Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)		Х	2009
A, part 2 (ii)			
A, part 2 (iii)			
В			
C		Х	2018
Ε			
F		Х	2001
G			

(Please mark the appropriate box(es) for each measure with a tick, and fill in the year of last declaration in the last column where applicable.)

Date: Monday, April 15, 2019

State Party to the Convention: Switzerland

Date of ratification/accession to the Convention: Tuesday, May 4, 1976

National point of contact:

Sergio Bonin (Section for Arms Control, Disarmament and Nonproliferation - Division for Security Policy -Swiss Federal Department of Foreign Affairs) - sergio.bonin@eda.admin.ch Political Affairs Officer BWC/CWC Address: Effingerstrasse 27, CH - 3003 Bern, Switzerland Telephone: +41 58 464 57 41 Fax: +41 58 464 38 39

Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

At the Third Review Conference it was agreed that States Parties continue to implement the following:

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO¹ Laboratory Biosafety Manual and/or OIE² Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories $\frac{3}{2}$

1. Name(s) of facility ⁴: Labor Spiez (Spiez Laboratory)

[Declared in accordance with Form A Part 2(iii)]

2. Responsible public or private organization or company:Federal Office for Civil Protection, Federal Department of Defence, Civil Protection and Sports

3. Location and postal address:

Labor Spiez, Bundesamt für Bevölkerungsschutz, Eidgenössisches Departement für Verteidigung, Bevölkerungsschutz und Sport, Austrasse, CH-3700 Spiez, Switzerland

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

Swiss Confederation (Federal Department of Defence, Civil Protection and Sports)

5. Number of maximum containment units $\frac{5}{2}$ within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 2: 483 SqM BL 3: 126 SqM BL 4: 118 SqM Of note, the BSL4 unit is operational and holds a license as follows: "Development of methods to detect and analyze viral pathogens of risk group 4 (clinical samples, environmental samples, including samples suspect of bioterrorism origin) as well as evaluation of antiviral substances, neutralizing antibodies and decontamination solutions".

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

Spiez Laboratory, which is part of the Federal Department for Civil Protection, is the Swiss Center of Expertise in NBC Protection. Its Biology Division has a range of activities including research, development, test & evaluation, training, as well as diagnosis in the fields of virology, bacteriology, toxinology and biosafety. The tasks include analysis of unknown samples, diagnostics and identification of potential biological warfare and bioterror agents, food and water analysis for the Swiss Armed Forces, and research & development in coordination with contractors. Spiez Laboratory deals with many different biological agents and toxins known to be pathogenic for humans.

Spiez Laboratory is also a National Reference Center mandated by the Swiss Federal Office of Public Health and a National Reference Laboratory mandated by the Swiss Federal Food Safety and Veterinary Office as follows:

- National Reference Center for Anthrax
 - Bacillus anthracis (anthrax)
 - Francisella tularensis (tularemia)
 - Yersinia pestis (plague)
 - Brucella spp. (brucellosis)
 - *Burkholderia pseudomallei* (melioidosis)
 - Clostridium botulinum (botulism)
 - other bacterial pathogens according to requirements of the national coordination committee of the Regional Laboratory Network
- National Reference Center for Tick-Transmitted Diseases
 - Tick-borne encephalitis virus (TBE)
 - *Coxiella burnetii* (Q fever)
 - Borrelia burgdorferi s.l. (Lyme disease)
 - Other rare / emerging tick-transmitted pathogens
- National Reference Laboratory for Staphylococcus enterotoxins
 - Staphylococcus enterotoxin B
 - other Staphylococcus enterotoxins

In addition, Spiez Laboratory supports the National Reference Center for Emerging Viral Infections responsible for the detection of emerging and reemerging viruses of all biosafety levels, especially hemorrhagic fever viruses and variola virus.

Spiez Laboratory's Biology Division holds an accreditation by the Swiss Accreditation Service as "Testing laboratory for the detection of biological agents" (STS 0054) according to the international standard ISO/IEC 17025:2005.

