Safety concept according to ESV and SAMV for Level 2 laboratories

Template for plant-specific additions.

*State 2019*

Imprint

Issued by

Federal Office for the Environment (FOEN)

FOEN is an agency of the Federal Department of the Environment, Transport, Energy and Communication (DETEC)

Authors

Dr. Valentin Küng, Küng–Biotech+Umwelt, CH-3006 Bern [on behalf of FOEN, Swiss Federal Office of Public Health (SFOPH), Cantonal Office of Zurich for Waste, Water,   
Energy and Air (OWWEA) and the Cantonal Laboratory   
Basel-Stadt (CLBS)]

Dr. Thomas Behrmann, OWWEA, CH-8090 Zurich

Dr. Thomas Binz, SFOPH, CH-3003 Bern

Dr. Alfred Feichtinger, University of Zurich, CH-8057 Zurich

Dr. Martin Gschwind, Swiss National Accident Insurance Fund (SNAIF), CH-6002 Lucerne

Dr. Edgar Käslin, SNAIF, CH-6002 Lucerne

Dr. Isabelle Lutziger, Berna Biotech, CH-3018 Bern

Dr. Carmen Spycher, FOEN, CH-3003 Bern

Dr. Urs Vögeli, CLBS, CH-4012 Basel

Consultant FOEN

Dr. Hans Hosbach, Substances, Soil, Biotechnology Divison, CH-3003 Bern

Suggested form of citation

Küng V., 2008: Operational safety concepts according to Containment Ordinance (CO). Guideline for enforcing the Containment Ordinance (CO). Updated version 2019; first edition 2008. Federal Office for the Environment, Bern. The environment in practice no. 0817.

Updated version 2019 © FOEN 2019

Explanatory notes

Starting situation and objectives

In Switzerland there is an increasing number of laboratories which work with pathogenic or genetically modified organisms. These laboratories are thus subject to the Ordinance on the contained use of organisms (Containment Ordinance, ESV[[1]](#footnote-1)) and Ordinance on the protection of personnel from hazards due to microorganisms (SAMV[[2]](#footnote-2)). This obliges them to *“... comply with the plant safety concept and the associated operating instructions and rules of conduct”*.

The present document is an almost complete plant safety concept for Level 2 laboratories and can relatively easily be adapted to the particular circumstances applicable in a specific plant.

Within the scope of their statutory responsibility, the Swiss federal government and the cantons monitor companies’ compliance in respect of the safety of people, animals and the environment. Within this framework, the cantonal enforcement authorities and the Swiss National Accident Insurance Fund (SNAIF) also check whether a company has acknowledged its responsibility and drawn up an appropriate plant safety concept. This template will serve as an aid to enforcement for the cantons and will also allow companies to check whether already existing safety concepts are complete.

In 2001, the Cantonal Laboratory Basel-Stadt published draft *Instructions for a plant safety concept focusing on biological safety*. On the basis of this draft, the Federal Office for the Environment (FOEN) drew up a corresponding guideline. The present document is consistent with this guideline and will serve as a template for specific and correct implementation of this guideline.

Fundamental principles for the present document are derived from the *Safety concept focussing on biological safety for the University of Zurich*, which was drawn up by the Safety and Environment unit at the University of Zurich in conjunction with the consultancy firm Küng–Biotech+Umwelt. Building on this basis, the working group, consisting of the institutions and companies listed in the publishing details, drew up this template for a plant safety concept, with the aim of offering laboratories and plants assistance in meeting the statutory obligation imposed on them. The template is directed primarily at plants with Class 2 activities. Some parts and documents may also be applied to Class 1 activities.

Content, structure and use

A plant safety concept is – as the term emphasizes – geared to the particular plant. The template therefore contains generally applicable texts on the one hand and sections which need to be added for specific plants on the other.

As far as its structure is concerned, the template is split into two levels:

1. The core document of the plant safety concept formulates the objectives with regard to the safety of people, animals and the environment and lists the appropriate plant safety measures.

2. The Annexes contain the associated templates for operating instructions and rules of conduct which need to be added for specific plants.

Table 1

Chart from the template to the plant-specific safety concept

|  |  |  |  |
| --- | --- | --- | --- |
|  | Safety concept template | Adaptations and steps | Plant safety concept |
| Core document | Safety concept according to ESV and SAMV for Level 2 laboratories (template) | Plant-specific adaptation by way of deletions or additions | Company’s safety concept according to ESV and SAMV |
| Annexes | Templates for operating instructions and rules of conduct  No templates | *Selection and plant-specific adaptation*  *Selection of safety-related documents*  *Selection of generally accessible documents* | Operating instructions and rules of conduct  In-house documents  Generally applicable leaflets |

The following steps are needed to adapt the template to a plant-specific safety concept:

1. Generally, the text passages which are irrelevant to the plant (because there is no practical application: e.g. with regard to radiation protection) should be deleted or adapted to the specific plant.

2. In the core document of the plant safety concept, various places, **highlighted in bold and green,** must be edited. Thus, for example:

a) the name of the company or laboratory must be inserted in place of **(company name),**

b) reference must be made to already existing documents which are relevant to safety in the plant. The corresponding references are indicated in the core document **(document A, B, C etc.);** the exact titles must be inserted there and the appropriate documents included in the Annex.

