Operating Instructions

Genetic Engineering Work according to
§12 Gentechniksicherheitsverordnung (Genetic Engineering Safety Regulations)
for Laboratories of Safety Level 1

Version: May 2014
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1. Scope

These instructions are to be followed in the genetic laboratory (Reg.-No. or file reference of the notification, issuing agency)

The scope includes the following rooms:

Laboratory rooms: (floor / room number)
Autoclave room: (floor / room number)
Centrifuge room: (floor / room number)
Storage room: (floor / room number)

(If appropriate the corridors, animal keeping rooms, climatic chambers, scullaries and so on, each with the floor, room number or location drawing)

The rooms are labelled as "Gentechnischer Arbeitsbereich S1" or "Genalbor S1" (genetic laboratory safety level 1 or genetic laboratory S1)
The break room is located *(room number, building xy)*, the washing/changing room is in *(room number)*.

### 2. Important people

**Responsible for the genetic laboratory (project supervisor):**

*(title, name, tel. office., tel. private if necessary)*

**Additional contact:**

*(If there is more than one project supervisor please give the name and the scope of responsibility/room numbers)*

**Biological safety representative:** *(title, name, tel. office., tel. private if necessary)*

**Emergency physician:** request through control room (tel. 23333)

**Next physician:** Dr. Besser, Sumperkamp 3, tel. (90) 971200

**Next accident insurance physician:** Fr. Dr. Russe, Buscheyplatz 15, tel. (90) 701052

**First aider:** *(state the institute first aider, room, tel)*

**Institute paramedic:** request through control room (tel. 23333)

**Hospital:** *(name, tel.)*

**Occupational safety and health professional:** *(title, name, tel. office, tel. private if necessary)*

**Fire brigade:** request through control room (tel. 23333) or by alarm button *(location)*

### 3. Genetic Engineering Work

In the genetic laboratory the following projects at safety level 1 are performed:

*(Project description in note form)*

The project supervisor has to be kept informed on all incidents concerning to the non-expected process of the genetic engineering work.

Adjacent to the generation of GMO the genetic engineering work includes the use of GMO, reproduction, storage, destruction or disposal as well as internal transportation.

The laboratory work for this and all further projects at safety level 1 (including a risk assessment) has to be recorded according to the Gentechnikaufzeichnungsverordnung "GenTAufzV".

### 4. Risk potential of GMO

The genetically modified organisms are assigned to risk group 1. This means that their appropriate usage—appropriate to this instructions—does not endanger healthy people or the environment. A comprehensive risk assessment is part of the records according to the" GenTAufzV".
A risk for persons suffering from a suppressed immune system, pregnant women or people suffering from allergies
- is not known based on current scientific knowledge
  or
- exists in the following cases: (state the specific cases in accordance with the risk assessment)

5. Safety Measures, Rules of Conduct, Hygienic Measures

Genetic engineering work has to be performed according to the general rules of microbiological techniques and the genetic engineering safety regulations. In particular the following points are to be taken into account:

5.1 Access to the Laboratory:

a) Access is restricted to people, which have obtained safety instructions before starting work and at least annually. The safety instructions must include information on necessary and project-related risks and safety measures related to the workplace based on this operating instructions.

b) Access to the laboratory by visitors is only permitted in presence of instructed people.

c) Cleaning and maintenance personnel must have obtained safety instructions on possible risks before starting the work in the laboratory. It is sufficient to provide information on conducted work and basic rules of conduct. For specific information a competent contact is (name, tel.).

5.2 General Instructions:

a) Keep the genetic laboratory tidy and clean. On benches only work-related devices and materials should be placed. Spare materials are to be stored in cabinets and rooms, provided for this use.

b) Writing is restricted to the necessary extent (recording, evaluation). Books and catalogues are only allowed if they are important for the working progress. General writing desks are located in (kind of room, room number).

c) Windows and doors shall be closed during genetic engineering work. (provision for ventilation breaks if necessary).

d) Oral pipetting is prohibited. Pipetting aids are to be used.
e) Only use injections, cannulas, blades, needles, lancets etc. if absolutely necessary. Collect them in puncture resistant, autoclavable containers before autoclaving. Use containers with stripping opening. Do not bend cannulas or plunge them back into their protective sleeve. Appropriate containers have to be provided at the workplaces before starting work.