For additional information please visit: https://www.labor-spiez.ch/enindex.htm

1. Name(s) of facility $\frac{4}{3}$:

Centre National de Référence pour les Infections Virales Emergentes (National Reference Center for Emerging Viral Infections)

[Declared in accordance with Form A Part 2(iii)]

2. Responsible public or private organization or company:

Virological Laboratory, University Hospitals of Geneva

3. Location and postal address:

Centre National de Référence pour les Infections Virales Emergentes, Laboratoire de Virologie, Hôpitaux Universitaires de Genève, Rue Gabrielle Perret-Gentil 4, CH-1205 Genève, Switzerland

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

Swiss Confederation (Federal Department of Home Affairs)

5. Number of maximum containment units $\frac{5}{2}$ within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 2: 29 SqM BL 3: 39 SqM BL 4: 36 SqM *Of note, the BSL4 unit is operational and holds a license for diagnostic purposes only, as follows: "Detection of viruses in clinical samples by molecular and/or serological methods".*

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

The National Reference Center for Emerging Viral Diseases (CRIVE/NAVI) is a national reference laboratory by order of the Federal Office of Public Health. Its task is the detection of emerging and re-emerging viruses of all biosafety levels, especially hemorrhagic fever viruses and smallpox virus. The BSL4 unit is approved for diagnostic purposes only, which does not allow any culturing or enrichment of such viruses. The National Reference Center for Emerging Viral Diseases is part of the Laboratory of Virology at the University Hospitals of Geneva. Since the 1st January 2018, the CRIVE acts also as WHO National Center for Measles and Rubella.

The Laboratory of Virology (LV) performs the analysis of many viruses impacting the human health as done in most of the hospitals (HIV, Hepatitis, CMV, EBV, respiratory and enteric viruses, etc.). LV does most of the viral analysis needed by a university hospital. LV also hosts the Swiss National Center for Influenza.

For further information please visit (website in French): <u>https://www.hug-ge.ch/laboratoire-virologie</u>

1. Name(s) of facility $\frac{4}{3}$:

Institut für Medizinische Virologie (Institute of Medical Virology)

[Declared in accordance with Form A Part 2(iii)]

2. Responsible public or private organization or company: Faculty of Medicine, University of Zurich

3. Location and postal address:

Institut für Medizinische Virologie, Medizinische Fakultät, Universität Zürich, Winterthurerstrasse 190, CH-8057 Zürich, Switzerland

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

Cantons of Appenzell Ausserrhoden, Appenzell Innerrhoden, Glarus, Graubünden, Sankt Gallen, Schaffhausen, Thurgau, Zug, Zürich, and the Principality of Liechtenstein

5. Number of maximum containment units $\frac{5}{2}$ within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 3: 25 SqM

Of note, the Institute of Medical Virology holds a BSL4 license for diagnostic purposes only, as follows: "Inactivation of environmental samples and of potentially highly pathogenic viruses for diagnostic purposes within the framework of the Regional Laboratory Network".

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

The Institute of Medical Virology at the University of Zurich is the Regional Competence Center for the primary analysis of viral samples suspicious of a bioterror-related background. This represents an additional and not a continuous task of the viral diagnostics laboratory.

For further information please visit: https://www.virology.uzh.ch/index_en.html

1. Name(s) of facility ⁴: Institut für Virologie und Immunologie (Institute of Virology and Immunology)

[Declared in accordance with Form A Part 2(iii)]

2. Responsible public or private organization or company: Federal Food Safety and Veterinary Office, Federal Department of Home Affairs

3. Location and postal address:

Institut für Virologie und Immunologie, Bundesamt für Lebensmittelsicherheit und Veterinärwesen, Eidgenössisches Departement des Innern, Sensemattstrasse 293, CH-3147 Mittelhäusern, Switzerland

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

Swiss Confederation (Federal Department of Home Affairs)