3. The Annexes contain the templates for operating instructions and rules of conduct (e.g*.* [Annex 1](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en)*, 2, 3 etc.)*[[3]](#footnote-3), which need to be added to or adapted according to the specific plant. This could mean, for example, adding the company name and logo or telephone numbers and addresses. The specially marked explanatory notes **(text in boxes)** must be deleted from the definitive plant safety concept.

There are at least two possibilities for further developing the template:

1. A (larger) company, in which concepts for the safety of people, animals and the environment already exist, may develop the template into a *plant bio-safety concept* and incorporate it into the company’s overall concept.

2. A company which is still young or smaller and does not yet have concepts for the safety of people, animals and the environment, may use the template as the starting point for a plant safety concept and incorporate into it, in the prepared places, other safety aspects such as chemicals, radioactivity or protection of the workforce, according to Guideline No. 6508 of the Swiss Federal Coordination Commission for Occupational Safety etc.

|  |
| --- |
| **Company Logo** |

Safety concept according to ESV and SAMV

**Adaptation of this template to a plant-specific safety concept is described in the “Explanatory notes” section of this guide.**

Valid from:

Signed:

***Management, Date***

Table of contents

[1 Validity of the plant safety concept 8](#_Toc31634114)

[2 Safety objectives 9](#_Toc31634115)

[3 Safety organization 10](#_Toc31634116)

[3.1 Responsibility and liability 10](#_Toc31634117)

[3.2 Organization chart 10](#_Toc31634118)

[3.3 Duties of the Biosafety Officers (BSO) and of the Laboratory and Project Managers 11](#_Toc31634119)

[3.4 List of employees 11](#_Toc31634120)

[4 Emergency organization: planning and incident management 12](#_Toc31634121)

[4.1 Emergency telephone numbers and contacts for safety issues 12](#_Toc31634122)

[4.2 Emergency planning: action in the event of incidents in the laboratory and emergency situations 12](#_Toc31634123)

[4.3 Report sheet for laboratory incidents 12](#_Toc31634124)

[4.4 Health file 13](#_Toc31634125)

[4.5 Safety documentation for emergency services 14](#_Toc31634126)

[5 Risk assessment 15](#_Toc31634127)

[5.1 Compulsory reporting of activities 15](#_Toc31634128)

[5.2 Project list and inventory of biological agents 15](#_Toc31634129)

[6 Safety measures and rules of conduct 16](#_Toc31634130)

[6.1 Access control and labelling of the Level 2 working area 16](#_Toc31634131)

[6.2 Instructions for safe working 16](#_Toc31634132)

[6.2.1 Operating instructions and rules of conduct (Standard Operating Procedures, SOPs) 16](#_Toc31634133)

[6.2.2 Laboratory safety rules 16](#_Toc31634134)

[6.2.3 Use of the Class 2 microbiological safety cabinet 17](#_Toc31634135)

[6.2.4 Biological safety during centrifuging 17](#_Toc31634136)

[6.2.5 Prevention of infectious diseases transmissible by blood 17](#_Toc31634137)

[6.3 Training / information to ensure safety at work 17](#_Toc31634138)

[6.4 Standards for laboratory cleaning 17](#_Toc31634139)

[6.4.1 Disinfection and cleaning – hygiene plan 17](#_Toc31634140)

[6.4.2 Safety instructions for the cleaning service 18](#_Toc31634141)

[6.5 Disposal of biologically contaminated waste 18](#_Toc31634142)

[6.5.1 Disposal plan 18](#_Toc31634143)

[6.5.2 Inactivating biological waste by autoclaving 18](#_Toc31634144)

[6.6 Purchase, servicing and maintenance of equipment 19](#_Toc31634145)

[6.6.1 Declaration of conformity and manuals 19](#_Toc31634146)

[6.6.2 Responsibility for servicing and maintenance of equipment 19](#_Toc31634147)

[6.7 Transportation of organisms or infectious biological agents 19](#_Toc31634148)

[6.8 Chemical safety 20](#_Toc31634149)

[6.8.1 Storage / quantities 20](#_Toc31634150)

[6.8.2 Disposal 21](#_Toc31634151)

[6.9 Radiation protection – use of ionizing radiation 21](#_Toc31634152)

[6.10 Planning, building, modification, demolition and relocation 21](#_Toc31634153)

[Annex 23](#_Toc31634154)

1. Validity of the plant safety concept

This plant safety concept was adopted by the management of **(company name)** on **(date).** It forms the binding framework for implementation of the statutory requirements which have to be complied with during activities involving pathogenic or genetically modified organisms in contained systems (Level 2).[[4]](#footnote-4) The plant safety concept incorporates the measures adopted by **(company name)** for occupational safety and for the safety of people, animals and the environment.

The plant safety concept of **(company name)**which is presented here is based on the document *Safety concept according to ESV and SAMV for Level 2 laboratories – Template for plant-specific additions*[[5]](#footnote-5) and the corresponding guideline of the Federal Office for the Environment (FOEN)[[6]](#footnote-6). The various templates for operating instructions and rules of conduct have been adapted to the particular plant and are listed in the Annexes together with the already existing company documents containing performance standards for environmental and occupational safety or for quality assurance.

The plant safety concept will be updated whenever the risk situation changes, especially if new working methods are adopted, new organisms are handled, new items of equipment which are relevant to biological safety are introduced, existing premises are used for different purposes or new rooms are used, though also if, in accordance with activities, the use of processes, rooms etc. has been discontinued (see Chapter 5.1).

