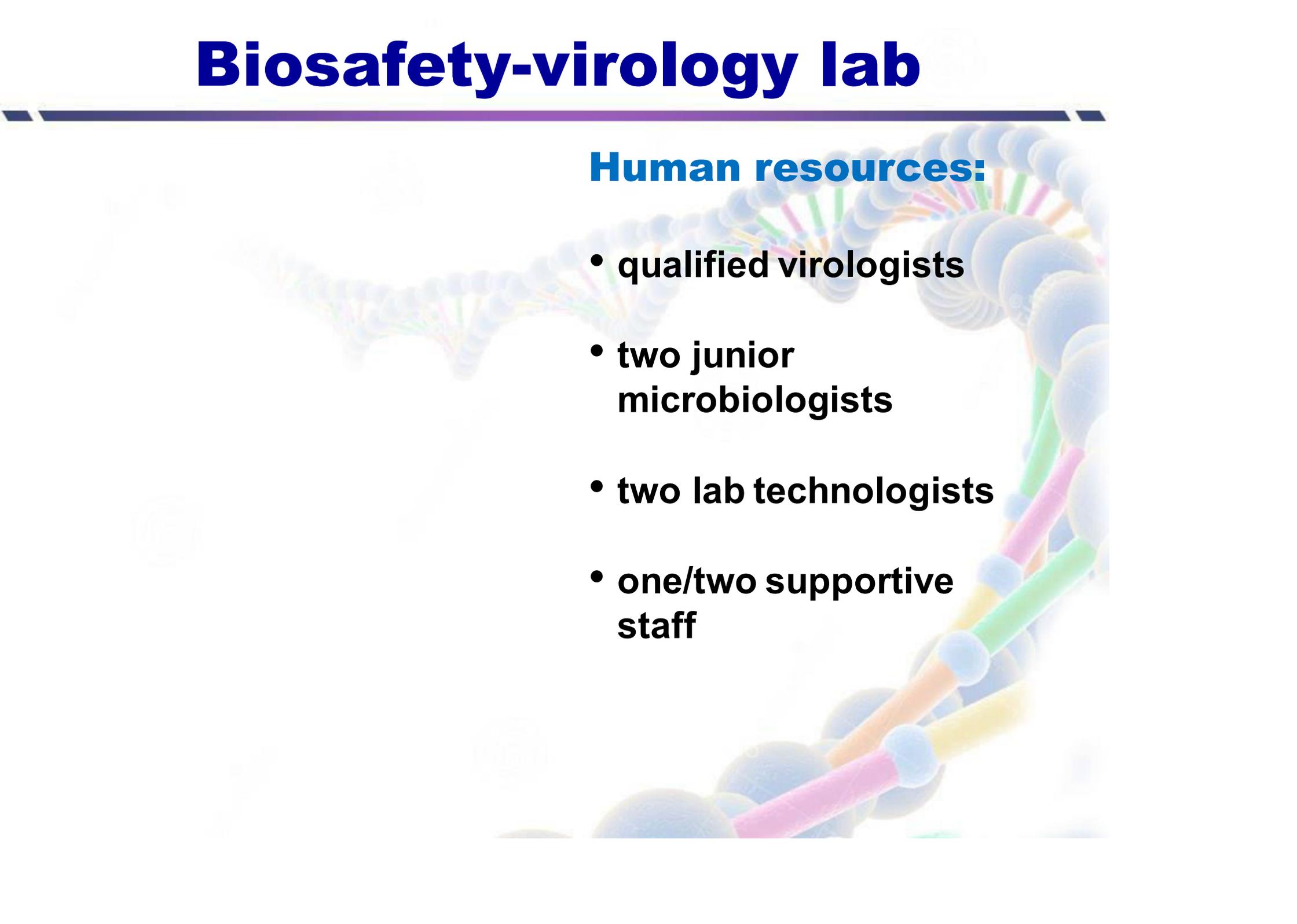
Biosafety-virology lab

Biosafety level 3 lab:

- basin with adequate water supply
- emergency exits



Biosafety-virology lab



Human resources:

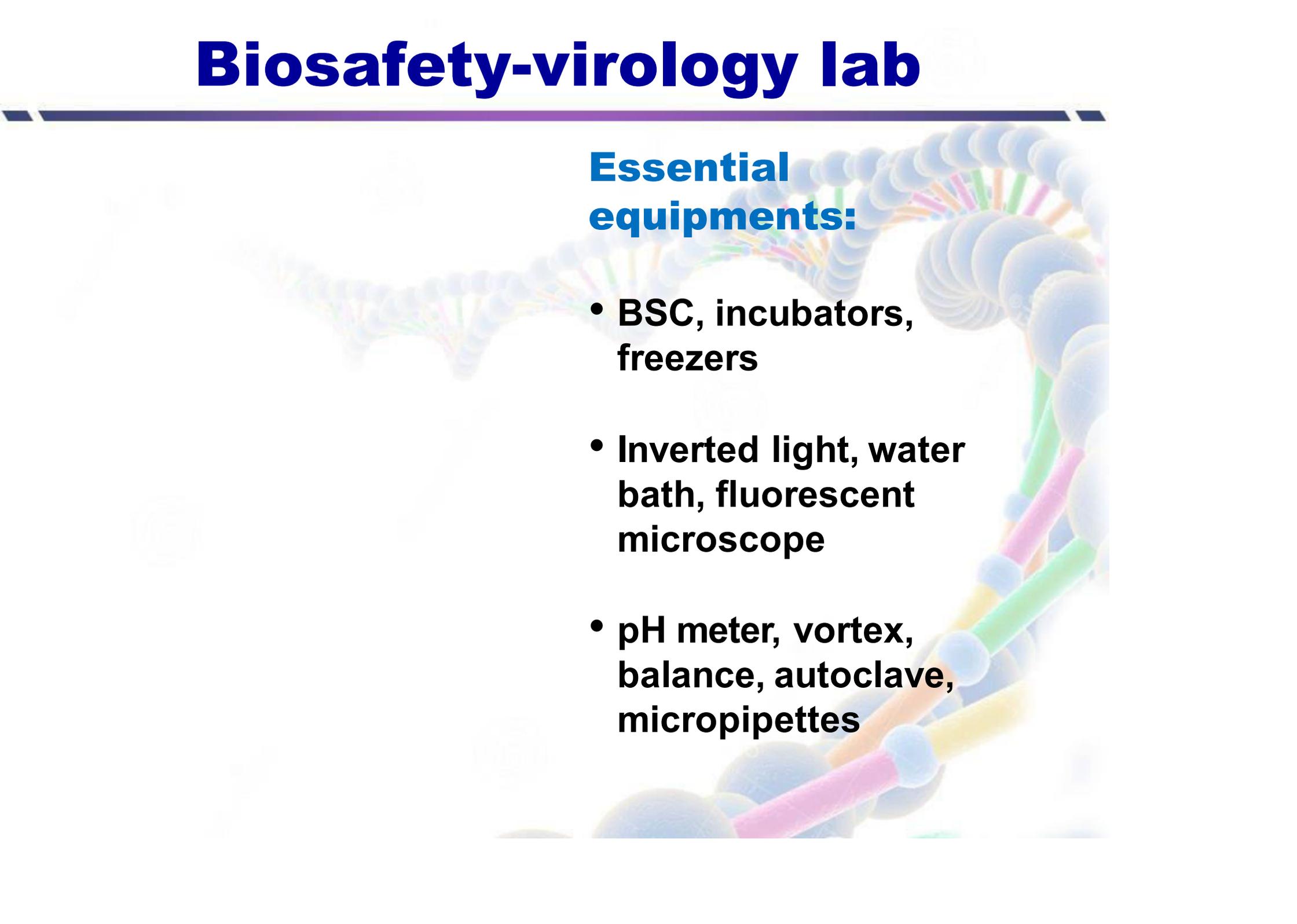
- qualified virologists
- two junior microbiologists
- two lab technologists
- one/two supportive staff

Biosafety-virology lab

Equipments and supplies:

- prevent/minimum contact-infectious material
- free of sharp edges
- resistant to corrosion
- impermeable to liquids

Biosafety-virology lab



Essential equipments:

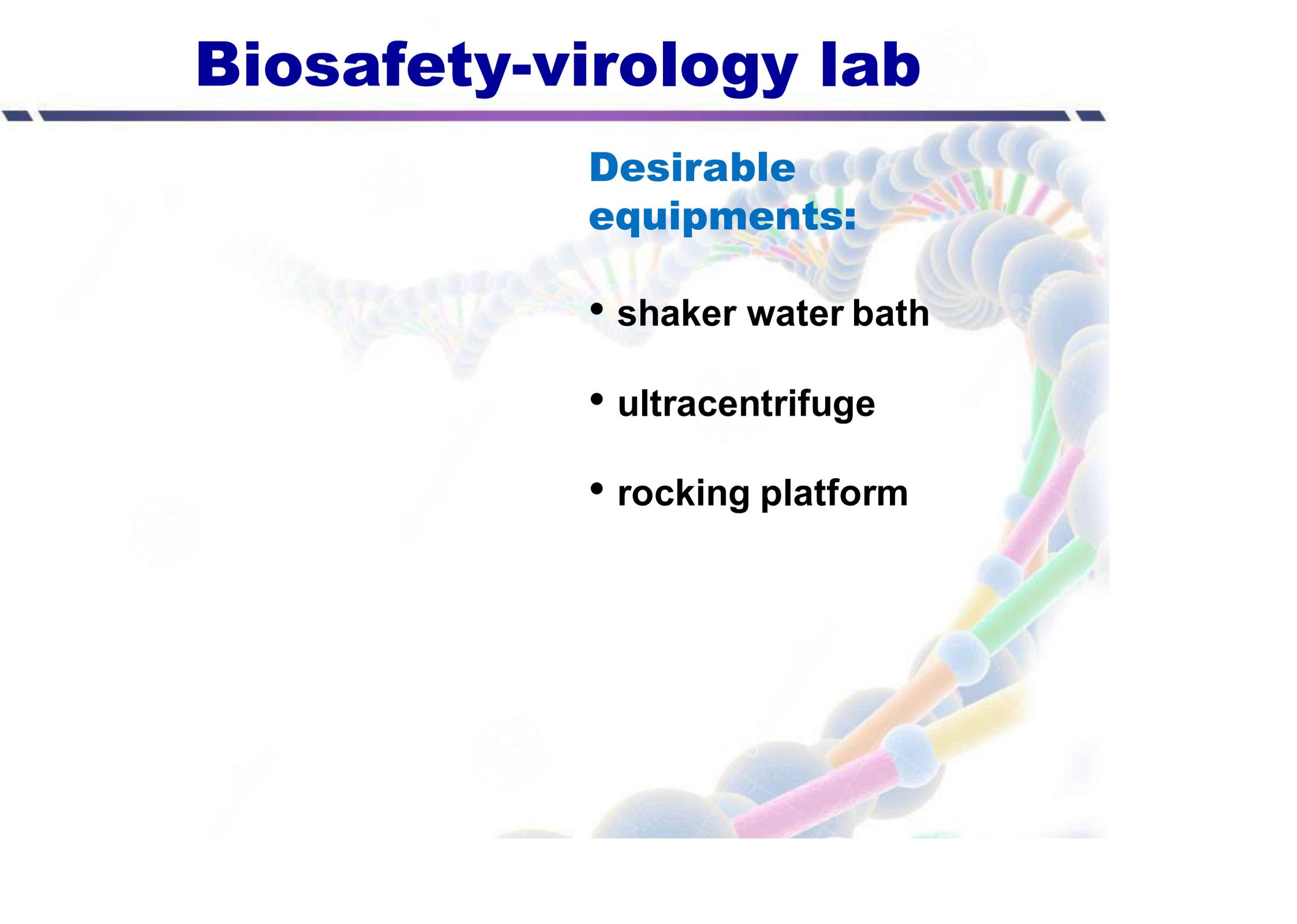
- BSC, incubators, freezers
- Inverted light, water bath, fluorescent microscope
- pH meter, vortex, balance, autoclave, micropipettes

Biosafety-virology lab

Essential equipments:

- ELISA, PCR
- Gel electrophoresis apparatus, UV illuminator
- glass ware

Biosafety-virology lab



Desirable equipments:

- shaker water bath
- ultracentrifuge
- rocking platform

Biosecurity



Lesson # 139

Biosecurity



**Fire
extinguishers**

Fire extinguishers



Fire extinguishers

Types of fire:

- **Class A:** wood, paper, fabric, cloth, trash and plastics
- **Class B:** flammable liquids-petroleum oil, paint, gasoline
- **Class C:** energized electrical equipments
- **Class D:** metal/**Class K:** cooking oil, grease

Fire extinguishers

Types of fire extinguishers:

- **water and foam -class A - separate oxygen**
- **carbon dioxide- class B and C - separate oxygen and heat**
- **dry chemical - class A, B, C- interrupt chemical reaction**

Fire extinguishers

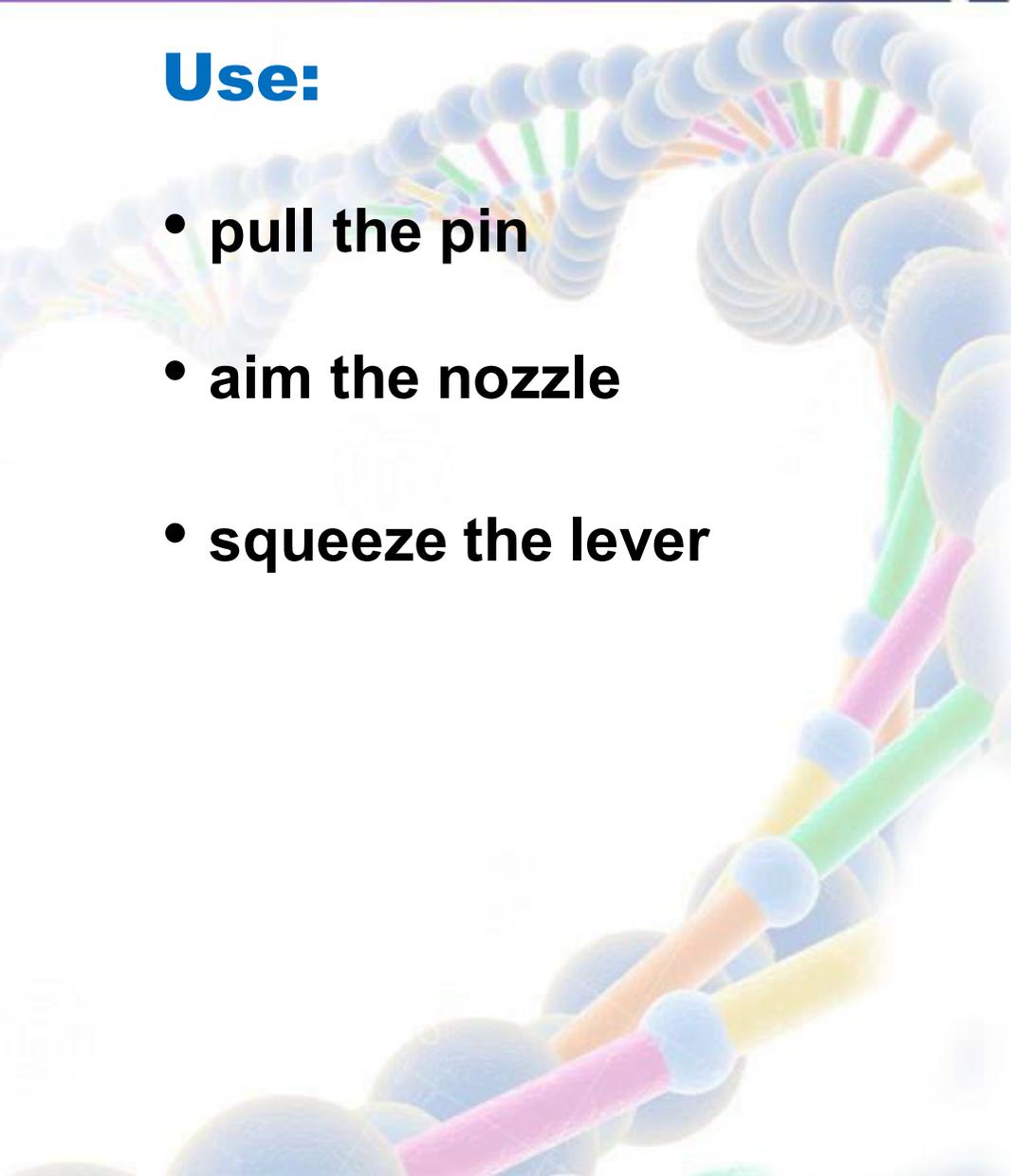
Types of fire extinguishers:

- **wet chemical-class K**
– remove heat
- **clean agents-class A, B and C (halogens)**
interrupt chemical reaction
- **water mist- class A,**
remove heat

Fire extinguishers

Use:

- pull the pin
- aim the nozzle
- squeeze the lever



Fire extinguishers

Inspection:

- **check after one month**
- **extinguisher is in the current location**
- **visible and accessible**
- **gauge and pressure show the correct pressure**

Fire extinguishers

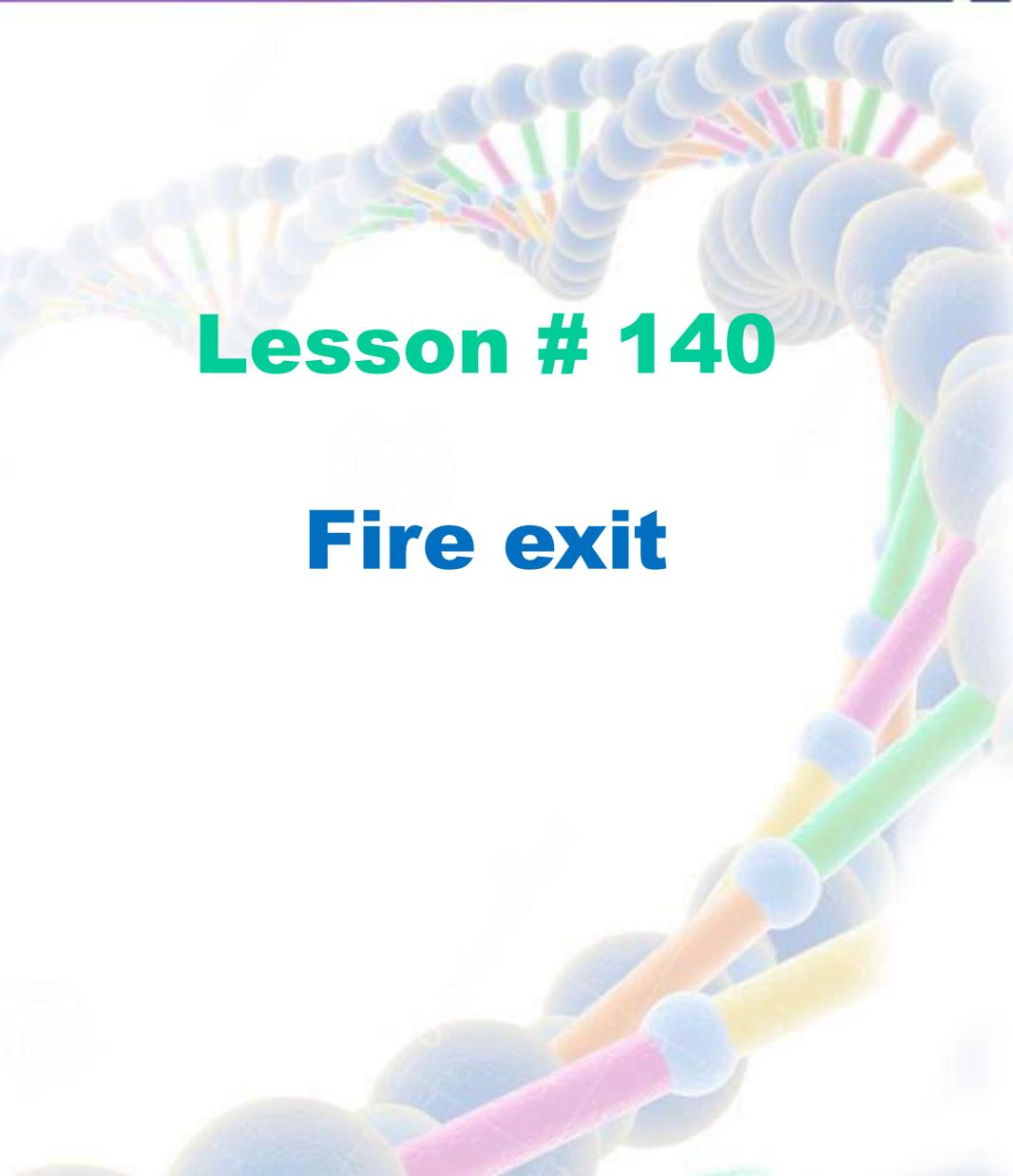
Maintenance:

- fire equipment professional-annually
- mechanical parts, agents, expellent gas

Biosecurity

Lesson # 140

Fire exit



Fire exit

Rules for fighting fire:

- fire is small and contained
- You are safe from toxic smoke
- means of escape
- your instincts tell you it okay

Fire exit

Fire exit:

- kind of emergency exit mounted to the outside of a building
- faster evacuation
- alternative routes when regular exit is blocked

Fire exit

History:

- **1883-England-180 children died**
- **1911- America- 146 factory worker died**
- **9/11- exit doors were locked**
- **all buildings have well - marked emergency exits**

Fire exit

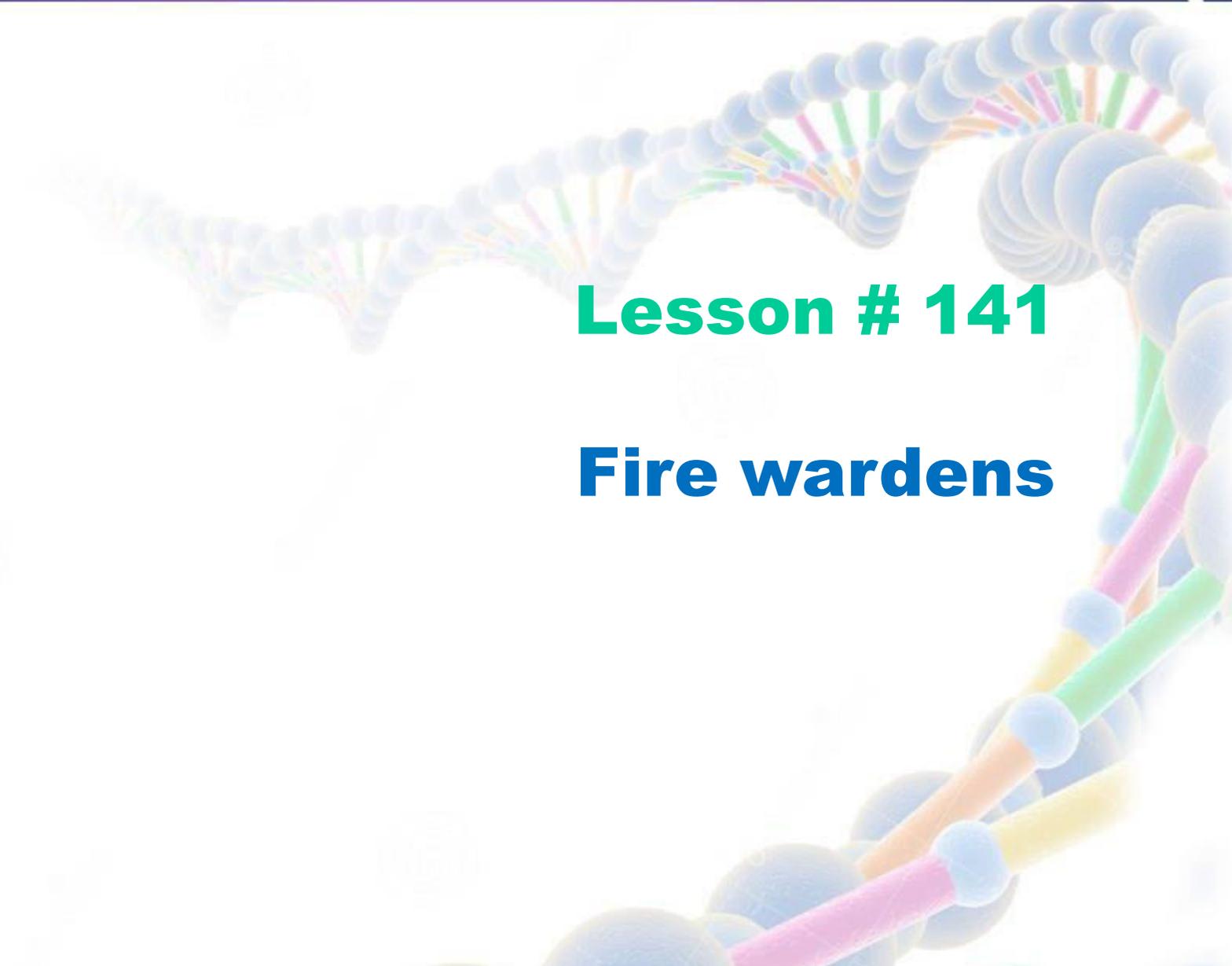
Signage:

- **“EXIT”**
- **running green man**
- **Introduced in 2003 by ISO 7010**

Fire exit



Biosecurity



Lesson # 141

Fire wardens

Fire wardens

Duties:

- a person employed to prevent / extinguish fire
- important risk measures
- raise awareness among staff
- how to respond in emergency

Fire wardens

Duties:

- ensure evacuation
- helping-wheelchair
- switch off electrical appliances
- close the doors to isolate fire
- guide everyone to assemble area

Fire wardens

Legislation:

- is there a legal requirement of fire wardens?
- is there a legal requirement for training fire wardens?
- how many fire wardens should be appointed?
- evacuation drills

Bioethics



Lesson # 142

**Fire assembly
area**

Fire assembly area

Guidelines:

- meeting place where staff, workers, students gathered
- choose a location
- open space
- easy access from your building

Fire assembly area

Guidelines:

- at least 50ft from the building
- don't evacuate within the structure
- primary/secondary meeting places

Fire assembly area

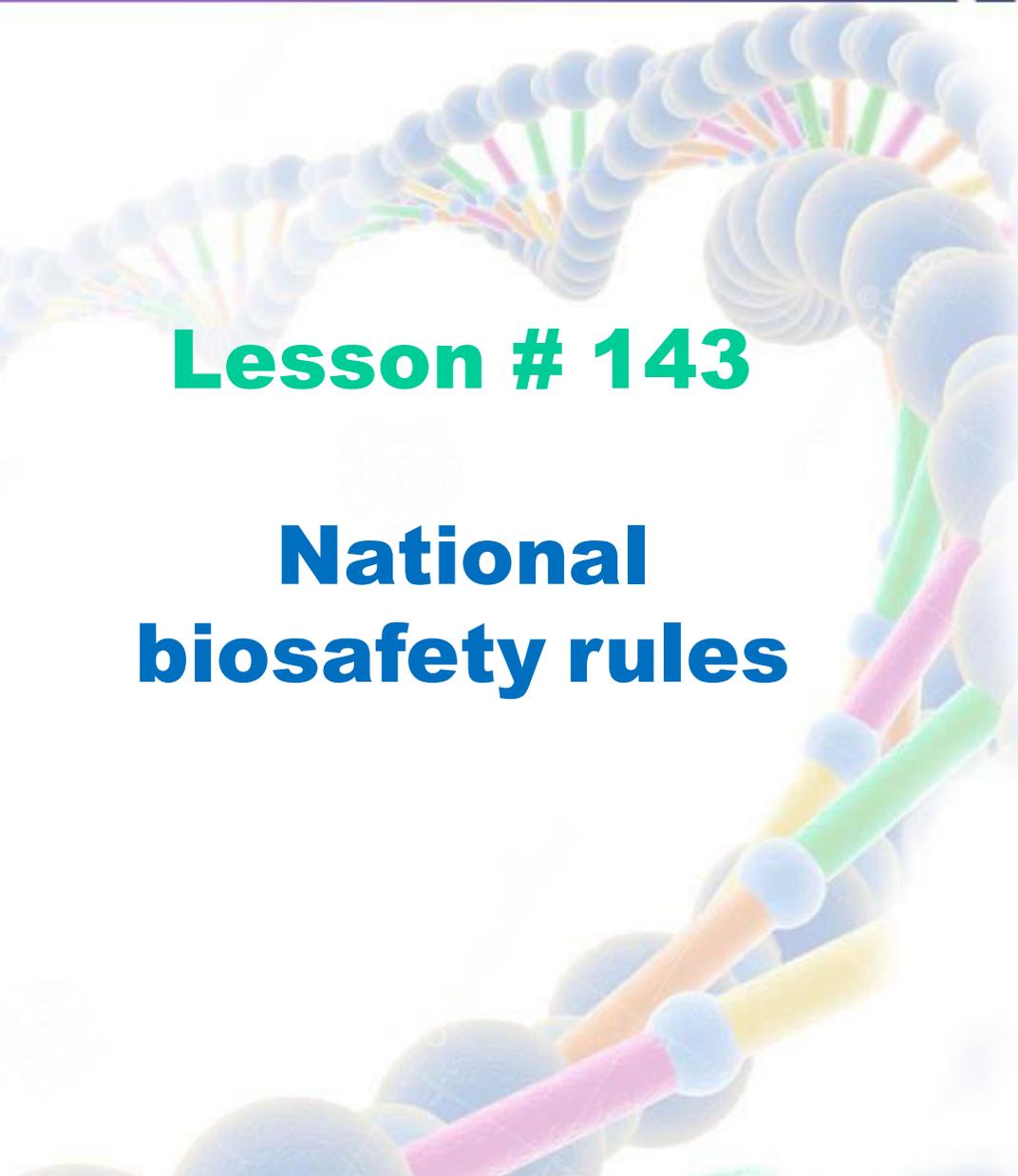
Guidelines:

- don't evacuate to locations where emergency personnel respond
- regular evacuation practice
- fire wardens will take updates from emergency crew

Biosafety

Lesson # 143

National biosafety rules



National biosafety rules

Introduction:

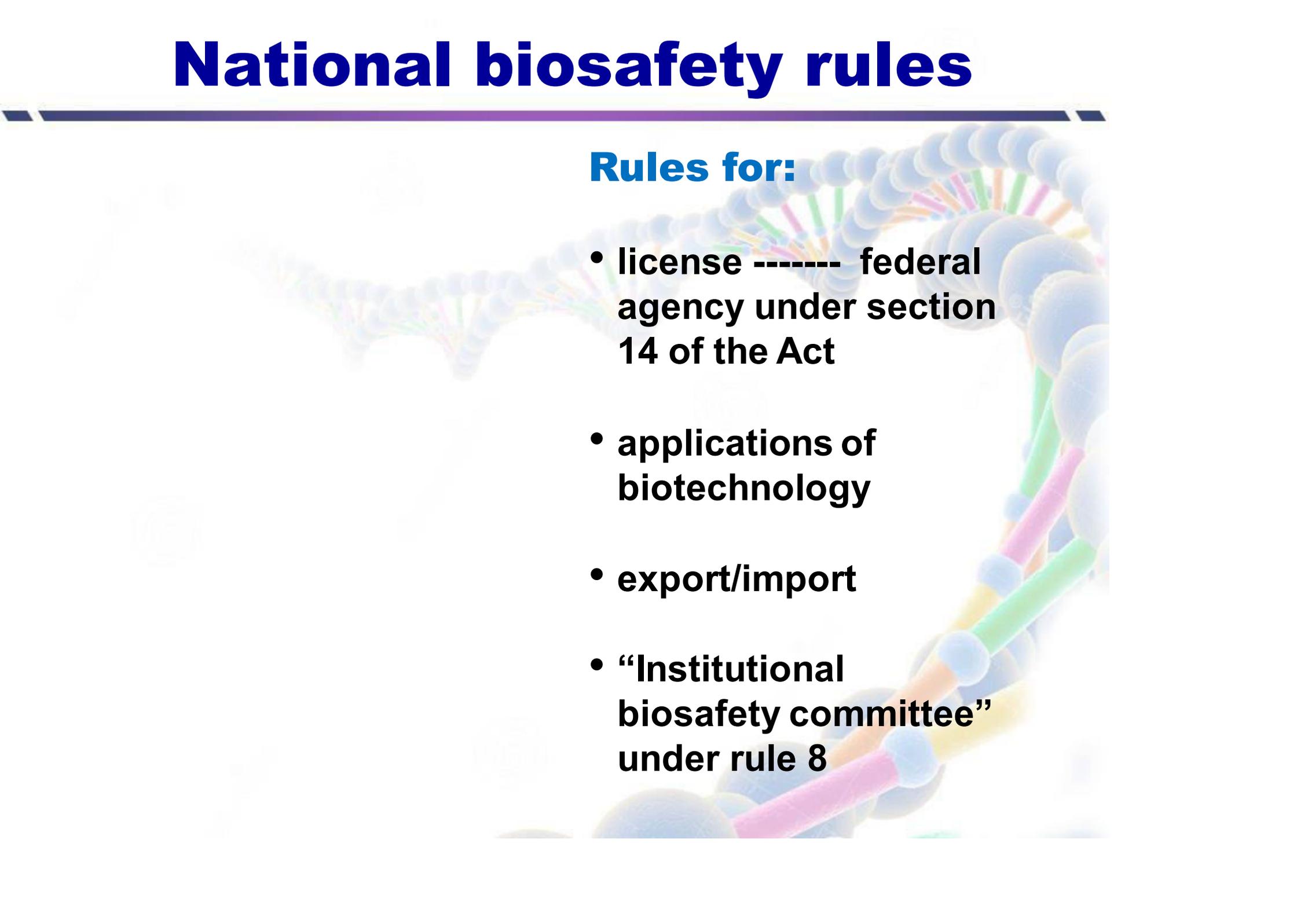
- **section 31-Pakistan Environmental Act, 1997**
- **federal government made rules 2005**

National biosafety rules

Rules:

- biosafety guidelines ministry of env
- commercial release
- deliberate release
- experimental release

National biosafety rules



Rules for:

- **license ----- federal agency under section 14 of the Act**
- **applications of biotechnology**
- **export/import**
- **“Institutional biosafety committee” under rule 8**

National biosafety rules

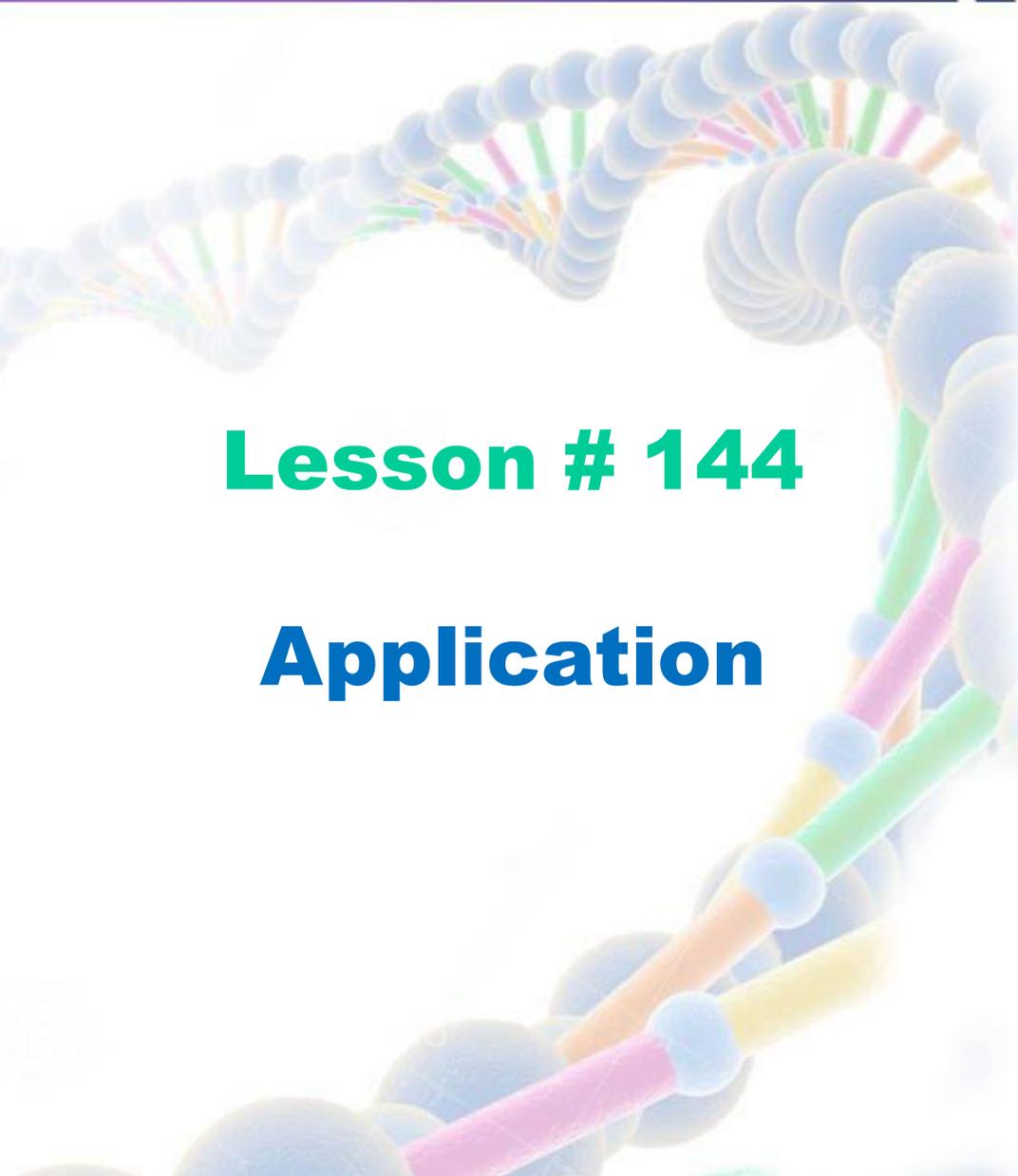
Rules for:

- “National biosafety committee” under rule 4
- “Technical advisory committee” under rule 6

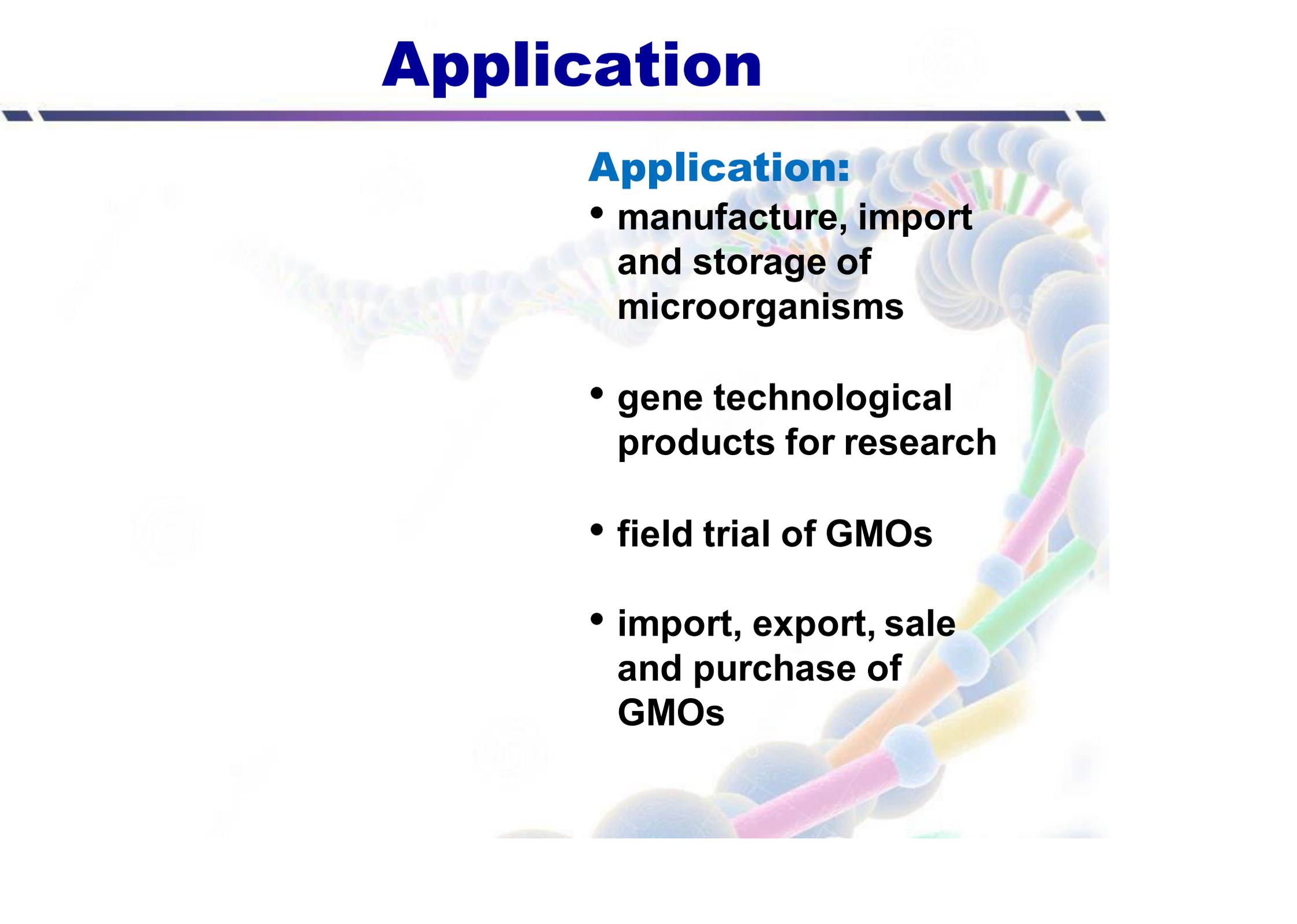
Biosafety

Lesson # 144

Application



Application



Application:

