

Operational safety concepts according to Containment Ordinance (CO)

Guideline for enforcing the Containment Ordinance (CO). State 2019



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Office for the Environment FOEN

Operational safety concepts according to Containment Ordinance (CO)

Guideline for enforcing the Containment Ordinance (CO). State 2019

Imprint

Legal status

This publication is an enforcement aid issued by the FOEN in its capacity as a supervisory authority and is aimed primarily at the enforcement authorities. It seeks to clarify federal environmental law provisions (in relation to indeterminate legal concepts and the scope for/exercise of discretionary powers) so as to facilitate consistent enforcement practices. Authorities that give due consideration to this enforcement aid can safely assume that federal law is being correctly implemented. Alternative approaches are, however, permissible provided they comply with the legal requirements.

Publisher

Federal Office for the Environment (FOEN)
The FOEN is an office of the Federal Department for the Environment, Transport, Energy and Communications (DETEC).

Authors

Dr Valentin Küng, Küng – Biotech + Umwelt, Bern

Guidelines Group

Dr Thomas Binz, BAG
Dr Karoline Dorsch-Häsler, Executive Secretary of SECB
Dr Daniel Fischer, AWEL (ZH)
Dr Martin Gschwind, SUVA
Dr Carmen Spycher, FOEN
Dr Urs Vögeli, KCB (BS)

ERFA BIO

(Draft Guidelines submitted to the Federal Council):

Dr Thomas Behrmann, AWEL (ZH)
Dr Daniela Burkart, AfU (LU)
Dr Alfred Feichtinger, UniZH
Dr Ursula Jenal, Beratung Biosicherheit (formerly FOEN)
Dr Valentin Küng, Küng – Biotech + Umwelt
Dr Andreas Riesen, F. Hoffmann-La Roche AG
Dr Alfred Stämpfli, AFU (SG)
Dr Urs Vögeli, KCB (BS)

In-house consultants

Dr Carmen Spycher and Dr Sabrina Leuenberger,
Biotechnology and Substance Flows Section, FOEN

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: 23 pp.

Translation

Jackie Leach Scully, Basel and FOEN Language Services

Layout

Cavelti AG, Marken. Digital und gedruckt, Gossau

Cover photo

Dr Kathrin Summermatter, FVO

Link to PDF file

www.bafu.admin.ch/uv-0817-e
(no printed version available)

This publication is also available in German, French and Italian.

Updated version 2019. © FOEN 2019

Table of contents

<u>Abstracts</u>	5
<u>Foreword</u>	6
<u>Summary</u>	7
<u>Preliminary remarks</u>	8
<u>1 Introduction</u>	9
1.1 Legal foundations	9
1.2 Safety concept: general	9
1.3 Purpose of a biosafety concept according to the CO	10
1.4 Scope and content of a biosafety concept according to the CO	10
<u>2 Content of the biosafety concept according to the CO</u>	11
2.1 Safety goals	11
2.2 Safety organisation	11
2.3 Safety analysis	12
2.4 Safety measures and documentation	13
2.4.1 Operating instructions, work instructions and codes of conduct	14
2.4.2 Basic and advanced training	14
<u>3 More detail on selected topics</u>	15
3.1 Instructions for waste disposal	15
3.2 Instructions for transport	15
3.3 Instructions for preventing and remedying accidents	16
3.4 Adaptation of the safety measures for building, modification, demolition and relocation	16
<u>Annexes</u>	18
<u>Index</u>	22

Abstracts

The Containment Ordinance (CO) requires for all types of activities as a general safety measure the observance of a safety concept for the installation (Art. 12 and Appendix 4 para. 1 CO). This implementation guide describes in concrete terms how biosafety should be treated in an installation's safety concept, and can therefore be used as instructions for drawing up, supplementing or monitoring such a concept. It also shows where interfaces with other aspects of safety could arise.

Die Einschliessungsverordnung (ESV) verlangt für alle Arten von Tätigkeiten als allgemeine Sicherheitsmassnahme die Einhaltung eines betrieblichen Sicherheitskonzeptes (Art. 12 und Anh. 4 Ziff. 1 ESV). Die vorliegende Vollzugshilfe konkretisiert, wie die biologische Sicherheit nach ESV in einem betrieblichen Sicherheitskonzept zu behandeln ist, und kann in diesem Sinne als Anleitung zur Erstellung, Ergänzung oder Überprüfung eines solchen Konzeptes verwendet werden. Es wird aufgezeigt, wo sich Schnittstellen zu anderen Sicherheitsaspekten ergeben können.

