

Managing biological risks in contained systems

Roles, qualifications and tasks of biosafety and/or biosecurity officers. Status 2021



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Abstracts

These enforcement aid on the roles, tasks and competencies of biosafety and/or biosecurity officers have been drawn up to assist companies in their activities involving genetically modified, pathogenic or alien organisms, i.e. in preventing the improper use of organisms. Specifically, this document supports the work of one or more individuals designated as biosafety and/or biosecurity officers. It sets out the responsibilities of company management as well as the rights and duties of the biosafety and/or biosecurity officers. The guidelines also cover the requirements with respect to public health and the environment as well as employee health and safety.

L'aide à l'exécution sur les rôles, les tâches et les compétences des responsables de la sécurité et/ou de la sûreté biologiques aide les entreprises utilisant des organismes génétiquement modifiés, pathogènes ou exotiques à assurer la coordination de la sécurité biologique et de la sûreté biologique, c'est-à-dire, de la prévention de l'utilisation d'organismes à des fins malveillantes. Cette aide à l'exécution soutient le travail d'une ou plusieurs personnes responsables soit de la sécurité biologique soit de la sûreté biologique ou les deux. L'aide à l'exécution précise les responsabilités de la direction des entreprises, ainsi que les droits et les obligations des responsables de la sécurité et/ou de la sûreté biologiques. Pour ce faire, elle prend en considération les exigences de la santé publique et de l'environnement, de même que de la protection des travailleurs.

Diese Vollzugshilfe zu der Rolle, den Qualifikationen und Aufgaben der Biosicherheits- und/oder Biosecurity-Beauftragten unterstützt Betriebe, die mit gentechnisch veränderten, pathogenen oder gebietsfremden Organismen umgehen, in der Organisation der biologischen Sicherheit und der Biosecurity. Dabei geht es darum, eine missbräuchliche Verwendung von Organismen zu verhindern. Die Vollzugshilfe unterstützt die Arbeit der Person oder der Personen, die für die biologische Sicherheit und/oder die Biosecurity verantwortlich ist bzw. sind. Sie präzisiert die Verantwortlichkeit der Betriebsleitung sowie die Rechte und Pflichten der Biosicherheits- und/oder Biosecurity-Beauftragten. Zu diesem Zweck werden die Erfordernisse der öffentlichen Gesundheit und der Umwelt sowie des Schutzes der Arbeitnehmerinnen und Arbeitnehmer mit einbezogen.

L'aiuto all'esecuzione sui ruoli, i compiti e le competenze dei responsabili della biosicurezza e/o della bioprotezione aiuta le aziende che utilizzano organismi geneticamente modificati, patogeni o alloctoni a garantire il coordinamento delle misure di sicurezza biologica, ossia a prevenire l'utilizzazione indebita di organismi. La direttiva sostiene il lavoro dei responsabili della biosicurezza e della bioprotezione e definisce le responsabilità della direzione aziendale come pure i diritti e gli obblighi dei responsabili della biosicurezza o della bioprotezione, tenendo conto sia delle esigenze legate alla sanità pubblica e all'ambiente sia di quelle relative alla protezione dei lavoratori.

Keywords:

biosafety officer, biosecurity officer, biosafety and biosecurity programme, biosafety and biosecurity knowledge, biosafety and biosecurity training

Mots-clés :

Responsable de la sécurité biologique, responsable de la sûreté biologique, programme de sécurité et de sûreté biologiques, connaissance en sécurité et sûreté biologiques, formation en sécurité et sûreté biologiques

Stichwörter:

Biosicherheitsbeauftragte/r, Biosecurity-Beauftragte/r, Konzept zur biologischen Sicherheit und zur Biosecurity, Kenntnisse im Bereich der biologischen Sicherheit und der Biosecurity, Ausbildung in biologischer Sicherheit und Biosecurity

Parole chiave:

responsabile della biosicurezza, responsabile della bioprotezione, piano di sicurezza e di protezione biologica, conoscenze in materia di biosicurezza e di bioprotezione, formazione in biosicurezza e bioprotezione

Preface

The role of biosafety and/or biosecurity officer in a company handling genetically modified, pathogenic or alien organisms entails complex tasks, requiring very specific knowledge and competencies. It also requires expert insight on the biological risks associated with the organisms in question and knowledge of measures to mitigate these risks appropriately. Moreover, the biosafety and/or biosecurity officer must fulfil management's high expectations in regard to biological safety and preventing the improper use of organisms in general. He or she also supports the scientific and research staff, whose main needs are in relation to advice and assistance with administrative tasks. The biosafety and/or biosecurity officer also acts as the point of contact with the authorities: he or she has a broad overview of the company's activities in this respect and is therefore ideally positioned to respond to all kinds of related requests. To meet all these expectations, the biosafety and/or biosecurity officers receive strong support from management.