1. Safety objectives

Work in the laboratories of**(company name)** involves the use of **(pathogenic or genetically modified)**organisms. In the course of this work, it is never possible to rule out entirely a potential risk to people, animals and the environment**. (company name)** takes the necessary safety measures to protect people, animals and the environment from negative effects.

As an employer, **(company name)** acknowledges its responsibility for occupational safety and the protection of its employees’ health and, accordingly, takes the necessary measures.[[7]](#footnote-7)

**(company name) has recorded its protection objectives with regard to occupational safety and environmental protection explicitly in its mission statement.[[8]](#footnote-8)**

Mission statement: **Document A**

1. Safety organization
   1. Responsibility and liability

The highest body within the company**(e.g. the board of directors)** acknowledges its paramount responsibility for all safety matters and therefore for environmental protection and occupational safety in the company.[[9]](#footnote-9)

The company management accepts operational responsibility for ensuring the safety of people and the environment as well as safety at the workplace.[[10]](#footnote-10) It ensures that the plant safety concept is implemented and followed and has established the organizational structure necessary for this purpose. The company management has entrusted at least one person with the task of monitoring biological safety and has set out the precise details concerning status, duties and responsibilities in the job description. The necessary financial and human resources have been made available.

*The company management makes the following clear.* As a matter of principle, **(company name)**shall be liable to third parties. It may exercise a right of recourse against employees who contravene safety provisions deliberately or through gross negligence, thereby inflicting harm on the company or on third parties, for which the plant is liable. The following applies to all persons who bear responsibility for safety aspects in the company: The responsibility of persons under criminal law is derived from their sphere of responsibility in relation to observance of safety rules. Only those persons who, by virtue of their position, are able to prevent hazards through their own intervention can be held accountable as guarantor under criminal law. This is the case if they have failed to intervene where intervention would have been appropriate and possible for them.

* 1. Organization chart

The organization chart shows the persons responsible for safety and the safety officers[[11]](#footnote-11) with their associated functions.

Organization chart (possibly a list of names): **Document B**

* 1. Duties of the Biosafety Officers (BSO)[[12]](#footnote-12) and of the Laboratory and Project Managers

The status, duties and responsibilities of the Biosafety Officers and of the Laboratory and Safety Managers are set out in the job requirements of the relevant employees.

A list of the duties can be found in:

Duties of the Biosafety Officers and of the Laboratory and Project Managers: [Annex 1](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B9gmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

Job descriptions of the Biosafety Officers: **Document C**

In this regard, **(company name)** is guided by the appropriate guideline of the Swiss Agency for the Environment, Forests and Landscape (SAEFL)[[13]](#footnote-13).

* 1. List of employees

Group 2 microorganisms represent a potential hazard for employees. **(The company)**keeps a list of persons who work with Group 2 organisms and, if required, arranges for a health file to be compiled according to the Ordinance on the protection of personnel from hazards due to microorganisms (SAMV) (see Chapter 4.4).

List of employees according to SAMV: [Annex 2](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B9hGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

1. Emergency organization: planning and incident management
   1. Emergency telephone numbers and contacts for safety issues

The emergency telephone numbers and contact addresses of persons able to provide information on safety matters are available in every laboratory and near the telephones. This is of paramount importance for dealing with an incident quickly.

Emergency telephone numbers and contacts for safety issues: [Annex 3](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B,fGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

* 1. Emergency planning: action in the event of incidents in   
     the laboratory and emergency situations

When organisms are being used, emergency situations of various degrees of seriousness may arise owing to spillage of infectious material, release of aerosols, injuries, fire, explosion and escape of water.

Whilst minor incidents are, in general, dealt with by the person(s) who caused them – with the assistance of the Biosafety Officers if appropriate – the emergency services must always be alerted in the case of serious incidents.

Emergency planning: action in the event of incidents in the laboratory: [Annex 4](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B,fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

* 1. Report sheet for laboratory incidents

In the event of a laboratory incident involving Class 2 activities, the precise circumstances leading to contamination of the body or to an injury – even if only a minor one – must be recorded. All laboratory incidents must be reported to the BSO and the managers.

Incidents must be recorded by completing the *Report sheet for laboratory incidents*.[[14]](#footnote-14)

Report sheet for laboratory incidents: [Annex 5](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B,gGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

The report sheets for laboratory incidents are used by the BSO to investigate the causes of incidents, so that measures can be initiated to reduce and prevent risks. The completed report sheets are kept by the BSO and the managers for at least 5 years.

* 1. Health file

In order to ensure rapid availability of the various employees' occupational health data, these data are collected together in the so-called health file.

**(company name)**keeps a health file for those employees for whom a medical examination has become necessary as a direct result of their work. This could involve either medical diagnoses and measures after an occupational accident or laboratory incident or after other forms of exposure to microorganisms or if there is good reason to suspect an infectious disease acquired during occupational activity, or preventive measures such as a vaccination[[15]](#footnote-15).

The following details are recorded in the health file (according to Art. 14(3) SAMV)[[16]](#footnote-16):

reasons for the particular medical precautions;

investigations into the employees’ immune status;

vaccinations given;

* results of medical examinations after accidents and incidents or other forms of exposure to microorganisms or if there is good reason to suspect an infectious disease acquired during occupational activity.