L'ordonnance sur l'utilisation confinée (OUC) requiert le respect d'un programme de sécurité d'entreprise comme mesure de sécurité générale pour tous les types d'activité (art. 12 et annexe 4, ch. 1, OUC). La présente aide à l'exécution précise comment la sécurité biologique au sens de l'OUC doit être traitée dans un programme de sécurité d'entreprise. Elle sert de mode d'emploi pour élaborer, compléter ou contrôler un programme de sécurité. Elle montre également où des recoupements sont possibles avec d'autres aspects liés à la sécurité.

L'ordinanza sull'impiego confinato (OIConf) richiede, quale misura di sicurezza generale, il rispetto del piano di sicurezza aziendale per tutti i tipi di attività (art. 12 e all. 4 n. 1 OIConf). Il presente aiuto all'esecuzione spiega nel dettaglio come trattare la sicurezza biologica secondo l'OIConf in un piano di sicurezza aziendale e può in questo senso servire da guida per l'elaborazione, l'integrazione o la verifica di un siffatto piano. Viene illustrato dove potrebbero esistere punti in comune con altri aspetti legati alla sicurezza.

Keywords:

Safety concept, safety measures, biosafety, organisms, biotechnology, gene technology

Stichwörter:

Sicherheitskonzept, Sicherheitsmassnahmen, Biosicherheit, Organismen, Biotechnologie, Gentechnologie

Mots-clés:

Concept de sécurité, programme de sécurité, mesures de sécurité, sécurité biologique, organismes, biotechnologie, génie génétique

Parole chiave:

piano di sicurezza, misure di sicurezza, biosicurezza, organismi, biotecnologia, ingegneria genetica

Foreword

Good company management includes drawing up a safety concept for the operation of an installation in order to ensure the safety of humans, animals and the environment. Accordingly, the Containment Ordinance (CO), which regulates the handling of genetically modified or pathogenic organisms in contained systems, requires compliance with the installation's biosafety concept, in particular the installation's associated instructions and codes of conduct.

A safety concept like this covers various aspects of biological safety, of which the risk assessment according to Articles 5.2, 7 and 12 CO for specific activities is best known. Obviously, however, the safety concept must go further and, for example, include the transport and disposal of organisms, or the procedure to be followed in case of industrial incidents. The evaluation of all these safety aspects is a continuing process, as ongoing developments in an installation and new findings mean that the safety measures taken and those planned must be examined repeatedly.

The CO does not specify details of how biosafety should be treated within a safety concept. This implementation guide therefore offers help to installations and to enforcement authorities in drawing up, supplementing and testing a biosafety concept.

Biosafety according to the CO is generally only one component of a higher-level concept that covers further aspects of safety. This document briefly describes the key interfaces that may affect installations with activities that fall within the CO's remit.

The FOEN thanks all those who helped to produce this implementation guide.

Franziska Schwarz, Vice Director
Federal Office for the Environment (FOEN)

Summary

The Containment Ordinance (CO) requires that all types of activity involving genetically modified or pathogenic organisms in contained systems must comply with the installation's biosafety concept and the associated instructions and codes of conduct (Art. 10 and Appendix 4 para. 1 CO). This implementation guide states in practical terms how biosafety according to the CO should be treated within an installation's safety concept, and can be used by installation owners and enforcement authorities as instructions for drawing up, supplementing or testing such a concept.

According to the CO, the safety concept should lay down all safety measures that are necessary to ensure the safety of humans, animals or the environment when handling genetically modified or pathogenic organisms. The safety concept forms the binding, written, established framework, which defines how an installation handles its responsibility under the CO from the strategic level down to the individual employee. The CO provides that the usual topics of a safety concept, i.e. safety goals, safety organisation, safety analysis and safety measures, should be considered in terms of biosafety. The central element is the safety analysis, a continual process, which records the risks of all activities according to the CO and evaluates and lays down the necessary safety measures for the installation in the context of the safety goals.