Under the Containment Ordinance, there must be at least one person employed to monitor biological safety and prevent the improper use of organisms. This person must be sufficiently knowledgeable and competent in the company's specific field and also in safety and security issues in order to carry out his or her duties.

In producing the present document, the authorities seek to define and specify this requirement. We hope that it offers the necessary management support and highlights the relevance of the position.

The Federal Office for the Environment (FOEN) would like to thank all those who contributed to making this document possible.

Anne Gabrielle Wüst Saucy, Biotechnology Section
Federal Office for the Environment (FOEN)

Introduction

Context and underlying legislation

The handling of genetically modified, pathogenic or alien organisms in research, diagnostics, education and industry involves risks not only for those directly concerned but also for the general public and the environment. Appropriate safety and security measures are taken to keep risks at the lowest possible level.

One such general safety and security measure, as stipulated in the Ordinance of 9 May 2012 (status as of 1 January 2020) on Handling Organisms in Contained Systems (Containment Ordinance, ContainO), requires that any company involved with genetically modified, pathogenic or alien organisms must appoint at least one person to monitor the biological safety aspects of its activities and prevent the improper use of organisms (biosafety and/or biosecurity officers)¹ (Annex 4 No 1 let. c ContainO).²

The ContainO requires that “the person must have sufficient knowledge of and competence in both technical matters and safety issues to carry out his or her duties; the tasks include in particular preparing, updating and implementing the safety concept, informing, advising and training staff, verifying compliance with biosafety and biosecurity rules and communicating with the authorities in relation to notifications, authorisation applications, biosafety measures and the safety concept”.

This document describes in detail the roles and tasks of these officers and provides useful indications for the definition of their status and their competencies. It is based on Art. 32 para. 1 ContainO, according to which the FOEN and the Federal Office of Public Health (FOPH) are authorised to issue directives as and when necessary for the implementation of the ordinance, in consultation with the specialist agencies involved (Art. 18 para. 2 ContainO).

The cost of monitoring biological safety and security can vary greatly from case to case, depending on the type and size of the company (production, research, education, diagnostics), the type and number of its activities and the related risks (Classes 1 to 4). To ensure that biological safety and the prevention of the improper use of organisms are given full consideration in its activities, it is important therefore for each company to carefully define the status, tasks and competencies of its biosafety and/or biosecurity officers.

It is thus left to each company to decide for itself whether one or more biosafety officers will be necessary. In addition, the company assesses and determines the extent of biosecurity monitoring and the need to assign one or more biosecurity officers.

The tasks related to biosafety and to the prevention of the improper use of organisms may be performed by the same person if he or she has the required knowledge in both areas. Otherwise, these tasks may be assigned to different individuals.

¹ See also: Swiss Academy of Sciences (2017). Misuse potential and biosecurity in life sciences research. Swiss Academies Report 12 (3): *Misuse potential and biosecurity in life sciences research* (scnat.ch)

² SR 814.912 – Ordinance of 9 May 2012 on Handling Organisms in Contained Systems (Containment Ordinance, ContainO) (admin.ch)

Definitions

Biosafety, biological safety (Art. 1 and Art. 3 let. h ContainO)

Protection of human health, animals and the environment, as well as biological diversity and its sustainable use, from hazards or harm caused by handling organisms, their metabolic products and wastes in contained systems by any installation involving the use of physical barriers or a combination of physical and chemical or biological barriers.

Biosecurity, biological security

Measures to prevent the improper use or intentional diversion of the contained use of organisms originally destined for lawful use.

Improper use (Art. 3 let. j ContainO)

The handling of organisms subject to a containment obligation which illegally and intentionally endangers or harms humans, animals, the environment or biological diversity and their sustainable use.

Project leader

Person responsible for the activities defined in the ContainO and serving as a contact person for technical enquiries from the authorities.