- **manufacture, import and storage of microorganisms**
- **gene technological products for research**
- **field trial of GMOs**
- **import, export, sale and purchase of GMOs**

Biosafety



Lesson # 145

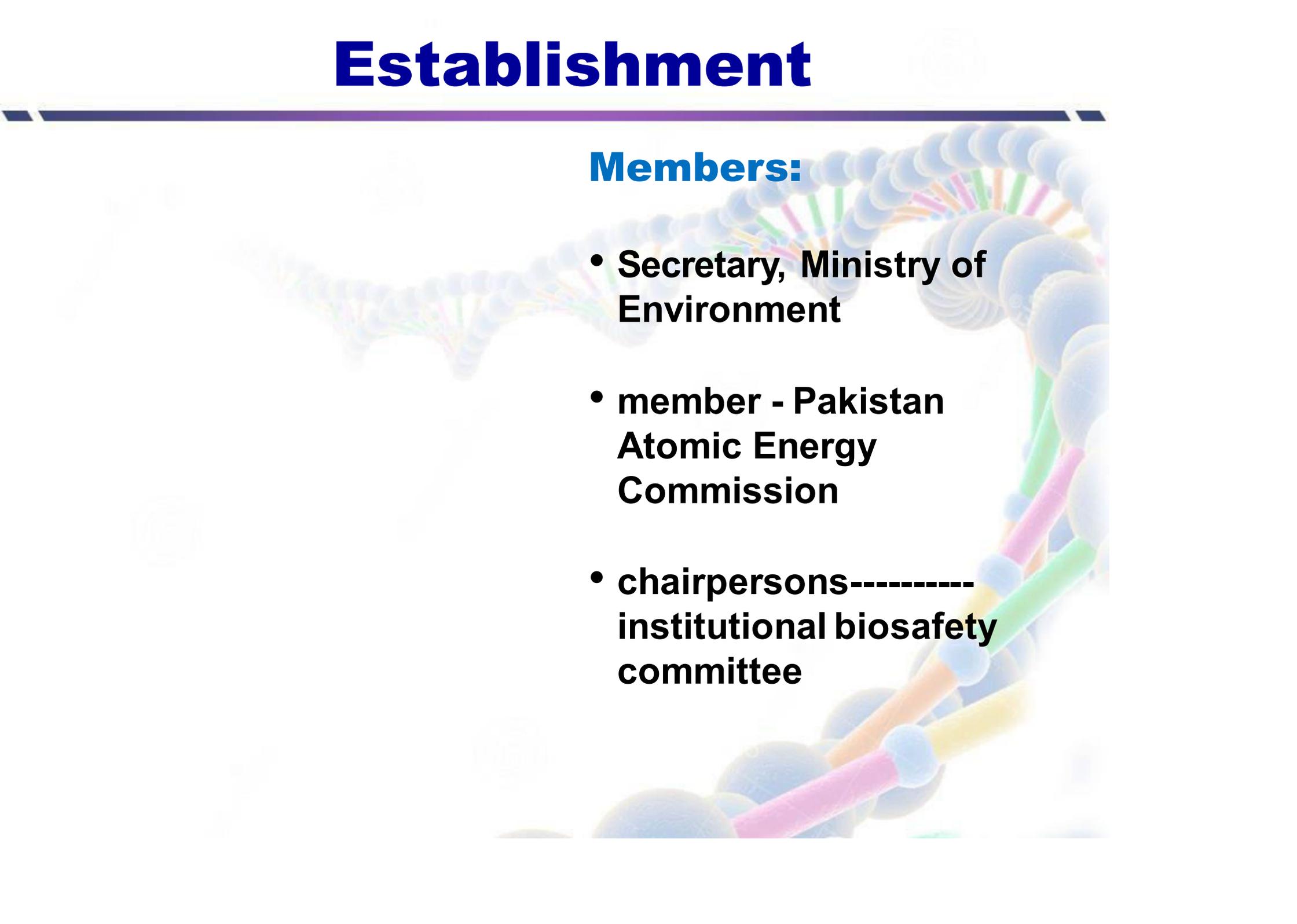
Establishment

Establishment

National Biosafety Committee:

- federal government establish
- director general, Pakistan- EPA - secretary
- hold office for term 3 years
- frame its own rules and procedures

Establishment



Members:

- **Secretary, Ministry of Environment**
- **member - Pakistan Atomic Energy Commission**
- **chairpersons-----
institutional biosafety
committee**

Establishment

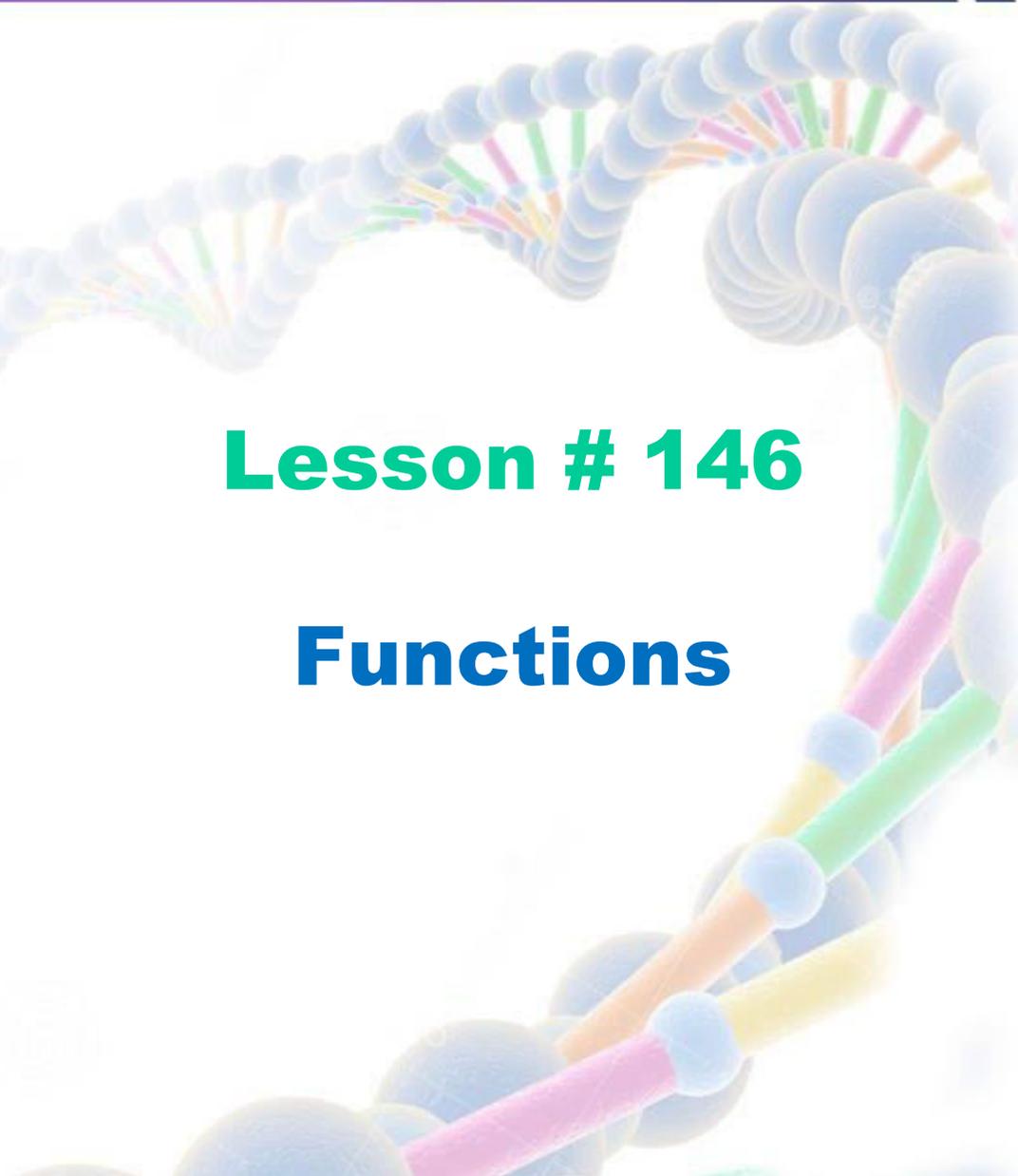
Members:

- **Director-General,
department of plant
protection**
- **chairman - PARC**
- **representative
Ministry of food and
agriculture**

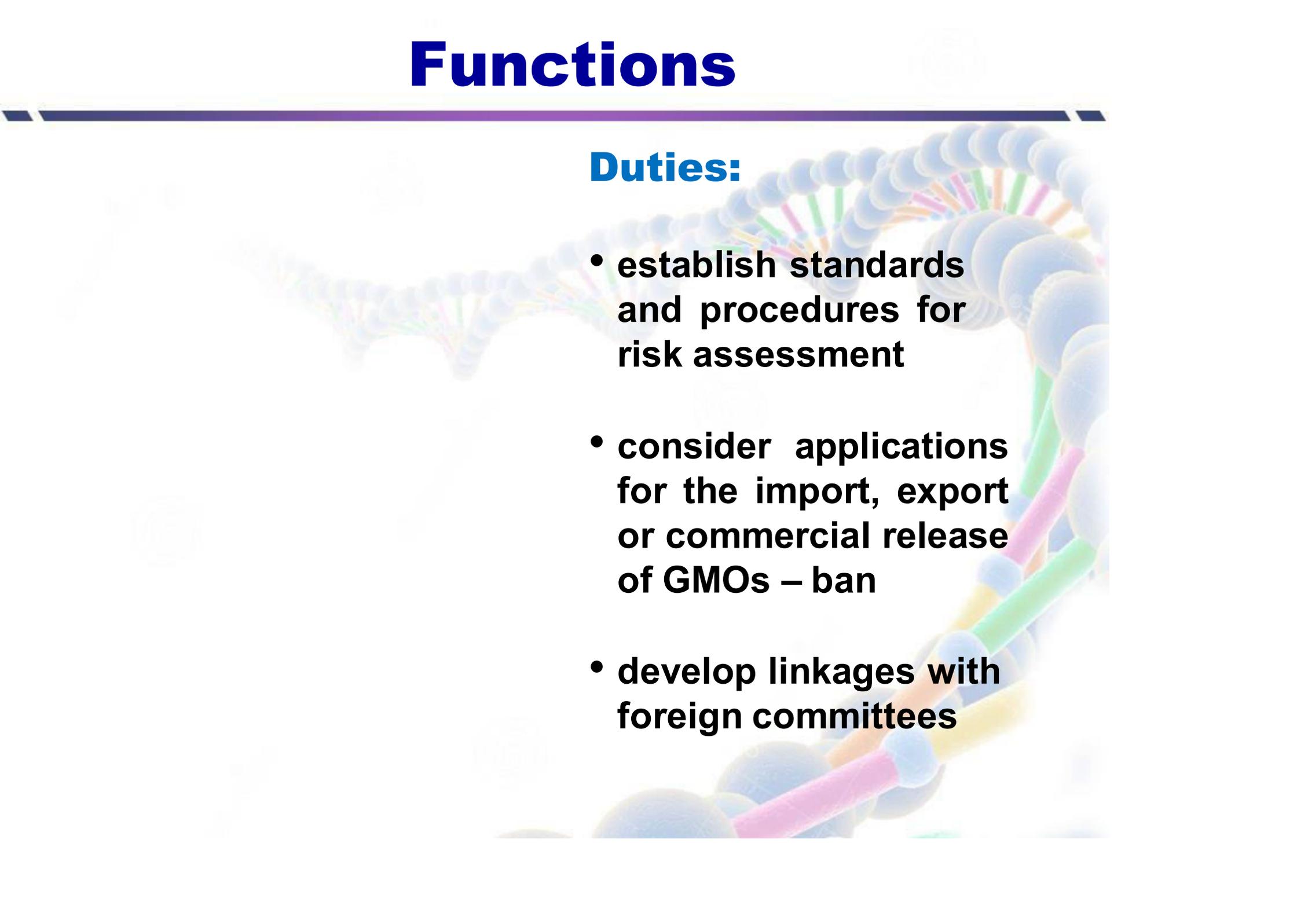
Biosafety

Lesson # 146

Functions



Functions



Duties:

- **establish standards and procedures for risk assessment**
- **consider applications for the import, export or commercial release of GMOs – ban**
- **develop linkages with foreign committees**

Functions

Duties:

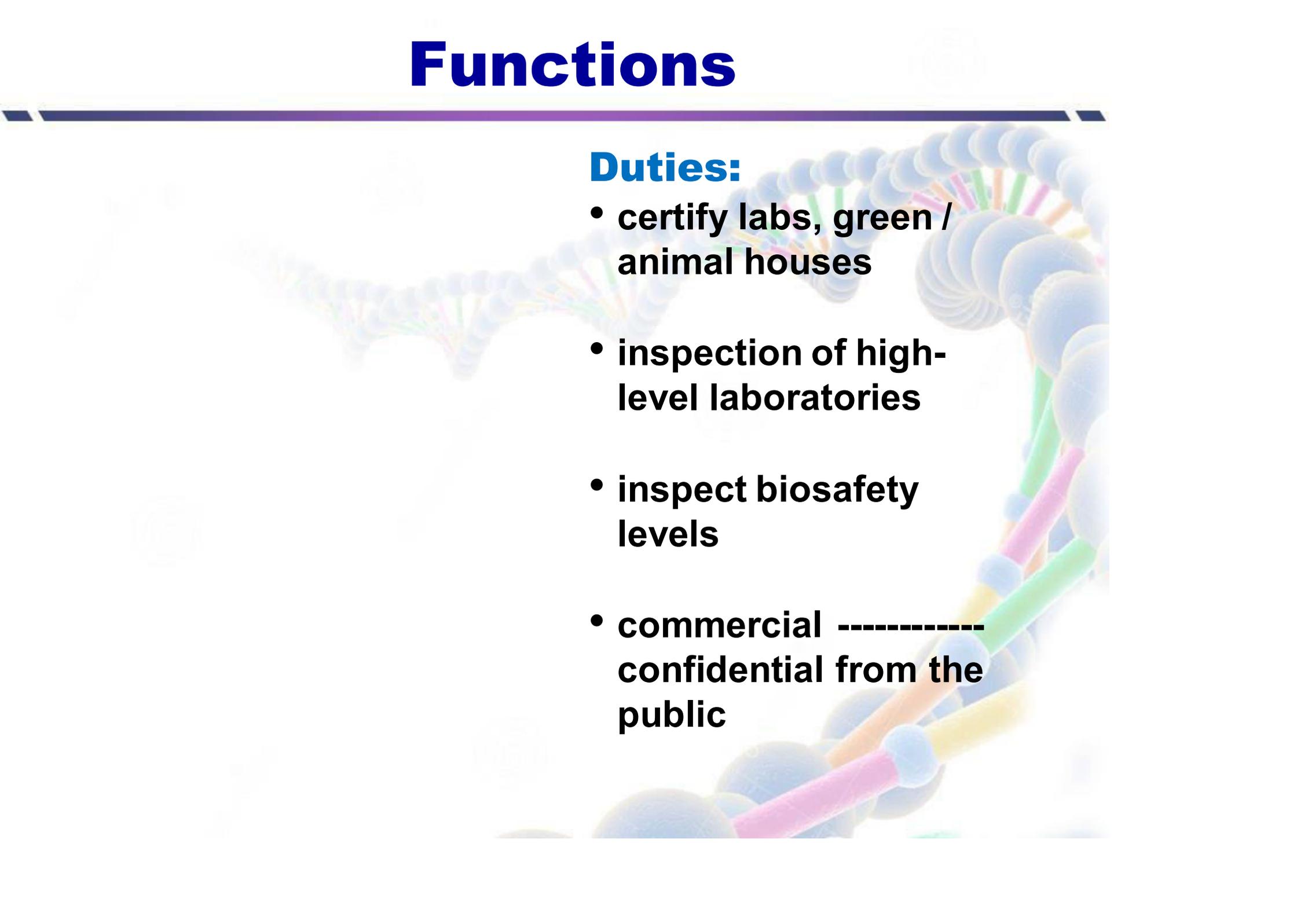
- **cooperate with federal /provisional agencies**
- **advice of technical advisory committee**
- **facilitate exchange of technical expertise**
- **educate public**

Functions

Duties:

- **implementation of biosafety guidelines**
- **inform institutions about new biosafety development**
- **coordinate efforts between private and government agencies**

Functions



Duties:

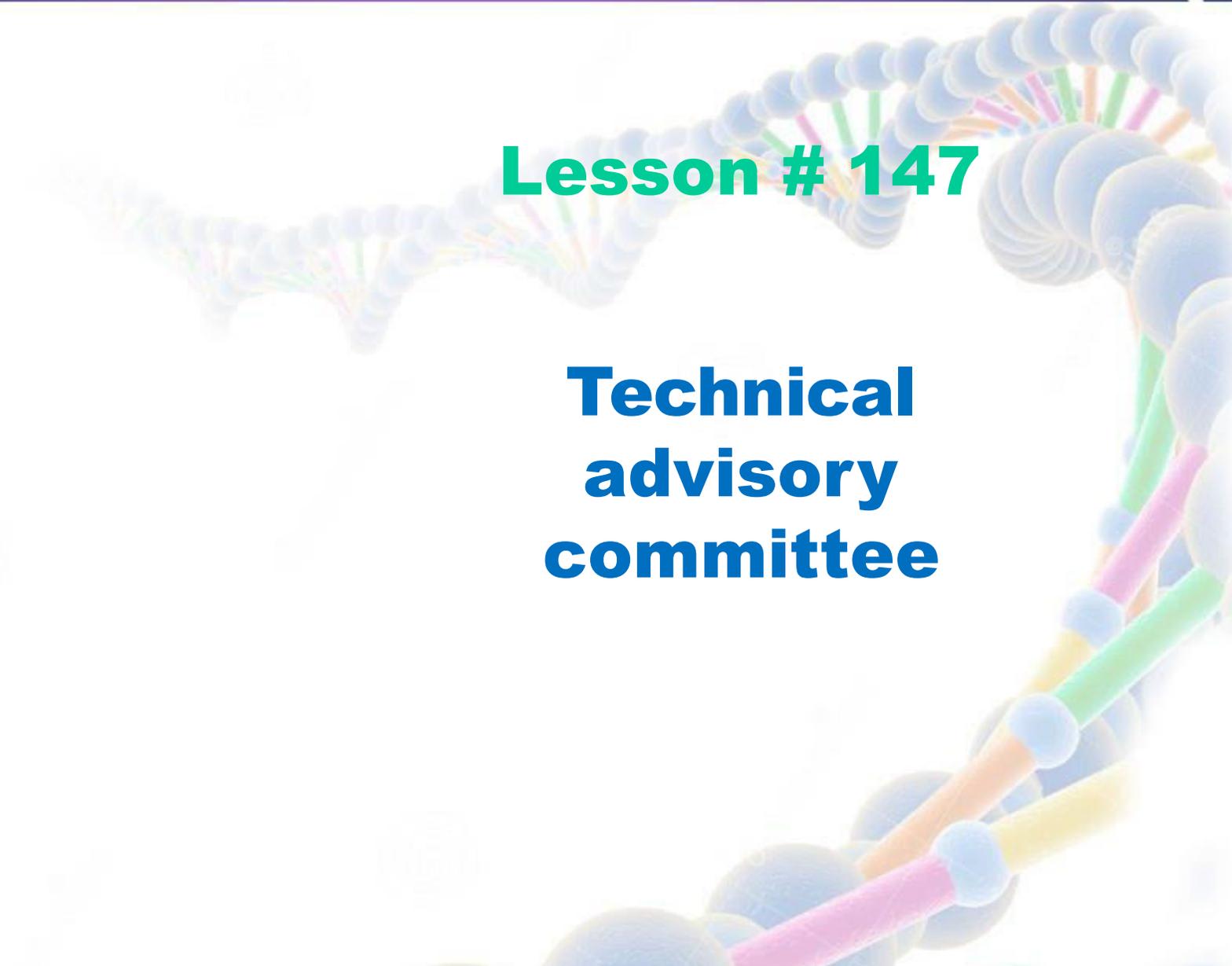
- **certify labs, green / animal houses**
- **inspection of high-level laboratories**
- **inspect biosafety levels**
- **commercial ----- confidential from the public**

Biosafety

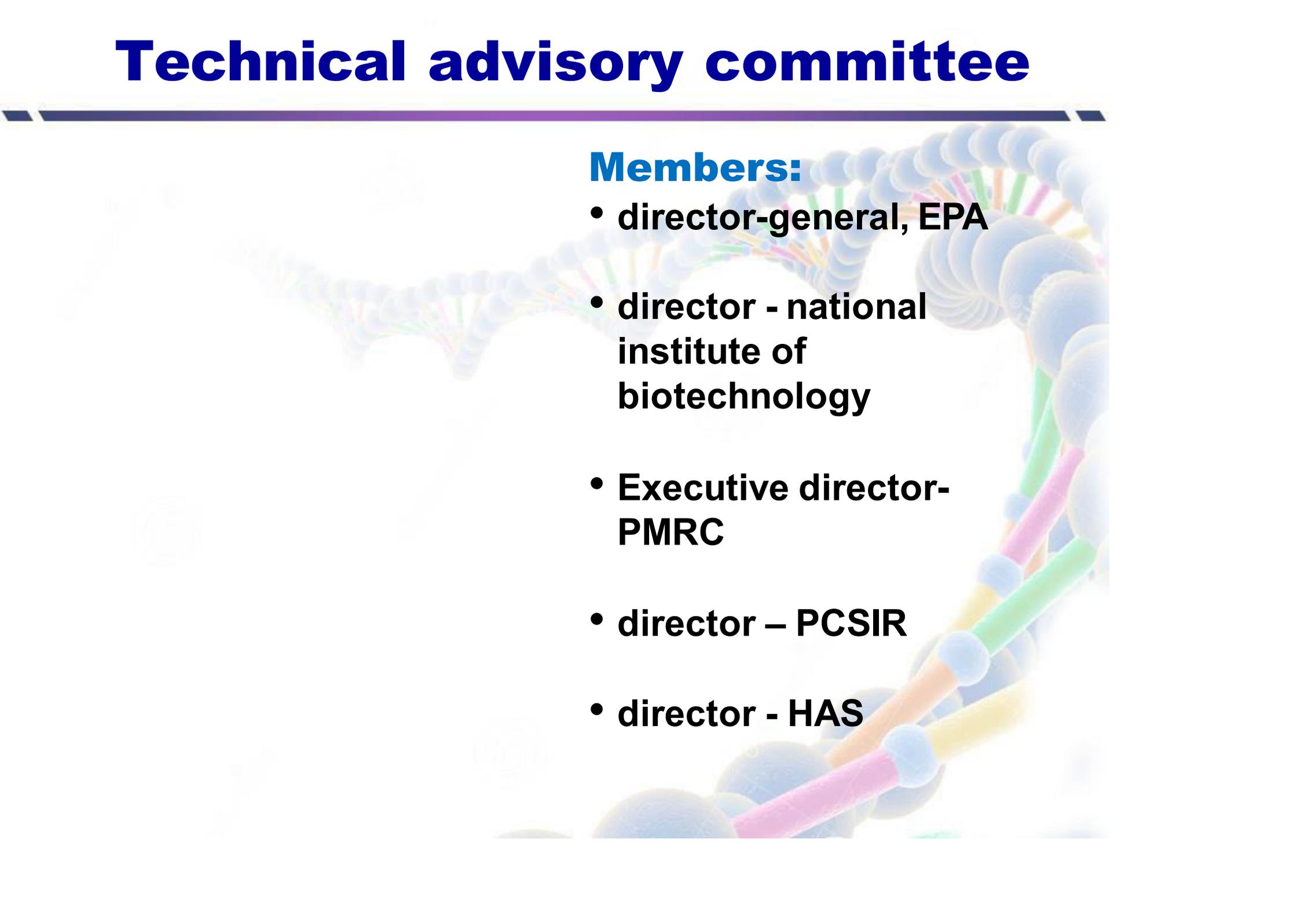


Lesson # 147

Technical advisory committee



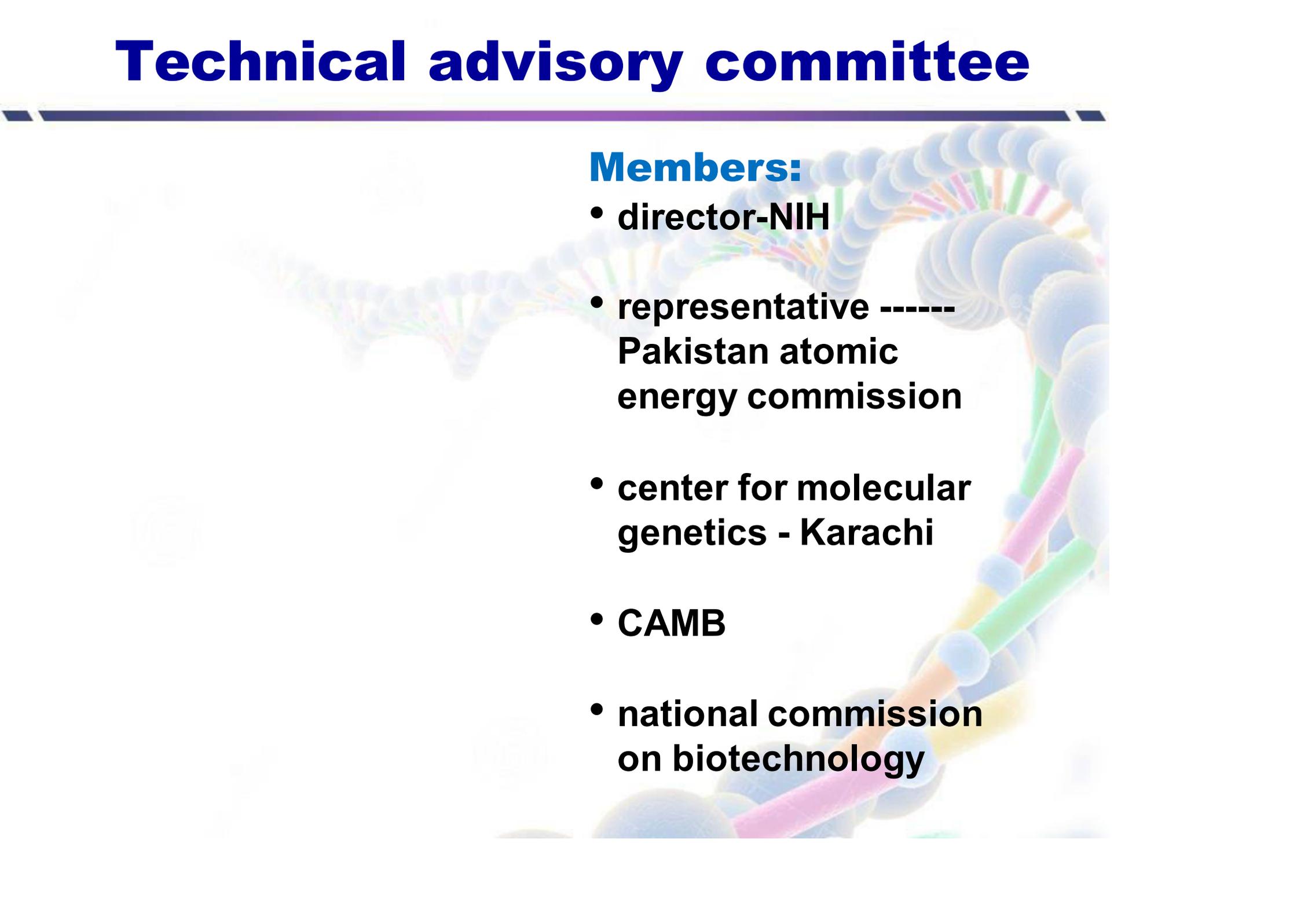
Technical advisory committee



Members:

- director-general, EPA
- director - national institute of biotechnology
- Executive director- PMRC
- director – PCSIR
- director - HAS

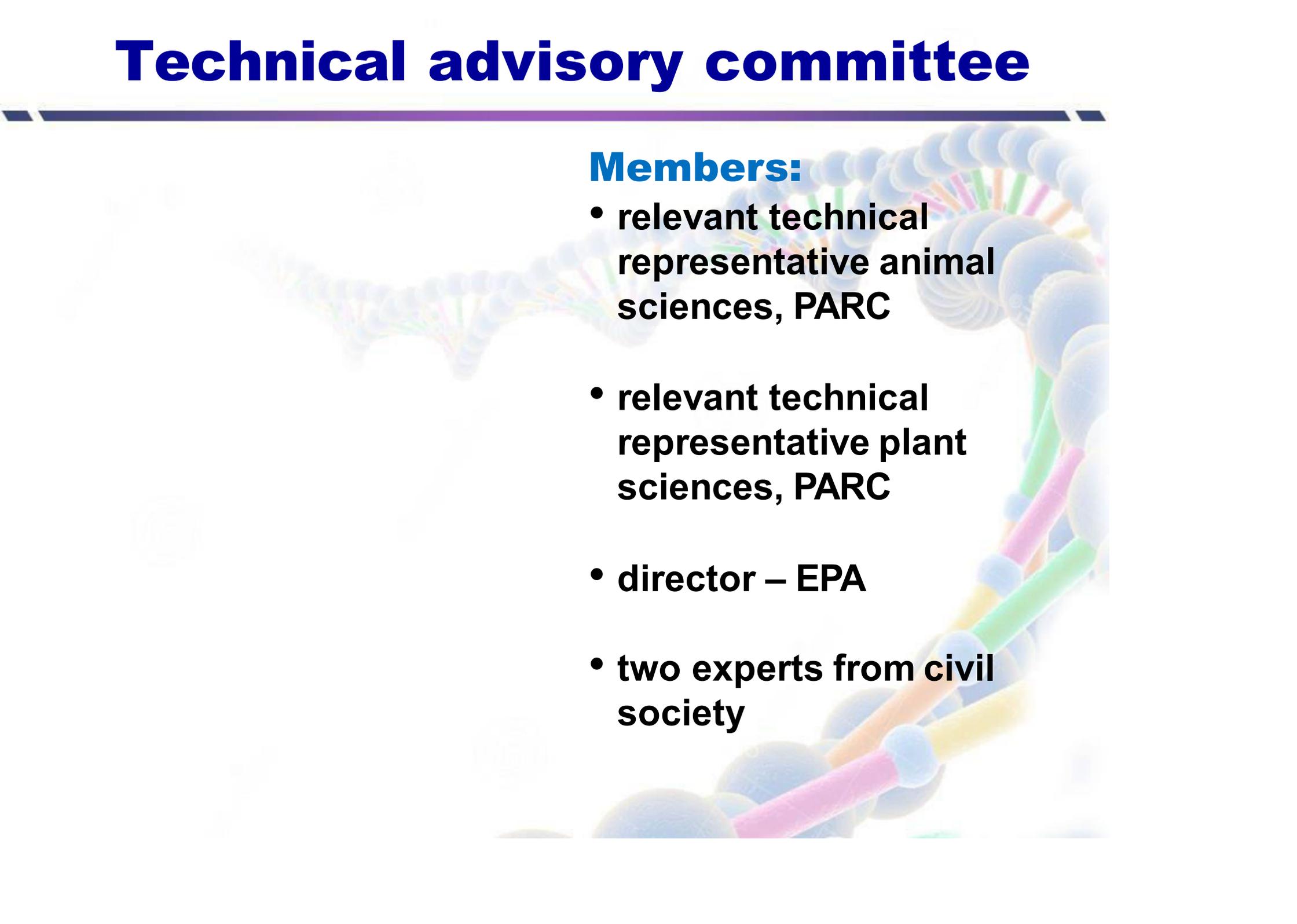
Technical advisory committee



Members:

- director-NIH
- representative -----
Pakistan atomic
energy commission
- center for molecular
genetics - Karachi
- CAMB
- national commission
on biotechnology

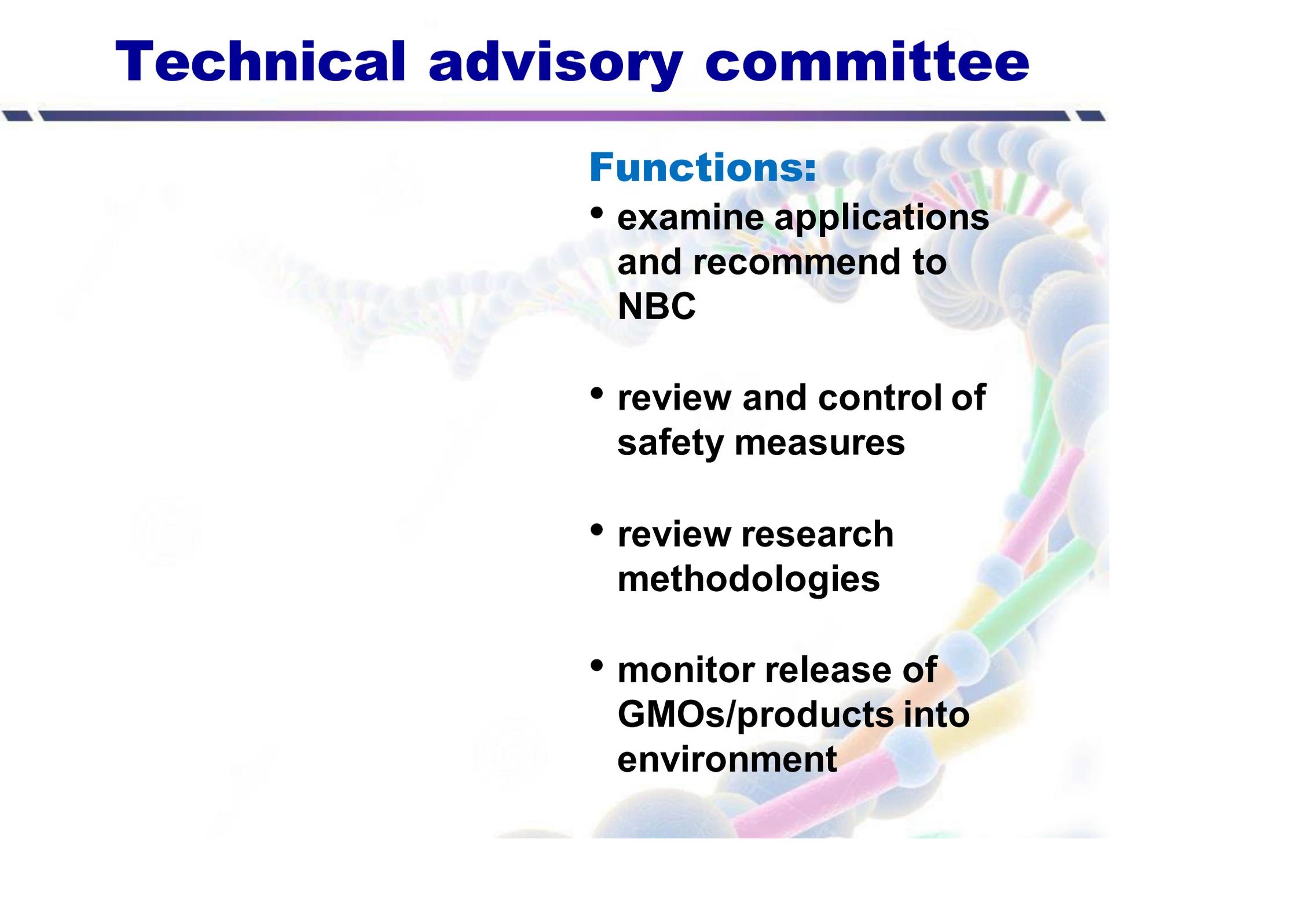
Technical advisory committee



Members:

- relevant technical representative animal sciences, PARC
- relevant technical representative plant sciences, PARC
- director – EPA
- two experts from civil society

Technical advisory committee



Functions:

- **examine applications and recommend to NBC**
- **review and control of safety measures**
- **review research methodologies**
- **monitor release of GMOs/products into environment**

Technical advisory committee

Functions:

- provide information to NBC about approved projects
- supervise the implementation of terms and conditions