The health file is kept by the doctor called in, either as a separate dossier or as a component/ folder in an already existing medical history, if, for example, the person examined also consults the same doctor privately. The form and layout of the health file are left to the doctor who has been called in[[17]](#footnote-17).

If other work-related medical examinations (e.g. concerning radiation protection) are also carried out by the doctor involved, these shall be included or combined in the same personal dossier.

* 1. Safety documentation for emergency services

In order to be able to ensure a reliable response in the event of a fire or other incidents, **(company name)**has informed the emergency services about its activities and the correspon­ding premises. The information required has been put together in direct consultation with the local emergency/disaster services and authorities.

This information consists of:

1. hazard plans / plan of the locality (fire zones; access routes; premises where work is carried out with organisms; storage locations and stored quantities of organisms as well as of radioactive isotopes or of flammable or explosive chemicals)
2. project list[[18]](#footnote-18)
3. protective measures required according to the response plan
4. **… (not a definitive list)**

Safety documentation: **Document D**

1. Risk assessment
   1. Compulsory reporting of activities

The risks of an activity and the reporting and authorization requirements according to [ESV](http://www.admin.ch/ch/d/sr/c814_912.html) (Art. 8–10) and [SAMV](http://www.admin.ch/ch/d/sr/c832_321.html) (Art. 5 and 6) are established at an early stage. To this end, before the start of the activity, the project managers report to the BSO all new activities, major changes (e.g. use of new organisms with significantly different characteristics) or significant new knowledge concerning safety-related aspects of an ongoing activity.

**(company name)**also informs the authorities of the end of an activity.

* 1. Project list and inventory of biological agents

The BSO has an overview of the activities involving organisms at **(company name)**and sets them all out in a project list.[[19]](#footnote-19)

* Project list: [Annex 6](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B,gmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

The project list is updated at least every six months and whenever there are new reports and applications.

1. Safety measures and rules of conduct
   1. Access control and labelling of the Level 2 working area

Access to Level 2 laboratory premises is restricted to an authorized group of persons and is governed by the containment concept of **(company name).**

* Rules on access to the Level 2 working area: [Annex 7](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B,hGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

Nonetheless, it shall always be ensured that, in the event of an incident (e.g. fire), the emer­gency services are able to access the area quickly and safely **(fire brigade’s key)** and the escape routes are available for use.

The entrance areas to the laboratories are labelled and warning signs (restricted access and warning of a hazard due to organisms) are in place. With regard to the labelling of laboratories and equipment with the “biohazard” warning symbol, **(company name)** is guided by the principles of the template specified below.

* Meaning and use of the “biohazard” warning symbol: [Annex 8](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B_fGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)
  1. Instructions for safe working
     1. Operating instructions and rules of conduct (Standard Operating Procedures, SOPs)

Rules concerning various aspects of occupational safety and environmental safety at **(company name)** are set out in operating instructions, work instructions or the so-called Standard Operating Procedures (SOPs).

These documents are attached to the Annex of the present plant safety concept.

**SOP on ...: Document E1**

* **SOP on…: Document E2**
  + 1. Laboratory safety rules

**(Company name)** adheres to the legally binding “Principles of good microbiological practice” according to Annex 3 of SAMV.

The laboratory rules applicable to **(company name)** are based on these “Principles of good microbiological practice”, which have been adapted and supplemented for the particular plant.

* Laboratory rules: [Annex 9](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B_fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)
  + 1. Use of the Class 2 microbiological safety cabinet

Correct operation and use and regular maintenance of the microbiological safety cabinets are essential for the protection of people and the environment as well as for the quality of research and test results and are explained in detail in a separate leaflet.

* Use of the Class 2 microbiological safety cabinet: [Annex 10](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B_gGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)
  + 1. Biological safety during centrifuging

In order to prevent the harmful formation of aerosols during centrifugation and the dispersal of organisms, **(company name)**adheres to the instructions of the centrifugation manufacturer and uses appropriate aerosol-tight covers with its rotors.

* + 1. Prevention of infectious diseases transmissible by blood[[20]](#footnote-20)

In order to prevent infectious diseases, the pathogens of which can be transmitted by blood or other body fluids, special safety precautions apply to the handling of relevant samples.[[21]](#footnote-21)

* Measures to prevent infectious diseases transmissible by blood: [Annex 11](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B_gmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)
  1. Training / information to ensure safety at work

At **(company name),** training is an important element for ensuring the safety of people and the environment. **The regular employee appraisal, containing specific measures for advance­ment as an integral component, serves as the basis for continuing training tailored to the particular person.*[[22]](#footnote-22)***

Introduction to work: **Document F1**

Employee appraisal: **Document F2**

* Support and training: **Document F3**
  1. Standards for laboratory cleaning
     1. Disinfection and cleaning – hygiene plan

The hygiene plan helps towards personal safety at work and also minimizes the escape of organisms into the environment.

* Disinfection and cleaning (hygiene plan): [Annex 12](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4B_hGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

Factors such as the spectrum of activity, concentration used and exposure time are crucial for optimized use of cleaning agents and disinfectants. Only disinfectants which are effective for dealing with the organisms to be rendered inactive may be used and the manufacturer’s instructions on use must be followed.

The directions for use, safety data sheets and the in-house instructions on use concerning the products used at**(company name)** are listed in separate documentation.