1 Tasks of the company

1.1 Job description of a biosafety and/or biosecurity officer

The company is required to ensure the proper monitoring of biological safety and the prevention of improper use of organisms by:

- Defining its needs in terms of biosafety and biosecurity
- Determining the line of reporting for biosafety and biosecurity (e.g. to corporate or institute management, management of the technical services, management of the health and safety and environmental services)
- Designating, on the basis of its own needs, one or more biosafety and/or biosecurity officers and their deputies.

Moreover, the company should create the necessary framework conditions³ for its biosafety and/or biosecurity officers by:

- Drafting a job description outlining their tasks, responsibilities, competencies, continuing education and decision-making powers in relation to their tasks
- Allocating the resources necessary for them to perform their tasks, in particular the necessary time and funds
- Determining their status within the company and whether the position is an internal appointment or as an external consultant
- Determining the manner and frequency with which the biosafety and/or biosecurity officers report to their line manager
- Ensuring the coordination of the biosafety and biosecurity functions with other areas related to safety and security within the company.

The job description is reviewed periodically and adapted if necessary. The biosafety and/or biosecurity officers are included in the process of drawing up and adapting the job description.

If the monitoring of biosafety and biosecurity in the company is to be performed by more than one officer within the company, the tasks, responsibilities and competencies of each are defined, particularly in relation to the notification of activities to the authorities. In addition, the details of their collaboration are set out. Furthermore, if the monitoring of biosafety and/or biosecurity requires different experts or a committee of different experts, the tasks and organisation of this committee are also laid down.

³ See also: ISO/FDIS 35001:2019(E) Biorisk management for laboratories and other related organizations

1.2 Qualifications, training and continuing education of biosafety and/or biosecurity officers

1.2.1 Qualifications of the biosafety officer

In order to monitor biological safety, the company is required to employ persons (Annex 4 No 1 let. c ContainO) with the following (or equivalent) qualifications:

- Practical experience in biology, preferably in microbiology or molecular biology
- A degree from a university or college of higher education or several years of experience in a biology laboratory in order to understand fully the activities carried out in the company and the related biological risks
- Specific knowledge in basic, applied or translational research adapted to the company's needs
- Specific knowledge related to the technical operation and construction of premises where biological materials are used
- Awareness in the field of biosecurity and the risks associated with dual-use research of concern (DURC)
- Specific biosafety knowledge adapted to the company's needs, i.e.
 - practical knowledge of the biosafety levels in place at the company
 - specific knowledge related to the handling, breeding and housing of vertebrate animals
 - specific knowledge related to the handling, breeding and housing of small invertebrates
 - specific knowledge related to the handling and husbandry of plants
 - specific knowledge related to the handling of prions and prion-like proteins
 - specific knowledge related to large-scale production
 - specific knowledge related to the analysis of organisms from clinical or other biological material for diagnostic purposes.

1.2.2 Qualifications of the biosecurity officer

In order to monitor biological security, the company is required to employ one or more persons with the following (or equivalent) qualifications:

- Specific knowledge in preventing the improper use of organisms, adapted to the company's needs. This knowledge can be acquired during employment.
- A degree from a university or college of higher education or several years of experience in order to understand fully the activities carried out in the company in relation to organisms and the risks of their improper use
- Skilled in communication and conflict management
- Awareness in the field of biosecurity and the risks associated with dual-use research of concern (DURC).

1.2.3 Training and continuing education

In the context of the training and continuing education of biosecurity and/or biosafety officers, the company:

- Ensures their participation in the basic courses of the Swiss Biosafety Curriculum (Art. 32 para. 2 ContainO) or other such training in biosafety or biosecurity⁴
- Provides these individuals with company-specific information on biosafety and/or biosecurity, as appropriate
- Gives such persons the opportunity, time and resources to obtain and regularly develop their knowledge in the specific areas of biosafety and/or biosecurity relevant to the company.

⁴ Meetings and courses for biosafety officers (BSO) (admin.ch)

2 Role and tasks of the biosafety and/or biosecurity officers

A biosafety and/or biosecurity officer is required to provide advice, instruction and information on biorisk management issues as well as to make researchers and laboratory staff aware of specific risks (e.g. genome editing, expression of critical inserts via viral parts, potential for malicious use, DURC). He or she has the delegated authority to prohibit work if this is deemed necessary for biorisk management, in order to comply with the relevant legislation or in the event of a potential accident. This is subsequently confirmed by the designated line manager (paragraph 1.1).