The safety concept should cover all handling of organisms according to the CO. This particularly applies to the culture, processing, multiplication, modification, detection, transport, storage or disposal of organisms (Art. 3 letter e CO). Beyond the actual operation, it also contains specially adapted safety precautions for a planned building or its modification, demolition or relocation.

In an installation, further areas associated with biosafety also generally need to be considered. The implementation guide shows where interfaces could arise with other safety aspects. These involve the direct protection of workers, accident prevention, other areas of environmental protection, chemical safety, and radiation protection.

Preliminary remarks

This FOEN implementation guide was drawn up by two working groups. On behalf of the State Laboratory of Canton Basel-Stadt and the FOEN, a working group from ERFA BIO¹, together with external experts, first drafted an implementation guide. Drawing up this draft was primarily financed by the State Laboratory of Canton Basel-Stadt. This draft was then reworked by the Guidelines Group (see Authors), under the direction of the FOEN and taking into account experience from installations which had already drawn up biosafety concepts using this first version. Finally, the specialist agencies involved, namely the Federal Office of Public Health (FOPH), the Federal Office of Agriculture (FOAG), the Federal Veterinary Office (FVO), the State Secretariat for Economic Affairs (seco), the Swiss Accident Insurance Fund (SUVA), the Swiss Ethics Committee for Non-human Gene Technology (ECNH), the Swiss Expert Committee for Biosafety (SECB), the cantons and selected installations, were all invited to express their point of view.

In preparing these instructions for an installation's biosafety concept, both working groups drew primarily on the practical experience of the installations and of enforcement practice. For this reason the implementation guide has no bibliography.

¹ ERFA BIO stands for the Intercantonal group ERFA BIO (exchange of technical agency experience in bio- and gene technology).

1 Introduction

1.1 Legal foundations²

The CO requires “compliance with the installation’s biosafety concept and the associated instructions and codes of conduct”

Based on the Environmental Protection Act (EPA), the Gene Technology Act (GTA), and the Epidemics Act (EpG), the Ordinance of 9 May 2012 on the Contained Use of Organisms (Containment Ordinance, CO) regulates activities involving genetically modified or pathogenic organisms in contained systems such as laboratories, growth rooms and greenhouses, animal units and production plants. To protect the environment and the population, safety measures should be taken for such activities according to the type of installation and the class of the activity (Art. 12 CO). Annex 4 of the CO lists the general and additional safety measures. The general safety measures required for all activities include “compliance with the installation’s biosafety concept and the associated instructions and codes of conduct”.

This implementation guide offers installation owners and the enforcement authorities practical guidance on how biosafety according to the CO should be treated in an installation’s biosafety concept. It shows how a safety concept that is adapted to the organisms used and activities performed should be drawn up, and how a new existing one should be examined for its quality, comprehensiveness and appropriateness. The interfaces with the protection of employees and with other aspects of safety will also be briefly explained (see Annex).

1.2 Safety concept: general

Safety goals Safety organisation Safety analysis Safety measures

A safety concept is a common tool for ensuring the safe handling of potential hazards in an installation. It is an all-encompassing concept, covering all aspects relevant to safety. Safety concepts show a uniform structure, i.e. they are divided into safety goals, safety organisation, safety analysis and safety measures.

Especially for installations that handle genetically modified or pathogenic organisms in contained systems according to the CO, biosafety forms a substantial part of this all-encompassing safety concept. In the installations in question there are additional safety aspects, linked more or less strongly to biosafety. Chemicals or radioactive substances are frequently used. In such cases it is important to take into account the interfaces between chemical safety or radiation protection and biosafety. Employees in these installations should be protected from any health hazards.

Overlaps with measures of safety at work or to protect against serious emergencies (industrial accidents)

Not all safety measures that are necessary to protect humans, animals and the environment in normal operations when handling genetically modified or pathogenic microorganisms can be clearly differentiated from measures

² Can be obtained from: <http://www.admin.ch/ch/d/sr.html> (official German, French and Italian versions)

to protect employees or to prevent serious emergencies (industrial accidents). Depending on the activity, there will in practice be varying degrees of overlap with the measures required for these protection objectives.

The Annex of this implementation guide will therefore deal with these interfaces in more detail; but below we will refer to the “Safety concept according to the CO”.