Biosafety

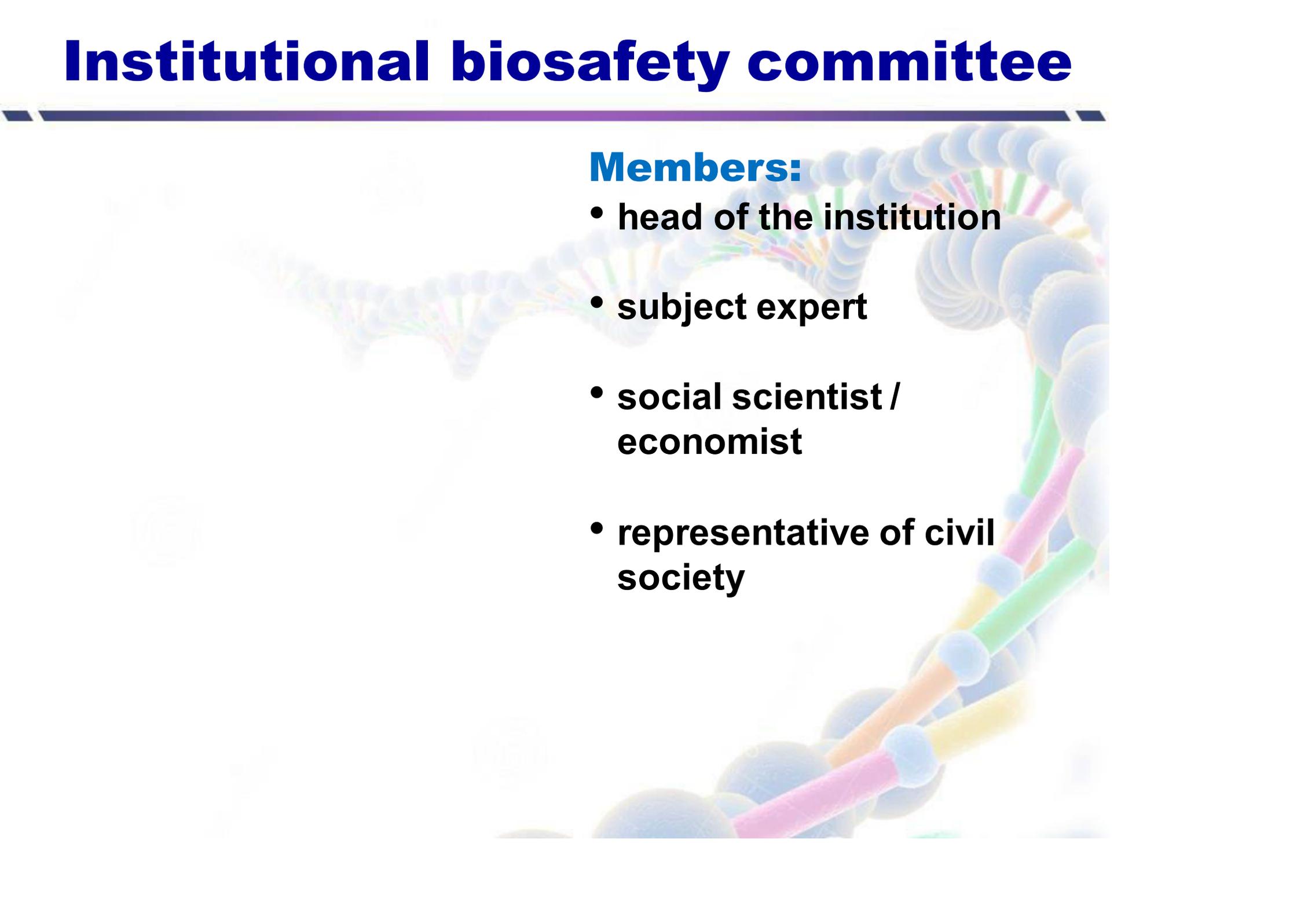


Lesson # 148

Institutional biosafety committee



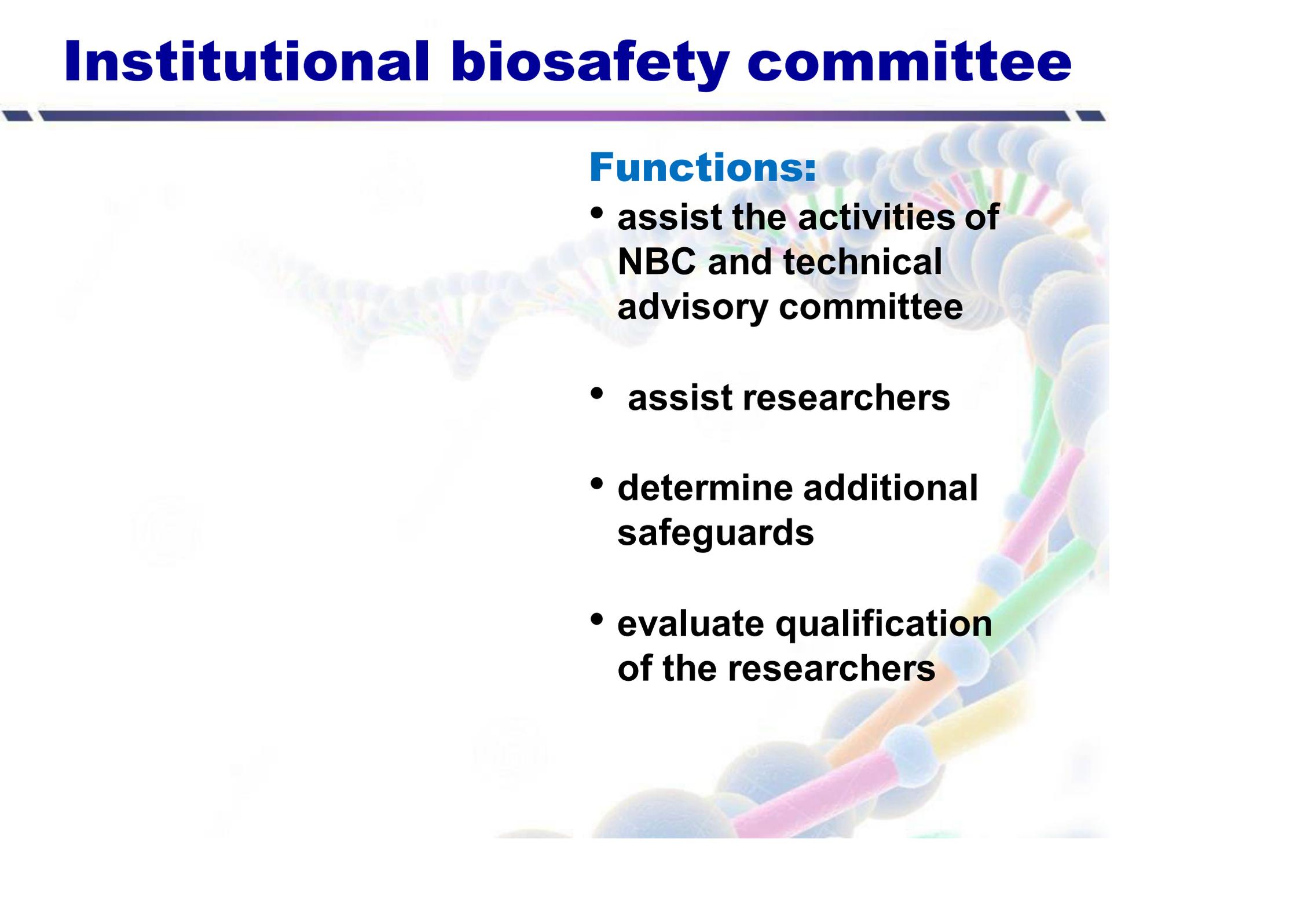
Institutional biosafety committee



Members:

- **head of the institution**
- **subject expert**
- **social scientist /
economist**
- **representative of civil
society**

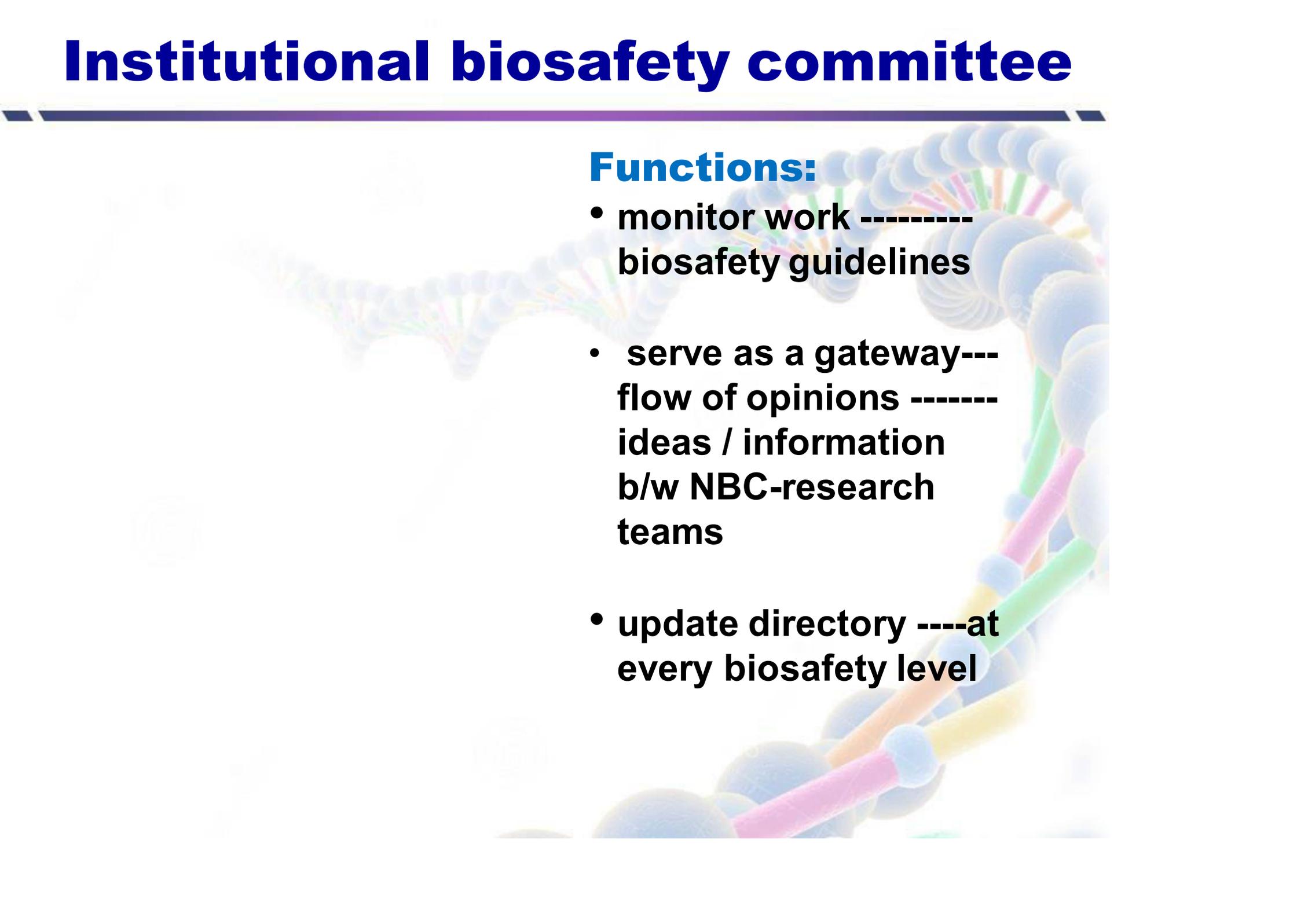
Institutional biosafety committee



Functions:

- **assist the activities of NBC and technical advisory committee**
- **assist researchers**
- **determine additional safeguards**
- **evaluate qualification of the researchers**

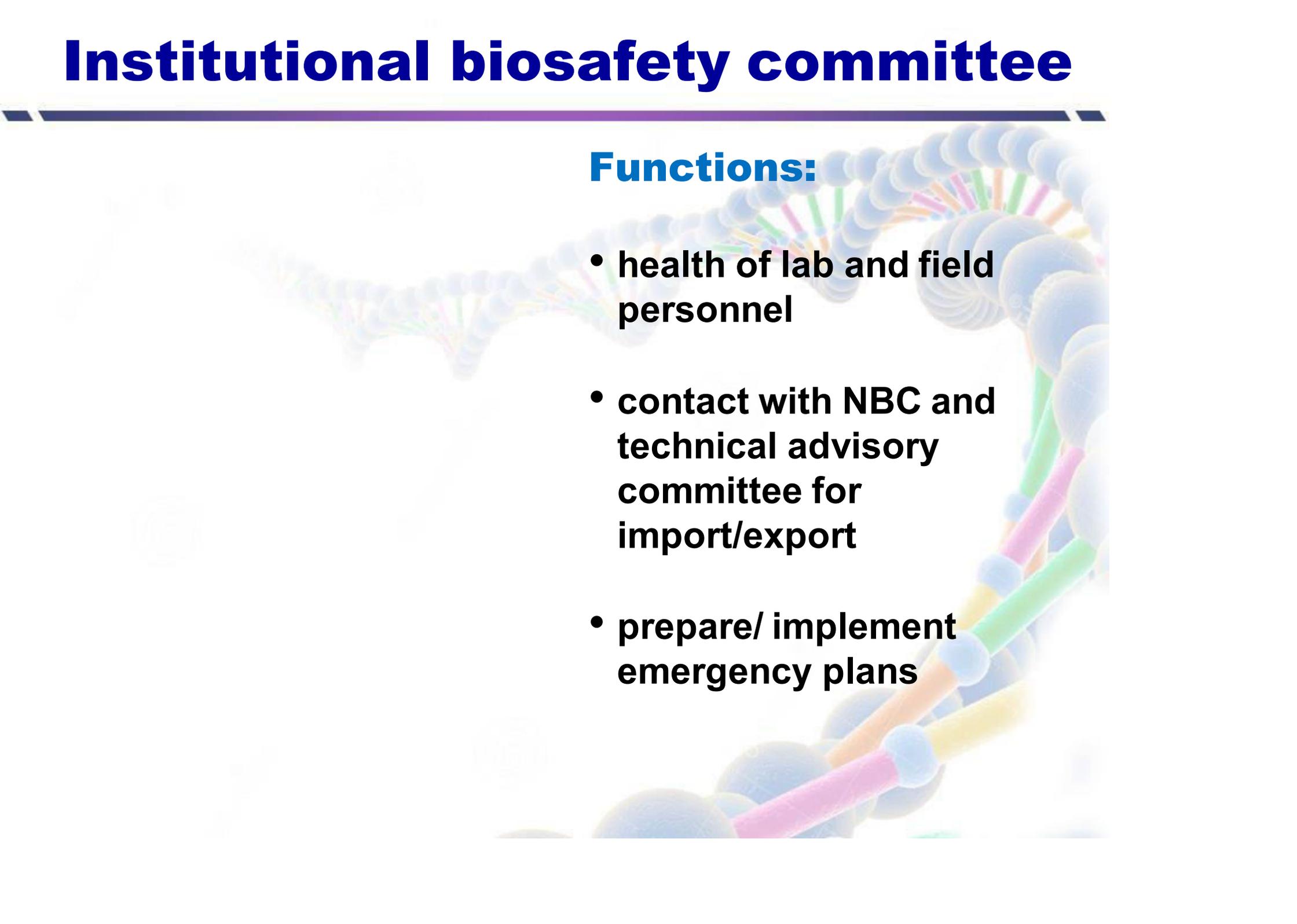
Institutional biosafety committee



Functions:

- monitor work -----
biosafety guidelines
- serve as a gateway---
flow of opinions -----
ideas / information
b/w NBC-research
teams
- update directory ----at
every biosafety level

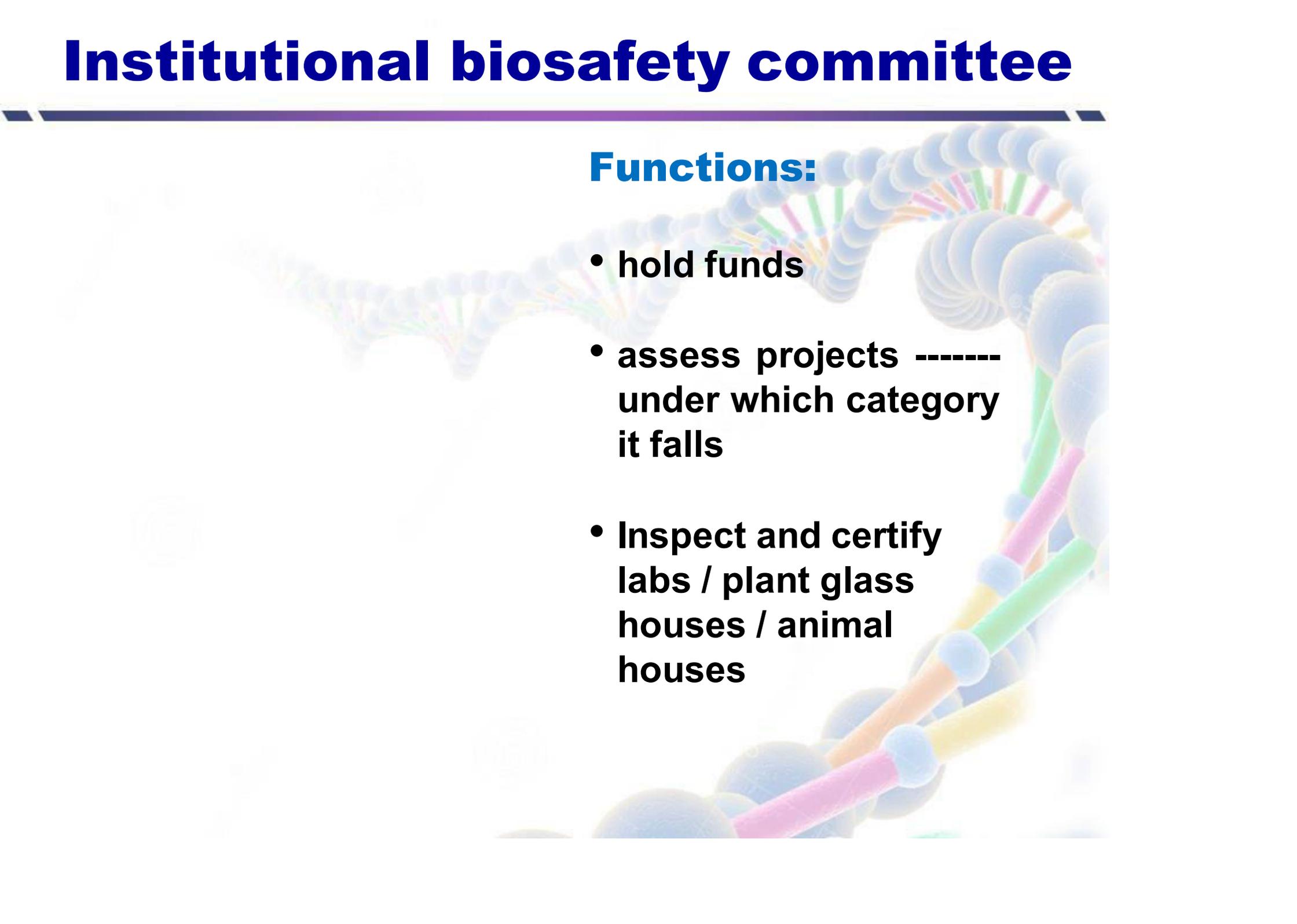
Institutional biosafety committee



Functions:

- health of lab and field personnel
- contact with NBC and technical advisory committee for import/export
- prepare/ implement emergency plans

Institutional biosafety committee



Functions:

- hold funds
- assess projects -----
under which category
it falls
- Inspect and certify
labs / plant glass
houses / animal
houses

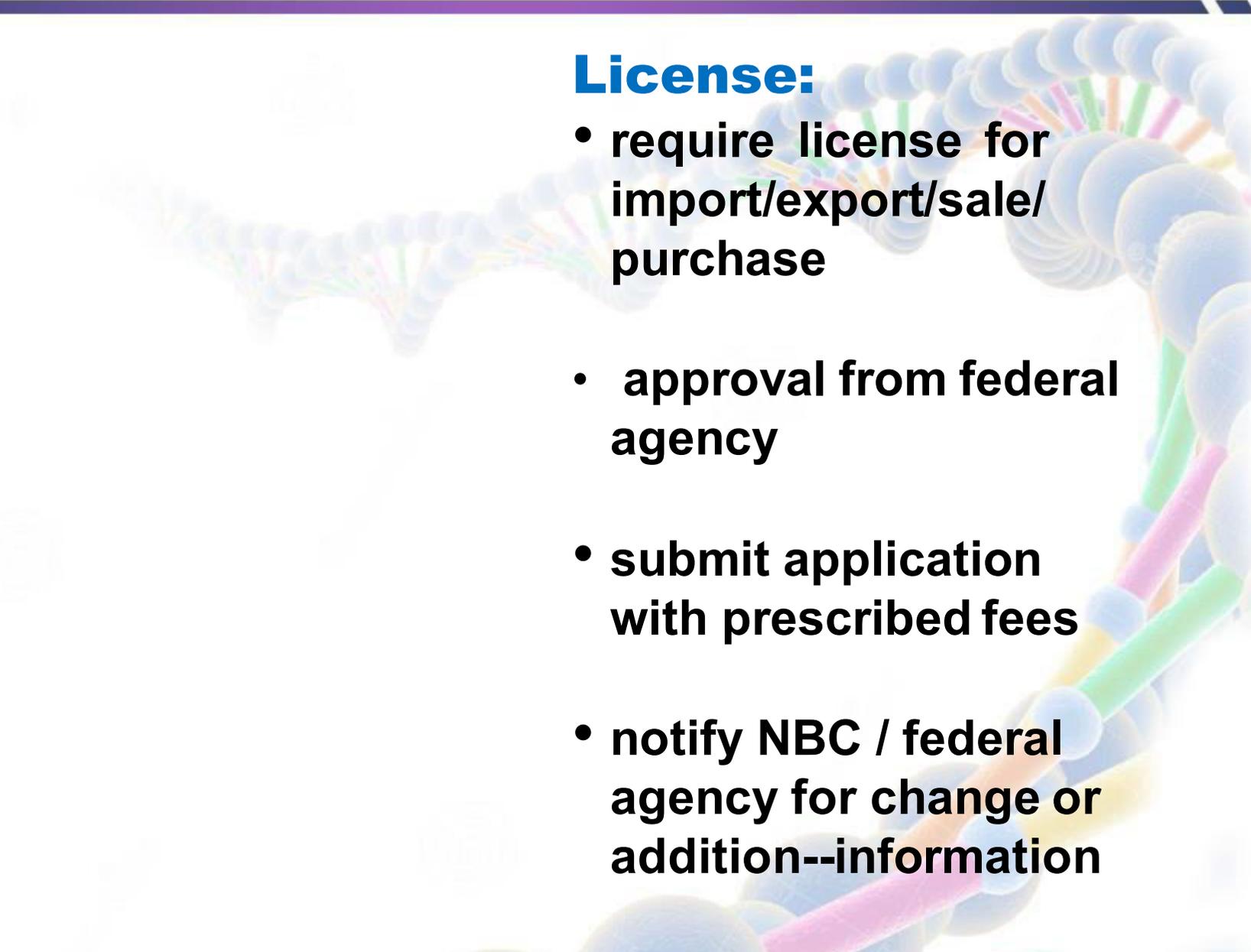
Biosafety

Lesson # 149

License requirements



License requirements



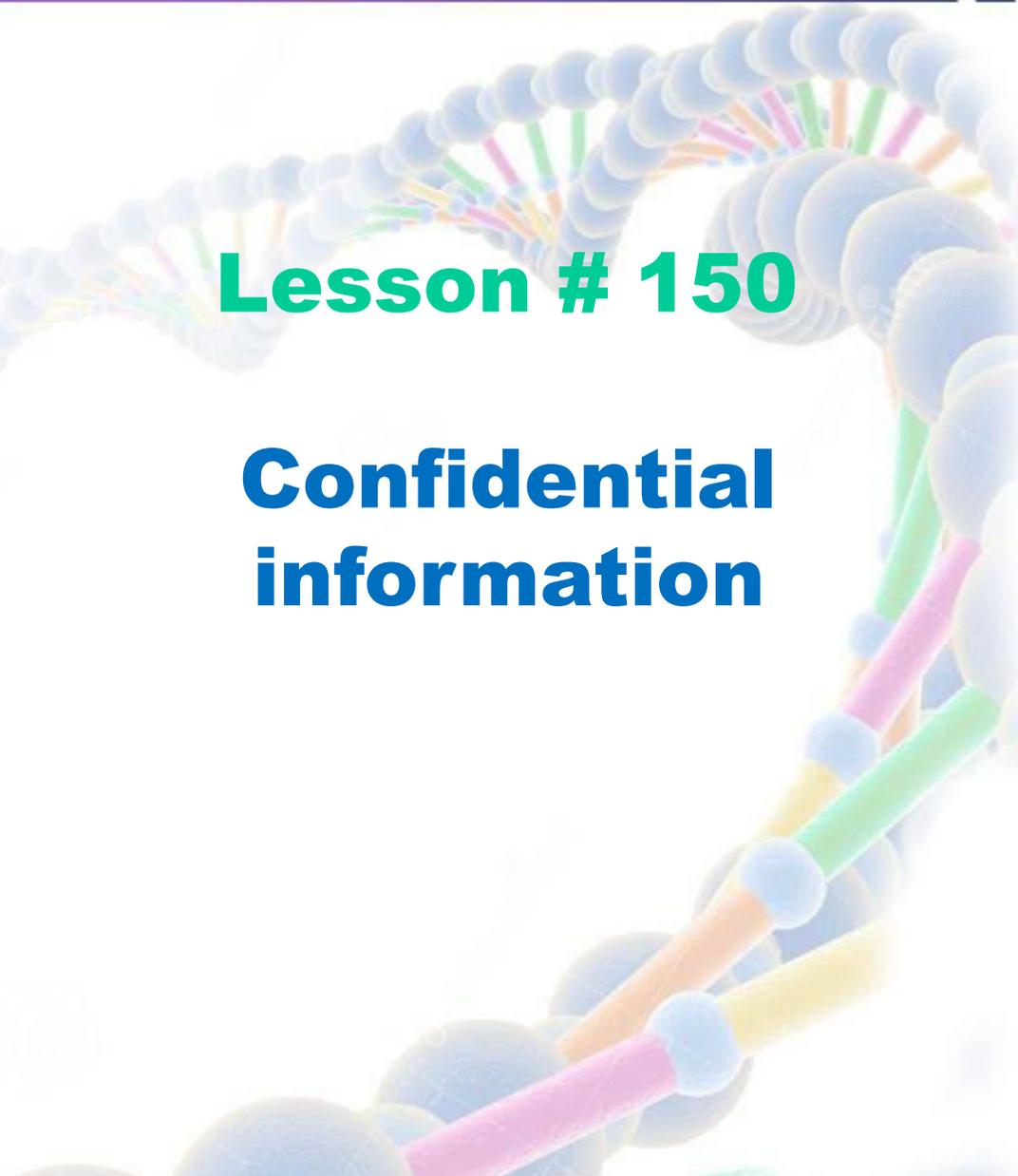
License:

- **require license for import/export/sale/purchase**
- **approval from federal agency**
- **submit application with prescribed fees**
- **notify NBC / federal agency for change or addition--information**

Biosafety

Lesson # 150

**Confidential
information**



Confidential information

Confidentiality:

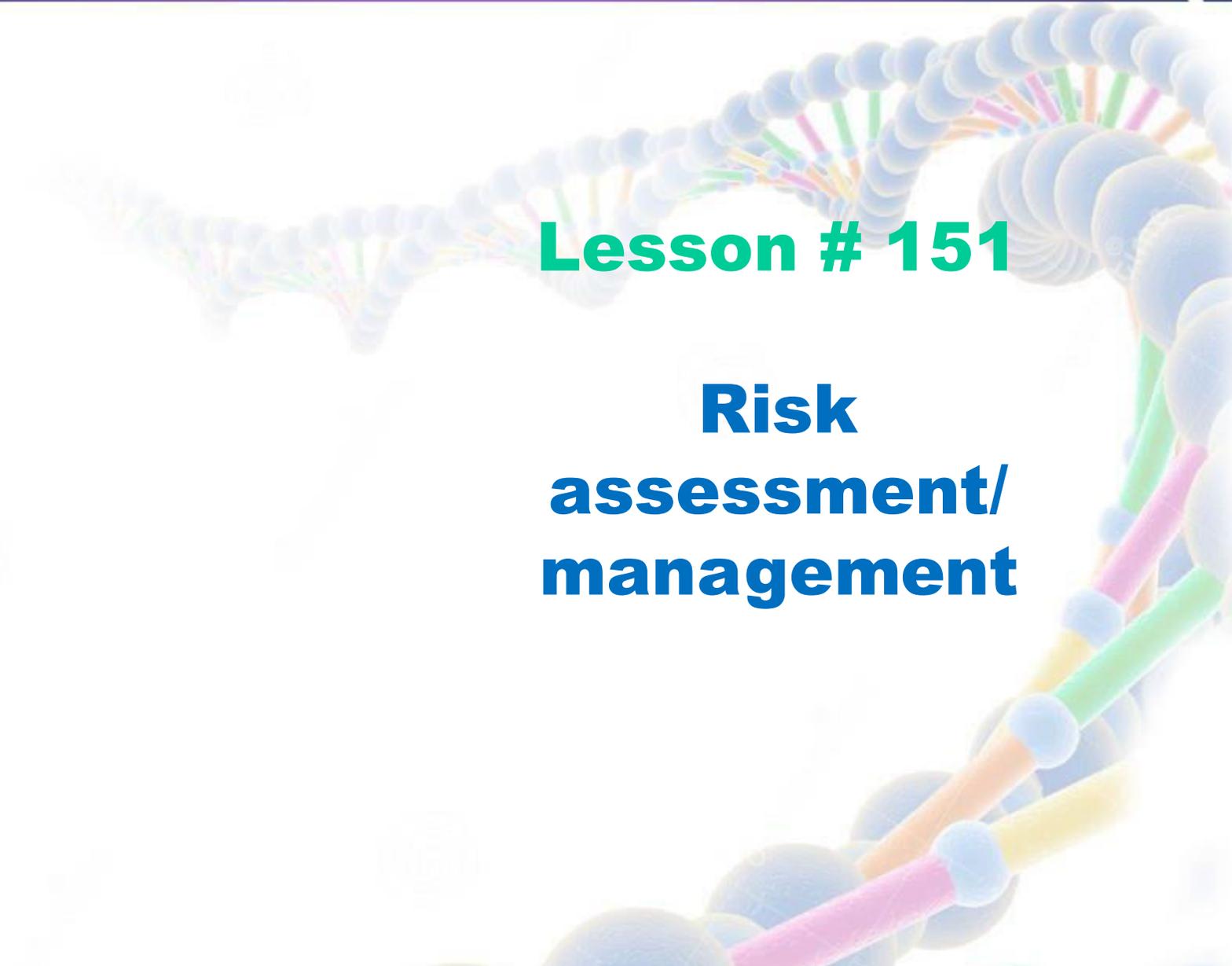
- **privileged or property information**
- **privileged information shared among few people for further processing**
- **unauthorized people shouldn't take advantage**

Confidential information

Confidentiality:

- Information of the applicant
- protected with article 21 of the Cartagena protocol
- set forth in the biosafety guidelines

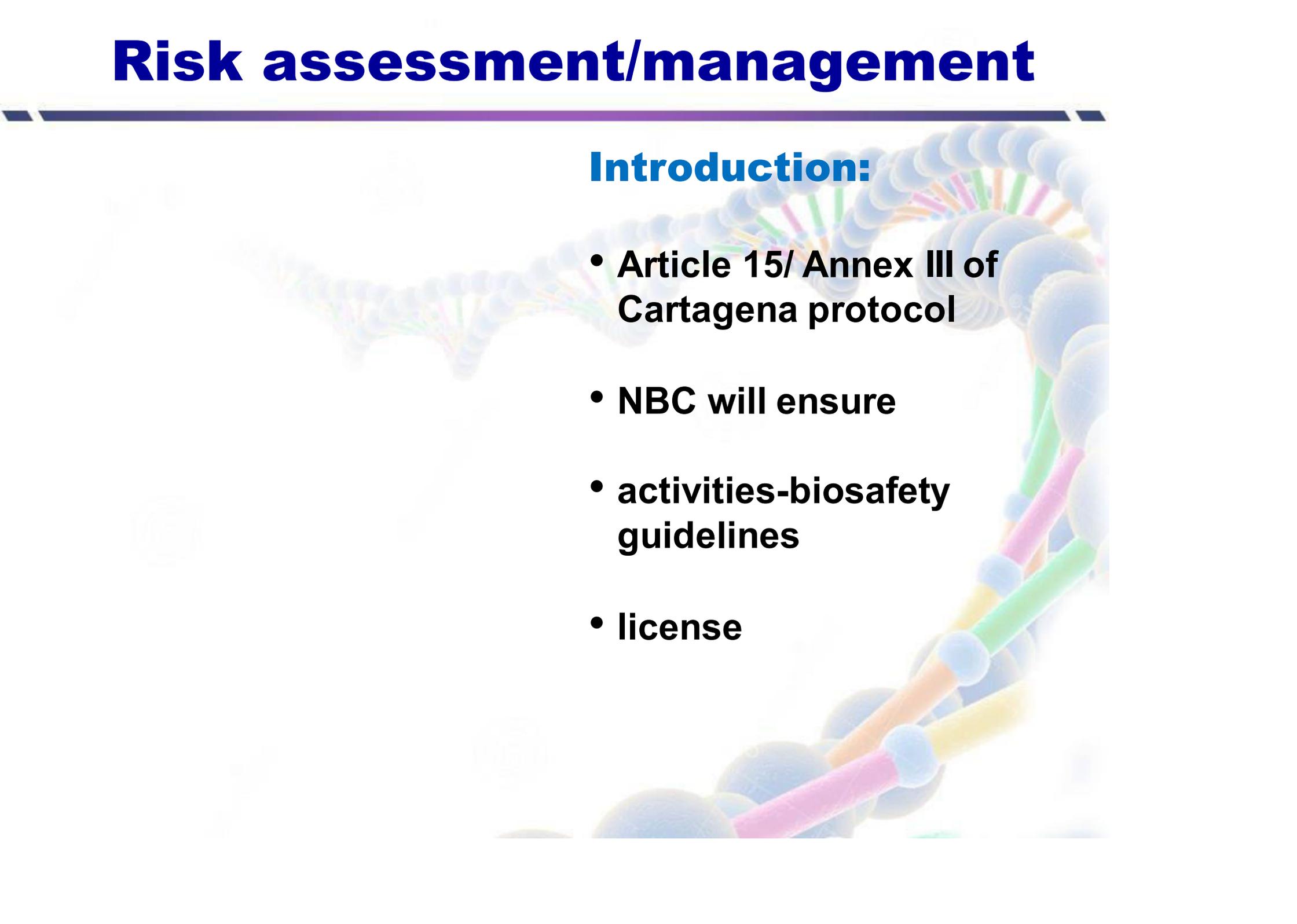
Biosafety



Lesson # 151

Risk assessment/ management

Risk assessment/management



Introduction:

- **Article 15/ Annex III of Cartagena protocol**
- **NBC will ensure**
- **activities-biosafety guidelines**
- **license**

Risk assessment/management

Risk assessment:

- auditing of risk assessment
- evaluation of risk management measures
- field trials

Biosafety



Lesson # 152

**Decision and
communication**

Decision and communication

Introduction:

- **final decision is made-communicated to the applicant**
- **60 days for risk category 2/3**
- **90 days for experimental release**
- **120 days for commercialization**

Decision and communication

Criteria of decision:

- based on information set forth in the application
- scientific risk assessment
- prior field experience with GMOs

Decision and communication

Final decision:

- recorded in a decision document---described in biosafety guidelines
- no person can vary the license activity
- license granted by federal agency under rule 11

Decision and communication

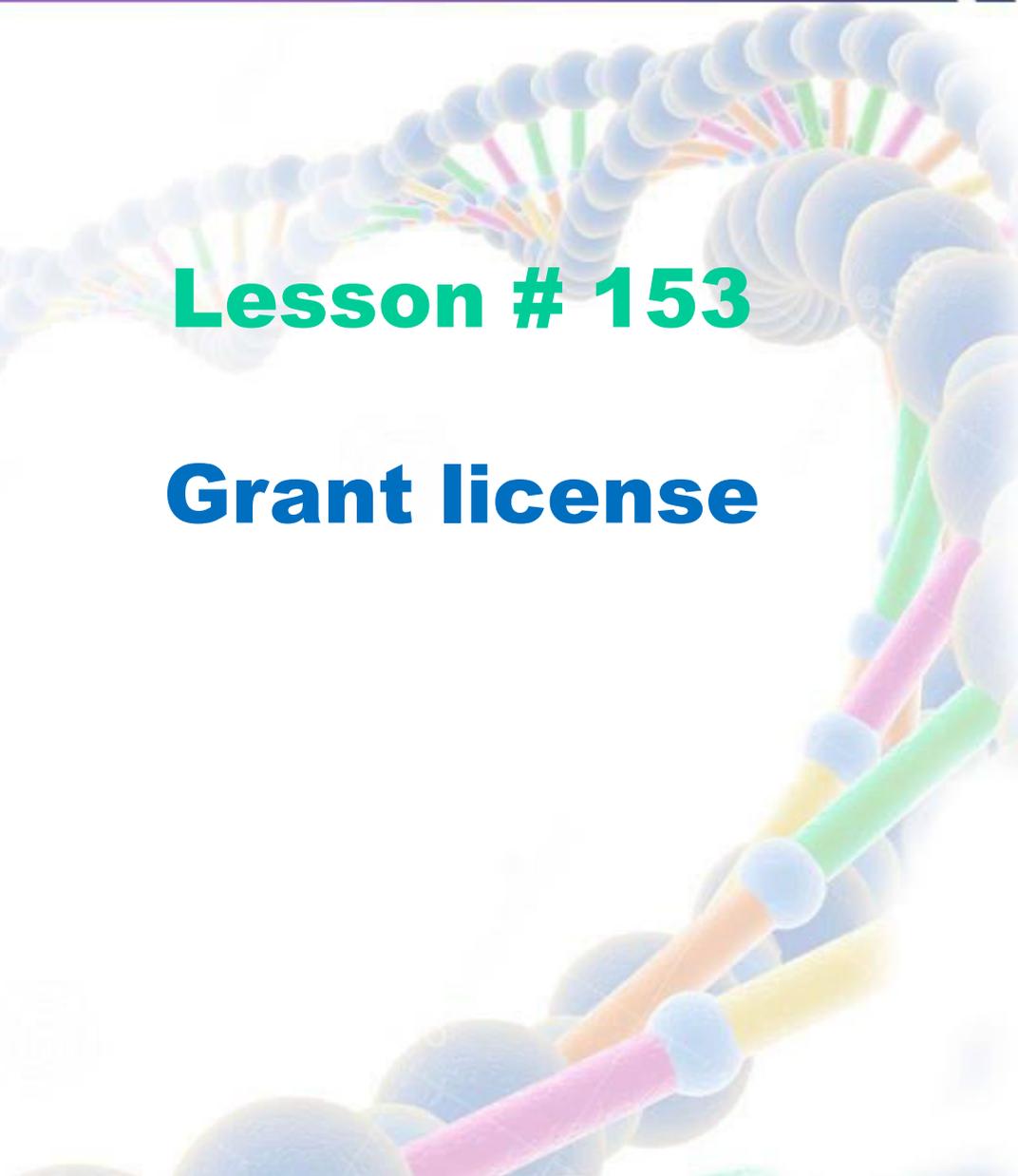
Functional:

- license remain ineffective
- until applicant executes an undertaking
- applicant will follow biosafety guidelines

Biosafety

Lesson # 153

Grant license



Grant license

Introduction:

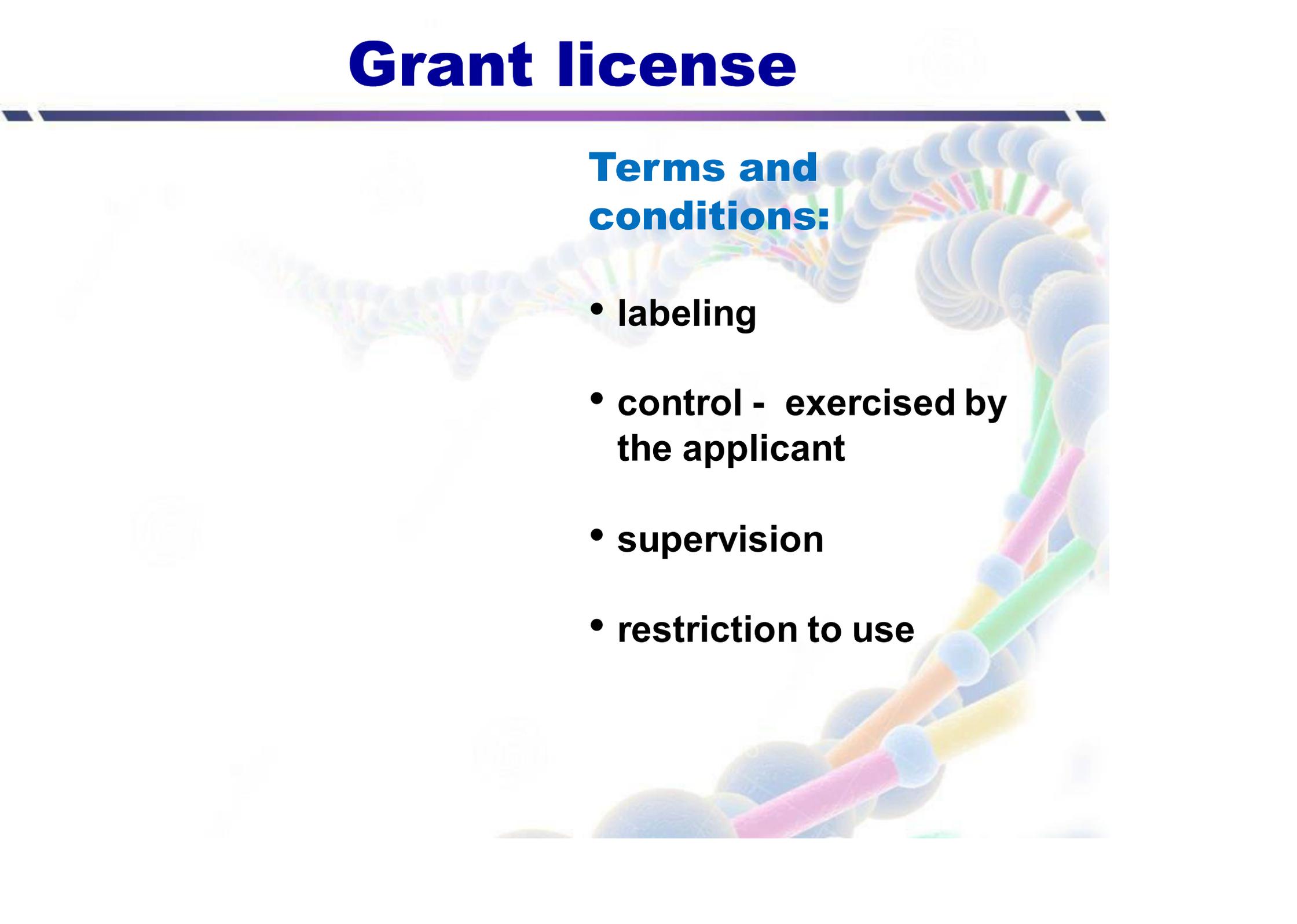
- **federal agency-rule 11**
- **license - specified time period**
- **cannot exceed more than 4 years**
- **renewable after every 2 years**

