





Risk assessment

The risk associated with the organisms and the planned activities must be determined in advance.



Notifying the Federal Government

Activities involving organisms that are genetically modified or pathogenic must be reported to the Federal Government.





Contained systems

Activities involving organisms that are genetically modified or pathogenic must be handled in contained systems.





Safety measures

Special safety measures must be taken.



Biological experiments are sometimes also carried out outside normal laboratories, e.g. in schools or in self-built laboratories at home. If living organisms are used, special care must be taken not to endanger humans, animals and the environment.

If genetically modified or pathogenic organisms (e.g. bacteria) are involved, strict rules apply.

For further information

FOEN: Activities in closed systems

www.bafu.admin.ch > Topics > Biotechnology > Information for specialists > Activities in contained systems

FOPH Biosafety

 $www.bag.admin.ch > Healthy \ living > Environment \ and \ health > Biosafety$

Cantonal offices: kvu Biotechnology

www.kvu.ch > addresses > biotechnology

Containment Ordinance

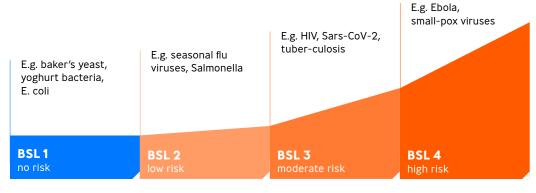
www.admin.ch > Federal law > Classified compilation > Internal law > 8 Health - Employment - Social Security > 8I Health > 8I4.9I2 Ordinance of 9 May 20I2 on Handling Organisms in Contained Systems



Risk assessment

The risks associated with the organisms and the planned activities must be determined in advance.

1



Microorganisms

Microorganisms are natural or genetically modified small organisms such as bacteria, viruses, fungi, cell cultures or parasites. Some microorganisms are harmless, while others can cause serious disease.

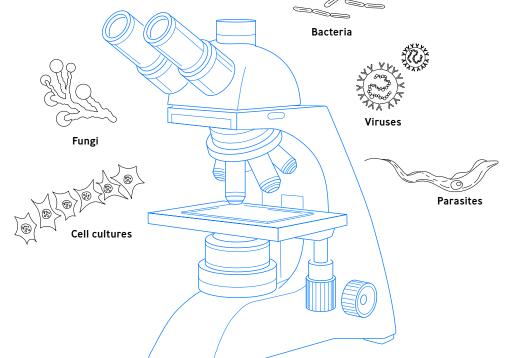
Microorganisms are classified according to the risk they pose (how dangerous they are) into four groups. The Federal Government maintains lists of microorganisms according to this classification.

Plants/animals

For experiments with animals or plants, additional regulations apply (e.g. animal welfare or protected animals / plants). Please contact the responsible federal and cantonal environmental or veterinary authorities in advance.

Activities

Planned activities with live organisms are classified according to one of four (risk) classes. Usually the classification of the activity corresponds to that of the group of organisms.





Biological Kits

Simple biological experiments are often also available as 'kits' – a kind of experiment set that includes instructions and all the equipment. Such kits can be ordered in Switzerland or abroad. But beware: the rules described here also apply to such kits!

For further information FOEN: Classification of organisms

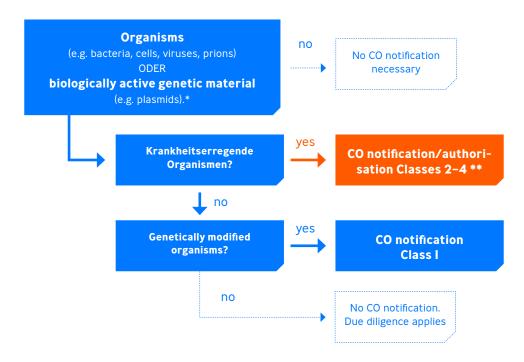
www.bafu.admin.ch > Topics > Biotechnology > Publications and studies > Publications > Classification of organisms



Notifying the Federal Government

Activities involving organisms that are genetically modified or pathogenic must be reported to the Federal Government.

2



For further information

FOEN: Notifications and authorisations

www.bafu.admin.ch > Topics > Biotechnology > Information for specialists > Activities in contained use > Notifications and authorisations

Federal Coordination Centre for Biotechnology

www.bafu.admin.ch > Topics > Biotechnology > Technical information > Activities in contained use > Federal Coordination Centre for Biotechnology

BSO Courses: Curriculum Biosafety www.curriculum-biosafety.ch BSO Guidelines FOEN

www.bafu.admin.ch > Topics > Biotechnology > Publications and studies > Biosafety Officer

- * Mixtures, articles and products containing such substances (e.g. fluorescent beer) are treated in the same way
- ** Classes 3/4 are generally only possible in professional laboratories

Obligation to notify

Anyone working with genetically modified organisms (from Group I) or with pathogenic organisms (Group 2 and higher) must notify the Federal Coordination Centre for Biotechnology. Changes in or termination of the activities must also be reported. There is no waiting period after submitting a notification for Class I and 2 activities. The fees are normally CHF IOO.