1.3 Purpose of a biosafety concept according to the CO

Safety concept as written, binding framework

The safety concept forms the binding, written, established framework documenting how an installation owner takes on the responsibility he or she has under the CO. This framework reaches from the strategic level of the installation down to the level of individual employees. The safety concept determines all measures that are necessary to ensure safety. The core of each safety concept is the safety analysis, which is based on the risk assessment according to Art. 5.2, 7 and 12 CO.

Risk assessment

Where a new building or laboratory is planned the main features of the safety concept should be integrated into the planning from the outset. It is often the case that construction measures determine whether planned processes and the corresponding safety measures can be guaranteed (see Chapter 3.4).

1.4 Scope and content of a biosafety concept according to the CO

Activity defines safety level

The classification of an activity according to the CO defines the safety level of an installation and thus the measures that are necessary for the safe handling of organisms. The higher the safety level, the more elaborate and numerous these measures generally are. This necessarily increases the demands on the installation's organisation, for example in terms of responsibility structures, duties of the Biosafety Officers, maintenance instructions for technical safety precautions.

2 Content of the biosafety concept according to the CO

This Chapter shows the key elements of biosafety according to the CO that should be described in a safety concept. It contains details of the safety goals, the safety organisation, safety analysis and safety measures. If building, modification, demolition or relocation are planned, the safety concept according to the CO should be supplemented for phases beyond the operating phase (see Chapter 3.4).

2.1 Safety goals

Safety goals for humans, animals and the environment when handling organisms

The safety goals of an installation contain concrete protection objectives for handling organisms in terms of humans, animals and the environment. These goals, together with the principles and strategies for them, can be formulated in the safety concept. When handling genetically modified or pathogenic organisms, contact between the organisms and humans, animals and the environment must be minimised (classes 1 and 2 activities) or prevented (classes 3 and 4 activities).

2.2 Safety organisation

Responsibility lies at the highest level of management

The highest level of management has responsibility for safety organisation. In order for the safety goals and safety provisions of the CO to be implemented, a clear organisational structure should be established and laid down in the safety concept, with designation of the positions with a function in biosafety. Such positions may be the installation management, project leaders, the Biosafety Officer³ and dangerous goods safety adviser.

Emergency planning and incident management

Responsibilities should be established for all biosafety concerns, particularly for performing the safety analysis and risk assessment, for the practical implementation and monitoring of safety measures, emergency planning and incident management (see Chapter 3.3), and drawing up and updating the documentation on biosafety. The following aspects should be laid down:

- Functions or descriptions of the positions (e.g. using an organigramme)
- Persons responsible, including deputies
- Duties
- Competencies assigned in the installation (e.g. authority to give orders)

³ See also: Biosafety Officers (BSO). Status, duties and responsibilities. FOEN implementation guides (2005), <https://www.bafu.admin.ch/bafu/de/home/themen/biotechnologie/publikationen-studien/publikationen/biosicherheitsbeauftragte-bso.html>

-
- Decision paths
 - Resources (financial and personnel)
 - Information exchange
 - Coordination of functions with other safety officers (in particular, for the interfaces listed in the Annex)

2.3 Safety analysis

Risk consciousness as foundation for safety

The safety analysis includes the risks of all activities involving organisms in an installation, and specifies the necessary operational safety measures according to the CO. An installation must be aware of all its potential risks in order to guarantee the appropriate biosafety. The safety analysis has central significance for each installation that is subject to the CO, and should therefore be performed with equal care for large- or small-scale installations and for every handling of genetically modified or pathogenic organisms according to the CO. Handling is defined as any deliberate activity involving organisms. This applies in particular to the culture, processing, multiplication, modification, detection, transport, storage or disposal of organisms (Art. 3 letter e CO).

Risk assessment according to the CO is a component of the safety analysis

The safety analysis contains a risk assessment according to Art. 5.2, 7 and 12 CO. “The possible damage to people and the environment, as well as the extent of potential damage and the probability of its occurrence” must be assessed. The risk assessment should include every handling of the organisms used, and the extent and purpose of the handling. The risk assessment should be performed for all activities, for the individual steps of each activity, and for processes involving organisms. The risk assessment places all these activities into one of four classes.

Notification and authorisation obligation

The handling of genetically modified or pathogenic organisms requires notification and authorisation in accordance with Art. 8-11 CO.