Grant license

Powers to revoke:

- **new information-harmful effects of GMOs**
- **damage - nature, health, environment**
- **any other condition**

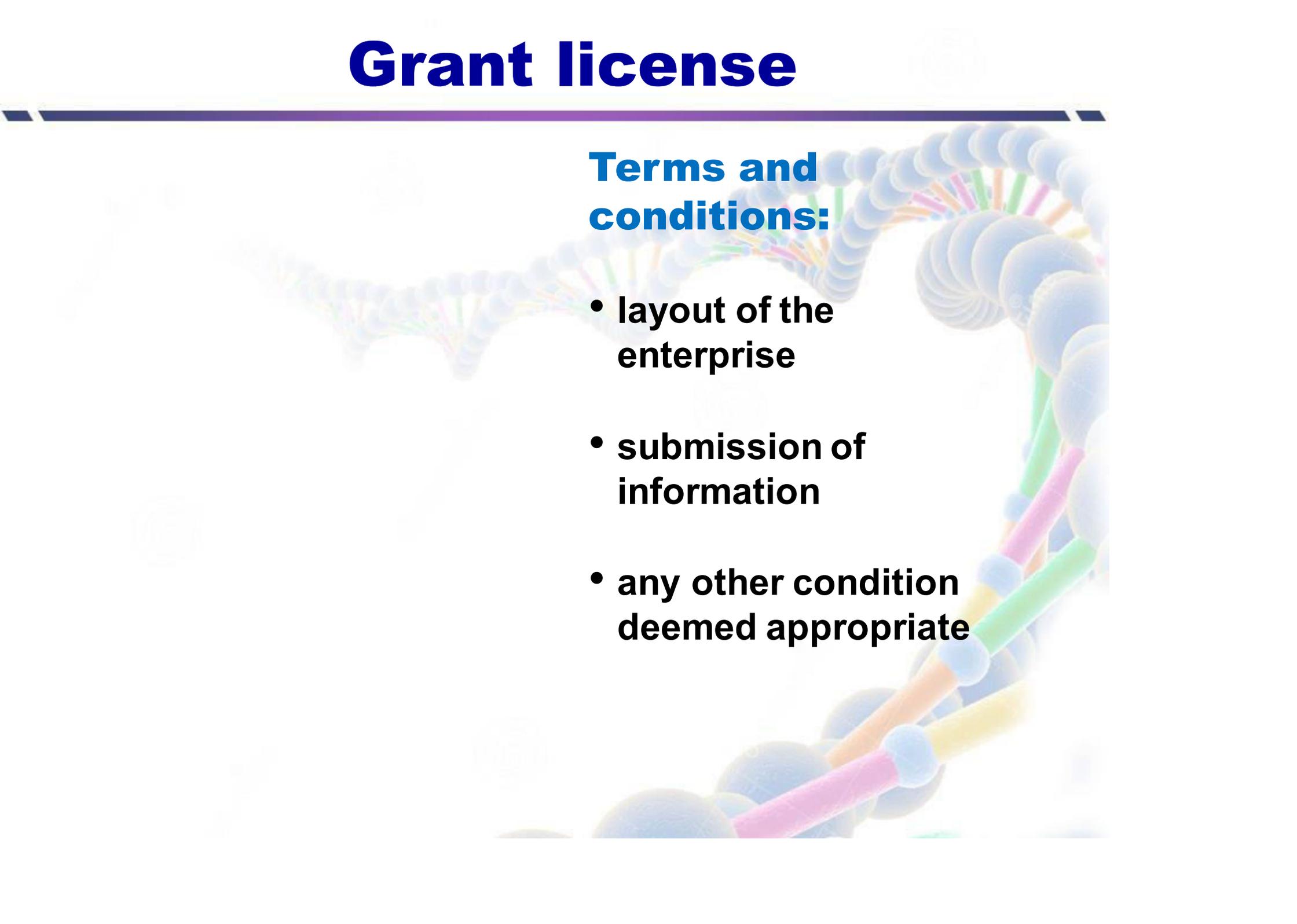
Grant license



Terms and conditions:

- labeling
- control - exercised by the applicant
- supervision
- restriction to use

Grant license



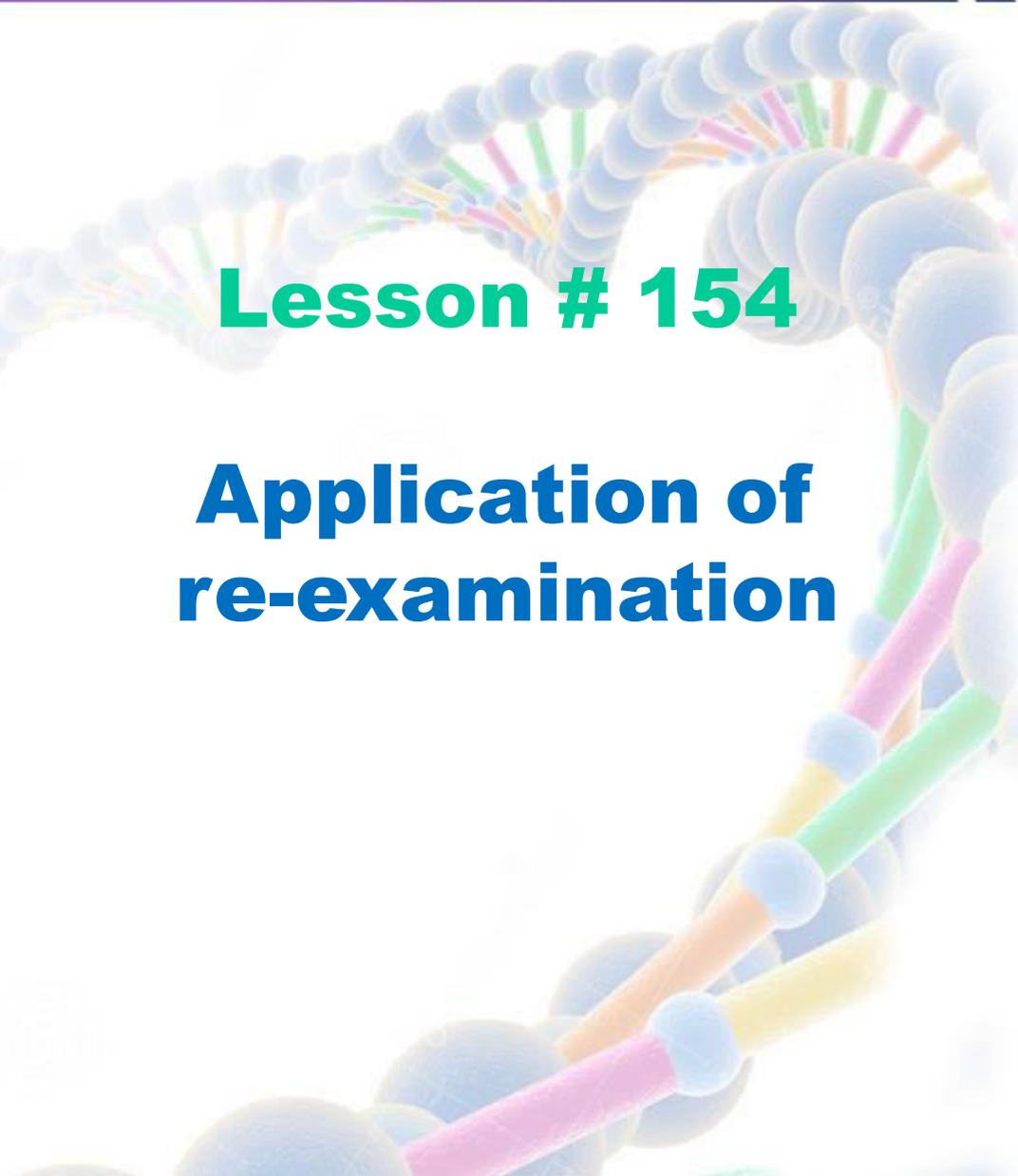
Terms and conditions:

- **layout of the enterprise**
- **submission of information**
- **any other condition deemed appropriate**

Biosafety

Lesson # 154

Application of re-examination

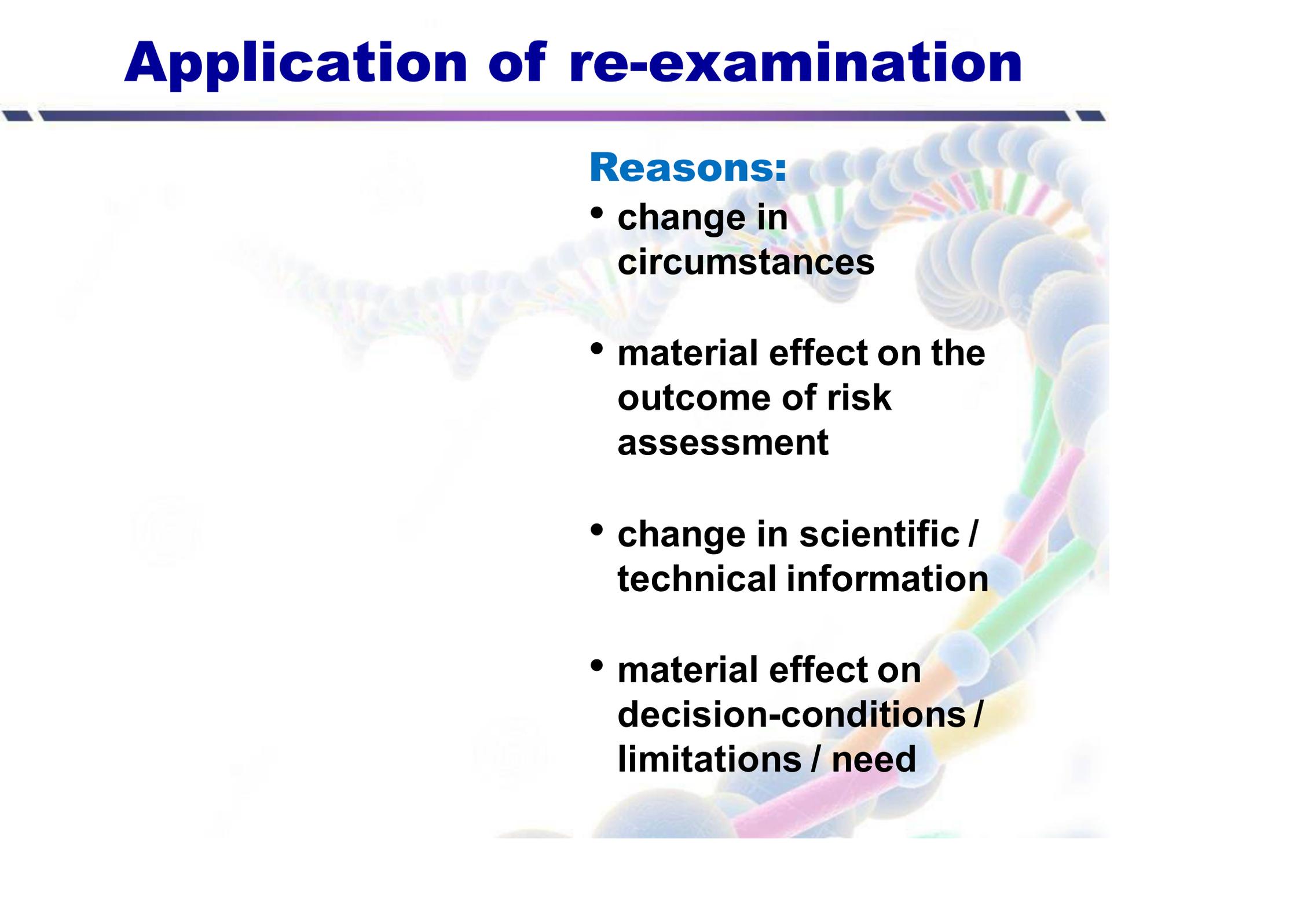


Application of re-examination

Introduction:

- applicant may file application
- NBC
- after a minimum time of 6 months

Application of re-examination



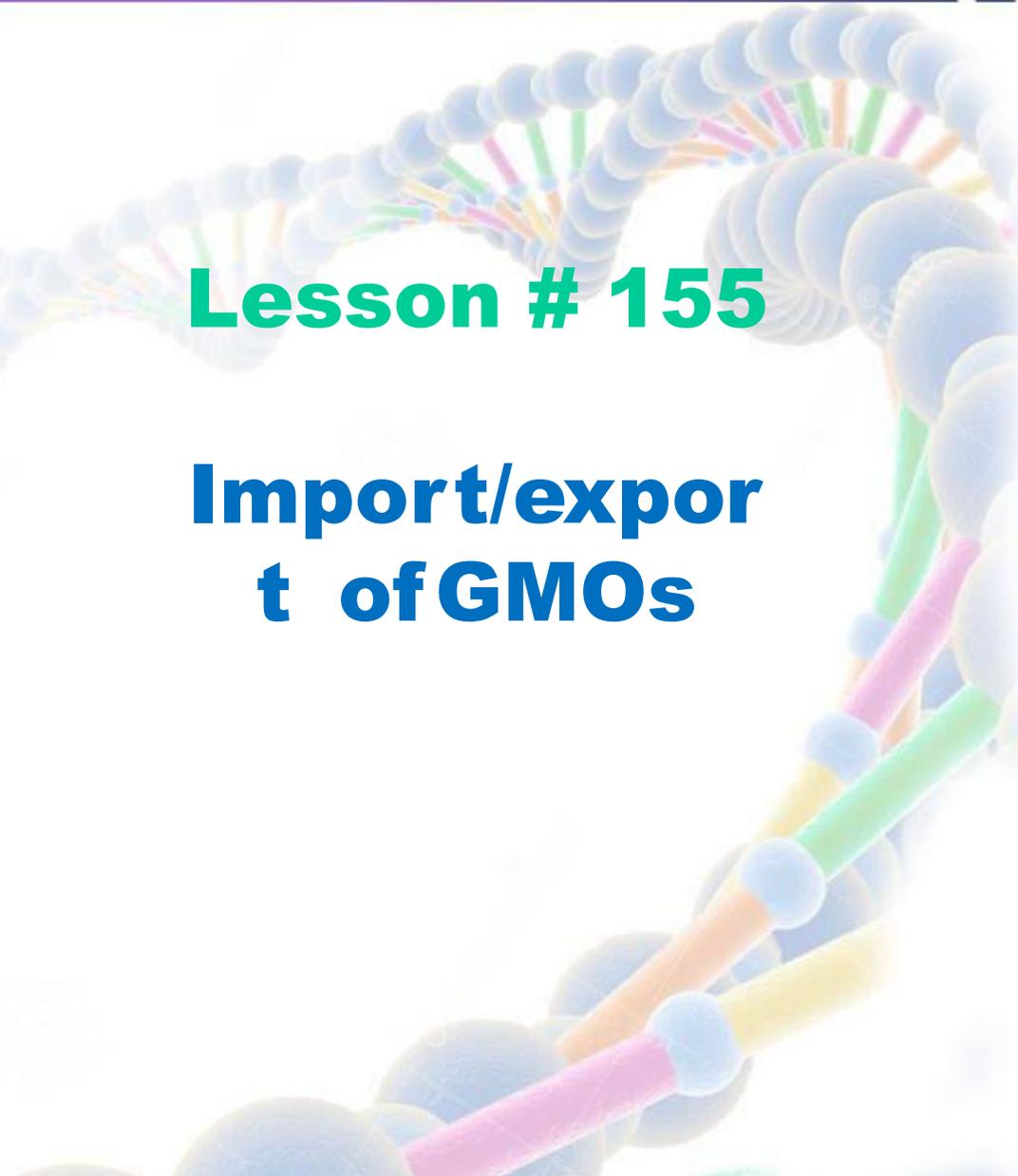
Reasons:

- change in circumstances
- material effect on the outcome of risk assessment
- change in scientific / technical information
- material effect on decision-conditions / limitations / need

Biosafety

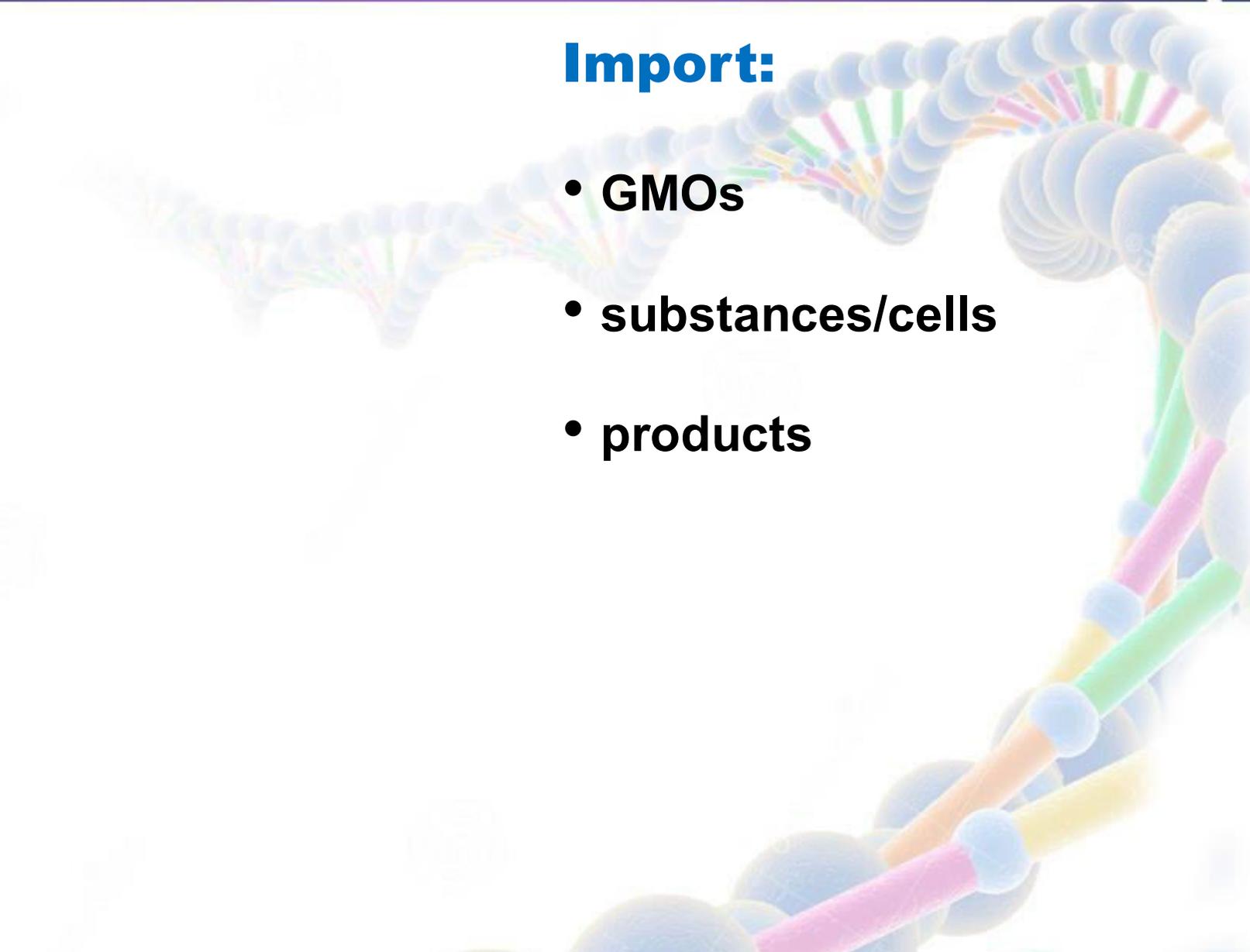
Lesson # 155

Import/export of GMOs

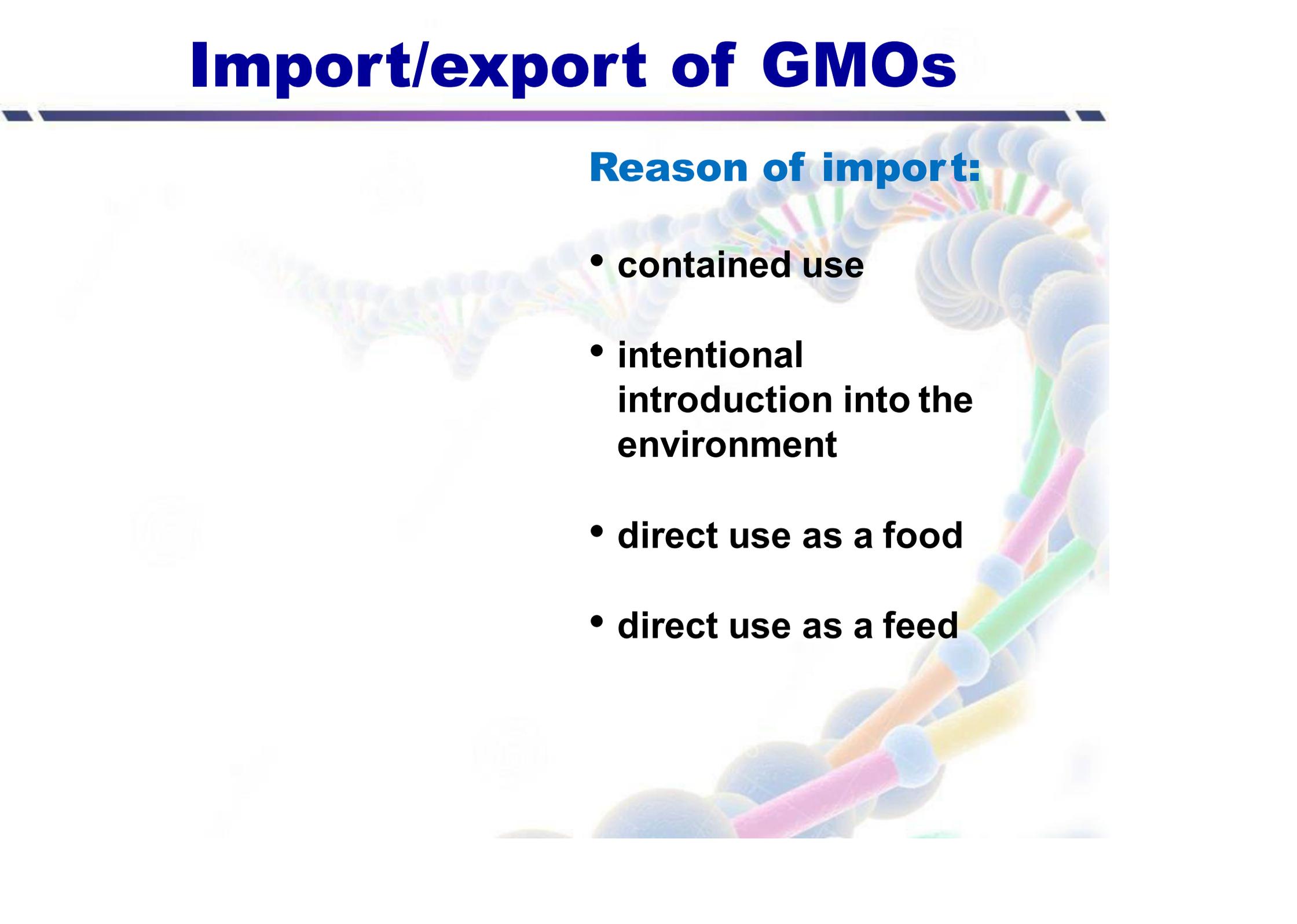


Import/export of GMOs

Import:

- **GMOs**
 - **substances/cells**
 - **products**
- 

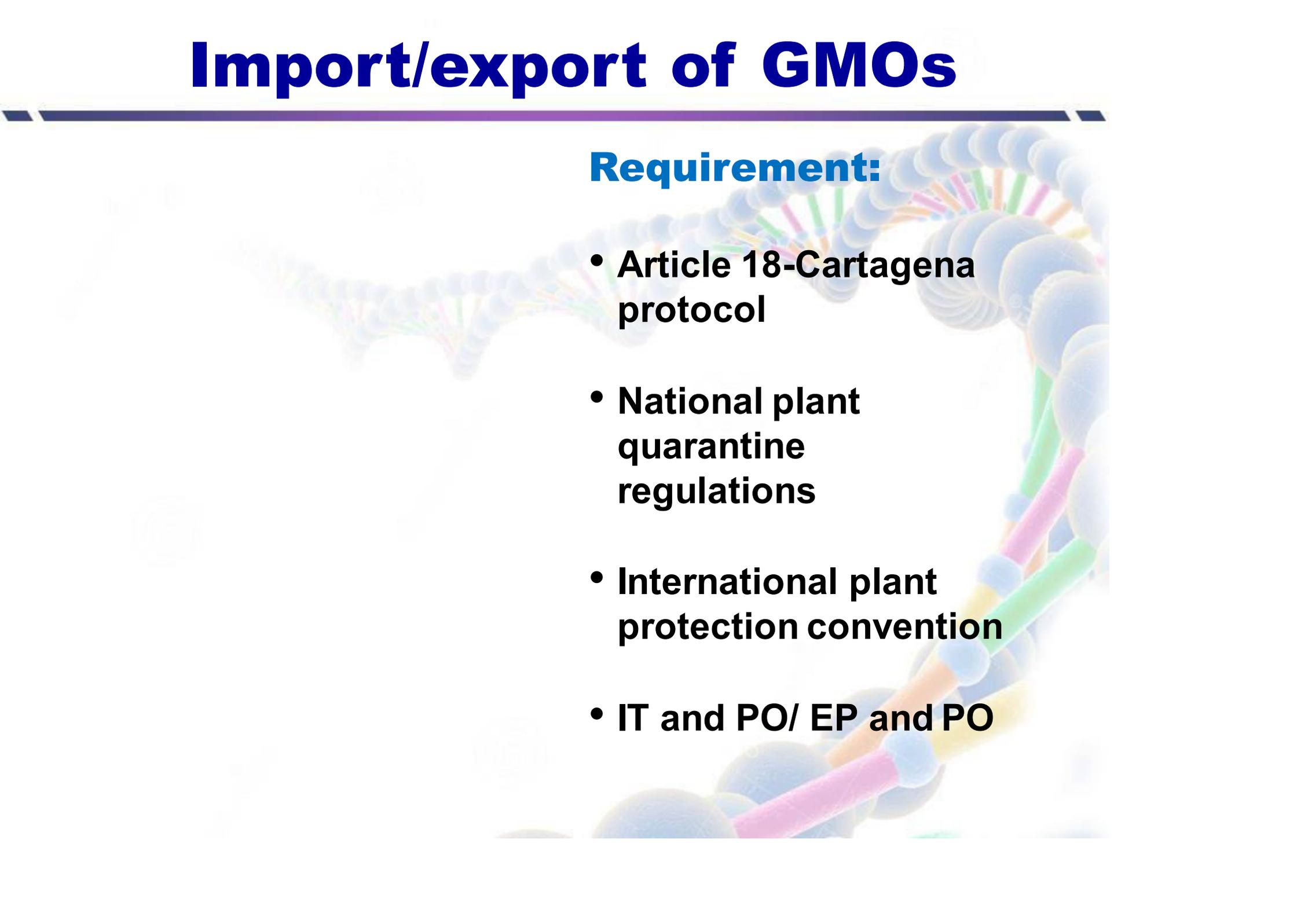
Import/export of GMOs



Reason of import:

- contained use
- intentional introduction into the environment
- direct use as a food
- direct use as a feed

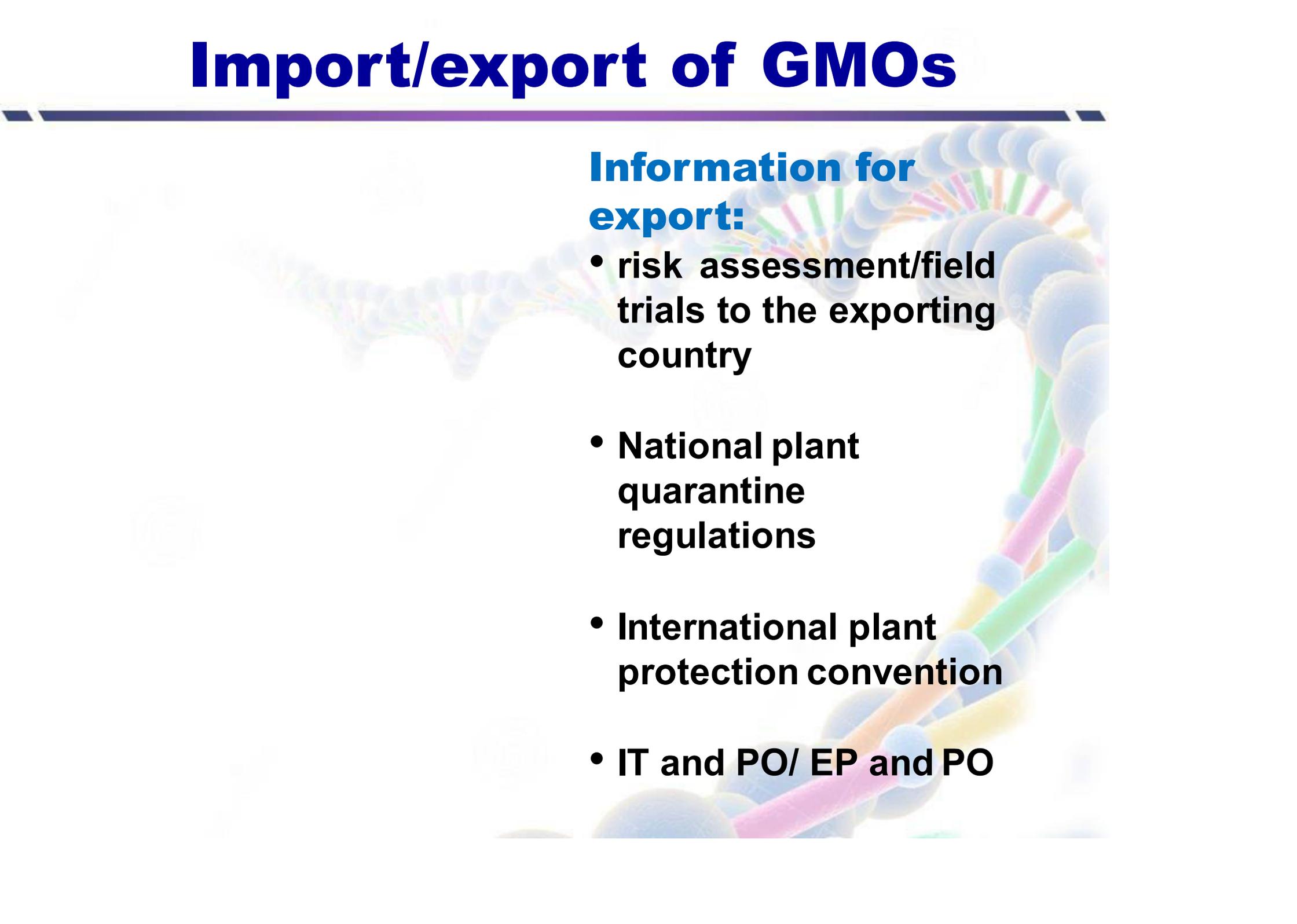
Import/export of GMOs



Requirement:

- **Article 18-Cartagena protocol**
- **National plant quarantine regulations**
- **International plant protection convention**
- **IT and PO/ EP and PO**

Import/export of GMOs



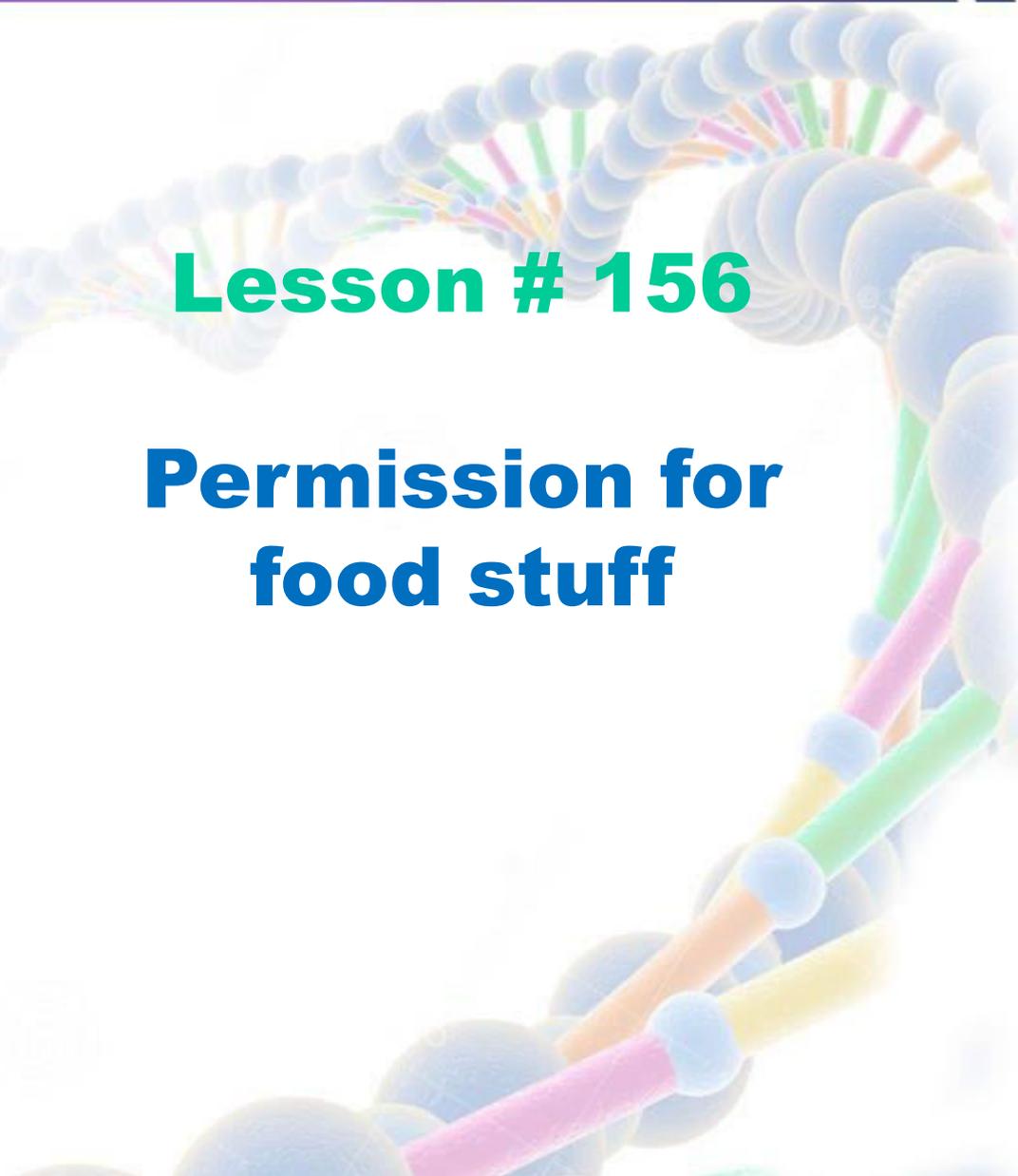
Information for export:

- risk assessment/field trials to the exporting country
- National plant quarantine regulations
- International plant protection convention
- IT and PO/ EP and PO

Biosafety

Lesson # 156

Permission for food stuff



Permission of food stuff

Introduction:

- food stuff
- ingredients of food stuff
- additives
- processing aid

Permission of food stuff

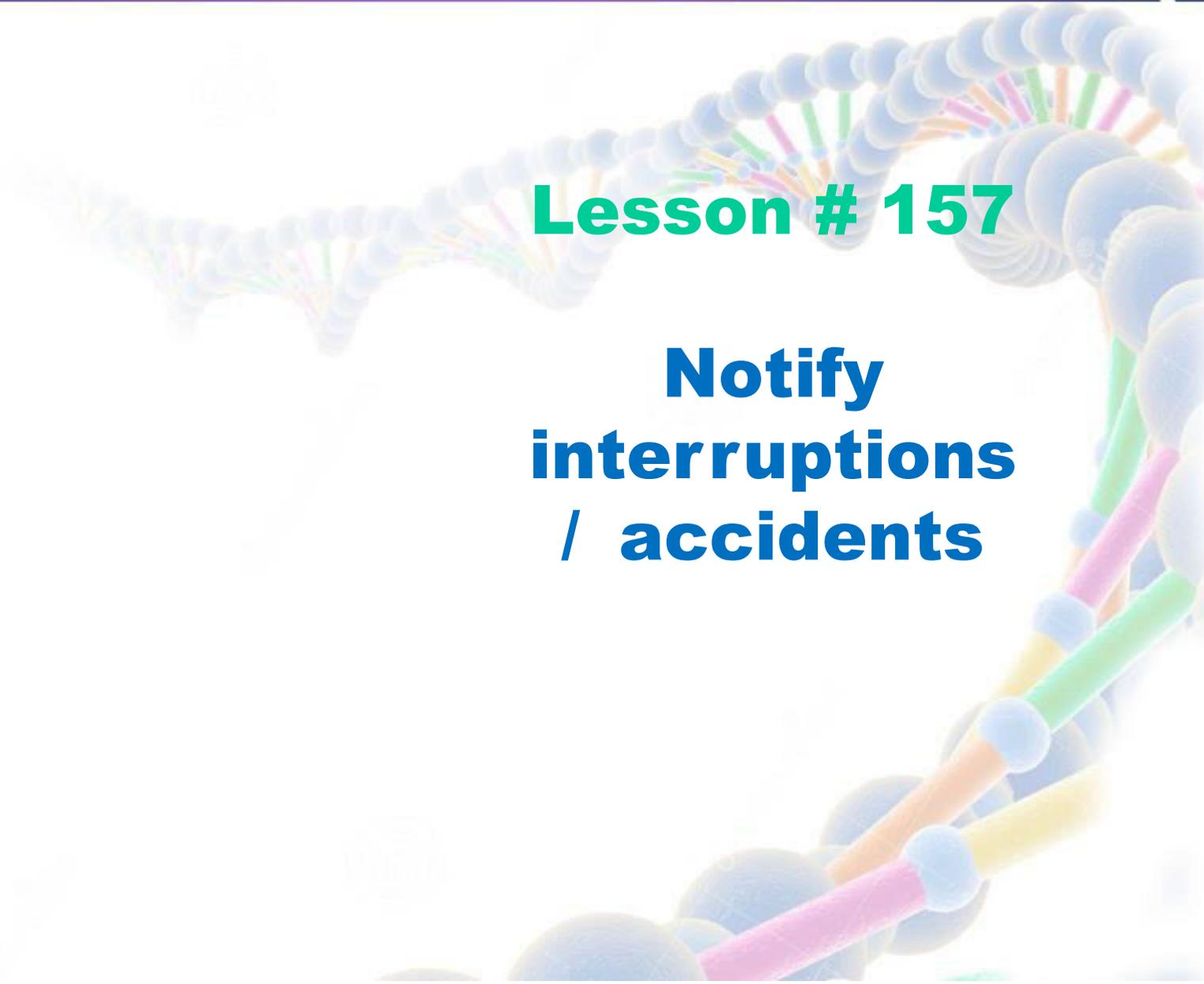
Approval:

- all food stuffs containing GMOs
- produced, sold, imported
- NBC
- sub-rule 2 of rule 20

Biosafety

Lesson # 157

**Notify
interruptions
/ accidents**



Notify interruptions/accidents

Interruptions:

- discharge of GMOs in to the environment
- harmful to the nature / health
- notify to technical advisory committee

Notify interruptions/accidents

Duty:

- shall not lessen the duty
- person, institution, organization
- whether got license

Notify interruptions/accidents

Solution:

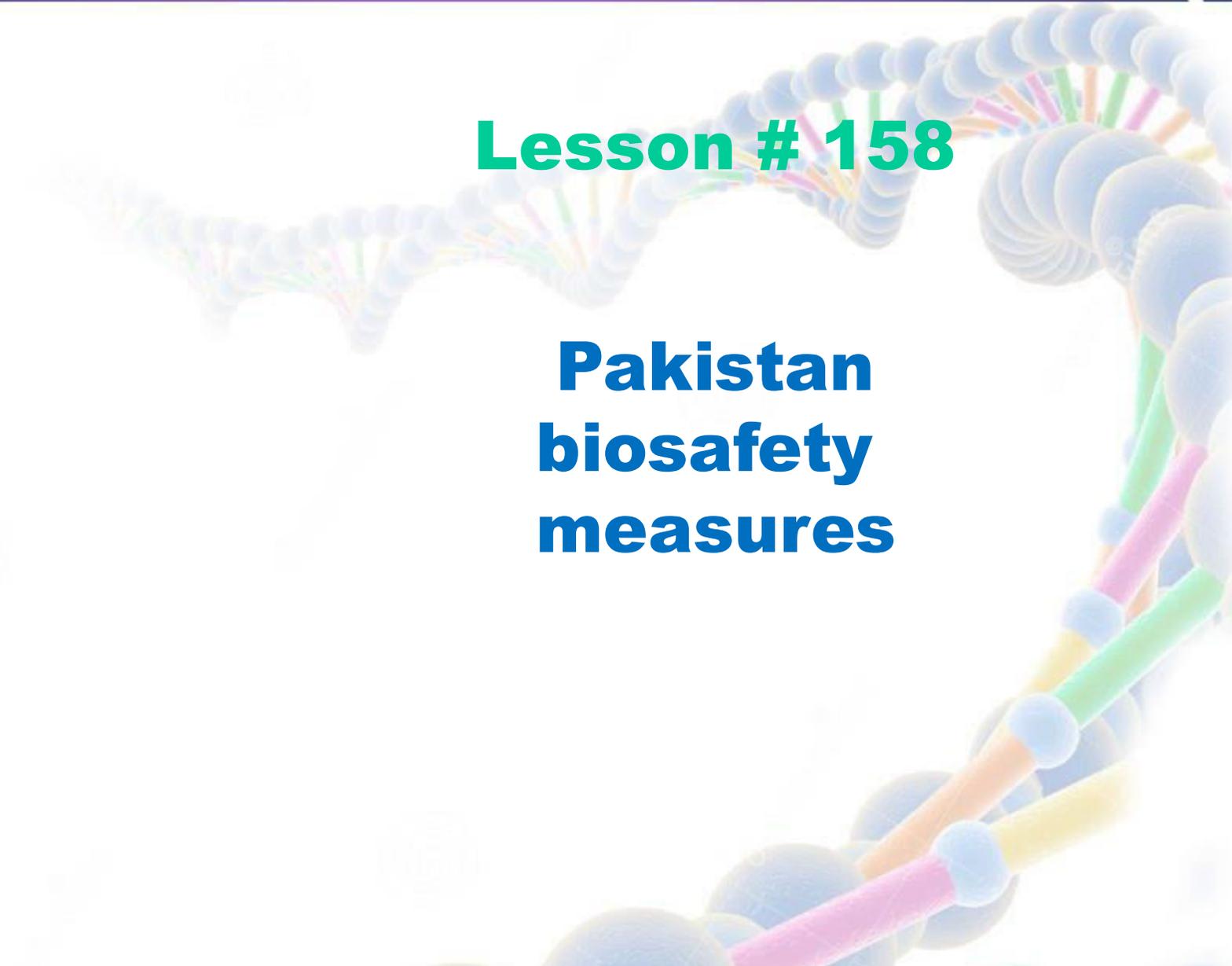
- **information - off-side effects**
- **technical advisory committee**
- **information related to off-side emergency plan**

Biosafety

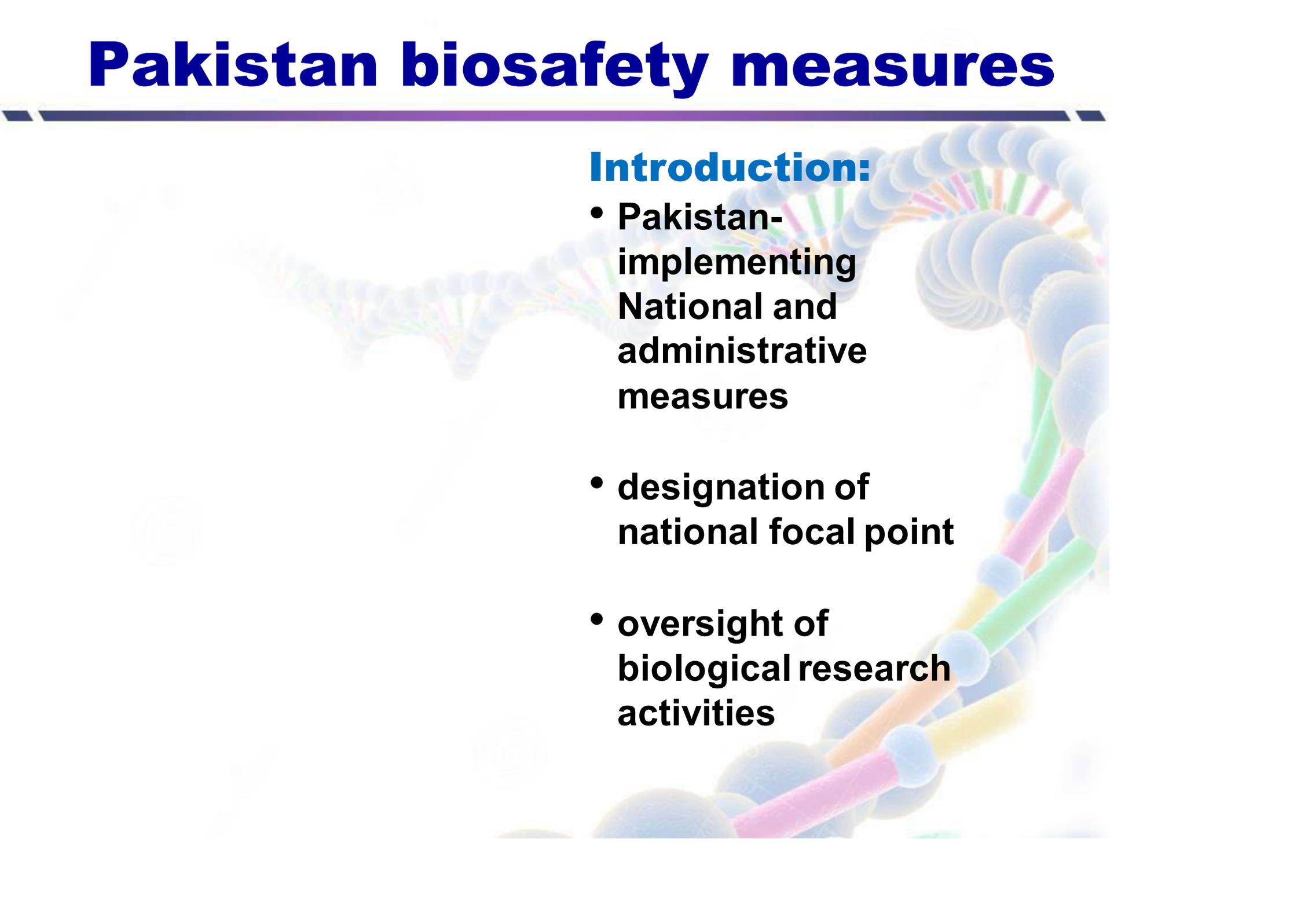


Lesson # 158

Pakistan biosafety measures



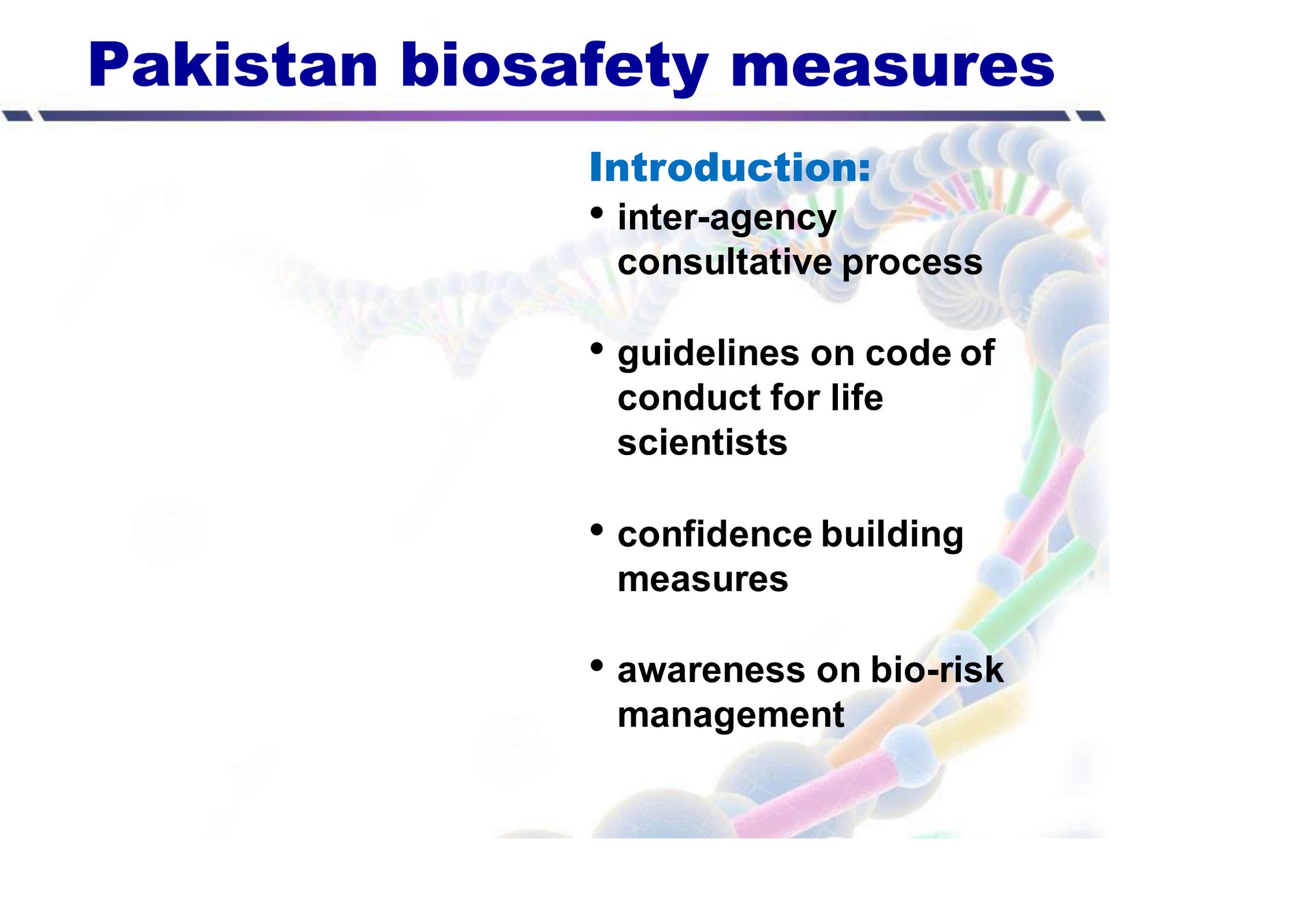
Pakistan biosafety measures



Introduction:

- **Pakistan-
implementing
National and
administrative
measures**
- **designation of
national focal point**
- **oversight of
biological research
activities**

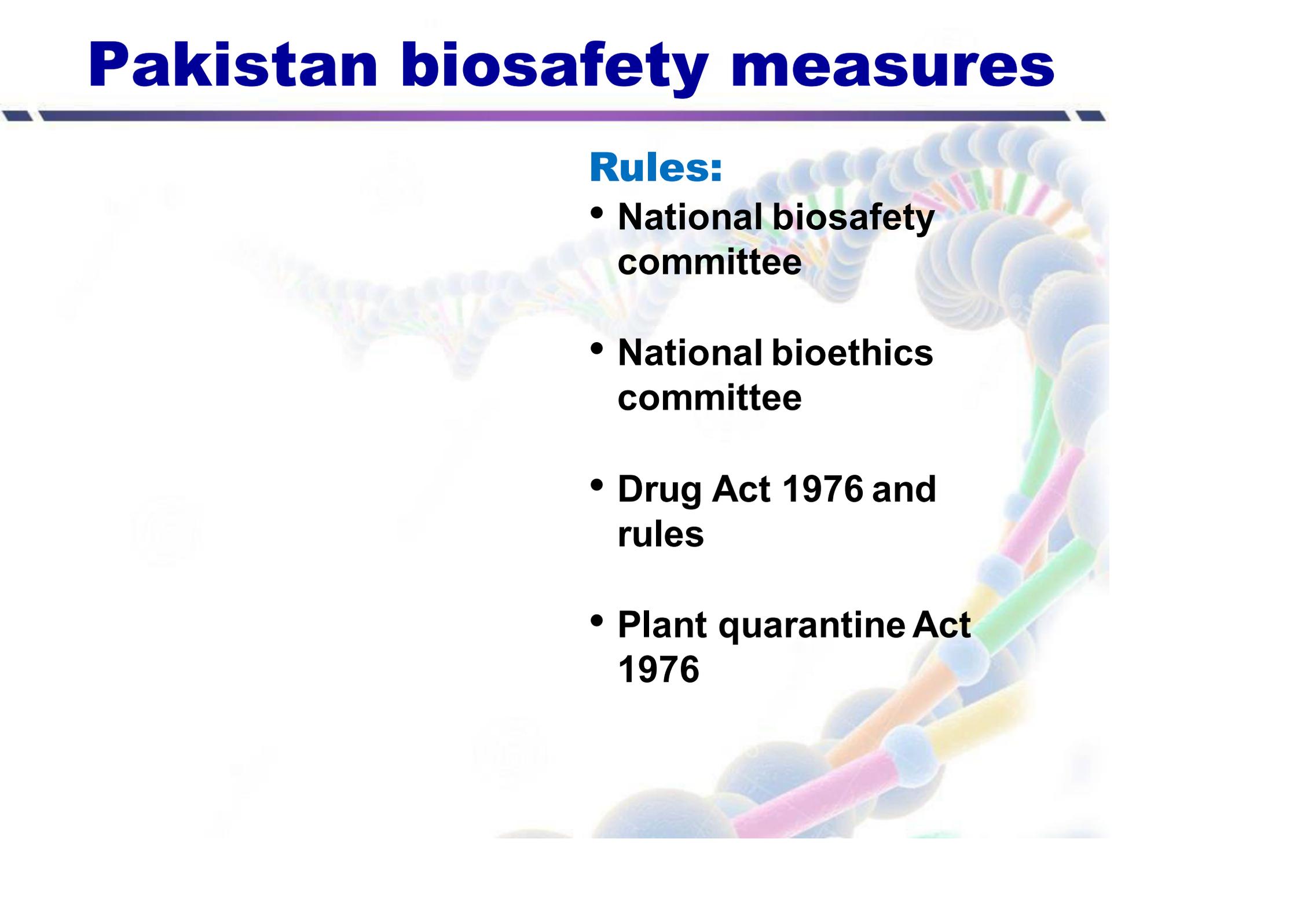
Pakistan biosafety measures



Introduction:

- **inter-agency consultative process**
- **guidelines on code of conduct for life scientists**
- **confidence building measures**
- **awareness on bio-risk management**

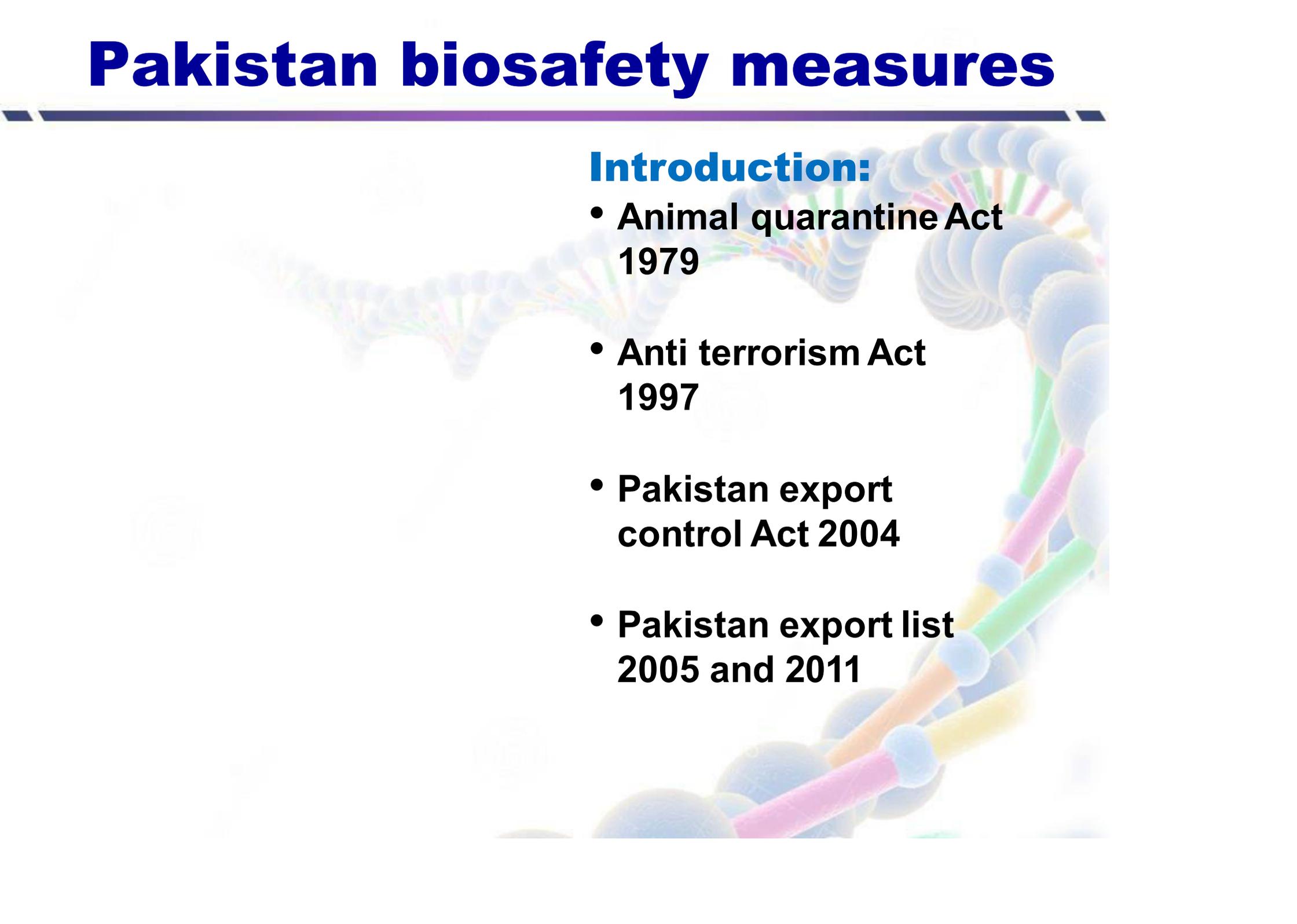
Pakistan biosafety measures



Rules:

- **National biosafety committee**
- **National bioethics committee**
- **Drug Act 1976 and rules**
- **Plant quarantine Act 1976**

Pakistan biosafety measures



Introduction:

- **Animal quarantine Act 1979**
- **Anti terrorism Act 1997**
- **Pakistan export control Act 2004**
- **Pakistan export list 2005 and 2011**

Pakistan biosafety measures

Introduction:

- **Pakistan biosafety rules 2005**
- **draft biological and toxin weapon convention**

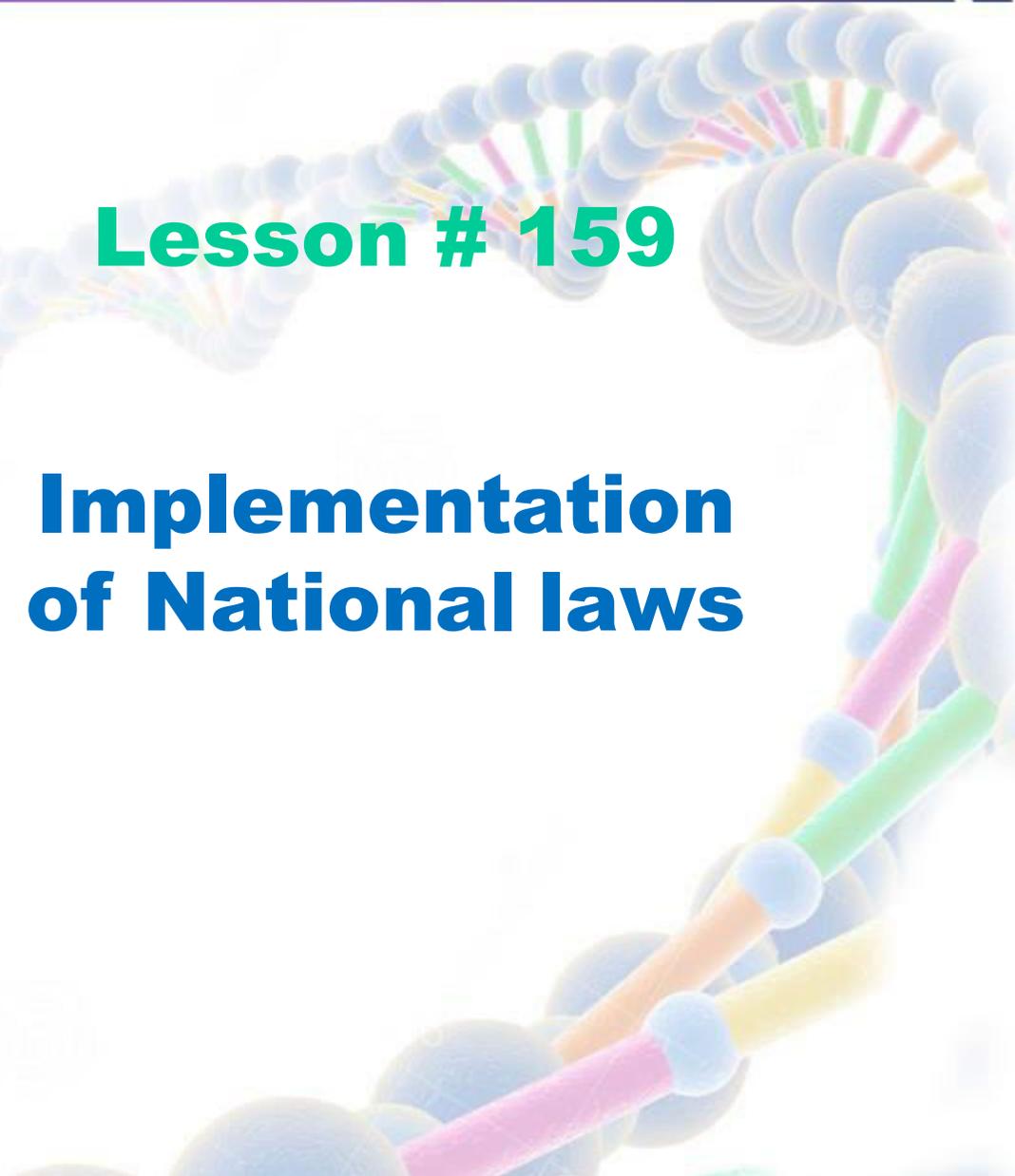
Pakistan biosafety measures



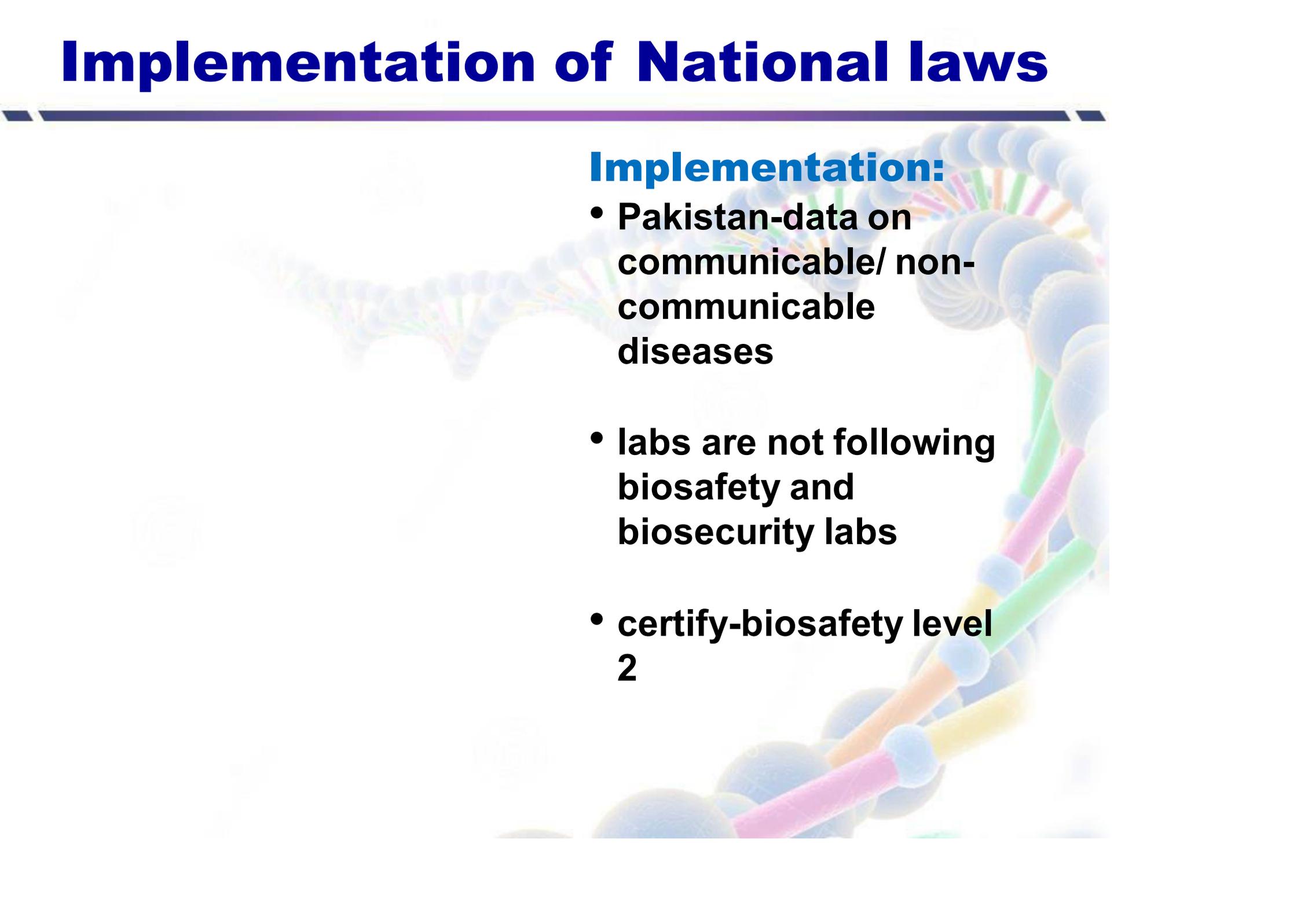
Biosafety

Lesson # 159

Implementation of National laws



Implementation of National laws



Implementation:

- **Pakistan-data on communicable/ non-communicable diseases**
- **labs are not following biosafety and biosecurity labs**
- **certify-biosafety level 2**

Implementation of National laws

Way out:

- need to conceptualize national strategic framework
- public sector labs
- efficient biosafety rules implementation

Implementation of National laws

Way out:

- **all provinces and stakeholders involved in loops-development cycle**
- **generate ownership**
- **mobilizing resources**
- **develop required human resource**

Biosecurity



Lesson # 160

Biosecurity



**Efforts to
mitigate
biological
threats**

Efforts to mitigate biological threats

Bioweapons:

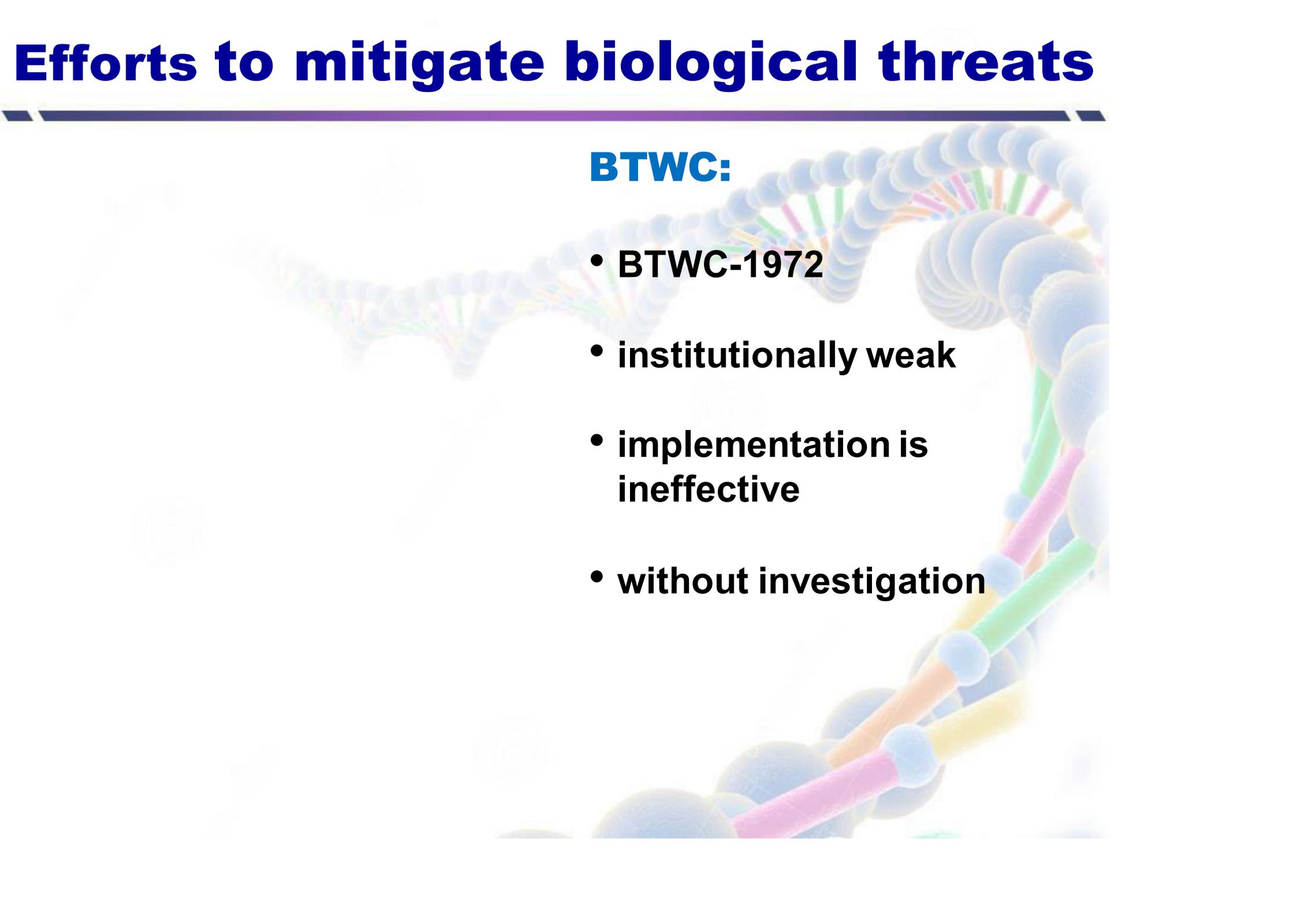
- any infectious agent used intentionally to cause harm to others
- planning of an effective biowar defence-difficult task
- nation and scientific community

Efforts to mitigate biological threats

Defence against bioweapons:

- international cooperation
- transfer of technology
- support national actions

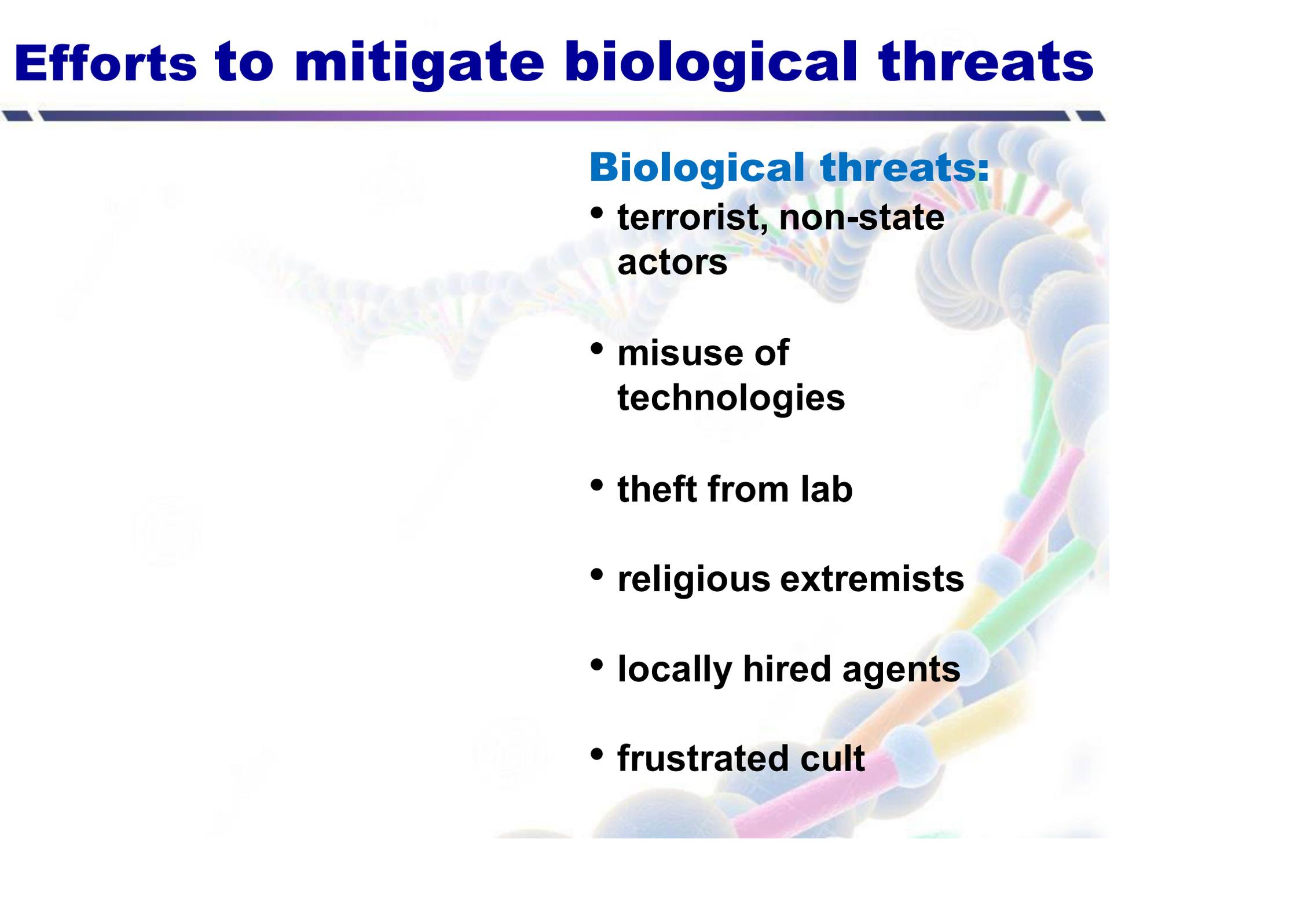
Efforts to mitigate biological threats



BTWC:

- **BTWC-1972**
- **institutionally weak**
- **implementation is ineffective**
- **without investigation**

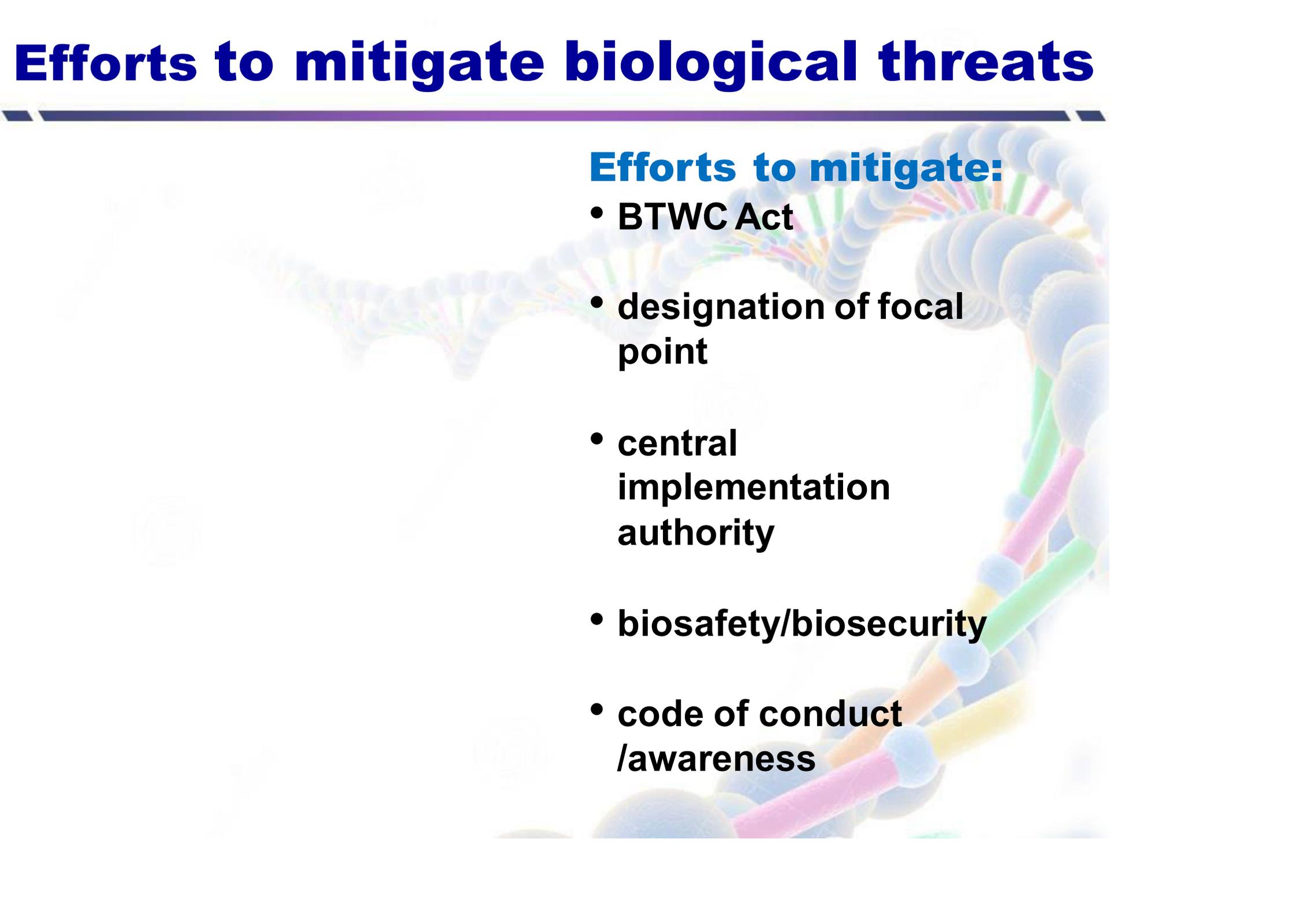
Efforts to mitigate biological threats



Biological threats:

- **terrorist, non-state actors**
- **misuse of technologies**
- **theft from lab**
- **religious extremists**
- **locally hired agents**
- **frustrated cult**

Efforts to mitigate biological threats



Efforts to mitigate:

- **BTWC Act**
- **designation of focal point**
- **central implementation authority**
- **biosafety/biosecurity**
- **code of conduct /awareness**

Efforts to mitigate biological threats



Pakistan's approach:

- **front-line of “War on terror”**
- **financial and human loss**
- **bioweapons are not the part of security matrix**

Efforts to mitigate biological threats

Pakistan's approach:

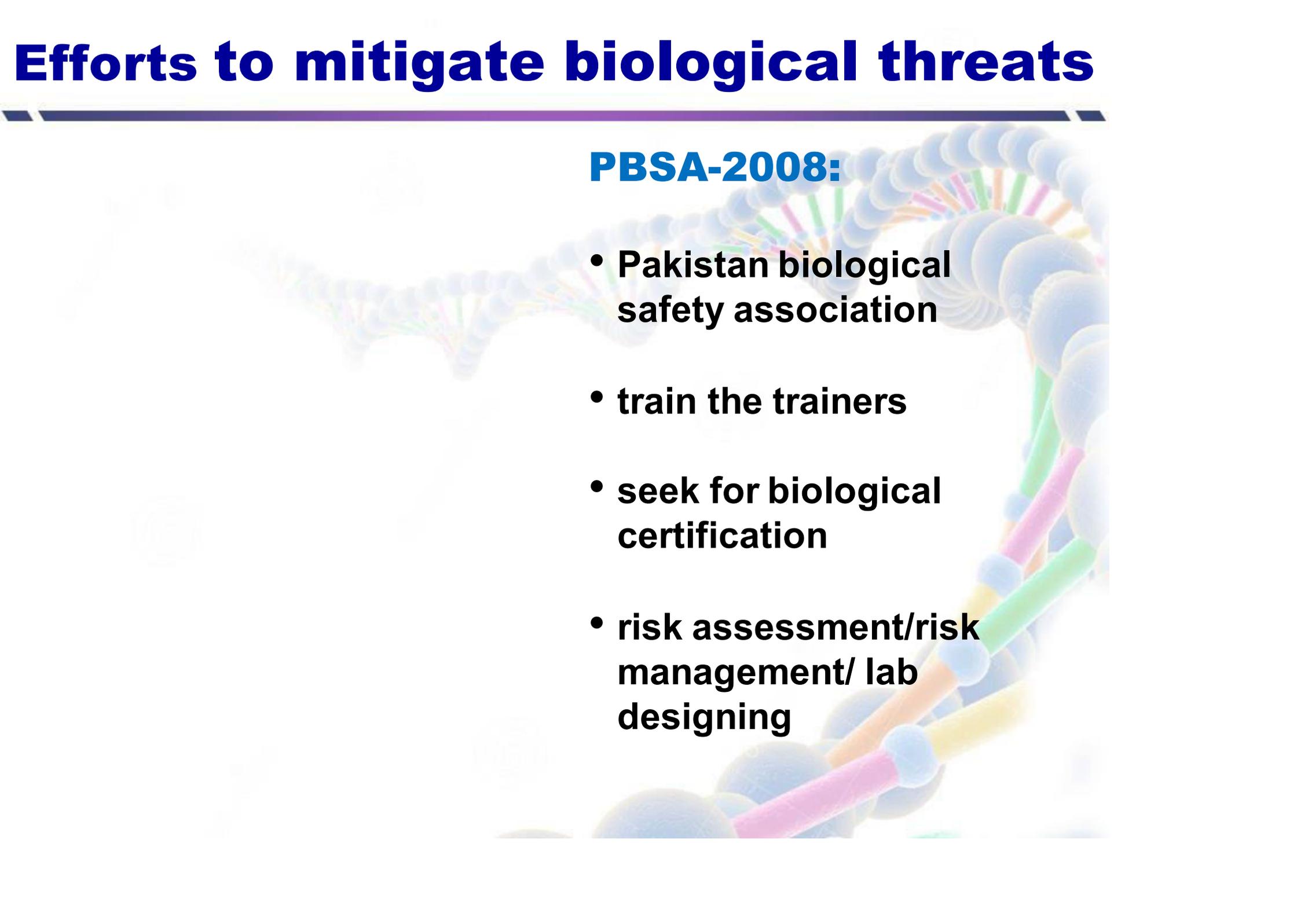
- tremendous progress
- legislations
- administrative measures

Efforts to mitigate biological threats

NCGLs-2007:

- **national core group of life sciences**
- **biosafety -syllabus**
- **final review by HEC**

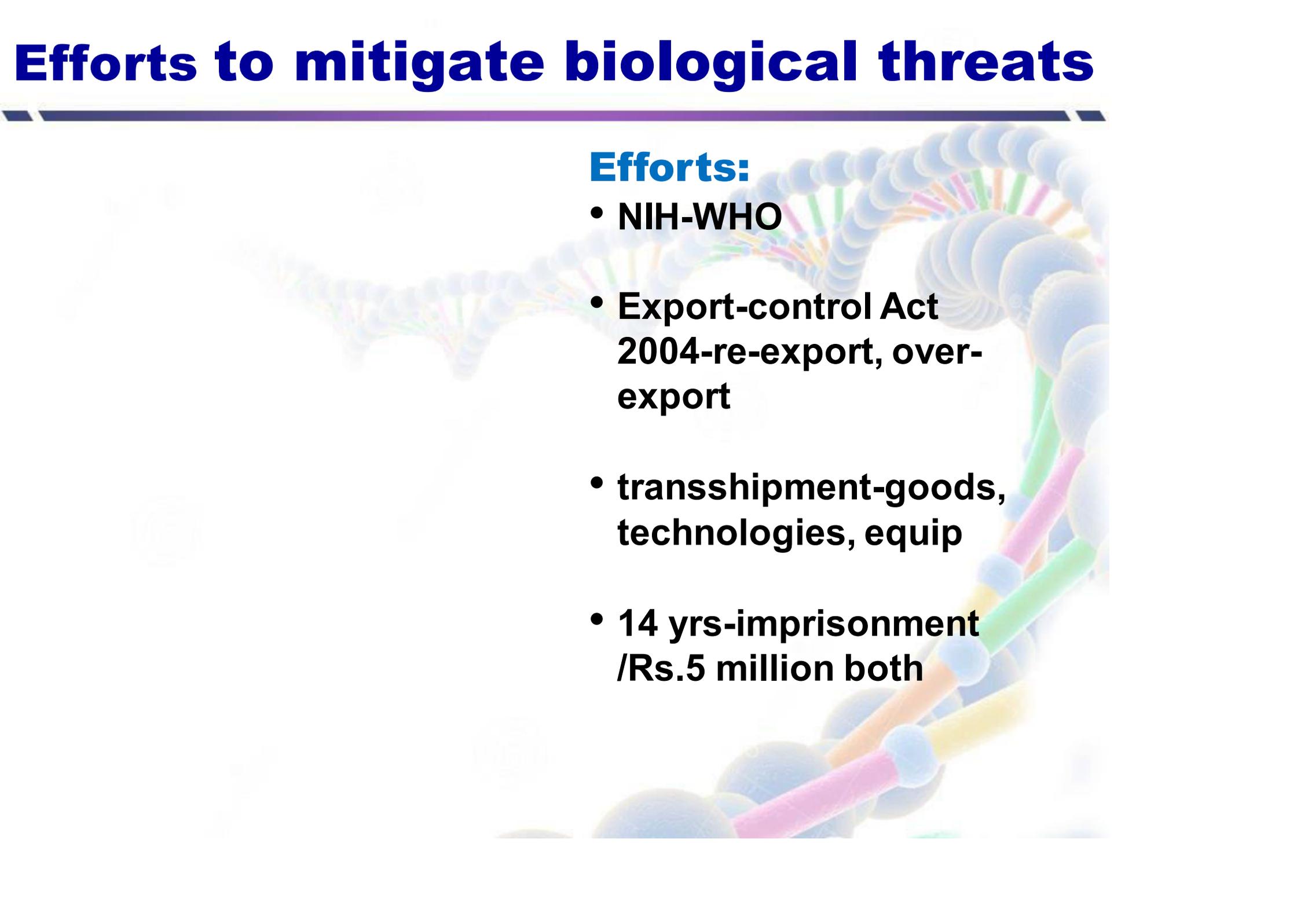
Efforts to mitigate biological threats



PBSA-2008:

- **Pakistan biological safety association**
- **train the trainers**
- **seek for biological certification**
- **risk assessment/risk management/ lab designing**

Efforts to mitigate biological threats



Efforts:

- NIH-WHO
- Export-control Act 2004-re-export, over-export
- transshipment-goods, technologies, equip
- 14 yrs-imprisonment /Rs.5 million both

Biosecurity

Lesson # 161

Threats of biological weapons



Threats of biological weapons

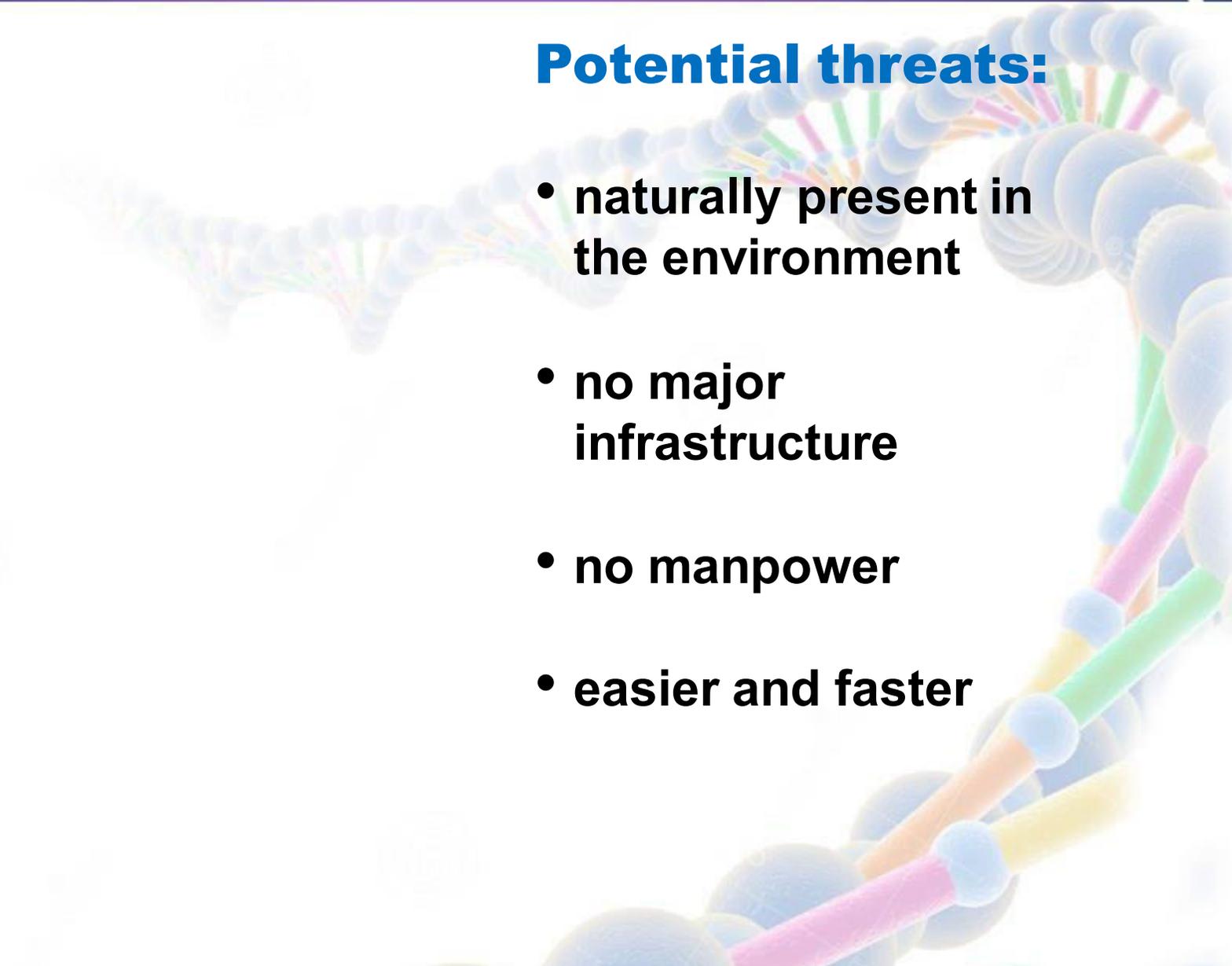


History:

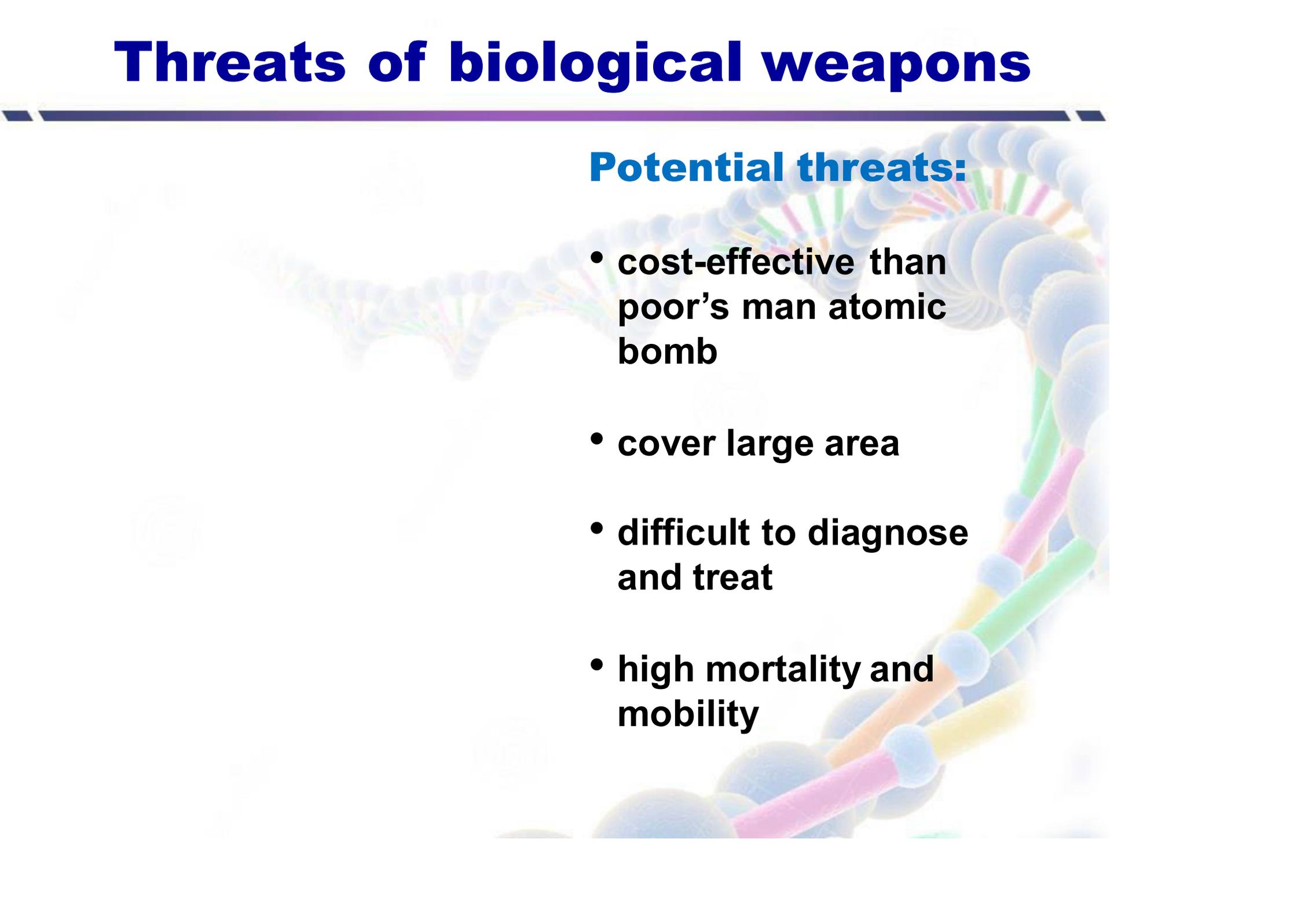
- 2001 - Tom Dachele – received a letter of anthrax
- 23 members of the staff
- 5 police officers
- positive-nasal swabs
- citizen-stockpiling - Ciprofloxacin

Threats of biological weapons

Potential threats:

- naturally present in the environment
 - no major infrastructure
 - no manpower
 - easier and faster
- 

Threats of biological weapons

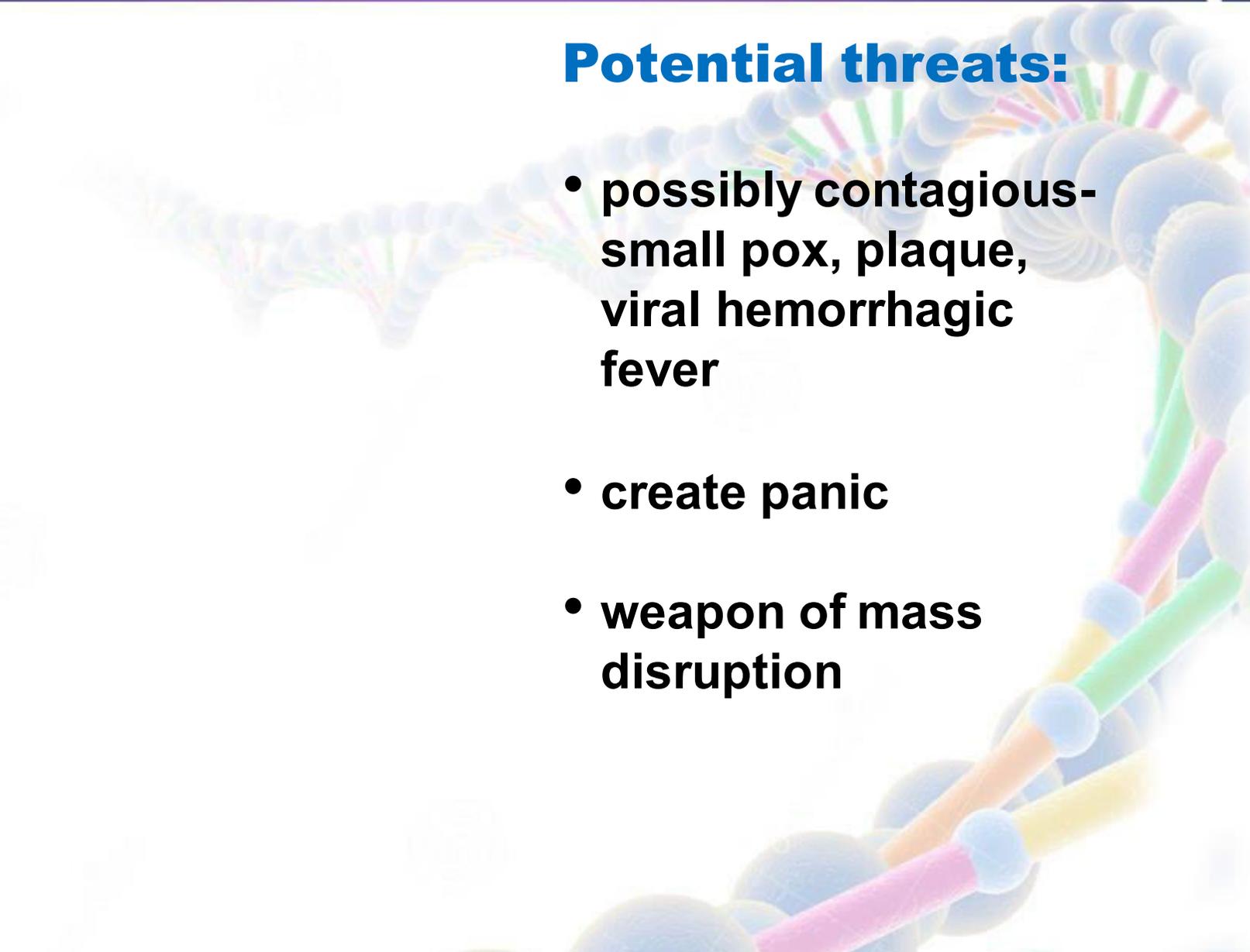


Potential threats:

- **cost-effective than poor's man atomic bomb**
- **cover large area**
- **difficult to diagnose and treat**
- **high mortality and mobility**

Threats of biological weapons

Potential threats:

- possibly contagious-
small pox, plaque,
viral hemorrhagic
fever
 - create panic
 - weapon of mass
disruption
- 

Threats of biological weapons

Potential threats:

- **detection devices, equipment for surveillance-expensive**
- **not present in many countries**

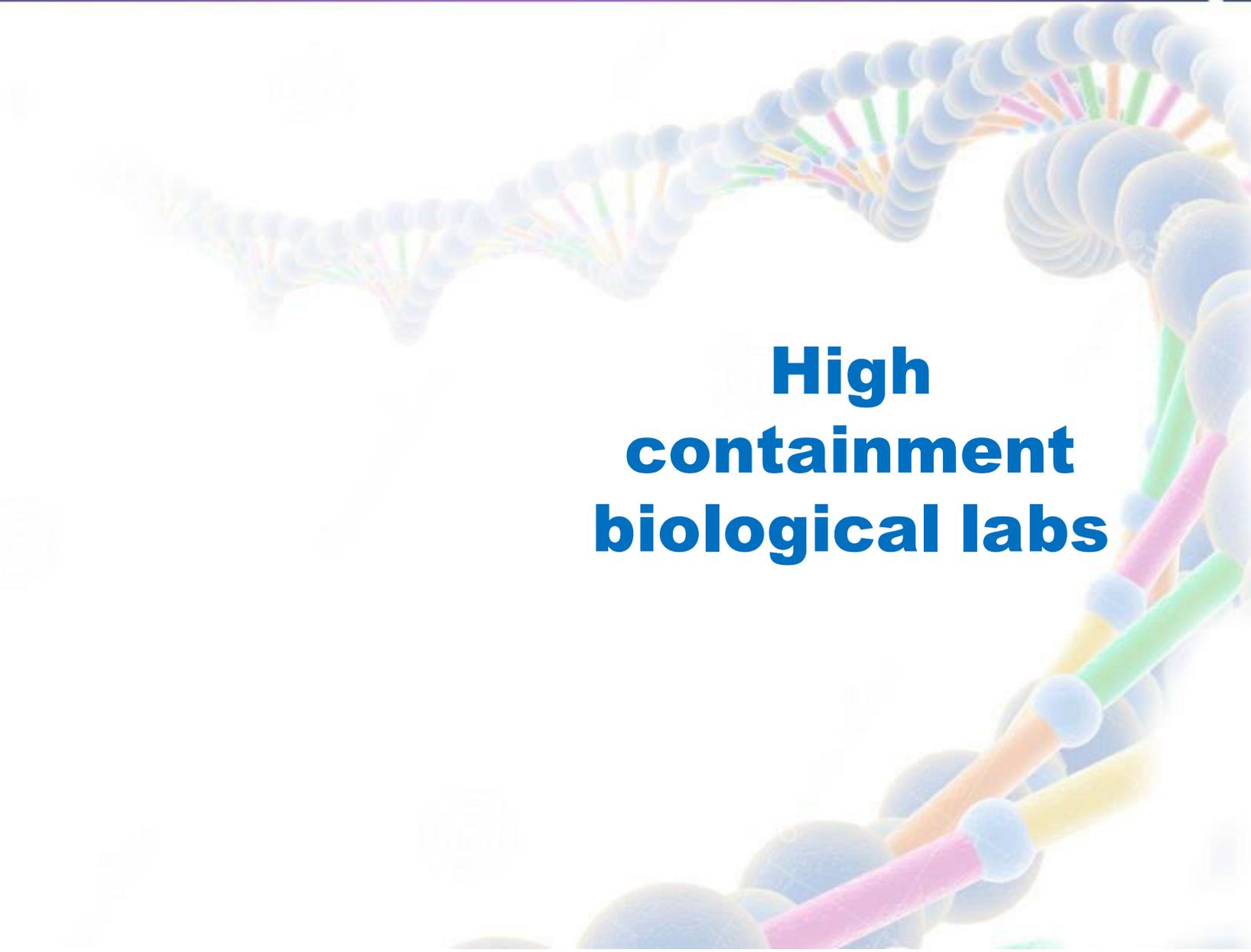


Biosecurity



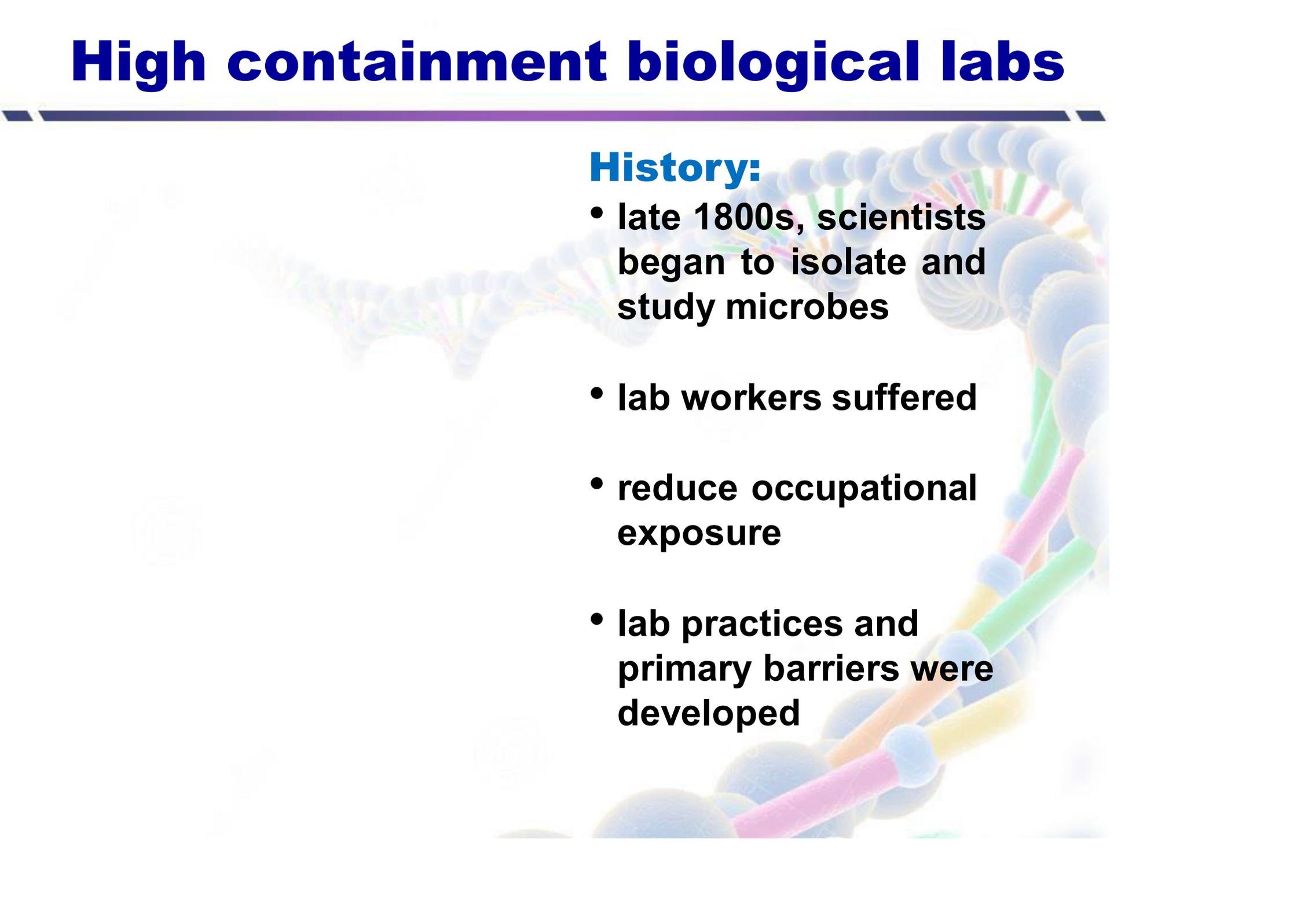
Lesson # 162

Biosecurity



**High
containment
biological labs**

High containment biological labs



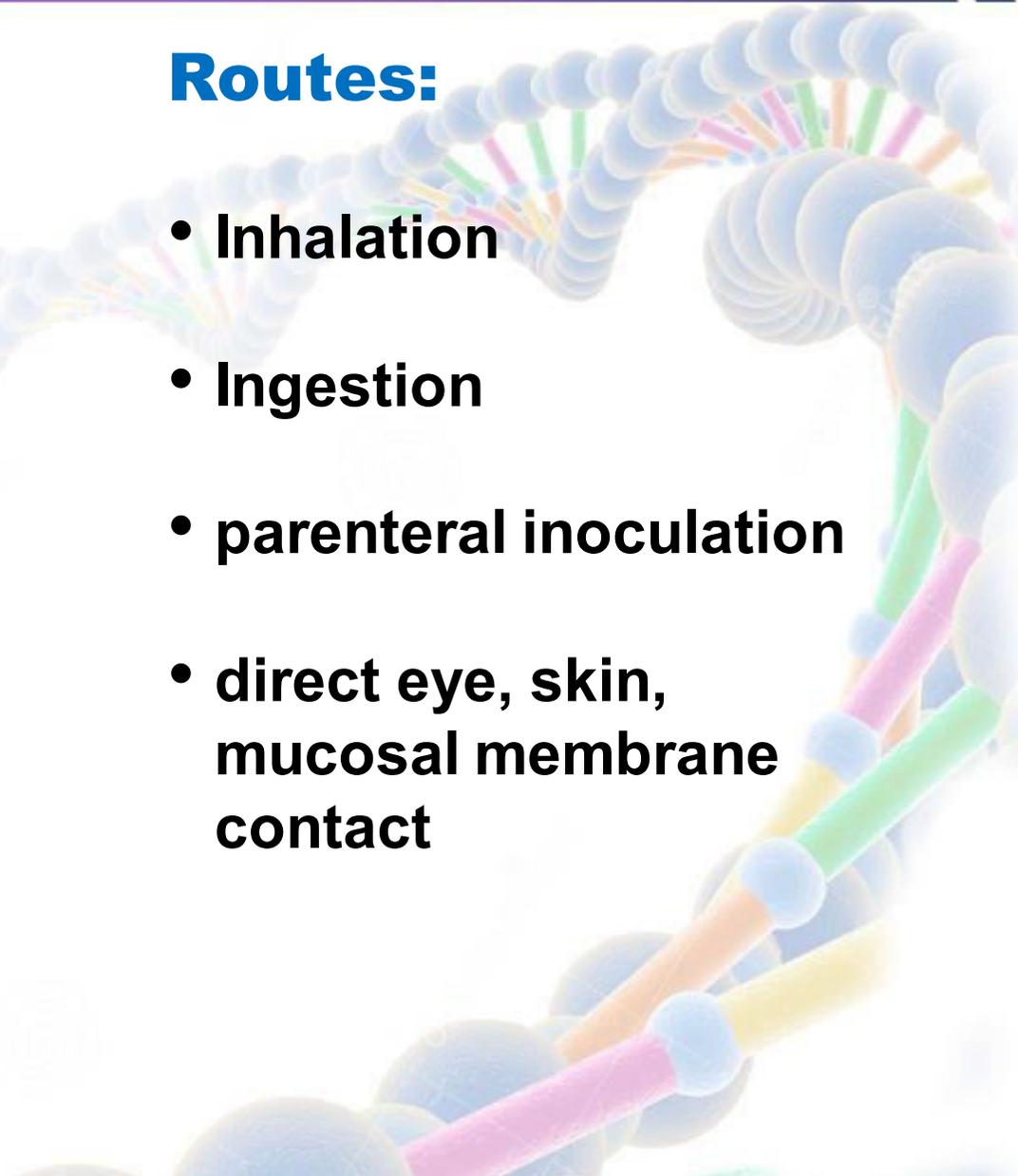
History:

- late 1800s, scientists began to isolate and study microbes
- lab workers suffered
- reduce occupational exposure
- lab practices and primary barriers were developed

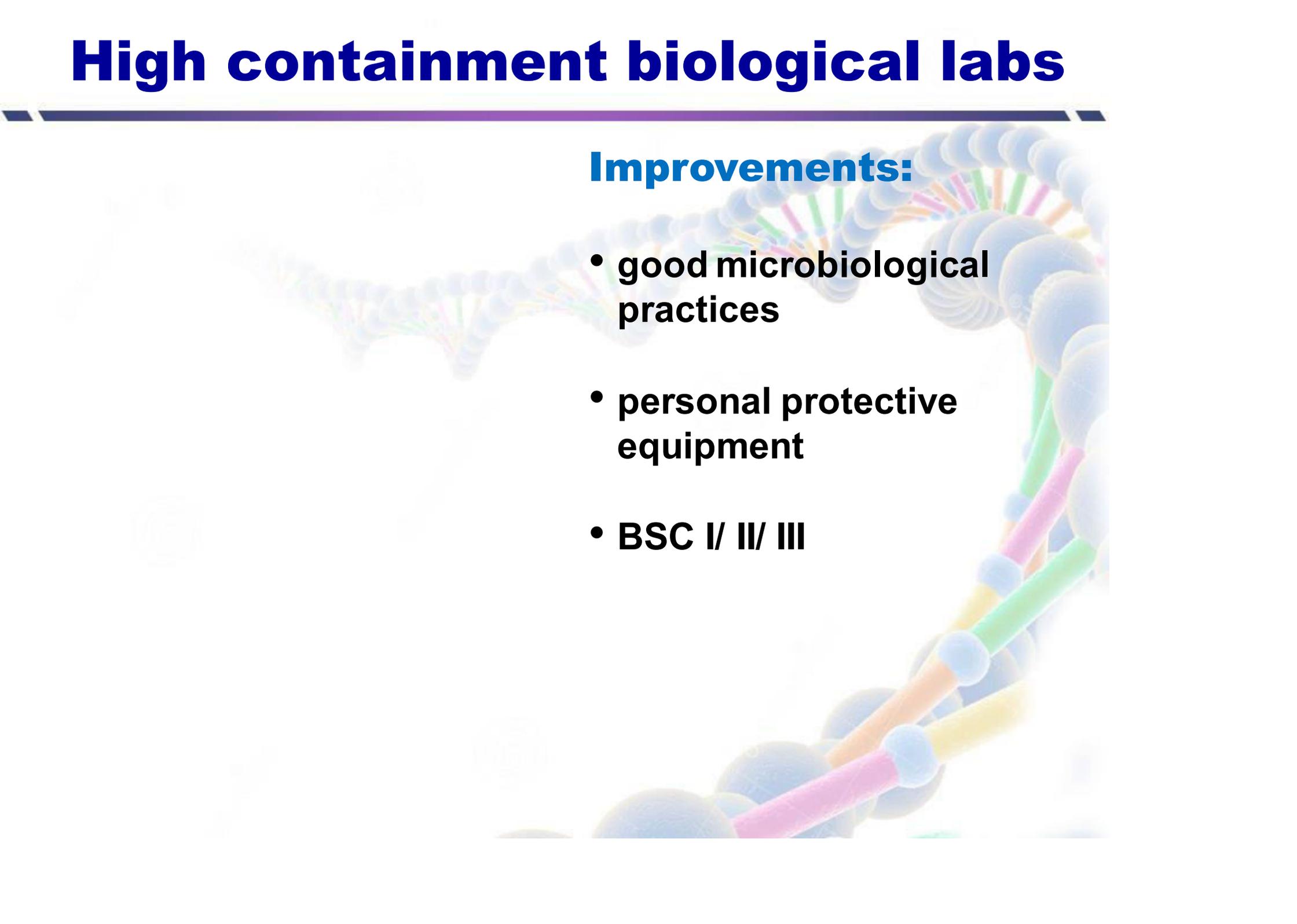
High containment biological labs

Routes:

- Inhalation
- Ingestion
- parenteral inoculation
- direct eye, skin, mucosal membrane contact



High containment biological labs



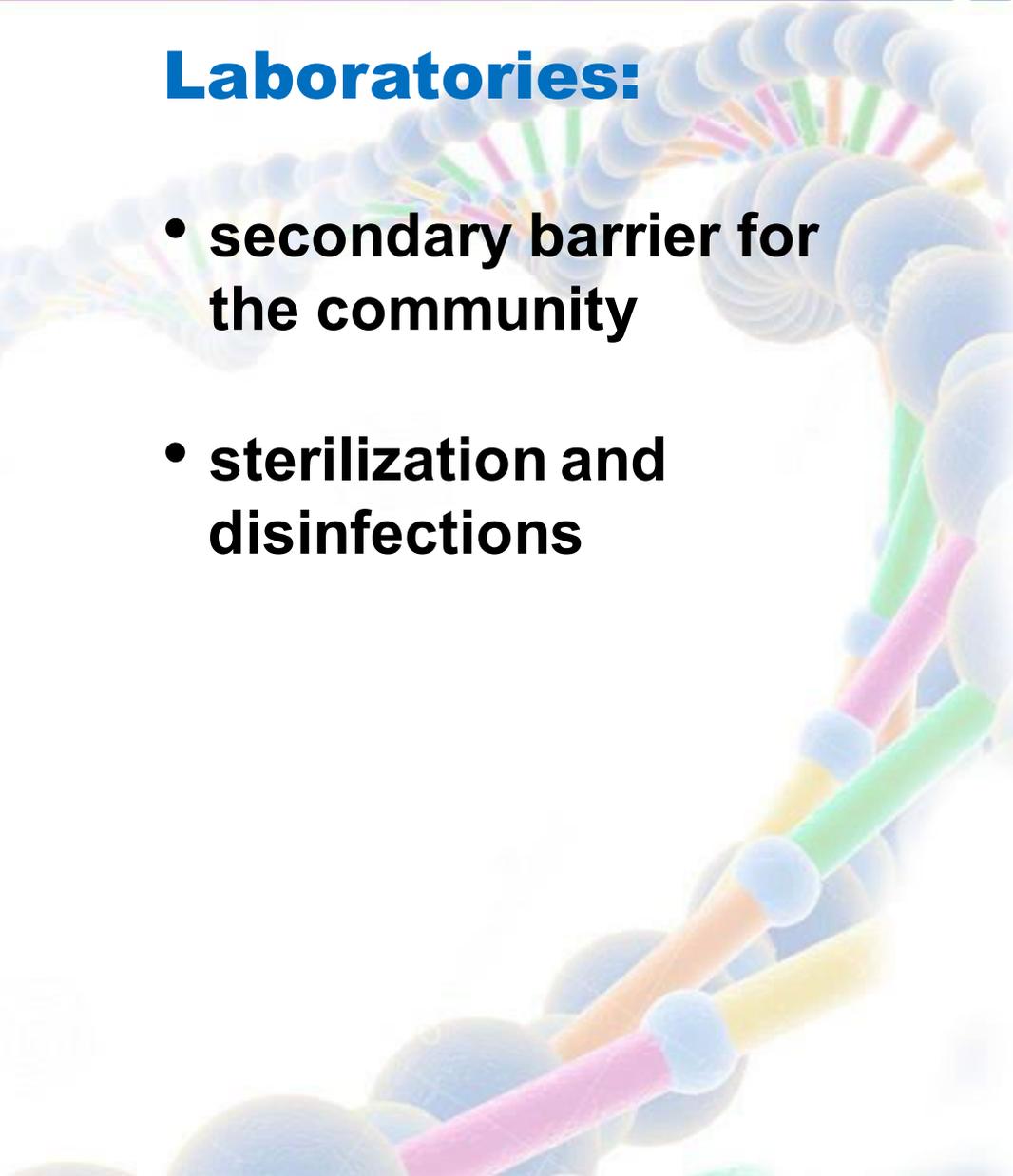
Improvements:

- good microbiological practices
- personal protective equipment
- BSC I / II / III

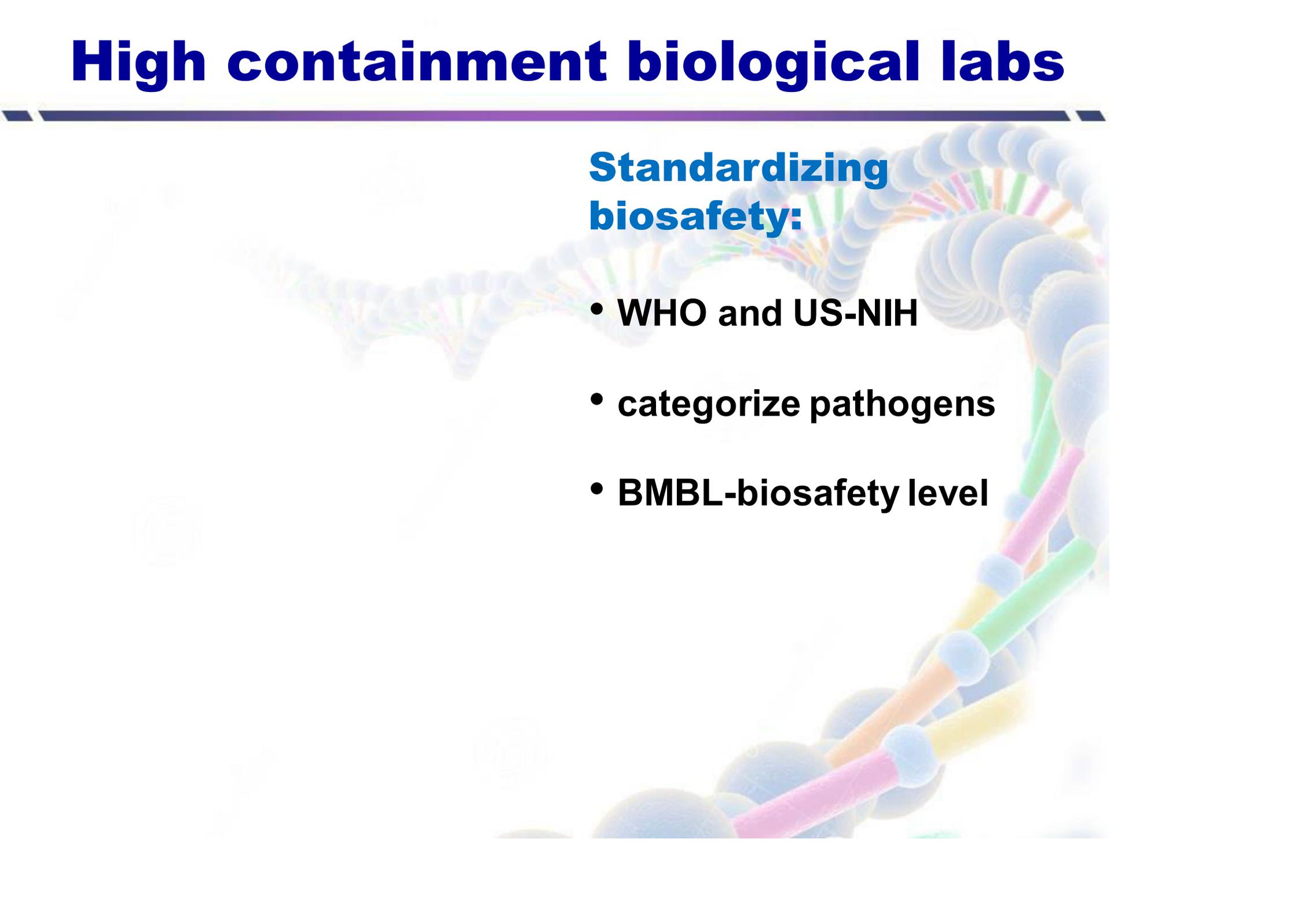
High containment biological labs

Laboratories:

- secondary barrier for the community
- sterilization and disinfections



High containment biological labs



Standardizing biosafety:

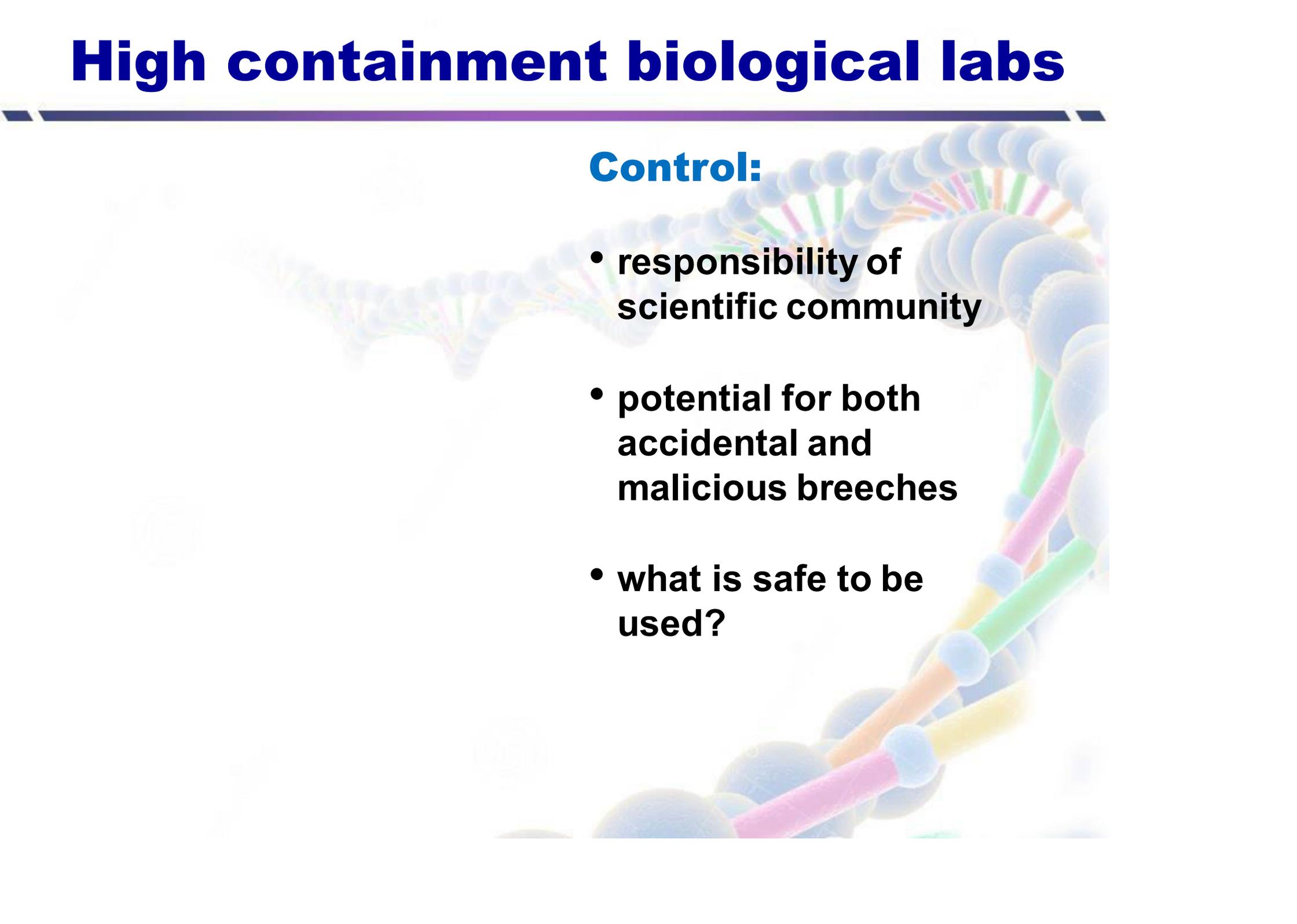
- WHO and US-NIH
- categorize pathogens
- BMBL-biosafety level

High containment biological labs

High containment labs:

- **Tsunami - blame government-lack of preparation**
- **Tsunami in labs**
- **biosafety and biosecurity-Africa and south Asian countries**

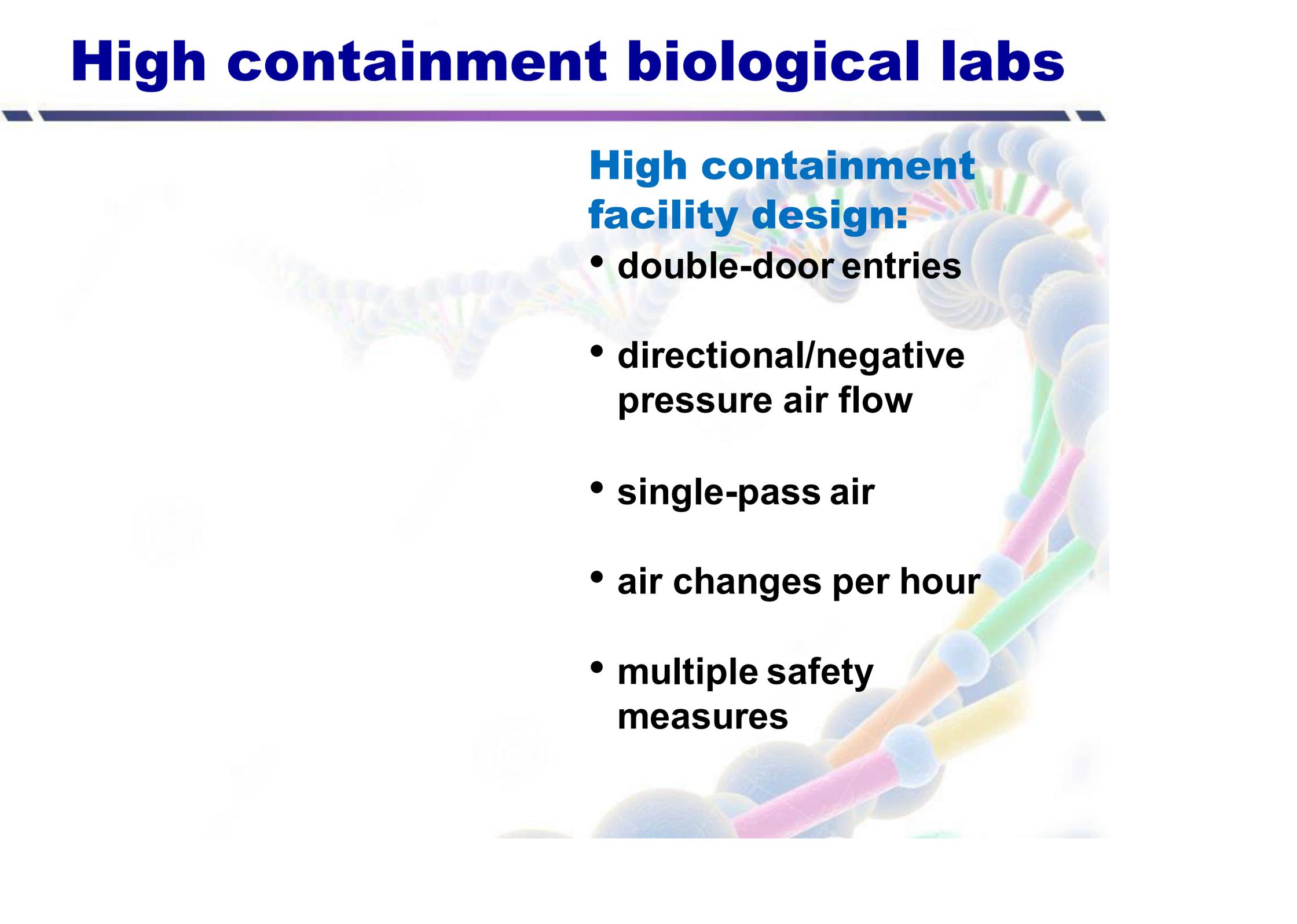
High containment biological labs



Control:

- responsibility of scientific community
- potential for both accidental and malicious breaches
- what is safe to be used?

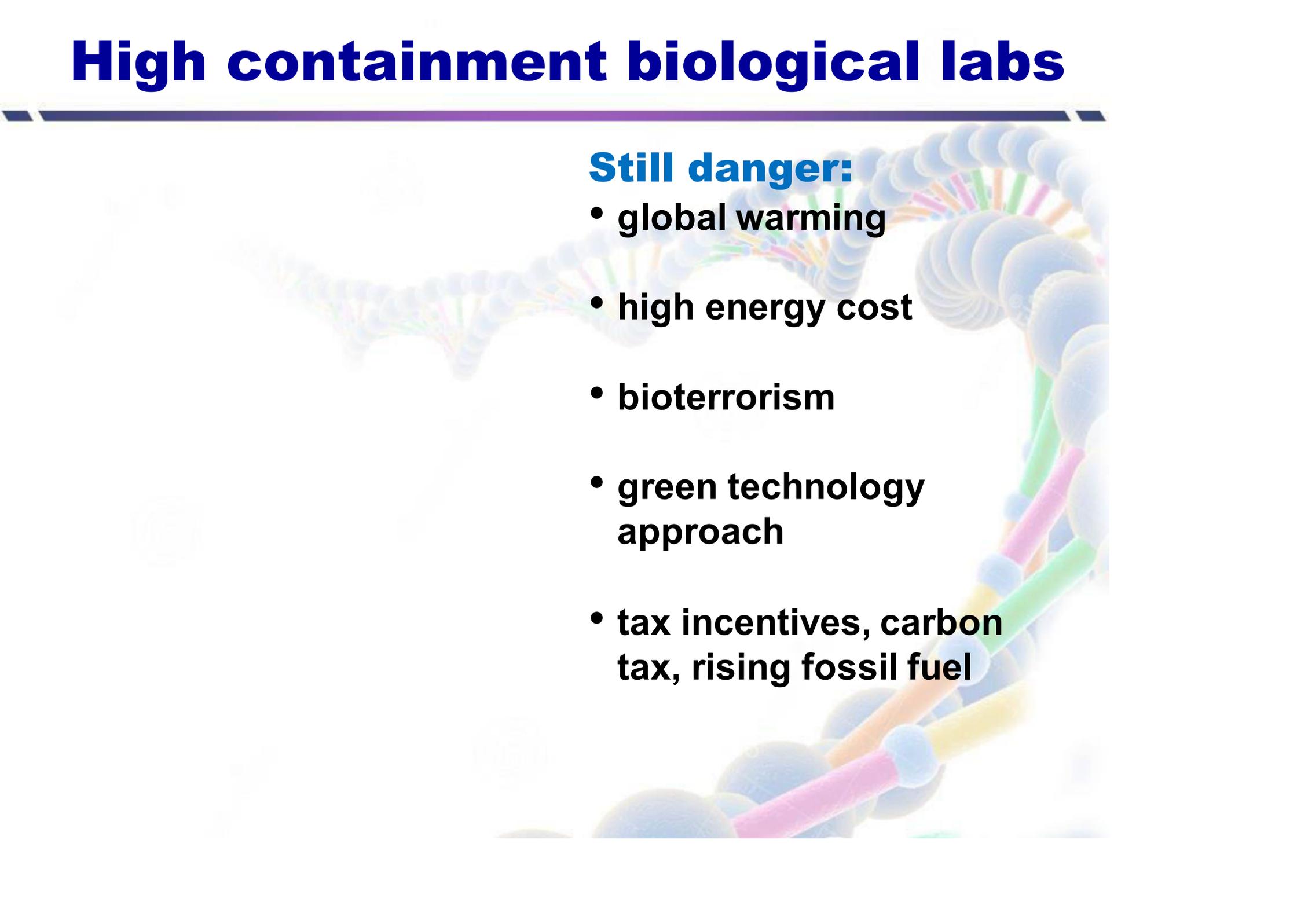
High containment biological labs



High containment facility design:

- double-door entries
- directional/negative pressure air flow
- single-pass air
- air changes per hour
- multiple safety measures

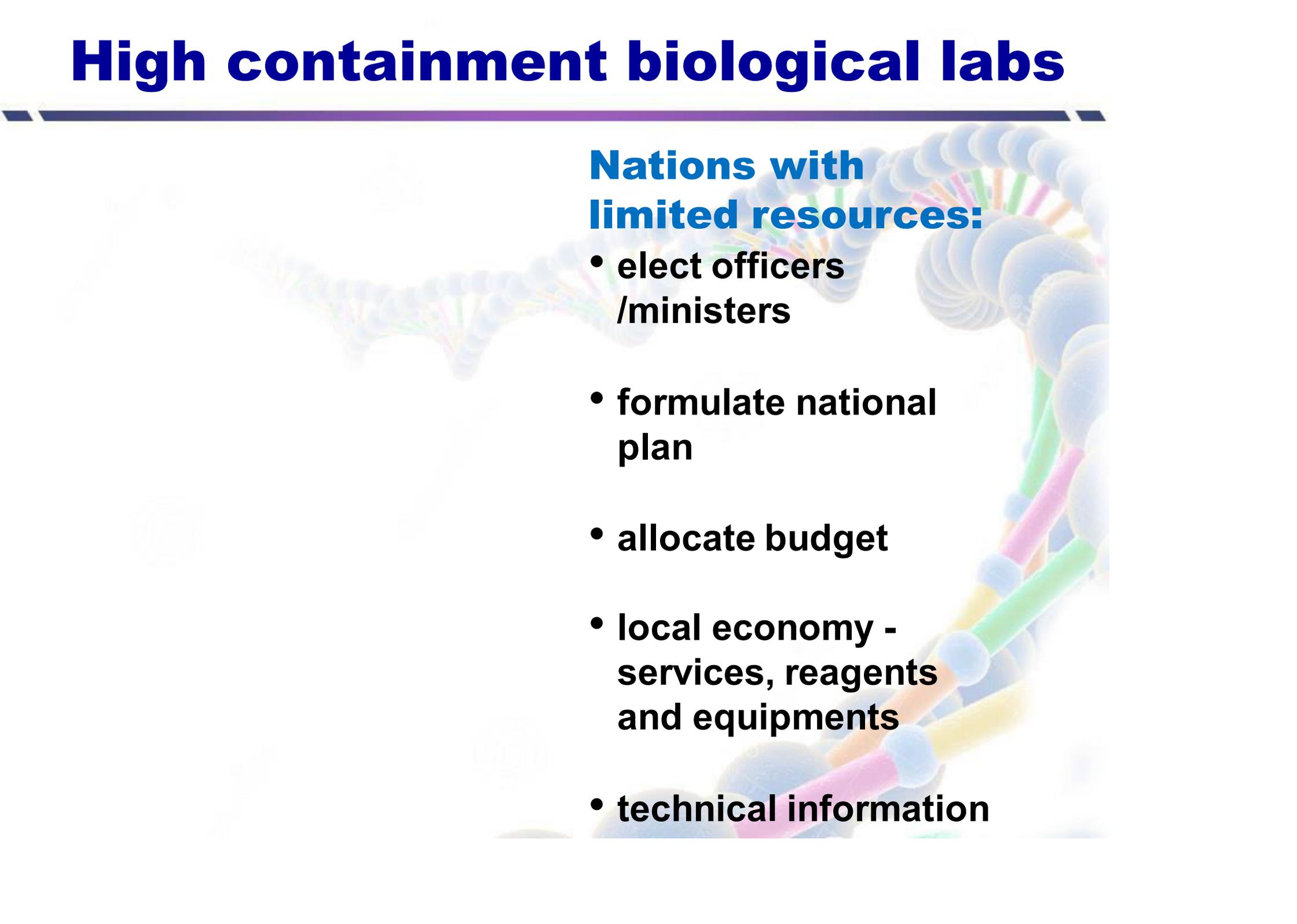
High containment biological labs



Still danger:

- **global warming**
- **high energy cost**
- **bioterrorism**
- **green technology approach**
- **tax incentives, carbon tax, rising fossil fuel**

High containment biological labs



Nations with limited resources:

- **elect officers /ministers**
- **formulate national plan**
- **allocate budget**
- **local economy - services, reagents and equipments**
- **technical information**

High containment biological labs

Global control:

- organizations
- legislations
- guidelines

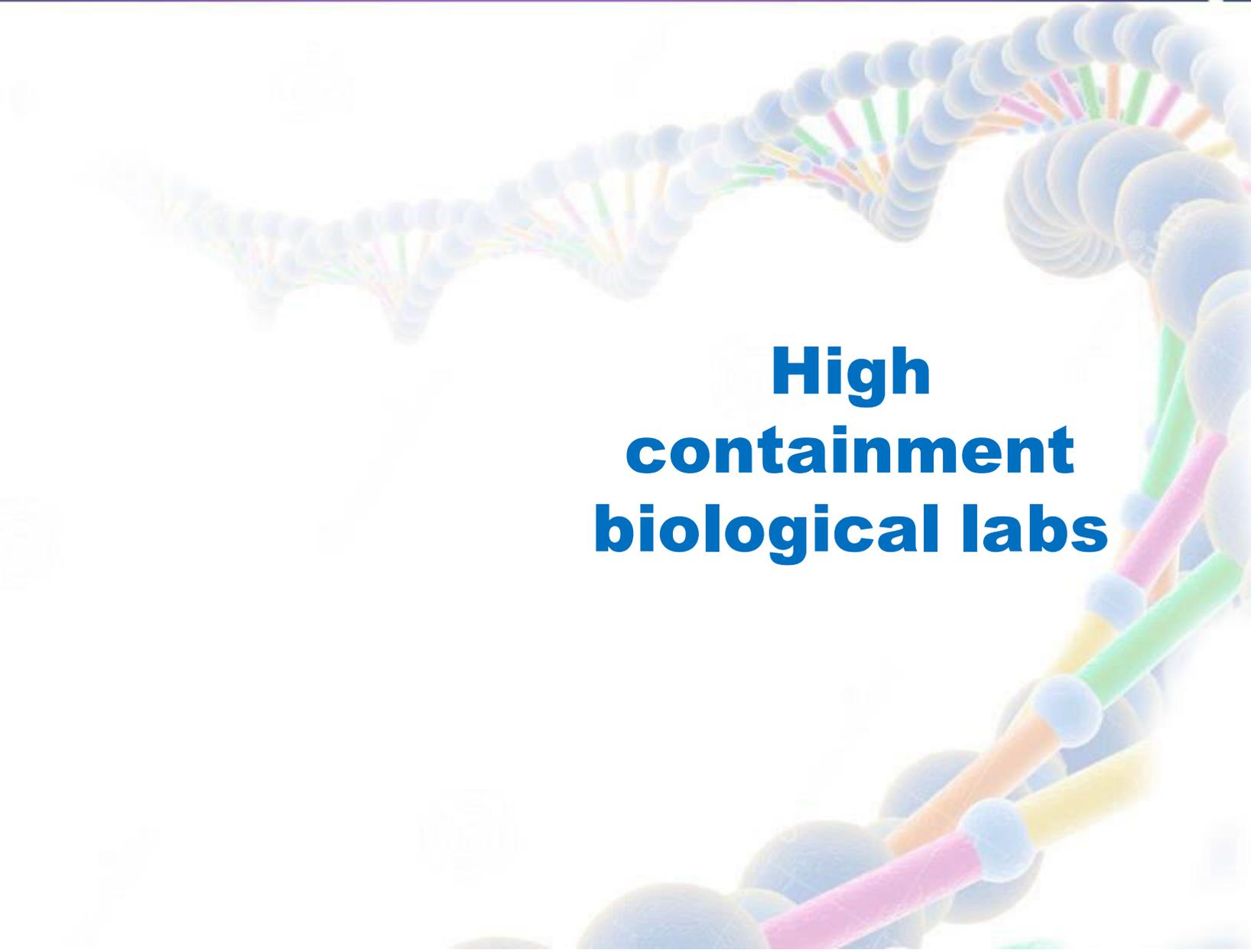


Biosecurity



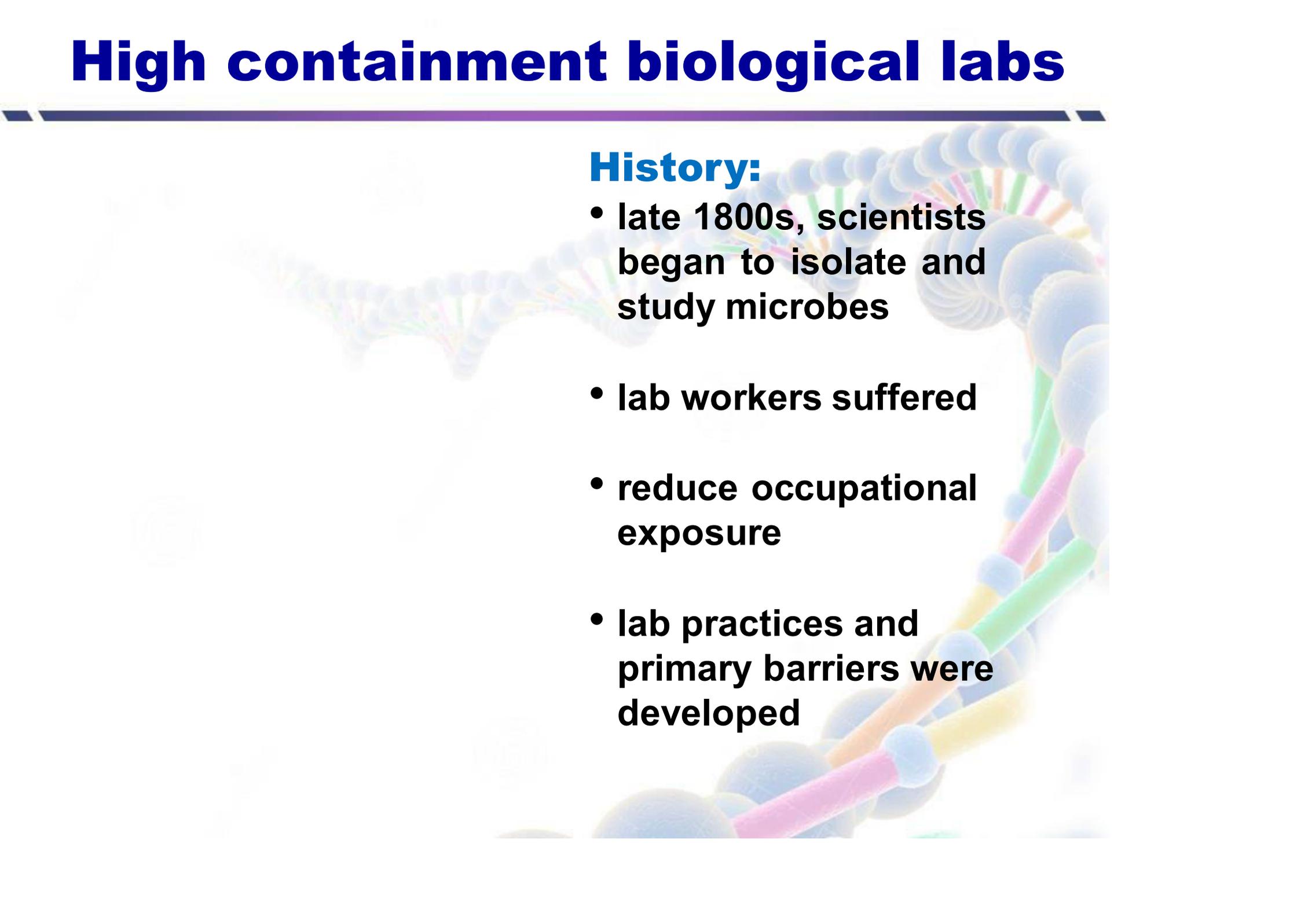
Lesson # 163

Biosecurity



**High
containment
biological labs**

High containment biological labs



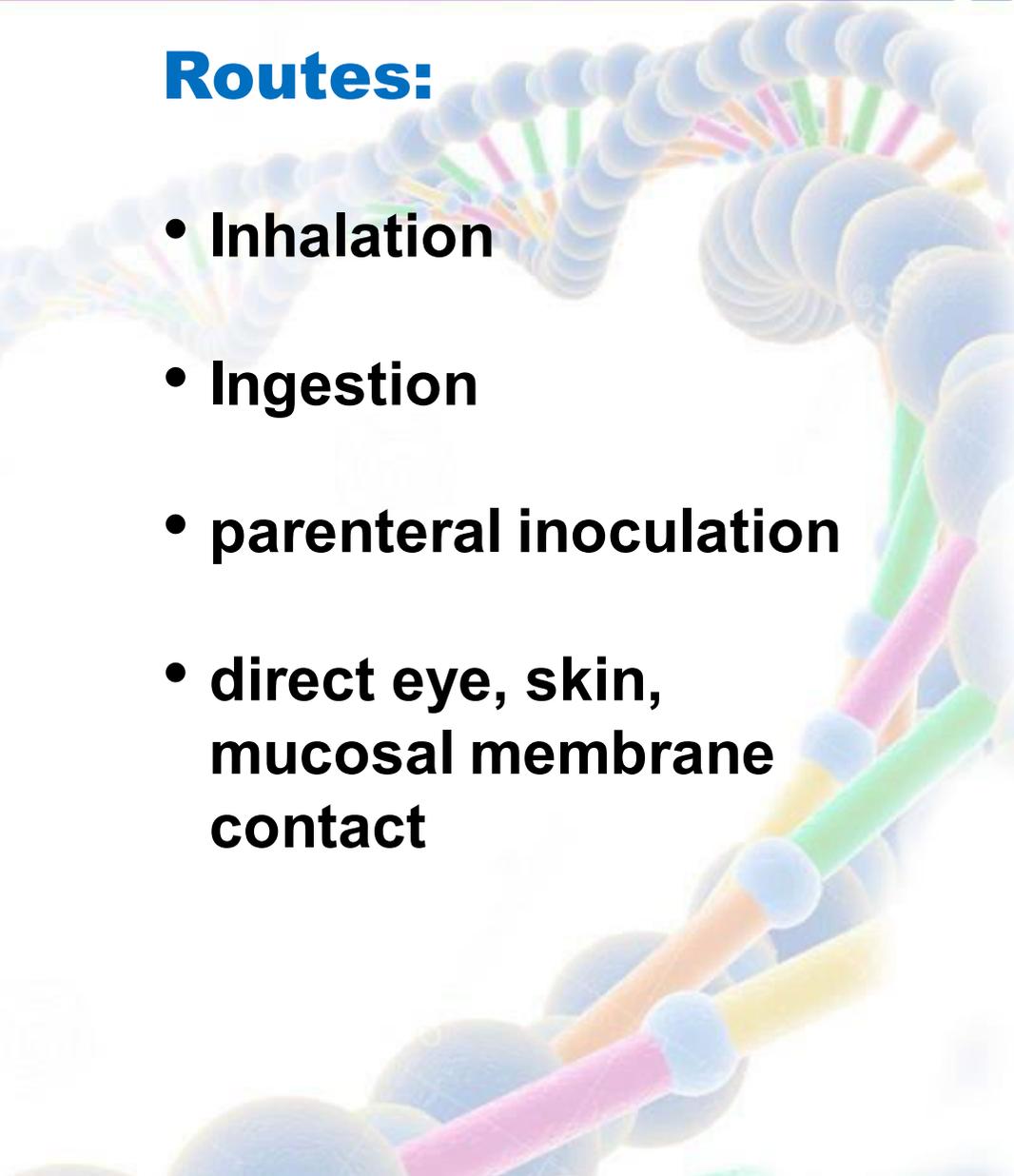
History:

- late 1800s, scientists began to isolate and study microbes
- lab workers suffered
- reduce occupational exposure
- lab practices and primary barriers were developed