His or her role is independent of that of the project leaders, so as to avoid conflicts of interest which could lead to a biorisk situation.

He or she advises and assists the designated line manager (paragraph 1.1) in ensuring that activities comply with the regulatory requirements of biosafety and the prevention of the improper use of organisms. In addition, he or she informs the designated line manager (paragraph 1.1) about international recommendations.

These tasks include the organisational or technical activities described in detail below.

2.1 Safety concept of the company

The safety officer works with the project leaders or the designated line manager (paragraph 1.1) to create a suitable biosafety concept for the company, in accordance with the ContainO (Annex 4 No 1 let. b).

In this context, and depending on the type of organisms involved (including their potential for improper use), the nature of the activities (research, production, training, diagnostics) and also on the class of activities involved (Classes 1 – 4), the duties of the biosafety and/or biosecurity officer are as follows:

- Development of a concept for ensuring and monitoring biosafety, complete with rules and regulations, procedures and measures of specific relevance to the company
- Inclusion of specific rules, procedures and measures where applicable within the company to prevent the improper use of organisms.

He or she is also responsible for:

- Allocation of responsibilities in relation to this concept
- Periodic updating of this concept
- Submission of the concept to his or her line manager (paragraph 1.1), who approves it and ensures its implementation
- Coordination of this programme with the programmes applied in other fields (chemistry, radiation protection, firefighting, occupational medicine, transport).

2.2 Internal communication and training

The biosafety officer provides information, guidance and advice on biological safety to laboratory staff as well as to other persons employed at locations where genetically modified, pathogenic or alien organisms are handled and also, if applicable, on biological security and the prevention of the improper use of organisms (if there is not another person employed for biosecurity).

The communication and training tasks of the biosafety officer also extend to the following:

- Issuing instructions for training new employees
- Arranging instructions for the cleaning, maintenance and emergency services
- Checking to ensure that training for the protection of staff and the environment is carried out in relation to biological safety and the prevention of improper use of organisms (if another person is not employed for biosecurity)
- Checking to ensure that biosafety and biosecurity training is carried out in such a way that the information given to staff is up-to-date and complete
- Checking to ensure that practical exercises are included in the training on incident and accident management in relation to genetically modified, pathogenic or alien organisms
- Checking to ensure that the staff concerned are taught the safe use of new appliances and methods (biosafety bench, autoclave, etc.)
- Informing all concerned parties about new legal requirements.

The project leader is responsible for introducing employees to the specific safety measures for a given project, in agreement with the biosafety officer.

2.2.1 External communication

The biosafety officer ensures that all activities subject to the ContainO are reported (by means of a notification or an authorisation request) to the Federal Coordination Centre for Biotechnology via the client portal set up for this purpose.⁵ He or she keeps the relevant authorities informed about reports, authorisation requests, safety measures, certain aspects concerning risk assessment, the biosafety concept, inspections, etc.

2.3 Risk assessment

2.3.1 Assessment of the biosafety risk

Assessing the risks involved in a given activity in accordance with the ContainO is the responsibility of the individual project leader, possibly in collaboration with the biosafety and/or biosecurity officer. However, one or more biosafety and/or biosecurity officers maintain an overview of the various activities and the risks they entail. These persons are informed about all activities carried out in the company.

⁵ Federal Coordination Centre for Biotechnology (admin.ch)

To ensure this overview, the biosafety officer performs the following tasks:

- Assess the risks involved in all activities involving genetically modified, pathogenic or alien organisms
- Keep a list of activities requiring registration, notification or authorisation under the ContainO
- Ask project leaders, for information purposes, to provide lists of the genetically modified, pathogenic or alien organisms used
- Keep a list of biosafety-related incidents
- Make sure that project leaders carry out risk assessments and submit reports and authorisation requests to the authorities, and give the necessary support to these project leaders.

2.3.2 Assessment of the biosecurity risk

The biosecurity officer(s), if different from the biosafety officer, assists the project leaders in assessing the risks related to the improper use of organisms.