* List of documentation concerning all disinfectants used: **Document G; Location …**
  + 1. Safety instructions for the cleaning service

The safety instructions to be followed during the cleaning of laboratories are recorded in a leaflet and the **(company name)** cleaning personnel has received appropriate instruction.

* Safety during the cleaning of laboratories by the cleaning service: [Annex 13](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4F2fGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

Special safety precautions are followed in respect of the handling of waste which could contain pathogens of infectious diseases transmissible by blood or other body fluids. See Chapter 6.2.5 in this regard.

* 1. Disposal of biologically contaminated waste
     1. Disposal plan

Correct disposal of contaminated waste is a key requirement for minimizing or preventing the escape of organisms from a laboratory and thereby averting a risk to people and the environment. The separate disposal plan contains detailed information on how the handling of waste is organized.[[23]](#footnote-23)+[[24]](#footnote-24)

* Disposal plan for biologically contaminated waste: [Annex 14](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4F2fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)
  + 1. Inactivating biological waste by autoclaving

The operation of the autoclave is set out in operating instructions.

* Autoclave operating instructions: **Document H; Autoclave location**
  1. Purchase, servicing and maintenance of equipment
     1. Declaration of conformity and manuals

**(company name)** ensures that the machinery (equipment) used in its plant complies with the applicable safety provisions. Therefore, when purchasing new equipment, it insists that the declaration of conformity[[25]](#footnote-25) and the manual[[26]](#footnote-26) are also supplied and files these documents in an orderly way in a place where they are accessible.[[27]](#footnote-27)

Equipment documents with declaration of conformity: **Documents I; Location …**

* + 1. Responsibility for servicing and maintenance of equipment

At **(company name),** all items of technical equipment are serviced regularly, so that, apart from the quality of the research and diagnostic results, the safety of the workforce and, generally, the protection of people and the environment can be ensured. Service plans for individual items of equipment and the rules concerning responsibilities are set down in writing.[[28]](#footnote-28)

Service plan and responsibility for maintenance of equipment: [Annex 15](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4F2gGym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc)

* Service contracts : **Documents J; Location …**
  1. Transportation of organisms or infectious biological agents

With regard to in-house and external transportation of organisms or infectious biological agents, **(company name)** adheres generally to the statutory requirements and follows the relevant national and international transport regulations[[29]](#footnote-29) on labelling and packing.

If a sample containing organisms is transported outside the plant for diagnostic or research purposes, the smallest quantities and lowest concentrations of cells possible are packed at **(company name)** for reasons of safety.[[30]](#footnote-30) The subsequent goods are transported with the appropriate labelling.

If, as a special case, wastes involving a risk of contamination (e.g. tissue waste, waste containing blood, secretions or excreta, blood bags and banked blood) or strong-smelling or nauseating wastes are transported, the labelling and packing regulations listed in [Annex 14](http://www.bafu.admin.ch/biotechnologie/01744/01752/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCFd4F2fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.doc) *Disposal plan for biologically contaminated waste* are used.

Table 2

In summary, the following applies:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| UN Nummber | Official description | Hazard label | ADR packing instruction | Field of application |
| UN 3373 | Biological substances category B | Class 6.2 | P 650[[31]](#footnote-31) | Group 2 (possibly 3) and Category B microorganisms[[32]](#footnote-32) |
| UN 3245 | Genetically modified microorganisms | Class 9 | P 904[[33]](#footnote-33) | Group 1 microorganisms[[34]](#footnote-34) |
| UN 1845 | Carbon dioxide, solid (dry ice), only to be named in the case of transportation by air | Class 9 |  | Packing material |
| UN 1977 | Nitrogen, refrigerated liquid | Class 2.2 |  | Packing material |

*Detailed and regularly updated information on the transportation of organisms* can be found on the homepage of the Biosafety Section of the Canton of Zurich's Office of Waste, Water, Energy and Air (WWEA) as well as in the information brochure *Transport biologischer Stoffe und Organismen* (Transportation of biological substances and organisms), published by Fachstelle Biologische Sicherheit Ost (FBSO) (version of March 2018).[[35]](#footnote-35)

* 1. Chemical safety
     1. Storage / quantities

As a general target, chemicals will only be kept in the laboratories of **(company name)**in the quantities necessary for uninterrupted daily working. Highly flammable liquids are kept in suitable marked cupboards or cupboard compartments. The long-term storage facility is located outside the laboratories and complies with the fire regulations. The relevant guidelines of the Federal Coordination Commission for Occupational Safety[[36]](#footnote-36) are complied with.

When handling and storing chemicals, **(company name)** follows the stipulations of the relevant safety data sheets which are filed in an orderly manner.

* Safety data sheets of the chemicals used: **Document K; Location …**
  + 1. Disposal

Chemical wastes, strong acids and alkalis, and (chlorinated) organic solvents are collected in accordance with the applicable rules[[37]](#footnote-37) and disposed of according to VeVA[[38]](#footnote-38). **(Company name)** has an appropriate collection point and operating number for the handover of hazardous waste.

* Operating number for the handover of hazardous waste: **…**
  1. Radiation protection – use of ionizing radiation[[39]](#footnote-39)

Rules on the use of ionizing radiation and handling of isotopes are set out in separate operating procedures and work instructions and are based on the regulations in force[[40]](#footnote-40) and the recommendations given in the Experts’ Course of the Paul Scherrer Institute (PSI).