Escape routes into the environment

The CO requires that when handling genetically modified or pathogenic organisms, certain safety measures to protect humans and the environment must be complied with. In normal operations these measures should minimise or – for activities of classes 3 and 4 – prevent the release of organisms through the possible escape routes (exhaust air, waste water, solid waste, vectors) from a contained system. For all types of activities the safety measures (Annex 4 para. 1 CO) and, depending on the class(es) of the activities and the type of installation(s), the additional safety measures of levels 1 to 4 (Annex 4 para. 2 tables 1 to 4 CO), must be observed.

Compliance with safety measures must signify achievement of safety goals

If the general safety measures for all activities and all additional measures for particular levels are observed, it may be assumed that the safety goals will be achieved.

Some of these additional measures may be altered, substituted or omitted. In order to do this the risk of the particular safety measure must be evaluated in the context of the safety goals. For one of the additional measures to be altered, substituted or omitted, it must be shown that the protection of humans and the environment is still ensured, and authorisation must be received from the competent federal authority (Art. 12 para. 3 CO).

Safety analysis is a continuous process

The safety analysis is a continual process, and within its framework the safety measures taken and those planned must be repeatedly examined on the basis of continuing developments in an installation and new findings.

The risk assessments and the safety measures implemented and planned should be documented (see Chapter 2.4).

2.4 Safety measures and documentation

Uniform information for all employees

The documentation of the risk assessments and the safety measures to be observed serves as the basis for informing all employees uniformly and adequately about bio-safety. It should list the documents that are available or will be produced within a set timeframe. It should also establish the actions or events that must be documented. These serve for example to reveal comprehensively any gaps in the safety concept or deficiencies in the implementation of safety measures. The following documents should be part of the safety concept according to the CO:

- Job descriptions of employees with safety responsibilities (see Chapter 2.2)
- Risk assessments, including literature on which they are based (see Chapter 2.3)
- Notifications and authorisation applications, as well as records in accordance with Art. 8-11 CO
- Inventory of biological agents
- Operating instructions, work instructions and codes of conduct (see Chapter 2.4.1), especially rules for waste disposal and transport (see Chapter 3.1) and instructions for prevention and amelioration of accidents (see Chapter 3.3)
- Documentation of basic and advanced training (see Chapter 2.4.2)
- Results of periodic monitoring of construction, technical and organisational safety measures
- Maintenance contracts, plans and documentation
- Records of incidents (event protocol)

Details of completion, access to and updating (periodicity or criteria) of the documents should be stipulated.

2.4.1 Operating instructions, work instructions and codes of conduct

User-friendly safety instructions

The results of the safety analysis indicate which operating instructions, work instructions (Standard Operating Procedures, SOPs) and codes of conduct are required for a safe installation. These instruments put into practical terms the rules for conduct or the use of equipment in the controlled area. They should be user-friendly, kept at a location in the workplace that is easily accessible to employees, and known to the persons responsible. Employees must be informed, and encouraged and supported in complying with the safety measures. Important topics include:

- Access rules from safety level 2 (also applies to visitors, maintenance and cleaning staff)
- Codes of conduct for entering and leaving the controlled work area
- Principles of good microbiological practice
- Measures to prevent formation of aerosols
- Personal protective measures (work clothing and protective equipment)
- Operation and maintenance of equipment (autoclaves, centrifuges, safety cabinets etc.)
- Disinfection and cleaning of workplaces, equipment and rooms (hygiene schedule)
- Waste disposal
- Transport (within the installation and external transport)
- Prevention of and procedures for remediation of an accident (spillage or escape of organisms into the environment)
- Monitoring the safety measures (frequency and type of monitoring, and monitoring tools).