2.4 Biosafety measures

Assessment of the risks involved in individual activities with genetically modified, pathogenic or alien organisms may point to the need for additional safety measures to meet the requirements of the ContainO (Annex 4 No 2.1, table). The latter does not go into great detail on safety measures however, providing only information of a very general nature which needs to be further developed for practical application (see also the section on the creation of a concept of biological safety specific to the company). The decision on what project-related safety measures are needed is the responsibility of the project leader, in consultation with the safety officer and the technical services management. With the support of the project leader, and their assistance where necessary, the safety officer ensures that the safety measures are complied with and may coordinate some of them where necessary. Some examples are as follows:

2.4.1 Safe handling of genetically modified, pathogenic or alien organisms

The biosafety officer provides advice to laboratory staff on best biosafety practices based on risk assessment of the organisms used and suggests adaptations to existing protocols to ensure safe working procedures. If necessary, he or she may draw on the expertise of persons trained in occupational health and safety.

2.4.2 Use of personal protective equipment

Together with the project leader, the biosafety officer provides advice and instructions on the selection, use and maintenance of appropriate personal protective equipment, taking into account the requirements of the ContainO and the PEMO, the risk assessment and the current knowledge of the biological materials and programmes in place. The designated line manager (paragraph 1.1) ensures that the personal protective equipment selected is readily available and accessible to personnel.

2.4.3 Methods of decontamination and inactivation

The biosafety officer provides advice on effective decontamination and inactivation procedures and their implementation, as well as on the selection and use of disinfectants.

He or she advises and liaises with the appropriate maintenance personnel to oversee the maintenance and, if necessary, decontamination of facilities and equipment where biological safety is concerned.

2.4.4 System for the collection and disposal of solid and liquid wastes

The biosafety officer provides guidance on the principles of biowaste management and ensures that all waste streams are defined and that biowaste is decontaminated or inactivated according to the requirements of the ContainO. If biological waste leaves the facility without being decontaminated or inactivated with approved methods, appropriate measures should be taken to ensure safe and secure transport to the final decontamination and disposal/destruction point.

2.4.5 Safe internal and external transport of genetically modified, pathogenic or alien organisms

The biosafety officer ensures that instructions are provided for safe internal transport. He or she coordinates the off-site transport of organisms, as well as export and import, with the person responsible for the transport of hazardous substances in accordance with national and international regulations and requirements.

2.4.6 Safe use of equipment and its selection, approval and maintenance if used with organisms

The biosafety officer provides advice on the selection and installation of equipment that may have an impact on biosafety, e.g. autoclaves, microbiological safety cabinets, centrifuges, automated analytical equipment, access controls. He or she ensures the validation and/or certification of maintenance before use, at appropriate intervals and after maintenance, relocation and/or reinstallation.

2.4.7 Procedures for incidents and accidents involving genetically modified, pathogenic or alien organisms

The biosafety officer ensures that procedures are developed, reviewed and communicated to prevent and manage incidents and accidents involving genetically modified, pathogenic or alien organisms. He or she ensures that contact persons for accidents and incidents are appointed by the designated line manager (paragraph 1.1). He or she also ensures that these persons can be reached in case of incidents and accidents. In addition, he or she ensures that materials and procedures for the management of incidents and accidents are available in strategic and easily accessible locations.

2.4.8 Reporting of incidents and accidents involving genetically modified, pathogenic or alien organisms

The biosafety officer ensures that there is a documented procedure in place for identifying, recording, analysing and learning from incidents and accidents.

In accordance with Art. 16 para. 1 ContainO, the biosafety officer ensures that the specialist agency designated by the canton is informed immediately of any event involving the handling of organisms in contained systems.

The biosafety officer ensures that all incidents and accidents related to the improper use of organisms are investigated, that the results are recorded and that any necessary recommendations or measures (in particular the adaptation of internal directives and rules) are implemented as soon as possible through changes in working practices and are taken into account in the risk assessment. All findings and decisions must be communicated to all laboratory staff and to the designated line manager (paragraph 1.1).

Summaries of incident and accident reports are sent to the designated line manager (paragraph 1.1) at regular intervals or immediately if deemed necessary.