**(company name)**is authorized to use ionizing radiation:

Authorization from the Federal Office of Public Health: **Document L; Valid, unless withdrawn, until: …**

Radiation protection file: **Document M; Location …**

* Work instructions on the use of isotopes: **Document(s) N**
  1. Planning, building, modification, demolition and relocation

One of the tasks of the Safety Officers is to submit to the company management the applications for changes to the safety precautions in line with the latest scientific and technical developments, even though this might mean structural modifications or a new building.

The relevant Safety Officers are always consulted whenever new building work or structural modifications are carried out at **(company name)** and whenever technical changes are made to safety-related facilities.[[41]](#footnote-41)

Specially adapted safety precautions, especially to decontaminate the laboratories and the technical facilities, are taken at the appropriate time for structural modifications, change of use, demolition and relocation. If, despite prior decontamination, it is impossible to rule out risks due to organisms completely, this aspect will be covered explicitly in the steps for dealing with incidents for the particular phase of building with an increased risk due to organisms (e.g. removal of filters etc.).

Annex

Index of templates

Annex 1

Duties of the Biosafety Officers and of the Laboratory and Project Managers

Annex 2

List of employees according to SAMV

Annex 3

Telefonnummern für Notfälle und Kontakte für Sicherheitsfragen

Annex 4

Emergency telephone numbers and contacts for safety issues

Annex 5

Report sheet for laboratory incidents

Annex 6

Project list

Annex 7

Rules on access to the Level 2 working area

Annex 8

Meaning and use of the “biohazard” warning symbol

Annex 9

Laboratory rules

Annex 10

Use of the Class 2 microbiological safety cabinet

Annex 11

Measures to prevent infectious diseases transmissible by blood

Annex 12

Disinfection and cleaning (hygiene plan)

Annex 13

Safety during the cleaning of laboratories by the cleaning service

Annex 14

Disposal plan for biologically contaminated waste

Annex 15

Service plan and responsibility for maintenance of equipment

Index of in-house documents

Document A

Mission statement

Document B

Organization chart (possibly list of names)

Document C

Job descriptions of the Biosafety Officers

Document D

Safety documentation

Document E

Spec. operating instructions, work procedures and Standard Operating Procedures (SOPs)