2.4.2 Basic and advanced training

Knowledge of safe conduct and work promotes safety

One key element in ensuring safety is basic and advanced training of the employees. They should be given regular training on their tasks and responsibilities according to their knowledge and experience. Documents for basic and advanced training could encompass the following topics:

- Contents (e.g. risk assessment safety measures, procedure for incidents and accidents)
- Communication of content (courses, written documents used, training monitoring)
- Target groups (Biosafety Officers, project leaders, academic and technical staff, laboratory, cleaning and transport staff, trainees etc.)
- Time point and periodicity of training (on starting a job, continuous)

3 More detail on selected topics

3.1 Instructions for waste disposal

Environmentally friendly disposal

According to the CO the safety concept should show how the installation ensures the safe handling of and the environmentally friendly disposal of wastes. The following steps should be clarified and regulated:

- Collection: principles of collection (solids/liquids), principles of waste separation
- Transport to the collection point and to the point of treatment (transport containers)
- Temporary storage: centralised / decentralised, duration, volumes
- Inactivation: principle of thermal or chemical inactivation, monitoring of success of inactivation, maintenance and validation of inactivation equipment (frequency and methods)
- Disposal: type and place of disposal, transport, special waste (yes/no⁴)
- Cleaning of equipment and transport vehicle.

3.2 Instructions for transport

The safety concept according to the CO should demonstrate how the installation transports genetically modified or pathogenic organisms. The following points are significant:

- Transported goods (genetically modified or pathogenic organisms, wastes, cultures, samples for diagnostics)
- Packaging, labelling, accompanying documents (for external transport)
- Means of transport and transport companies used
- Differentiation between transport internal and external to the installation.

⁴ Depending on the type of waste, it may count as special waste, according to the Ordinance on the Movements of Waste (OMW); the applicable regulations must be observed.

3.3 Instructions for preventing and remedying accidents

Knowledge and rapid information about existing potential hazards

The safety concept according to the CO includes measures to prevent or remedy an incident. It should show how external authorities (e.g. the fire service) are rapidly and adequately informed about the potential hazard within the installation. To obtain an overview of the handling of organisms and associated risks, it is recommended that an inventory of biological agents be drawn up. This is an important document for emergency planning and incident management. It usually contains the following information:

- Information on how the organisms used are classified into groups, and the class of the activities
- Data on buildings and rooms where the organisms are handled (address of the installation, designation of buildings and rooms, floor plans)

Minimising the adverse effects of incidents

Incidents can result in organisms contaminating or infecting employees, spreading inside the working area, or escaping into the environment. The safety concept according to the CO should not only show how the occurrence of such incidents can be reduced through specific measures, but also how to minimise or prevent the effects on employees and spread in the environment. Important points include:

- Provision of effective disinfectants and disinfecting procedures in the case of spillage or escape of organisms
- Ensuring rapid alarm and aid
- Procedure for incidents (inactivation of organisms, e.g. emergency hygiene plan with emergency disinfection, detection of organisms, medical measures)
- Recording of incidents using an event protocol

3.4 Adaptation of the safety measures for building, modification, demolition and relocation

Safety precautions in special situations

The provisions of the CO must be complied with both during the phase of operation and during other phases such as building, modification, demolition and relocation. For these phases, specially adapted safety precautions should be taken at the required time. These should be specified in the safety concept according to the CO. Important topics include:

- Decontamination and release of the old rooms and areas, limits on working (scheduling), protection of other rooms and areas
- Decontamination and if necessary disposal of equipment (dismantling filters)
- Transport of equipment and organisms.

For these structural, technical and organisational safety measures it is advisable to consider other safety aspects in addition to biosafety at the planning stage. A general safety concept should give further details on topics such as:

-
- Requirements for the construction in terms of the intended work processes
 - Possible integration of the required safety systems into the existing systems (e.g. ventilation, wastewater, sterilisation)
 - Potential risk to the neighbourhood: endangering the neighbourhood: sensible spatial organisation within the installation, separation of hazard zones

Coordination: e.g. between functions involved in the planning procedure; on procedures to be taken into consideration (e.g. CO, OMA, OEIA, planning application under ArGV4, procedure for planning permission)

Annexes

Biosafety according to the CO interfaces with the following additional safety areas, and these should accordingly be included in a general safety concept according to the activities performed in the installation.

A1 Occupational safety

OOSB: Ordinance on Occupational Safety in Biotechnology

The protection of employees affects not only activities that involve organisms in the workplace, but all the operating activities in which internal or external workers are involved or could be involved.

Based on the Ordinance on the Prevention of Accidents and Occupational Diseases, in 1996 the Swiss Federal Coordination Commission for Occupational Safety published Guidelines on the involvement of occupational health physicians and other specialists in occupational safety (FCOS Guidelines no. 6508, in German⁵).