The following do not have to be reported

- Activities involving natural, non-genetically modified organisms in group I (e.g. yoghurt production)
- Analyses of soil, water, air or food samples (as long as they are not known to be heavily contaminated)

Biosafety Officer

If a notification has to be submitted, a Biosafety Officer(s) (BSO) must also be appointed. The BSO serves as the internal contact person as well as the contact person for the authorities. He or she ensures that all the people involved are familiar with the safety measures and comply with them. He or she is also responsible for the safety concept (see next page).

Qualifications

Expertise in the areas of biology and biosafety. The Federal Government offers special in-depth courses with a focus on biosafety.

Duty of care

Even those activities with organisms that do not require notification must be carried out with due care. So-called due diligence applies:

The activities must not endanger humans, animals or the environment, and must not impair

biodiversity and its functions.



Contained systems

www.bafu.admin.ch > Topics > Biotechnology >

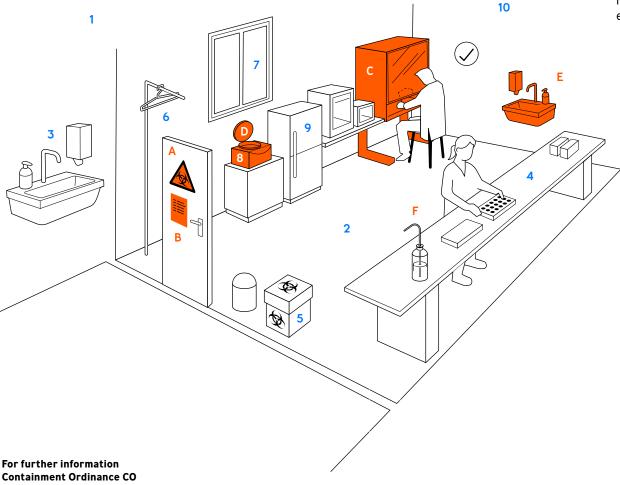
Operational Safety Concepts according to

Publications and studies >

Containment Ordinance (CO)

Activities involving organisms that are genetically modified or pathogenic must be handled in contained systems.





Containment obligation

Handling of genetically modified or pathogenic organisms must take place in a contained system.

Normally this is a specially equipped laboratory. In a contained system, the organisms' contact with humans, animals and the environment can be restricted.

Safety concept

For contained systems, a safety concept must be drawn up with detailed instructions on topics such as laboratory rules, waste disposal, and contact people. It is usually prepared by the BSO and updated regularly. A template for such a safety concept can be found on FOEN's homepage.

Level I Basis

- 1 Properly constructed and well-maintained building
- 2. Easily washable floors
- Washbasins with water, soap and hand disinfection
- Workbenches resistant to water, acids, bases, solvents, disinfectants
- Separate, covered wast e disposal for biologically active waste
- Separate cloakroom for laboratory clothing
- 7. Doors and windows to be kept shut during work
- 8. Clean centrifuges regularly
- **9.** Do not keep food in the laboratory refrigerator
- IO. All equipment must be well-maintained and checked regularly

Level 2 Additional specifications

- A biohazard warning sign on the door
- B Access for authorised persons only (e.g. lock, badge or list of names on the door)
- C Microbiological safety cabinet when handling microorganisms
- D Avoid aerosols (e.g. centrifuges with aerosol-tight lids)
- Washbasins with water, soap and hand disinfection in the laboratory.
- **F** Regular disinfection of the workplaces



Safety measures

Special safety measures must be taken.





Good microbiological practices

The microorganisms you use may come in contact with your body unintentionally. This could lead to you transporting them out of the contained system and thereby endangering not only your environment, but also yourself. You must therefore protect yourself with the following safety measures (see the illustration on the left).

Important

- When you finish work, clean all work surfaces and wash your hands
- Eating, drinking, smoking, snorting snuff, putting on make-up and storing foodstuffs are forbidden in the work areas.
- Use syringes and needles only if really necessary and dispose of them safely (see next page).

Accidents

- Always consult a doctor!
- Wounds: rinse them under running water, disinfect.
- Skin: disinfect and then wash off.
- Mouth: spit out, rinse with water.
- Eyes: rinse with water or eye wash.