Document F

Introduction to work / employee appraisal / support and training

Document G

List of documentation concerning all disinfectants used

Document H

Autoclave operating instructions

Document I

Equipment documents with declaration of conformity

Document J

Service contracts

Document K

Safety data sheets of the chemicals used

Document L

Authorization from the Federal Office of Public Health

**Document M**

Radiation protection file

**Document N**

Work instructions on the use of isotopes

1. Verordnung vom 25. August 1999 über den Umgang mit Organismen in geschlossenen Systemen (Einschliessungsverordnung, [ESV](http://www.admin.ch/ch/d/sr/c814_912.html), SR 814.912) or Containment Ordinance ([CO](http://www.bafu.admin.ch/biotechnologie/02618/index.html?lang=en&download=NHzLpZig7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCEdH58fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf)) [↑](#footnote-ref-1)
2. Verordnung vom 25. August 1999 über den Schutz der Arbeitnehmerinnen und Arbeitnehmer vor Gefährdung durch Mikroorganismen ([SAMV](http://www.admin.ch/ch/d/sr/c832_321.html), SR 832.321) or Ordinance on the protection of personnel from hazards due to microorganisms [↑](#footnote-ref-2)
3. *In italics* means “activatable link”. By clicking on it, it is possible to open the corresponding document directly in the MicrosoftWord or Acrobat-Reader (PDF) program and – in the case of MicrosoftWord – edit it. [↑](#footnote-ref-3)
4. A plant where work is done with pathogenic or genetically modified organisms falls within the scope of the Containment Ordinance ([ESV](http://www.admin.ch/ch/d/sr/c814_912.html), SR 814.912) and the Ordinance on the protection of personnel from hazards due to microorganisms ([SAMV](http://www.admin.ch/ch/d/sr/c832_321.html), SR 832.321). The scopes of these ordinances complement each other and contribute to protection of the environment, protection of the population and protection of the health of individual employees. [↑](#footnote-ref-4)
5. *Safety concept according to ESV and SAMV for Level 2 laboratories – Template for plant-specific additions;* 24 pages plus an annex of 30 pages; published by: Federal Office for the Environment (FOEN); obtainable from: [http://www.bafu.admin.ch/](http://www.umwelt-schweiz.ch/) » Topics » [Biotechnology](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/index.html) » [National activities](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/national/index.html) » Contained use » Implementation guides for the use of organisms [↑](#footnote-ref-5)
6. *Richtlinie: Betriebliches Sicherheitskonzept nach ESV;* published by.: Federal Office for the Environment (FOEN); 2008; obtainable from: [http://www.bafu.admin.ch/](http://www.umwelt-schweiz.ch/) » Topics » [Biotechnology](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/index.html) » [National activities](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/national/index.html) » Contained use » Implementation guides for the use of organisms [↑](#footnote-ref-6)
7. The company defines its protection targets to prevent accidents at work as well as harmful and annoying effects on the environment and the population. [↑](#footnote-ref-7)
8. The drawing-up of the plant safety concept may act as a trigger for formulating a company mission statement and for incorporating the safety principles set out in chapter 2. [↑](#footnote-ref-8)
9. There is an occupational safety interface to Guideline No. 6508 of the Federal Coordination Commission for Occupational Safety (Richtlinie über den Beizug von Arbeitsärzten und anderen Spezialisten der Arbeitssicherheit; EKAS 6508.d – 10.98 ; address for orders: <http://www.suva.ch/> > Direktzum Thema > Infomittel (Waswo) –> SUVA - enter Order No. 6508 or direct <https://wwwsapp1.suva.ch/sap/public/bc/its/mimes/zwaswo/99/pdf/06508_d.pdf> [↑](#footnote-ref-9)
10. According to Article 7 Paragraph 4 of Ordinance 3 from the 18th of August 1993 to the Employment Act (ArGV 3, SR 822.113) the following applies: “The rules regarding responsibilities in the plant do not exempt the employer from his responsibility to protect health.” [↑](#footnote-ref-10)
11. Depending on the plant, there are various areas for which Safety Officers need to be designated: Biosafety Officers, Chemical Safety Officers, Radiological Safety Officers, Fire Protection Officers, Security Officers and Staff Medical Service. [↑](#footnote-ref-11)
12. BSO = Biosafety Officer [↑](#footnote-ref-12)
13. Guideline: Biosafety Officer (BSO) – Status, duties and responsibilities. Published by: Swiss Agency for the Environment, Forests and Landscape (SAEFL), 2005; obtainable from: [http://www.bafu.admin.ch/](http://www.umwelt-schweiz.ch/) » [Topics](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/index.html) » [Biotechnology](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/index.html) » [National activities](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/national/index.html) » Contained use » Implementation guides for the use of organisms   
    or direct: <http://www.bafu.admin.ch/php/modules/shop/files/pdf/phpjYQ7Xf.pdf> [↑](#footnote-ref-13)
14. For this purpose it is also possible to use the “Ereignisprotokoll” (incident report) – SNAIF, Order No. 66100/1.d, which enables a laboratory incident to be recorded in more detail. Order address: <http://www.suva.ch/> > Direkt zum Thema > Infomittel (Waswo) –> SUVA - enter Order No. 66100/1 or direct <https://wwwsapp1.suva.ch/sap/public/bc/its/mimes/zwaswo/99/pdf/66100_1_d.doc> [↑](#footnote-ref-14)
15. In this connection, a vaccination is the most important example of “a particular occupational health measure”. [↑](#footnote-ref-15)
16. In the event of any queries, it is possible to contact SNAIF’s Occupational Health Department; Tel. 041 419 57 60. [↑](#footnote-ref-16)
17. The doctor called in does not necessarily have to be an occupational health specialist, but may, according to SAMV, also be a company doctor or an independent medical examiner. What is crucial, however, is that this person knows the work situation and the working conditions, so that a link to the workplace can be esptablished during the health assessment and the necessary plan of occupational health measures can be drawn up. In this regard, compare Art. 2.4 of guideline 6508 of the Federal Coordination Commission for Occupational Safety concerning the calling-in of occupational health doctors and other occupational safety specialists (“Beizug von Arbeitsärzten und anderen Spezialisten der Arbeitssicherheit”); order address: <http://www.suva.ch/> > Direkt zum Thema > Infomittel (Waswo) –> SUVA - enter Order No. 6508 or direct <https://wwwsapp1.suva.ch/sap/public/bc/its/mimes/zwaswo/99/pdf/06508_d.pdf> [↑](#footnote-ref-17)
18. Note Chapter 5 in this connection. [↑](#footnote-ref-18)