5. Number of maximum containment units $\frac{5}{2}$ within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 2: 210 SqM BL 3: 44 SqM ABL 3 Ag: 10446 SqM Of note, BSL3Ag facilities have special features not comparable to standard BSL3 or BSL4 facilities. The shell is considered BSL4, whereas inside the containment area BSL1, BSL2 and BSL3 space is common standard. Personnel enters through a shower barrier and is provided with suitable laboratory clothing for BSL1, 2 and 3 inside the containment area. Personnel has to shower out when leaving the containment area and has to keep a 72h quarantine (no contact to cloven hoofed animals). The IVI fulfills the requirements of the EU Minimum Biorisk Management Standards for Laboratories Working with Foot-And-Mouth Disease Virus. Due to these special features of BSL3Ag facilities, the BSL3Ag area is not limited to laboratory units only, but also includes engineering floors such as effluent treatment plant or ventilation units and animal units, which are all located within the containment area. Therefore, all maintenance work has to be done during operation – the facility has never been shut down so far. This also means that a direct comparison with BSL4 facilities is not practicable. Licenses are as follows: "Quality controls of immuno-biological products for use in applications of veterinary medicine"; "Establishment of a cell-based rapid test to determine protection provided by vaccination against foot-and-mouth disease virus"; "Validation of decontamination by H2O2"; "Diagnostics of viral pathogens causing highly contagious animal diseases".

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

The Institute of Virology and Immunology (IVI), which is part of the Swiss Federal Food Safety and Veterinary Office, is the ISO 17025 accredited institute for the diagnosis, surveillance and control of highly contagious epizootics. In addition, the IVI pursues research both on these viruses and emerging viral diseases, as well as their potential transmission to man. The IVI is also the competent authority issuing the licenses required for the sale of veterinary immunobiological products. Basic research is carried out in the fields of immunology and virology, and involves influenza virus, foot-and-mouth disease virus, classical swine fever virus and porcine circovirus type 2. The development and diagnostics branches focus on assays and tests for classical and african swine fever, foot-and-mouth disease, avian influenza, bluetongue, and other highly contagious infectious diseases. In this domain, the IVI occupies a leading position internationally.

For further information please visit: <u>https://www.ivi.admin.ch/ivi/en/home.html</u>

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents⁶ on a State Party's territory:

Biosafety level 3 ⁷	N/A
Biosafety level $2^{\frac{8}{2}}$ (if applicable)	N/A

Any additional relevant information as appropriate:

N/A

Part 2 Exchange of information on national biological defence research and development programmes

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

(1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;

(2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;

(3) The organizational structure of the programme and its reporting relationships; and

(4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated;

(a) location;

(b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;

(c) the total number of staff employed, including those contracted full time for more than six months;

(d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;

(e) a list of the scientific disciplines of the scientific/engineering staff;

(f) the source and funding levels in the following three areas: research, development, and test and evaluation; and

(g) the policy regarding publication and a list of publicly-available papers and reports.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

yes

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

Form A, part 2 (ii)

National biological defence research and development programmes

Description

National Biological Defense Program

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The objective is to establish national biological defense proficiency by developing and improving precise and accurate tests for the rapid diagnosis as well as for identification, including characterzation, of different biological agents and toxins using various methods. Spiez Laboratory is assigned to fulfill this task and to close any gaps to reach national biological defense excellence. To improve the national biological defense capabilities of Switzerland, Spiez Laboratory has funds available to run a dedicated program with the goal of added research and development mainly benefitting detection, diagnostic and identification techniques. A major part of the program is conducted under contract with national and international industries, academic institutions as well as domestic and foreign governmental agencies, as detailed in paragraph 5.

Spiez Laboratory is part of the Federal Office for Civil Protection FOCP within the Federal Department of Defence, Civil Protection and Sports DDPS of the Swiss Confederation. Spiez Laboratory is the Swiss center of expertise in protection against nuclear, biological and chemical (NBC) threats and hazards. Besides delivering its expertise to relevant stakeholders, the Biology Division of Spiez Laboratory is concerned with the identification of biological agents and toxins, as well as supports military biological protection units. The Biology Division has three main branches that are engaged in the fields of virology, bacteriology and toxinology, respectively.