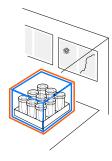
Spilt microorganisms

- Small amounts: soak paper towels in disinfectant and use them to wipe clean the contaminated area (DO NOT use a spray).
- Large quantities: use binding agent or old bath towels to absorb them, then autoclave.
- Ensure the equipment needed for this are available in a "spill kit"



IncidentsAlways inform the BSO if an incident occurs.





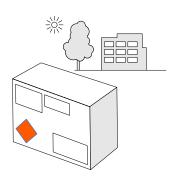
Transporting microorganisms

Inside the building

Use single (Class I) or double (Class 2) packaging. Ensure escaping liquids can be captured (e.g. transport them in a basin).

Outside the building

transport regulations apply for packaging and labelling. Even if properly packed: public transport may not be used to transport microorganisms!



For further information SECB Transport of biological substances www.efbs.admin.ch > Topics > Transport of biological substances Transport AWEL Canton Zurich www.zh.ch > Environment and animals > Environmental protection > Biosafety > Biosafety on farms > Transport and waste

Waste

Waste contaminated with microorganisms must be collected and disposed of properly. Such waste usually consists of solid or liquid cultures, as well as contaminated cultures and contaminated disposable items (e.g. pipette tips).

For Class I and 2 activities, the waste can either be inactivated on site or, with a federal permit, inactivated elsewhere or disposed of as hazardous waste*.

Exception: Liquid cultures from Class 2 activities may not be disposed of as hazardous waste.

* A federal permit is required for the disposal of solid cultures as hazardous waste. Contact the responsible cantonal or federal authorities in advance.



Collection

- Separate from normal waste
- Labelling (Class 2 needs an additionally warning sign 'biohazard')
- Safeguard against tipping and leaking (e.g. place in a basin)
- Access for unauthorised people is forbidden
- Avoid long storage



Inactivation

- Method depends on the organism. Its effectiveness must have been proven.
- Autoclaving (usually for 20 minutes at I2I °C, 2 bar)
- Chemical inactivation (for E. coli liquid cultures use e.g. javel water, 2% final concentration, for I6-24 hours)
- A pressure cooker, microwave, or dry steriliser may be used if its efficacy has been demonstrated.



Disposal

- Dispose of inactivated waste with normal waste.
- Remove labels beforehand.



Exceptions: waste that could cause injury ('sharps'):

- In secure, puncture-resistant, unbreakable containers, e.g. in so-called 'sharp-safe boxes'.
- Always dispose of as hazardous waste.

Checklists

Check whether you have thought of everything.
You may carry out your experiments only if you can tick **Yes** everywhere.

⚠ Risk assessment	1	Yes	No
Is the risk group of the microorganisms used known?			
Is the risk class of the activities known?			

Notification of the Federal Government 2	Yes	No
Have any necessary notification documents been submitted to the Federal Government?		
Has a BSO been designated?		

	Contained System	3	Yes	No
Has a s	afety concept been drawn up?			
Are buil	dings and premises properly constructed and well maintain	ined?		
Is the fl	oor easily washable?			
Is the w	orkbench resistant to water, acids, alkalis, solvents and di	isinfectants?		
Are was	shing facilities available? (Running water, soap and disinfec	ctant)?		

Safety Measures 4	Yes	No
Are the safety measures necessary for all activities known?		
Have the people involved been adequately instructed?		
Have you checked whether special measures are necessary for certain people?		
Is laboratory clothing worn when working with microorganisms?		
Is the personal protective equipment (safety goggles, gloves, protective mask) used appropriate for the hazards?		
Is all equipment checked and maintained regularly?		
Are the microorganisms used disposed of properly? How?		
Are contaminated substances/equipment disposed of properly? How?		
Is it clear what measures are to be taken in the event of an incident or emergency?		
Are the first-aid facilities (running water, eye-wash if necessary) in good condition?		
Is disinfectant available for both people and surfaces?		
Is an emergency first-aid kit available?		

Additional safety measures only for class 2 activities:	Yes	No
Are the work areas/rooms marked? (Yellow biohazard warning sign).		
Are the work areas separated and accessible only for authorised persons?		
Is there a list of the people working in the area?	_	
ls a microbiological safety cabinet available?	_	

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Commissioned by the Federal Office for the Environment FOEN, Soil and Biotechnology Division, 3003 Bern Federal Office of Public Health FOPH, Biosafety, Human Genetics and Reproductive Medicine Section, 3003 Bern Service provider Baudirektion des Kantons Zürich, AWEL Section Biosafety SBS, 8090 Zurich Author Claudia Ruprecht SBS

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