19. One possibility is to coordinate this overview of activities (Template 6) with the details for the project-specific list according to Art. 13 SAMV (for the attention of the Swiss National Accident Insurance Fund and the Factory Inspectorate) and to draw up a combined project list. [↑](#footnote-ref-19)
20. If no work is done with the relevant organisms in a particular plant, the whole of Chapter 6.2.5 can be omitted. [↑](#footnote-ref-20)
21. Explanatory information can be found in Verhütung blutübertragbarer Infektionen im Gesundheitswesen; 2869/30; order address: <http://www.suva.ch/> > Direkt zum Thema > Infomittel (Waswo) –> SUVA - enter Order No. 2869/30; or direct <https://wwwsapp1.suva.ch/sap/public/bc/its/mimes/zwaswo/99/pdf/02869_30_d.pdf> [↑](#footnote-ref-21)
22. Introduction to work, employee appraisal, support and continuing training are regulated as a component of QA Management at (company name). [↑](#footnote-ref-22)
23. See also the implementation guide issued by SAEFL: BULETTI M. 2004: Entsorgung von medizinischen Abfällen. Vollzug Umwelt. Swiss Agency for the Environment, Forests and Landscape, Berne. 72 pp.; Order No.: VU-3010-D.  
    Obtainable from: <http://www.bafu.admin.ch/> » Documentation » Publication » Waste or direct: <http://www.bafu.admin.ch/php/modules/shop/files/pdf/phpi9yclR.pdf> [↑](#footnote-ref-23)
24. See also the Statement of the Swiss Expert Committee for Biosafety: Waste disposal in medical microbiology diagnostic laboratories, 10 pages, Revised edition, August 2006; Swiss Expert Committee for Biosafety, c/o Swiss Agency for the Environment, CH-3003 Berne; obtainable from: [http://www.efbs.admin.ch/](http://www.umwelt-schweiz.ch/) » [Documentation](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/index.html) » [Statements](http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/index.html) on permit application » Closed Systems; or direct: <http://www.efbs.admin.ch/uploads/media/e-empfehlung-abfallentsorgung-2006_02.pdf> [↑](#footnote-ref-24)
25. With a declaration of conformity the manufacturer or supplier (the so-called “distributor”) confirms that the basic safety and health requirements have been met and the machine sold has been built according to the state of the art. In the event of an accident due to a technical fault in the machine, the distributor is liable and the purchaser, therefore, better protected. [↑](#footnote-ref-25)
26. The machine or item of equipment must also be supplied with a **manual** (with details regarding installation, operation, rectification of faults and maintenance) which is used to instruct the employees. [↑](#footnote-ref-26)
27. Explanatory information can be found in the leaflet: Sicherheit beginnt beim Einkauf!; SNAIF; February 2000, Order No.: 66084.d; <https://wwwsapp1.suva.ch/sap/public/bc/its/mimes/zwaswo/99/pdf/66084_d.pdf> [↑](#footnote-ref-27)
28. If a plant has already established clear rules concerning these aspects by way of its Quality Assurance Management, a reference to the relevant chapters in the Quality Assurance Manual or Quality Management Manual shall suffice. [↑](#footnote-ref-28)
29. International transport regulations: “UN Recommendations on the Transport of Dangerous Goods, Model Regulations”. [↑](#footnote-ref-29)
30. The dispatch of concentrated organisms in the form of cultures belonging to Group 2 or 3 and to Category A according to the international regulations, must be carried out by the company’s Dangerous Goods Safety Adviser or under his supervision and the relevant packing and labelling regulations must be complied with. Regarding the function of the Dangerous Goods Safety Adviser, refer to the Ordinance on Dangerous Goods Safety Advisers for the transport of hazardous materials by road, rail and waterways (Verordnung vom 15. Juni 2001 über Gefahrgutbeauftragte für die Beförderung gefährlicher Güter auf Strasse, Schiene und Gewässern [SR 741.622](http://www.admin.ch/ch/d/sr/7/741.622.de.pdf) (Gefahrgutbeauftragtenverordnung, GGBV). [↑](#footnote-ref-30)
31. For packing instructions P650, search for P650 in the following PDF document: <http://www.unece.org/trans/danger/publi/adr/adr2007/English/04-0%20E_Part%204.pdf> [↑](#footnote-ref-31)
32. See UN Regulation 2.2.62.1.4.2 <http://www.unece.org/trans/danger/publi/adr/adr2007/English/02-0%20E_Part%202.pdf> [↑](#footnote-ref-32)
33. For packing instructions P904, search for P904 in the following PDF document: <http://www.unece.org/trans/danger/publi/adr/adr2007/English/04-0%20E_Part%204.pdf> [↑](#footnote-ref-33)
34. These are GMOs which do not correspond to the definition of potentially infectious substances, but are nonetheless able to modify animals, plants or microbiological substances in a way that does not normally result from natural reproduction (quoted from ADR). [↑](#footnote-ref-34)
35. [*https://awel.zh.ch/content/dam/baudirektion/awel/biosicherheit\_neobiota/biosicherheit\_in\_betrieben/transport/Transportvorschriften%202018.pdf*](https://awel.zh.ch/content/dam/baudirektion/awel/biosicherheit_neobiota/biosicherheit_in_betrieben/transport/Transportvorschriften%202018.pdf) [↑](#footnote-ref-35)
36. Chemische Laboratorien (Guideline No. 1871 of the Federal Coordination Commission for Occupational Safety)   
    Brennbare Flüssigkeiten – Lagern und Umgang (Guideline No. 1825 of the Federal Coordination Commission for Occupational Safety)   
    Säuren und Laugen (Guideline No. 6501 of the Federal Coordination Commission for Occupational Safety)  
    Order address: <http://www.suva.ch/> > Direkt zum Thema > Infomittel (Waswo) –> enter appropriate number. [↑](#footnote-ref-36)
37. As footnote 36 [↑](#footnote-ref-37)
38. Ordinance on the Movement of Waste (Verordnung vom 22. Juni 2005 über den Verkehr mit Abfällen; VeVA; SR 814.610. [↑](#footnote-ref-38)
39. If no work is done with ionizing radiation or with isotopes in a particular plant, the whole of Chapter 6.9 can be omitted. [↑](#footnote-ref-39)
40. Radiation Protection Act (Strahlenschutzgesetz vom 22. März 1991 ([StSG](http://www.admin.ch/ch/d/sr/c814_50.html), SR 814.50)), Radiation Protection Ordinance (Strahlenschutzverordnung vom 22. Juni 1994 ([StSV](http://www.admin.ch/ch/d/sr/c814_501.html), SR 814.501)) and Ordinance on the Use of Open Sources of Radiation (Verordnung vom 21. November 1997 über den Umgang mit offenen radioaktiven Strahlenquellen ([SR 814.554](http://www.admin.ch/ch/d/sr/814_554/index.html))) [↑](#footnote-ref-40)
41. Safety aspects such as fire prevention, rules on access or environmental and occupational safety are closely linked to planning and construction. Constructional measures are often a prerequisite for technical safety precautions. Constructional and technical safety measures which are considered together with the proposed operating procedures at the planning stage ensure trouble-free operation in the future. [↑](#footnote-ref-41)