2.4.9 Inspections

The biosafety officer undertakes regular internal inspections in locations where organisms are handled so as to monitor the observance of safety measures and to identify, assess, control and avoid potential sources of danger. If an internal inspection reveals the need to modify or add safety measures, the project leader is informed, a deadline for the modification is set and the biosafety officer checks that this deadline is met. If an inspection reveals shortcomings in the safety measures that present an immediate danger to workers or to the environment, the biosafety officer, together with the project leader, may require the activity to be stopped while measures are taken to eliminate the danger.

The biosafety officer prepares the cantonal inspections (Art.°23 ContainO) together with the project leaders and accompanies the inspectors during the inspection. The inspection report is sent to the project leaders concerned, to the technical services management and to the designated line manager (paragraph 1.1).

2.5 Biosecurity measures

The biosecurity officer raises awareness among company personnel of the potential for improper use of organisms.

He or she is involved in approving the acquisition, possession, use, storage and transfer of any biological materials that have the potential for misuse.

He or she is informed by project leaders of the safe and secure storage inventories of organisms that could potentially be subject to improper use.

If a risk has been previously identified, he or she advises the designated line manager (paragraph 1.1) on appropriate measures to be implemented to minimise the potential for unauthorised removal and escape of organisms from the facility (in particular restricting access to the premises and recording the identity of persons with access to the organisms used; see Annex 4 No 1 let. k ContainO). This includes appropriate measures to identify vulnerabilities and to establish effective control and monitoring mechanisms.

2.6 Interaction with other safety areas

2.6.1 Occupational health

The Ordinance on the Protection of Employees from Dangerous Microorganisms (PEMO)⁶ stipulates that, in addition to the requirements of the ContainO – which are primarily aimed at protecting humans and the environment – the requirements for the protection of workers must also be met. However, certain requirements are specific to the PEMO, i.e. limitation of exposure to micro-organisms, provision of protective equipment, its maintenance and disinfection, hygiene measures, medical surveillance and preventative medicine measures.

⁶ <https://www.admin.ch/opc/fr/classified-compilation/19994946/index.html> (not available in English)

The use of micro-organisms of Classes 2 to 4 constitutes a special hazard within the meaning of the Accident Prevention Ordinance (APO).⁷ The designated line manager (paragraph 1.1) is obliged to call in an occupational physician and other occupational safety specialists in accordance with Guideline No 6508 of the Federal Coordination Commission for Occupational Safety (FCOS).⁸ If these areas are not otherwise regulated, the designated line manager may include them in the job description of the biosafety officer.

2.6.2 Chemical and radiation protection

In most companies which handle genetically modified, pathogenic or alien organisms, toxic, inflammable and radioactive substances are also frequently in use. In principle, the protection of the public and the environment in the handling of these substances does not fall within the remit of the biosafety officer, as this is regulated in accordance with different standards, e.g. in the framework of chemical safety, radiation protection and the transport of dangerous goods. However, the biosafety officer is responsible for coordinating his or her work with these other safety aspects, particularly in relation to mixed waste management.

2.6.3 Security

The biosecurity officer liaises with information technology and physical security experts, as appropriate, to advise the designated line manager (paragraph 1.1) on measures to prevent unauthorised disclosure of sensitive information (e.g. inventories, data, security plans, access codes).

2.6.4 Accident prevention and relief

Major emergencies, e.g. large-scale spills and other unintentional releases, fires, medical problems, power failures, safety incidents, natural disasters or any other emergency situation, may involve not only biosafety aspects (in relation to genetically modified, pathogenic or alien organisms) but also other aspects of safety in the company. Although these emergencies may not be directly related to biosafety, the biosafety officer nonetheless participates in coordinating the prevention and control of such emergencies. He or she also participates in an emergency preparedness training programme.

2.6.5 Construction/transformation/relocation

Another challenge is ensuring biological safety at the time of building, transforming or relocating facilities in which organisms have been handled. In such cases, the biosafety officer is involved in the planning and (re)design of the facilities. Together with the biosecurity officer, he or she advises on the measures needed to ensure biosafety and to prevent the improper use of organisms in consultation with those responsible for the design, construction, conversion or relocation (architects, construction management, authorities, project leaders, etc.). The biosafety officer also provides information on the commissioning process, as well as on operations, maintenance and de-commissioning with regard to biological safety.

⁷ <https://www.admin.ch/opc/de/classified-compilation/19830377/index.html> (not available in English)

⁸ <https://www.ekas.ch/download.php?id=6560> (not available in English)