FCOS Guidelines No. 6508

These Guidelines regulate not only the engagement of specialists as mentioned in the title, but also covers the development of appropriate safety systems (occupational safety management). The FCOS Guidelines no. 6508 names, in addition to other hazards, humanpathogenic microorganisms of groups 2 to 4 as “particular hazards” which require a risk analysis to be performed, a safety concept to be drawn up, and corresponding documentation to be completed.

OOSB on the handling of humanpathogenic micro organisms

The protection of employees handling humanpathogenic microorganisms is also covered in detail by the Ordinance on Occupational Safety in Biotechnology (OOSB)⁶, which came into force at the same time as the CO in 1999.

Additional measures to protect employees in the OOSB

Many safety measures are identical in both the OOSB and the CO, because they serve both the protection of employees and the protection of the population and the environment. The OOSB however also lists some measures that are not mentioned in the CO and which particularly affect employees (the reverse also applies to the CO). Among other things, the following important measures are explicitly mentioned in the OOSB:

- Minimise exposure (by substituting microorganisms of high potential risk by less hazardous ones, and by the design of working procedures)
- Particular protective measures of occupational health (vaccinations etc.)

⁵ The Guidelines can be obtained from: <http://www.ekas.ch/download.php?cat=3EwKyuta1vc%3D&id=6943>

⁶ The OOSB is based on the Accident Prevention Act (UVG) and the Labour Act (ArG)

- Personal protective equipment and protective clothing
- Keeping registers of employees and health files
- Obligation to provide information (internally and externally) on incidents, accidents and industrial accidents (notification form for laboratory incidents)

A2 Industrial accident prevention

Accident prevention for class 3 and 4 activities

Installations in which class 3 or 4 activities involving genetically modified or pathogenic microorganisms are subject to the Ordinance of 27 February 1991 on Major Accidents (OMA⁷). In exceptional cases the enforcement authorities can also subject installations with class 2 activities to the Ordinance. The purpose of the OMA is the protection of the population and the environment from severe damage as a result of industrial accidents.

Prevention and managing of major accidents

Industrial accident prevention contains measures for preventing and managing an event on the scale of an industrial accident. The safety measures according to the CO, which are designed for the safe handling of organisms in normal operations, already cover most of the measures to prevent industrial accidents. For class 3 or 4 activities, however, industrial accident prevention requires further measures to prevent events and additional measures to limit the impacts and to remedy industrial accidents.

The safety concept for installations that are subject to the OMA therefore combines the areas of biosafety for normal cases (according to the CO) and for the prevention and the management of serious emergencies (according to the OMA). The safety concept should show how industrial accidents can be prevented, how fire protection is guaranteed, and how to proceed in the event of an emergency. These measures should as far as possible prevent the release and spread of organisms. Important topics include:

- Rooms that can be sealed using a control system, to enable fumigation
- A ventilation system separate from the door-locking/ventilation system of the building as a whole
- HEPA-filtered exhaust air (HEPA = high-efficiency particulate air)
- Permanent negative pressure in the laboratory and airlock (also functioning as an escape route), with two pressure levels
- Controlling ventilation in the event of an incident (fire dampers, gas-tight dampers)
- Limiting the fire load to an acceptable minimum, explosion protection
- Alarms/alerts
- Emergency and incident planning with internal and external emergency services
- Access arrangements for emergency services
- Choice of extinguishing agents, where relevant firewater retention and disposal
- Measures to prevent the spread of released organisms and combat them (decontamination, disinfection) if an exceptional event occurs
- Information strategy (for informing the relevant authorities and the public)

⁷ The OMA is based on the Environmental Protection Act (EPA) and the Water Protection Act (GSchG)

-
- An airlock with two-way lockable doors
 - A controlled access system
 - A double-door autoclave
 - An uninterruptible emergency power supply for selected equipment and for control systems
 - An alarm system for equipment failures
 - Designing the floor to act as a containment system for firewater (or alternative measures)
 - Prevention of waste water discharge into the sewage system or the complete inactivation of all waste water
 - Compliance with earthquake safety standards.