f) During all work the formation of aerosols should be avoided. The formation of aerosols is to be expected when decanting, stirring, high pressure pressing, inoculating, shaking, pipetting, centrifuging and working with ultrasound. Measures of prevention from aerosols are for example:
- use closed containers or apply encapsulated working procedures
- wait a sufficient amount of time for the aerosol to sink before opening the container
- adhere to low filling levels when decanting and pipetting
- do not blow out pipettes and do not spray the content of injections and cannulas into the air.

g) The identity of used organisms has to be verified periodically. The intervals are determined by the project supervisor.

h) The operating instructions of laboratory devices e.g. autoclave, centrifuge, safety workbench must be followed.

i) For internal transportation of GMO use closed, break-proofed containers labelled with "biologische(r) Stoffe / Abfall S1, Lehrstuhl, Name des Projektleiters, ggf. Raumnummer" (biological material/waste S1, institute, name of project supervisor e.g. room number).

j) Genetically modified organisms have to be stored in (kind of container like fridge, deep freezer or liquid nitrogen, storage room).

k) Containers with GMO have to be labelled clearly.

l) Information concerning certain working steps (e.g. handling of nucleic acid with an oncogene potential, safety measures when using UV radiation, handling liquid nitrogen, working with a fermenter, working steps which shall or must be carried out under a safety workbench etc.).

5.3 Additional Operating Instructions:

   e.g.
   a) instructions for handling hazardous substances
   b) instructions for using centrifuges
   c) radiation protection instructions according to "Strahlenschutzverordnung"
   d) supplementary instructions for animal keeping, greenhouses, production areas, if necessary.
5.4 Hygienic Measures:

[It is recommended to tabulate a hygienic plan]

a) At the end of work clean all benches (prophylactic disinfection, stipulate the agent and the procedure) *(disinfectant, concentration, contact time listed by the VAH or RKI)*

b) Disinfect thermolabile devices by immersion disinfection *(disinfectant, concentration, contact time listed by the VAH or RKI)*.

b) At the end of work the hands must be disinfected and washed *(disinfectant, contact time, hand washing agent and protective cream)*

c) Inform the project supervisor of any existence of vermin for taking suitable pest control measures.

5.5 Prohibitions:

a) Food, stimulants and cosmetics have not be stored in the genetic laboratory. Storage is possible in *(room n.)*.

b) It is not permitted to eat, drink or smoke in the genetic laboratory. Do not enter the break room with the laboratory coat.

c) The use of suction devices (e.g. water jet vacuum pump) for fluids which may contain GMO is only allowed if appropriate measures can avoid a leakage of GMO (e.g. sterile filter).

d) The storage of GMO is only allowed at stipulated location.

e) Additional prohibitions *(e.g. prohibition of genetic engineering work underneath product protection workbenches)*.

5.6 Personal Protective Equipment:

a) Laboratory coats must be weared in the genetic laboratory. These are to be laundered *(give it to room.../ laundry..)* as needed, at least *(weekly or bi-weekly)*.

b) Laboratory coats and protective gloves are to be removed before leaving the laboratory.

c) To avoid contamination working clothes and protective clothing must be stored apart from outdoor clothes.

working clothes and protective clothing: *(place of storage)*

outdoor clothes: *(place of storage)*

protective gloves are to be weared in the genetic laboratory all the time.
5.7 Special Regulations: (e.g. animal breeding and keeping, animal experiments, plant breeding)

6. Conduct in the Case of Danger

- Keep calm, avoid precipitate and blindfold action.
- Warn people at risk, demand them to leave the rooms if necessary.
- Experiments have to be stopped, gas, electricity and water switched off at the taps.
  *(emergancy deactivation where and und where for)*

- In all emergency cases the project supervisor (or other contact) must be informed.

6.1 Contamination with Biological Material:

In case of spilling biological material, the contaminated area is to be closed off. If the material contains GMO it is to be inactivated immediately.