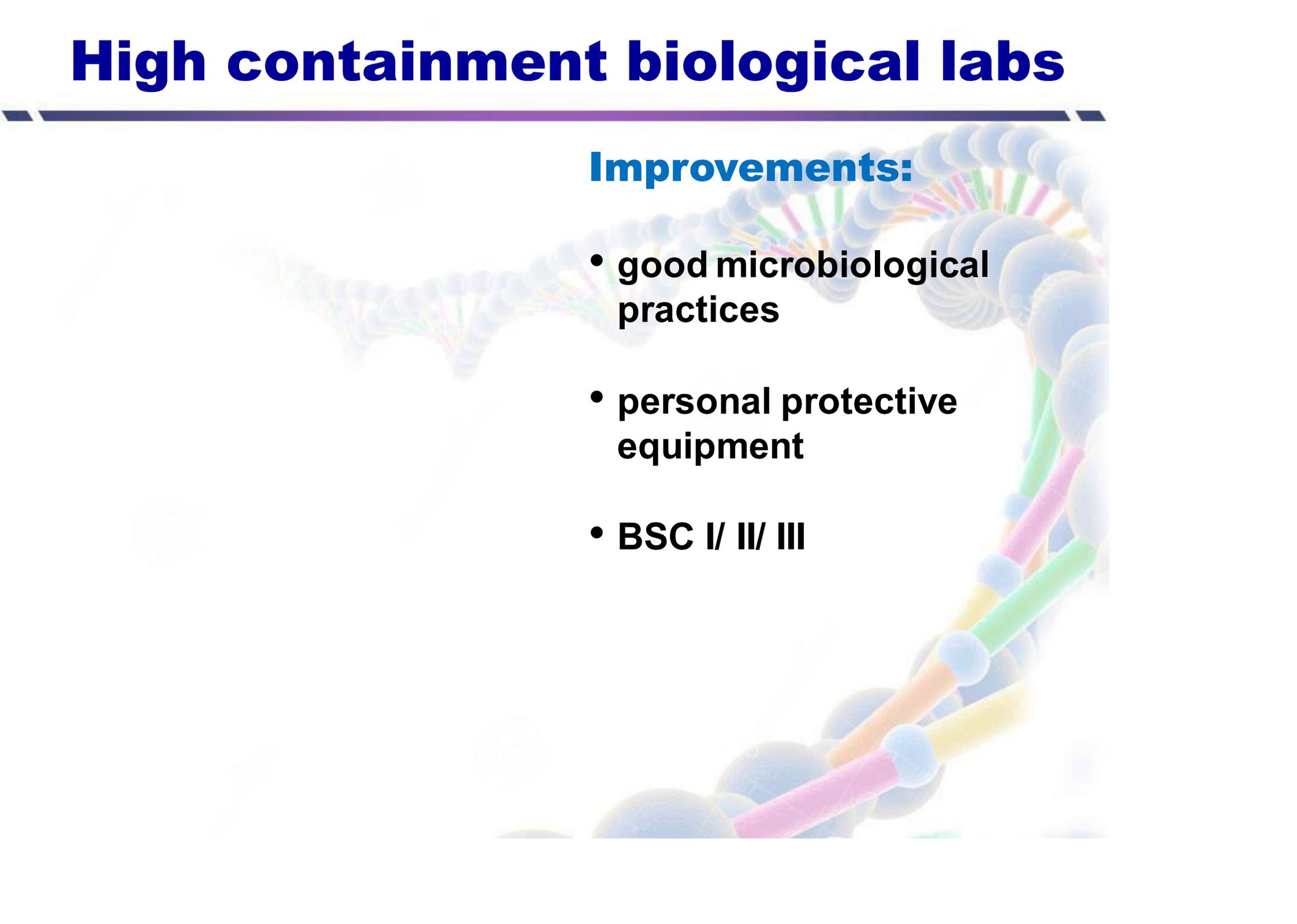
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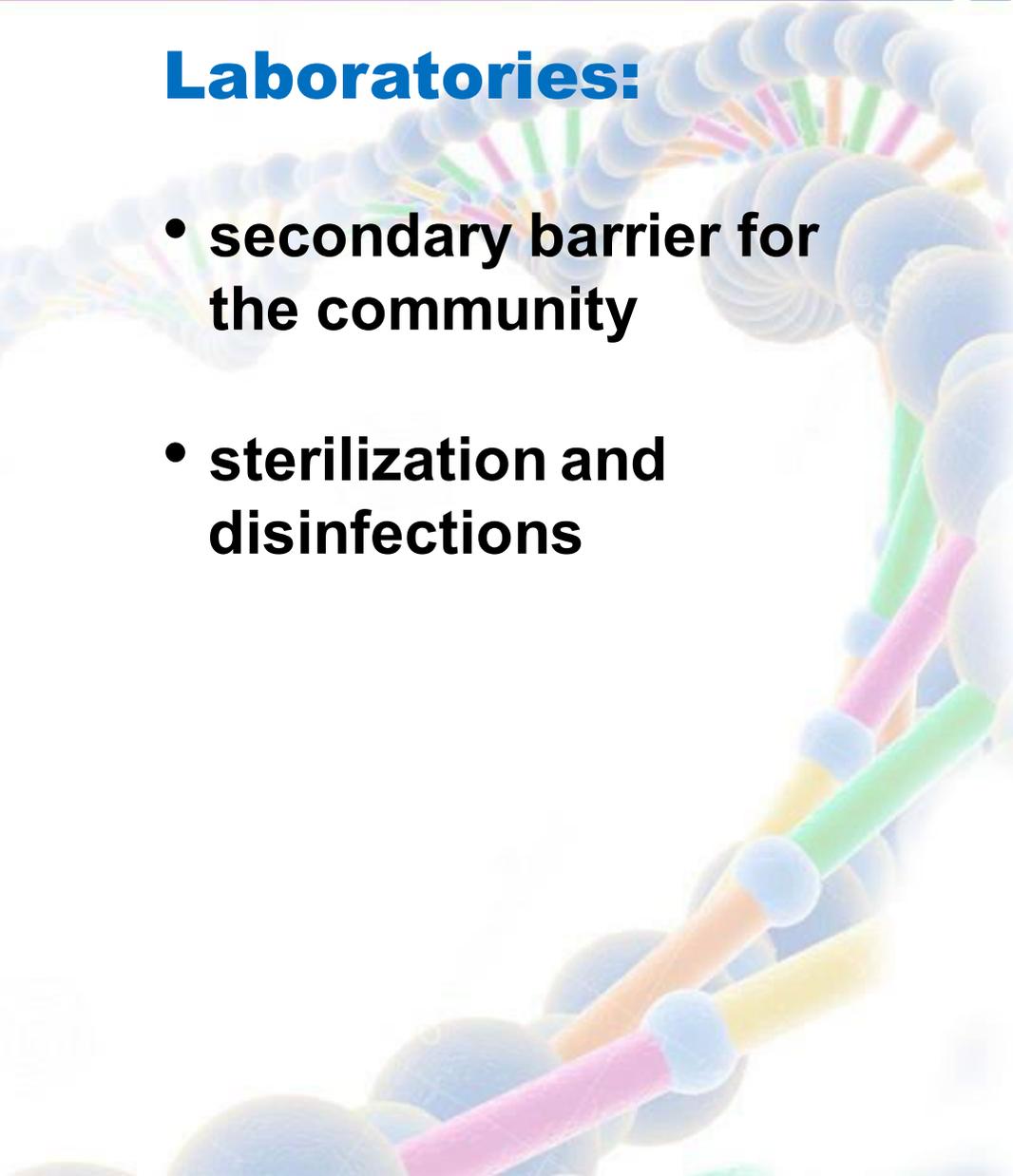
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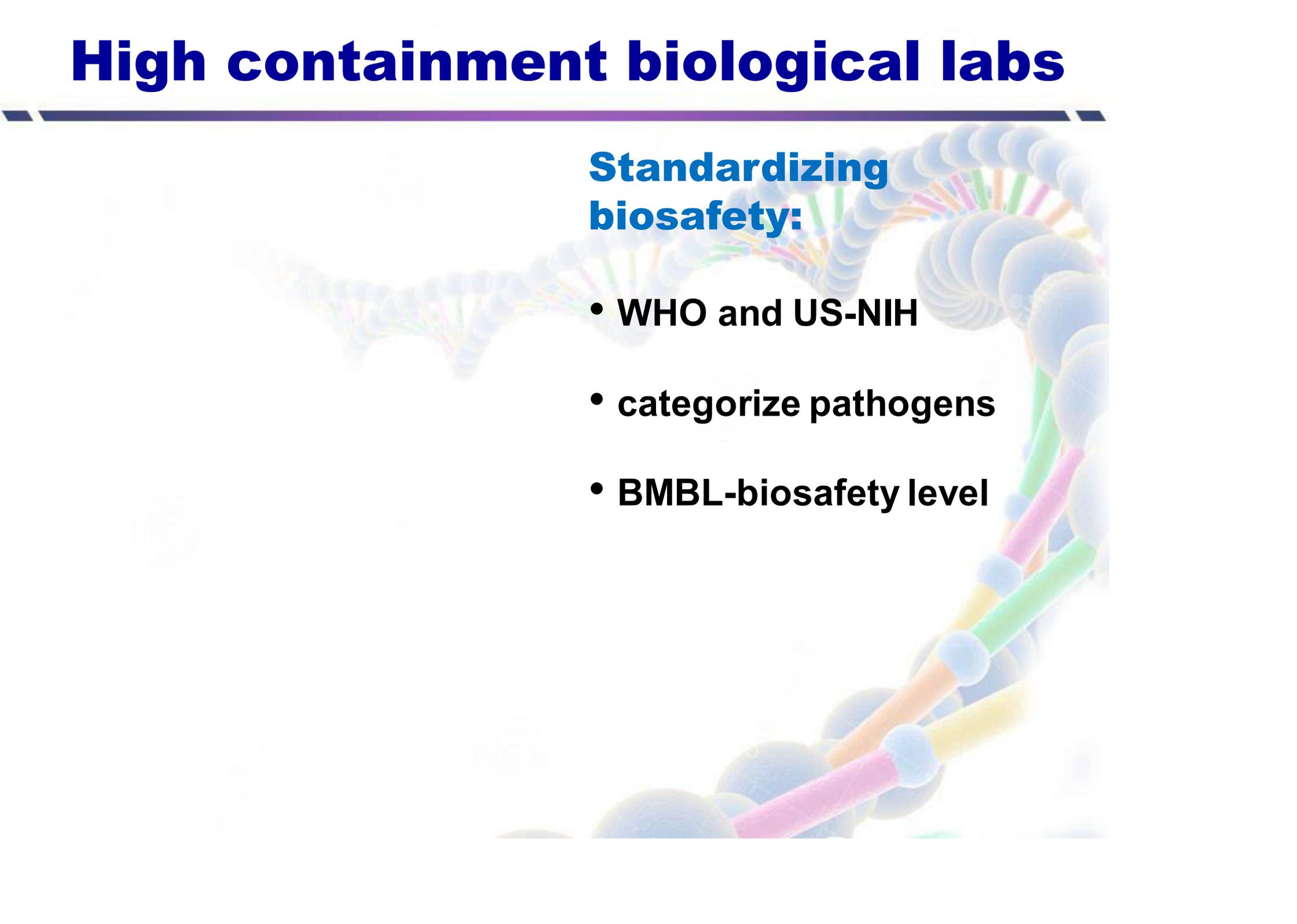
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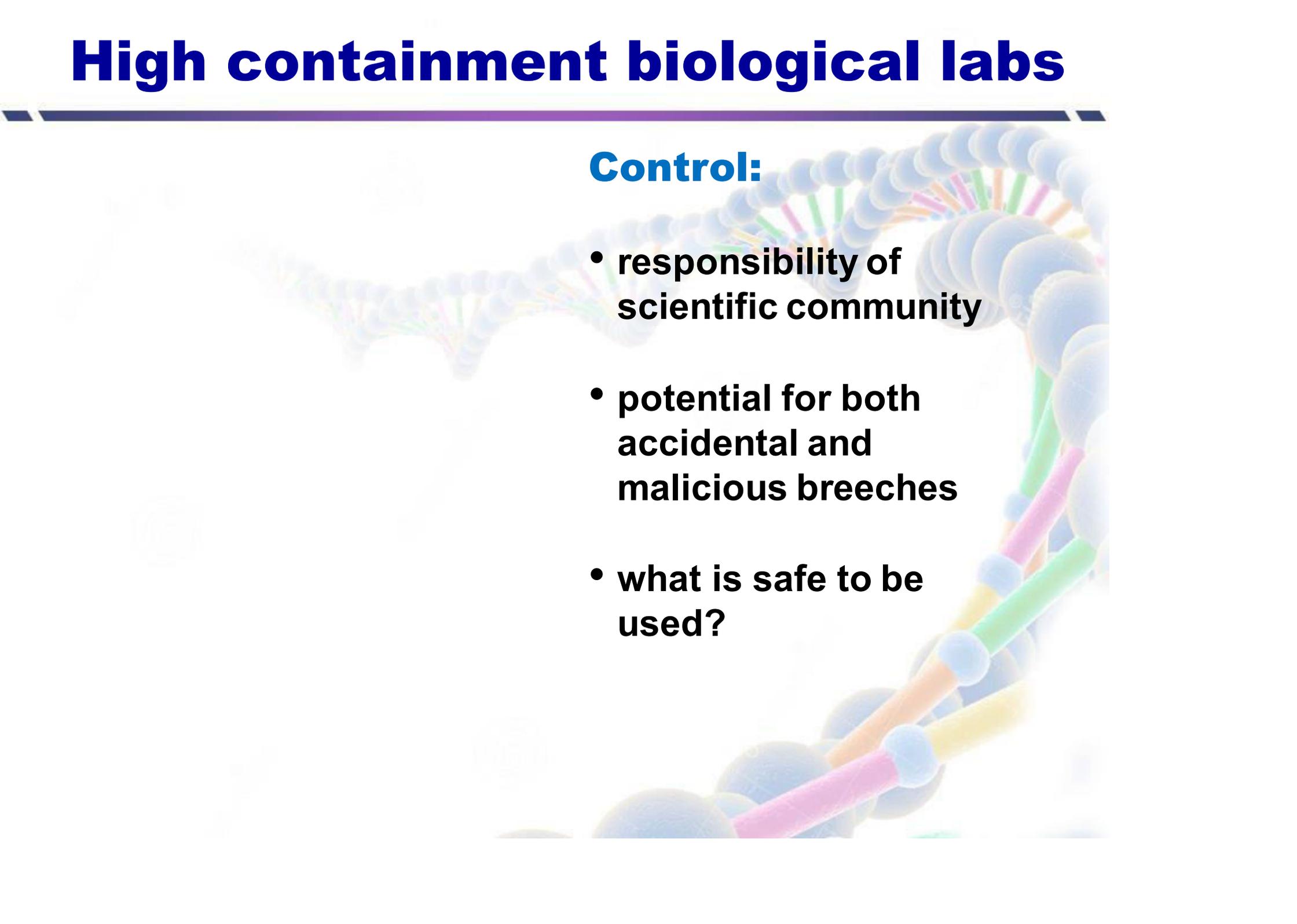
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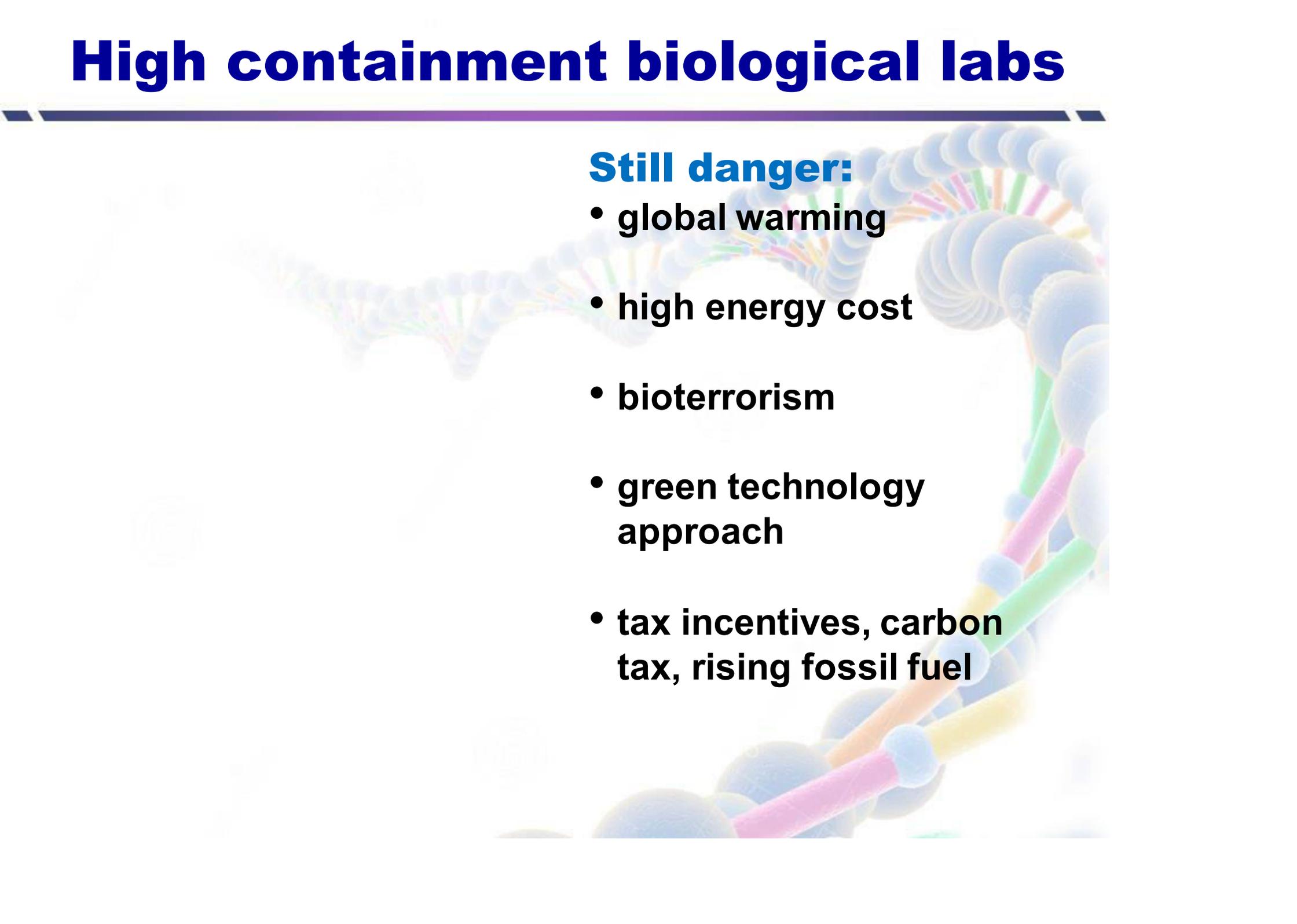
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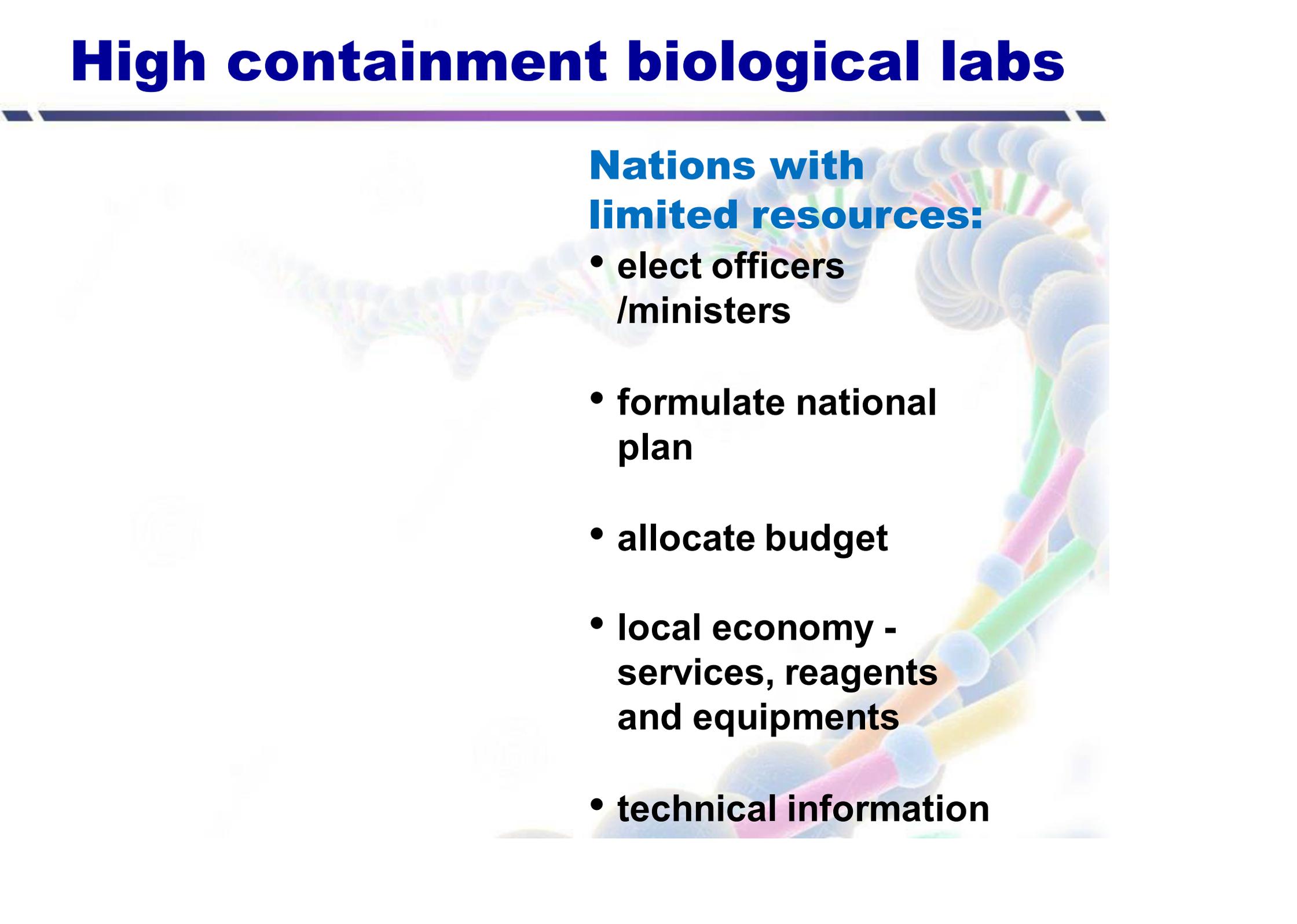
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High containment biological labs

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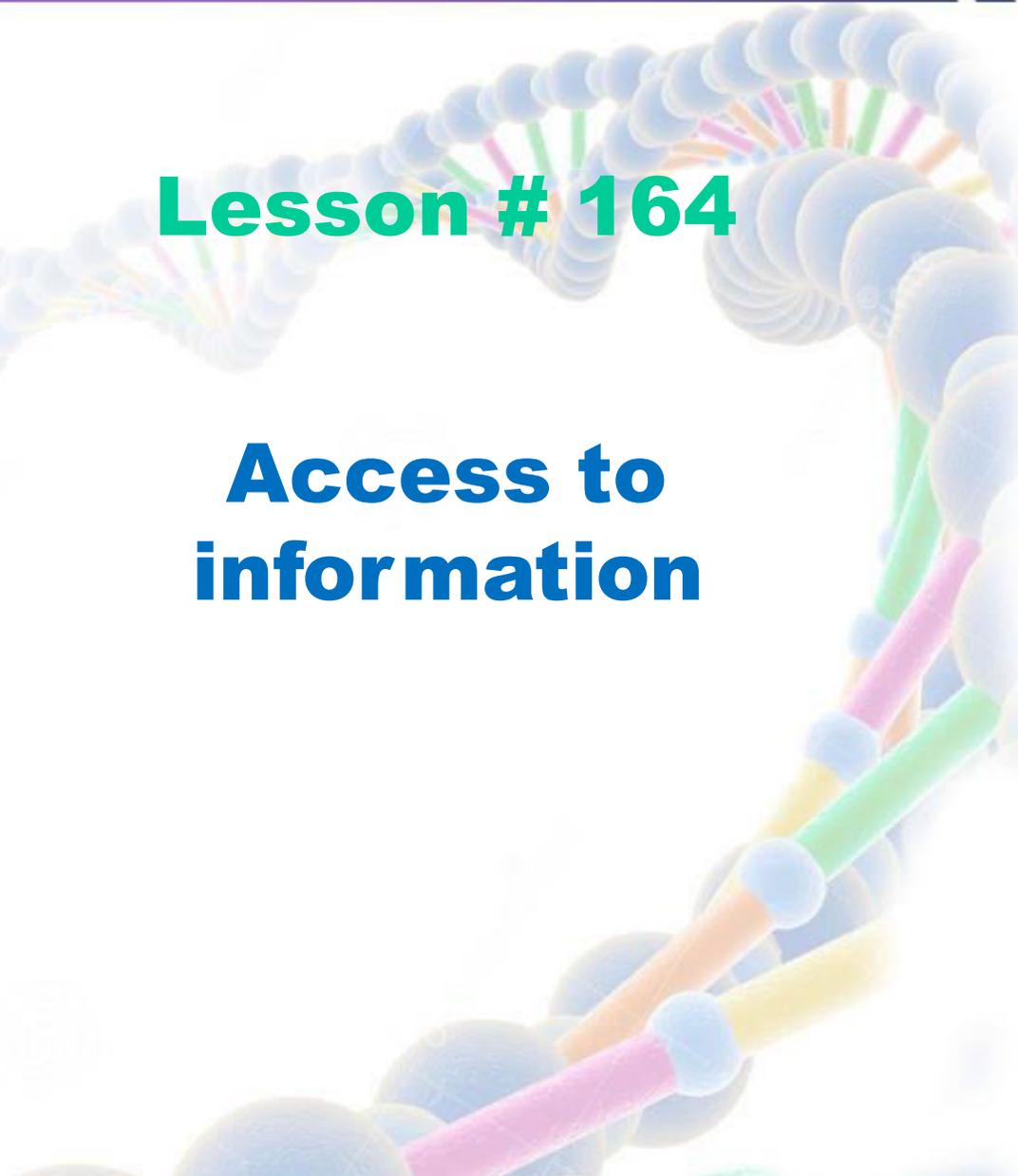
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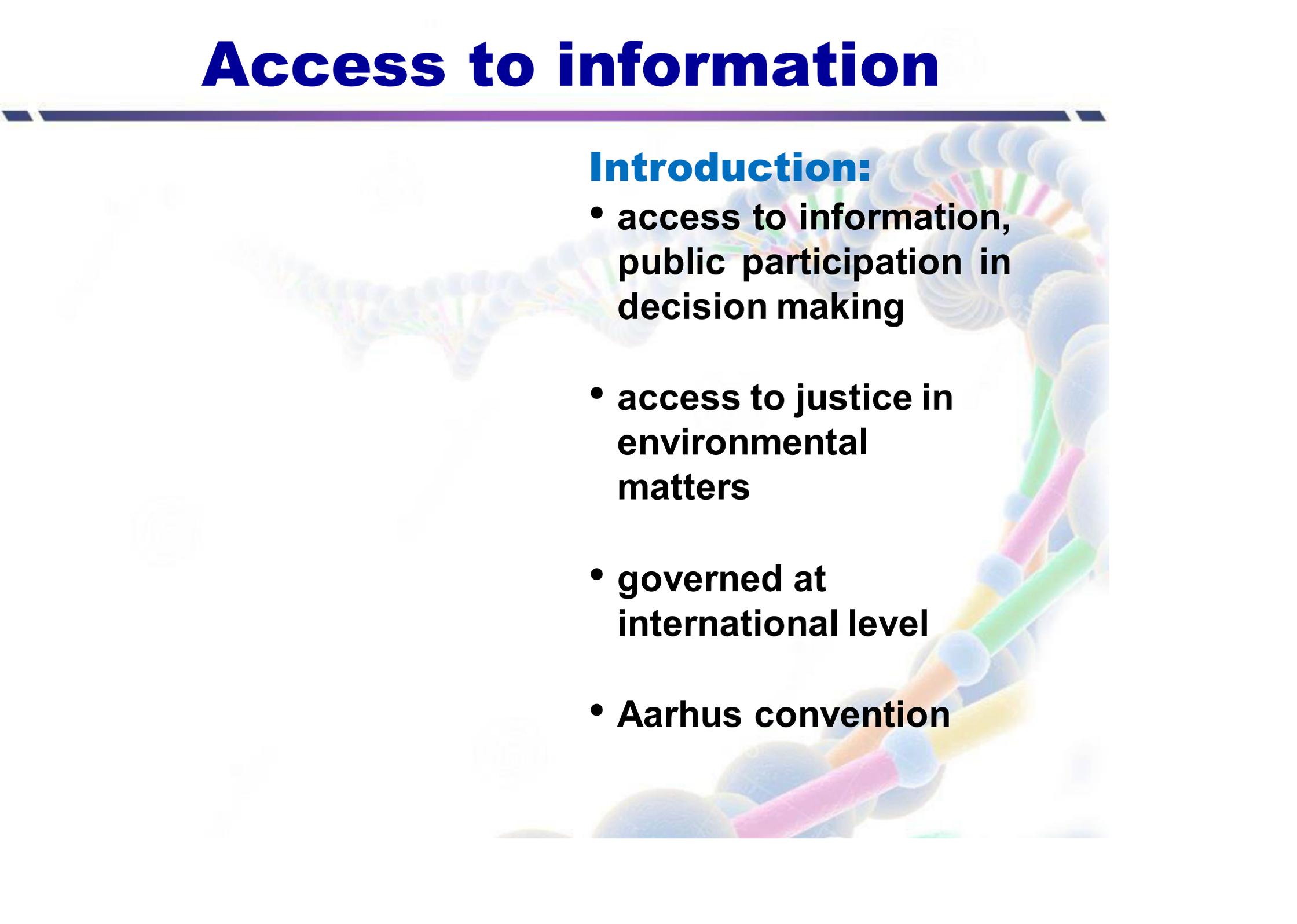
Biosecurity

Lesson # 164

Access to information



Access to information



Introduction:

- **access to information, public participation in decision making**
- **access to justice in environmental matters**
- **governed at international level**
- **Aarhus convention**

Access to information

Aarhus regulation:

- grants public rights
- imposes obligations
- community/institution access environmental information

Access to information

Access to information:

- telecommunication networks
- community legislation
- policy related documents
- plans, procedures, progress

Access to information

Environmental information:

- **soil, water marine, landscapes**
- **factors effecting**
- **substances, energy, waste, radiation, nuclear waste**
- **not available-with in 15 working days-informed**

Access to information

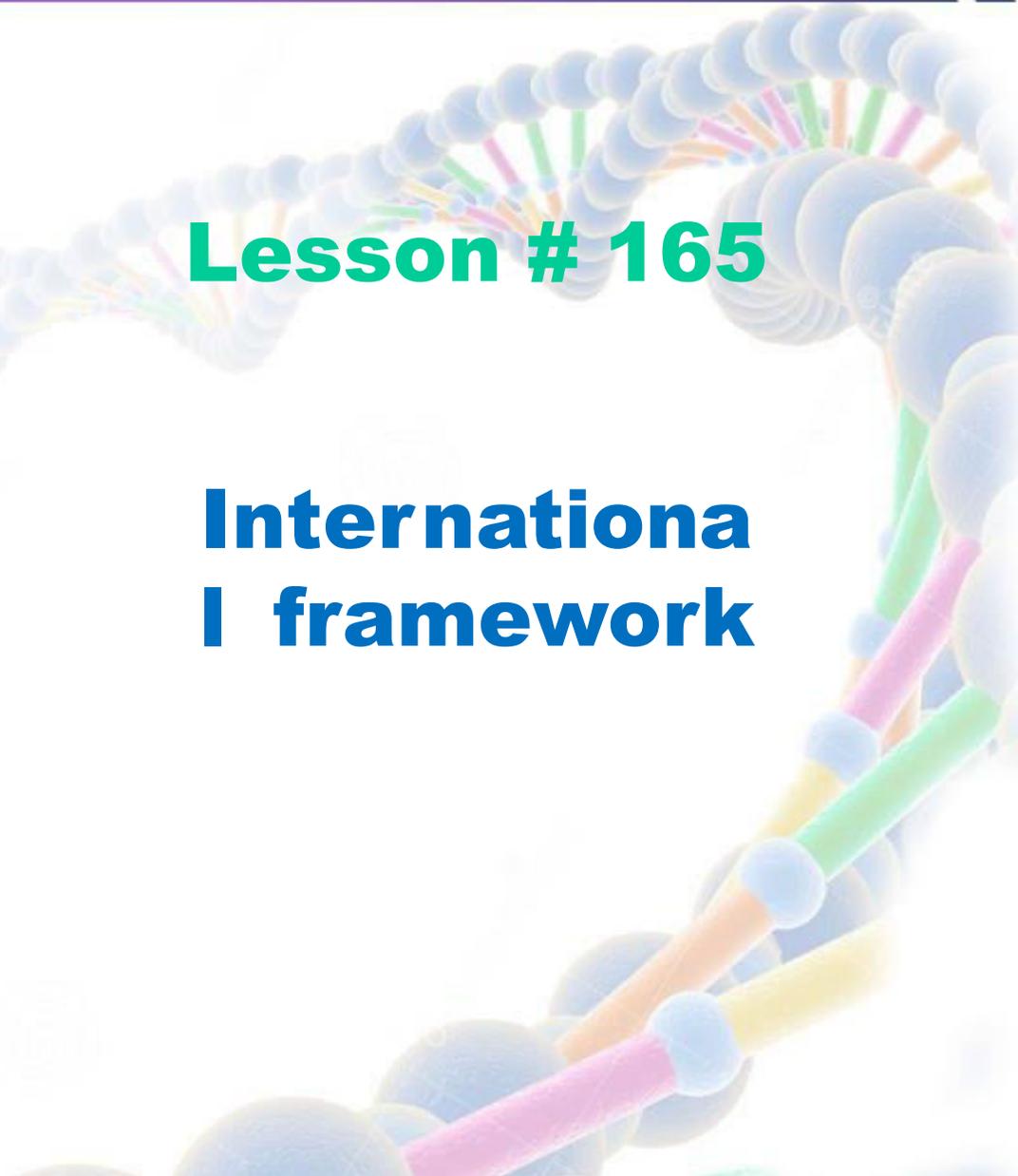
Public participation:

- plans / programs / procedures / review
- access to review
- internal review-NGOs

Biosecurity

Lesson # 165

International framework

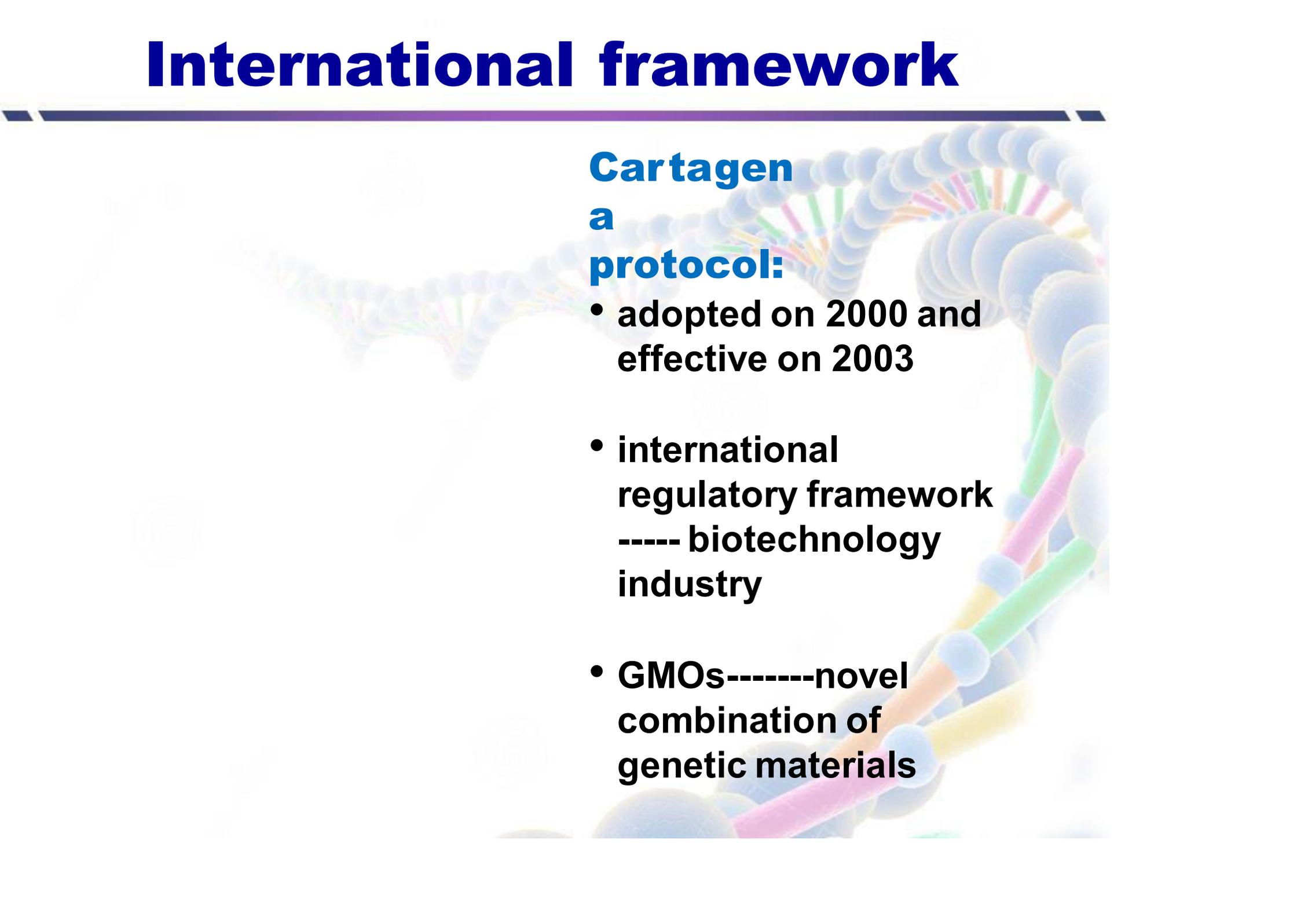


International framework

Introduction:

- two protocols ----- address GMOs
- Cartagena protocol on biosafety
- Nagoya kaula lampur supplementary protocol

International framework



Cartagen

a

protocol:

- adopted on 2000 and effective on 2003
- international regulatory framework ----- biotechnology industry
- **GMOs-----novel combination of genetic materials**

International framework

Cartagen a protocol:

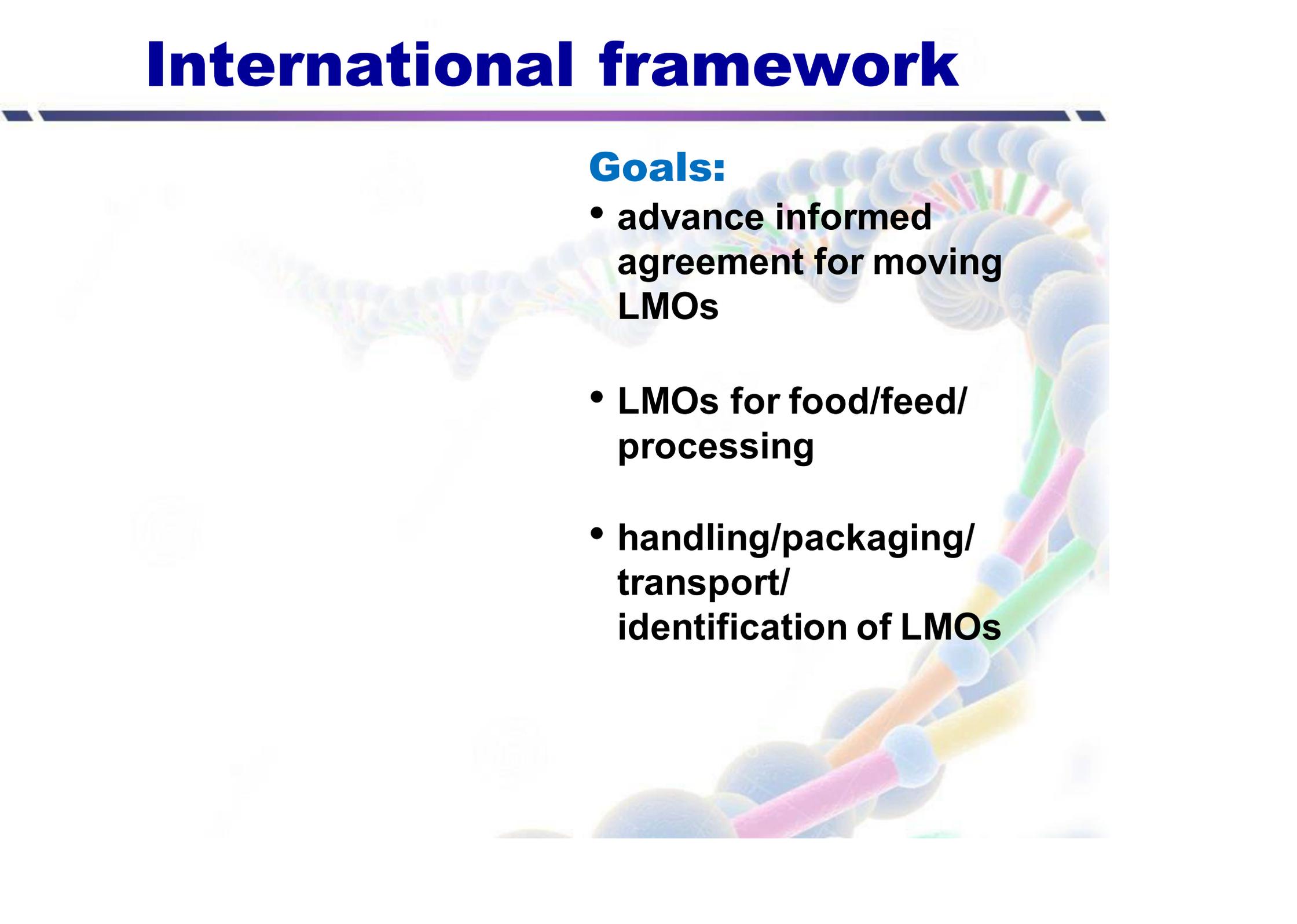
- **166 parties to the protocol-not USA**
- **protocol promotes biosafety**
- **use, movement, transit, handling and use of GMOs**

International framework

Biosafety clearing house:

- **implementation of procedures**
- **parties-exchange information**
- **capacity building, financial mechanism**
- **compliance methods, awareness programs**

International framework



Goals:

- advance informed agreement for moving LMOs
- LMOs for food/feed/processing
- handling/packaging/transport/identification of LMOs

International framework

Nagoya kaula- Lampur protocol:

- **address GMOs-
damage to
biodiversity-2010**
- **short and long term
change**
- **temporary and
permanent change**
- **inform high
authorities**

International framework

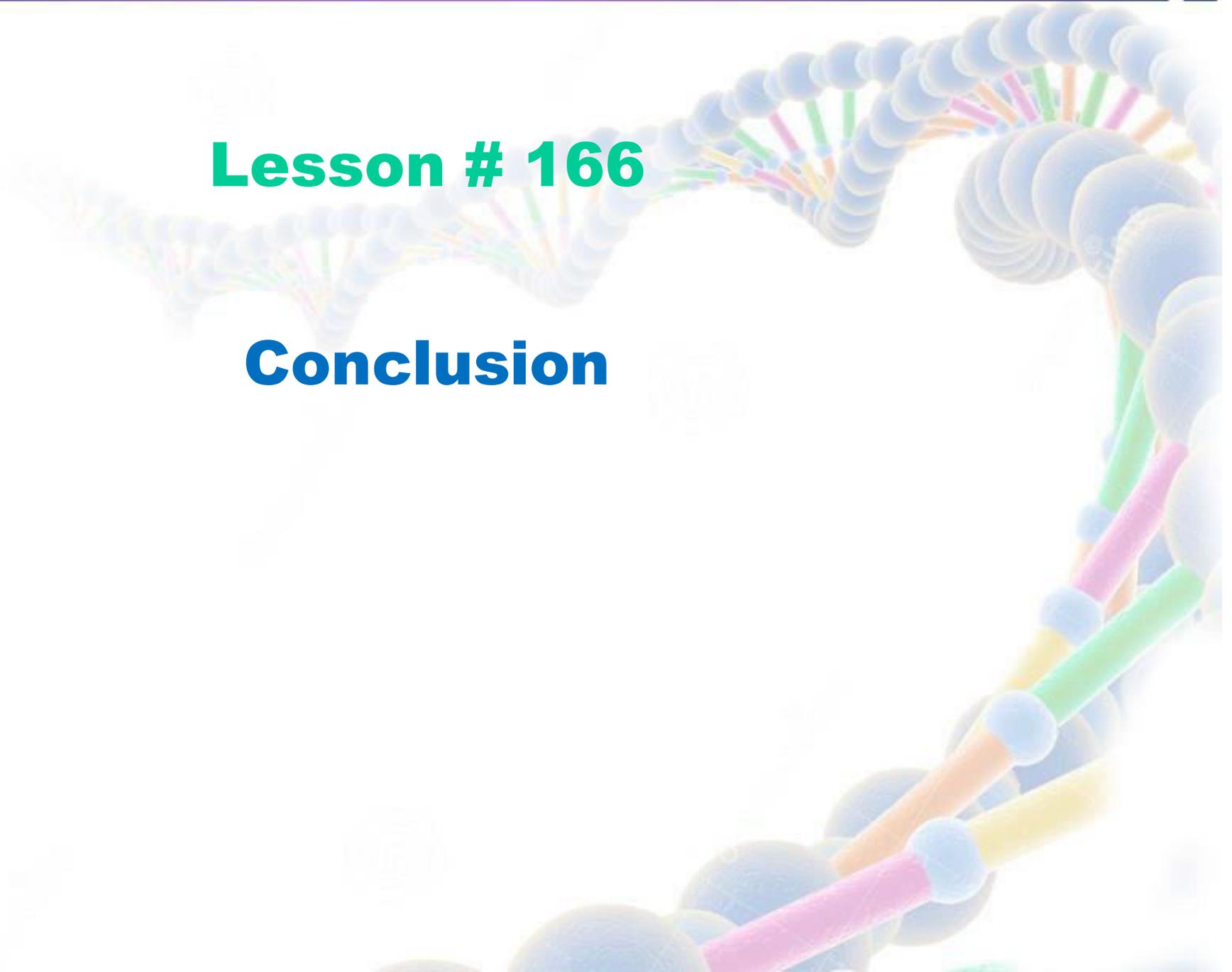
Nagoya kaula-Lampur protocol:

- **contribute to conservation**
- **sustainable use**
- **risk to human health**
- **resolve-domestic laws**

Bioethics, biosecurity, biosafety

Lesson # 166

Conclusion



Conclusion

Bioethics:

- due to health and social benefits
- to individual and families living free of mitochondrial disorders
- parents having the preference to have genetically related children

Conclusion

Bioethics:

- novel tech prove to be safe
- acceptable and effective as treatments
- would be ethical for parents to use them

Conclusion

Bioethics:

- ethical to gather information ----- pronuclear transfer and maternal spindle transfer
- ethical issues raised-discussed-----wider policies

Conclusion

Biosecurity:

- **the emergence of biosecurity-critical policy area in 21st century**
- **revolutionary changes-transformed**
- **government approaches**

Conclusion

Biosecurity:

- **the emergence of biosecurity-critical policy area in 21st century**
- **revolutionary changes-transformed**
- **government approaches**

Conclusion



Biosafety:

- prevention of large-scale loss-biological integrity
 - ecology-human health
 - man made unicellular organisms-effect on biomass
 - enter into food chain, reproduction and competition b/w species
- 