A3 Environmental protection and sustainability

Implementing ordinances to the Environmental Protection Act and the Water Protection Act

The safety concept should show how an installation complies with the implementing ordinances to the Environmental Protection Act (EPA) and the Federal Act of 24 January 1991 on the Protection of Waters (GschG), e.g. the Ordinance on Air Pollution Control, Technical Ordinance on Waste, Ordinance on the Movements of Waste, Noise Abatement Ordinance, Water Protection Ordinance, and cantonal legislation on environmental protection (e.g. Energy Act). Important topics include:

- Coordination of safety and environmental protection
- Integrating environmental protection into the safety concept (environmental protection in the service of safety) or integrating this concept in the installation's environmental management system EMS: (ISO 14001)
- Environmentally friendly waste disposal
- Observing emission limits in normal operations
- Prevention (search for alternative, environmentally friendlier procedures and materials etc.)
- Sustainability: establishment or optimisation of circuits for water, air, materials (procurement, disposal)
- Life Cycle Analysis (products, construction, modification etc.)

A4 Chemical safety

The safety concept should show how the requirements of the legislation on chemicals for handling dangerous chemicals can be adhered to.

A5 Radiation protection

Regulating the order in which biological wastes are inactivated and radioactive wastes are disposed of

When using radioactive materials, the legislation on radiation protection must be adhered to. For activities involving genetically modified or pathogenic organisms the safety concept should show how the handling of radioactive substances and plants, apparatus and objects that contain radioactive substances or transmit ionising radiation, is regulated. Important topics include:

- Preventing all possible forms of radioactive and biological contamination
- Safe storage of radioactive substances in laboratories that are also used for organisms
- Inactivation of both radioactive and infectious wastes
- Coordination of the order of inactivation of biological wastes and the disposal of radioactive wastes in accordance with the regulations
- Disposal, or temporary storage, in a decay chamber, while observing biosafety

A6 Word templates for a biosafety concept, which can be supplemented with details specific to the installation

Online: www.bafu.admin.ch/uv-0817-e

Index

Please note: the English names of Swiss legal texts have recently been standardised. In particular, the term Law has been replaced by Act: e.g. Feral Law of 7 October 1983 relating to the Protection of the Environment → Federal Act of 7 October 1983 on Environmental Protection.

Abbreviations

ArG

Federal Act of 13 March 1964 on Work in Industry, Handicrafts and Commerce (Labour Act; SR 822.11)

ArGV4

Ordinance 4 of 18 August 1993 on the Labour Act (SR 822.114)

BSO

Biosafety Officer

CO

Ordinance of 25 August 1999 on the Contained Use of Organisms (Containment Ordinance; SR 814.912)

ECNH

Swiss Ethics Committee for Non-human Gene Technology

EMAS

Eco-Management & Audit Scheme technology)

EMS

Environmental management system

EPA

Federal Act of 7 October 1983 on Environmental Protection (Environmental Protection Act; SR 814.01)

EpG

Federal Act of 18 December 1970 on the Control of Transmissible Human Diseases (Epidemics Act; SR 818.101)

ERFA BIO

Intercantonal group (exchange of technical agency experience in bio- and gene)

FCOS

Federal Coordination Commission for Occupational Safety

FOAG

Federal Office of Agriculture

FOEN

Federal Office for the Environment

FOPH

Federal Office of Public Health

FVO

Federal Veterinary Office

GILSP

Good Industrial Large Scale Practice

GSchG

Federal Act of 24 January 1991 on the Protection of Waters (Water Protection Act; SR 814.20)

GTA

Federal Act of 21 March 2003 on Non-Human Gene Technology (Gene Technology Act; SR 814.91)

ISO

International Standardization Organisation

OMA

Ordinance of 27 February 1991 on Protection against Major Accidents (SR 814.012)

OOSB

Ordinance of 25 August 1999 on Occupational Safety
in Biotechnology (SR 832.321)

SECB

Swiss Expert Committee for Biosafety

seco

State Secretariat for Economic Affairs

SOP

Standard Operating Procedure

SUVA

Swiss Accident Insurance Fund

OEIA

Ordinance of 19 October 1988 on Environmental
Impact Assessment (SR 814.011)

OMW

Ordinance of 22 June 2005 on the Movements of
Waste (SR 814.610)

UVG

Federal Act of 20 March 1991 on Accident Insurance
(SR 832.20)

VUV

Ordinance of 19 December 1983 on the Prevention of
Accidents and Occupational Diseases (SR 832.30)