Take the following decontamination measures:

- Areas and: Put on protective gloves. Pick up the leaked or spilled material using autoclavable materials (e.g. paper towels) and autoclave them.
- Surfaces of Devices: Afterwards the contaminated area must be disinfected *(disinfectant, concentration, contact time listed by the RKI)*. Remove glass splinters by using an appropriate instrument and autoclave them.

- Clothing: Protective or outdoor clothing must be disinfected *(disinfectant, concentration, contact time registered by the RKI)* and washed afterwards.

- Skin: Contaminated skin has to be disinfected with *(handdisinfectant and contact time registered by the RKI)* and thereafter rinsed with plenty of water. *(Consult a physician if necessary)*

- Eyes: Eyes have to be rinsed out with plenty of water (eye shower). *(Consult a physician if necessary)*

- Mucosa Membrane: Rinse mucosa membranes with plenty of water.
  *(Consult a physician if necessary)*
6.2 Fire:

Incipient fire is to be fought by using the available fire extinguisher. Follow the instructions "Brandschutzordnung der RUB" (fire protection code of the RUB).

7. First Aid

- Injuries:
  - If possible, attend to wounds in the scope of first aid.
  - The project supervisor, in absence his representative or the biological safety representative must be informed about injuries without delay.
  - In case of exposure or suspected exposure to GMO-containing substances give notice to a physician. In case of inhalation or swallowing the attending physician must be informed about the kind (species, antibiotic resistance) and amount of incorporated organism.
  - Injuries are to be recorded in the accident book.

8. Correct Disposal

[According to § 13 GenTSV the duty for disposal is to be specified for individual case in question. Wording recommendation in case of using organisms with mandatory inactivation:]

Solid and liquid waste containing GMO is to be autoclaved prior to disposal at 121°C for 20 min. The autoclave in room (room number) is available for this.
Is a deactivation by autoclaving not possible [or not permitted (e.g. genetically engineered radioactive waste)], a chemical deactivation is required (disinfectant, concentration, contact time). The effectivity of the deactivation method must be verified.
The waste is to be collected in a container (what) in room… until it is deactivated.
The inactivation is carried out periodically (time interval) by .. (responsible person).

(If necessary further advices for collecting, transporting and deactivating of solid and liquid waste)
Annex: Note on General References

[Select the relevant statutory provisions for the particular work to be carried out. The latest version always has validity.]

Acts/Regulations

- Genetic Engineering Act
  - Genetic Engineering Safety Regulations and Annexes
  - Genetic Engineering Recording Regulations
- Health and Safety at Work Act/Occupational Health and Safety Act
- Bio-Material Regulations
  - Technical Regulations for Biological Agents - TRBA
- Hazardous materials regulations and Annexes
  - TRGS (Technical regulations for Hazardous Substances) 555 Operating Instructions
- Industrial Health and Safety Regulations - including the currently valid technical regulations for flammable liquids and the technical regulations for pressure vessels
- Radiation Protection Regulations
- Maternity Protection Act
- Maternity Protection Guidline Regulations

Publications of BVL, RKI, VAH

- BVL (German federal Office for Consumer Protection and Food safety)-list of risk-evaluated donor and receiver organisms for genetic engineering work.
- List of disinfecting agents and procedures tested and accepted by the Robert-Koch-Institut (RKI).
- List of disinfecting agents and procedures tested and accepted by Applied Hygiene Network (VAH).

Regulations of the Institution for Stationary Accident Insurance and Prevention

- BGV A1 "Principles of Prevention"
- BGR 500 (2.11 Teil 3) "Centrifuges"
- ArbMedVV "Occupational Medical care Regulations"
- GUV-I 850-0 "Working safely in Laboratories"
- TRGS 526 "Laboratories"
- Activities involving Hazardous Substances at Universities. (BGI/GUV-I 8666).
- Fire and Explosion Prevention when Using alkohol containing disinfectants. (in BGR 206)
- "Safe Biotechnology" Series from the Institution for Stationary Accident Insurance and Prevention of the Chemical Industrie (BG-Chemie)
- Leaflet M 007 "Animal Laboratories" from the BG-Chemie

DIN-Guidelines

- Safety Workbenches (DIN EN 12469)
- Steam Sterilizers (DIN 58951-2)
- Fume Hoods (DIN EN 141751 T 1-3)

(Location of provisions if appropriate)