Spiez Laboratory possesses a high containment facility that allows for the safe handling of biological agents of all risk groups. It is the only BSL4 high containment facility in Switzerland holding a license which is not limited to diagnostic purposes. It serves towards the comprehensive detection and identification of human pathogens. This enables Spiez Laboratory to act in the Regional Laboratory Network as both a Regional Competence Center and as a National Reference Center / National Reference Laboratory having all necessary capabilities and capacities at hand.

For additional information and more on the vision of a world without weapons of mass destruction please visit: <u>https://www.labor-spiez.ch/enindex.htm</u>

2. State the total funding for each programme and its source.

Swiss Confederation, Federal Department of Defence, Civil Protection and Sports DDPS, Federal Office for Civil Protection FOCP.

Total Funding: 5'000'000 p.a.

Funding Currency: CHF

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other nondefence facilities?

yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

10%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

All contracted research and development of the program is supervised by Spiez Laboratory. Please also refer to paragraph 1 above for additional details. The contractors part of the program in 2018 were as follows:

- Eidgenössische Technische Hochschule Zürich ETHZ Functional Genomics Center Zurich – FGCZ Winterthurerstrasse 190 CH-8057 Zürich Switzerland Project title: "Next Generation Sequencing"
- Eidgenössische Technische Hochschule Zürich ETHZ Center for Security Studies – CSS Haldeneggsteig 4, IFW CH-8092 Zürich Switzerland Project title: "Analysis of trends in science and policy"
- Medizinische Hochschule Hannover MHH Institut f
 ür Toxikologie Carl-Neuberg-Strasse 1 DE-30625 Hannover Germany
 Project title: "Development of recombinant botulinum neurotoxins and assessing proteolytic stability and transepithelial transport"
- Universität Bern UniBE Institut für Infektionskrankheiten – IFIK Friedbühlstrasse 51 CH-3010 Bern Switzerland Project title: "Next Generation Sequencing"
- Universität Bern UniBE Interfaculty Bioinformatics Unit – IBU Baltzerstrasse 6 CH-3012 Bern Switzerland Project title: "Comparative genome-based analysis of Naegleria"
- Université de Lausanne / Centre Hospitalier Universitaire Vaudois Unil / CHUV Institut de microbiologie – IMUL Rue du Bugnon 48 CH-1011 Lausanne Switzerland Project title: "Assessment of tenacity of highly pathogenic viruses and evaluation of inactivation strategies for clinical samples and contaminated materials" Project title: "Evaluation of an immune response against Ebolavirus after vaccination" Project title: "Identification and evaluation of antiviral substances against Hantavirus infections"
- Zürcher Hochschule für Angewandte Wissenschaften ZHAW Institut für Chemie und Biologische Chemie – ICBC Einsiedlerstrasse 31 CH-8820 Wädenswil Switzerland Project title: "Detection of proteinaceous toxins"

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and nongovernmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Please refer to Form A, part 2 (iii).

Attachments: N/A

Regional Laboratory Network

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The objective is the establishment and maintenance of capability and capacity for the rapid laboratory-based identification of pathogens in case of a biological emergency, whether it be of natural or accidental origin or due to deliberate release. This forms the basis for any adequate countermeasures that need to be planned and implemented to ensure the protection of the population. The consequent integration of state of the art detection and diagnostic techniques as well as their constant refinement and improvement is therefore indispensable for a holistic biological emergency concept.

The implemented structure is a decentralized network of Regional Competence Centers and National Reference Centers, all of which have been mandated by the Federal Office of Public Health. This network benefits from already existing infrastructure. The network is embedded in the Swiss CBRN concept and is coordinated by the Regional Laboratory Coordination Committee that consists of federal, cantonal and scientific experts. There is a total of three National Reference Centers and six Regional Competence Centers called Regional Laboratories. The task for Regional Laboratories is the rapid identification of pathogens, whereas National Reference Centers are qualified for confirmatory analysis. All facilities pursue civil duties and are put on assignments of the Regional Laboratory Network in the event of biological emergencies only. All cantons are part of the network either as a host canton of a Regional Laboratory (bold) or as an affiliated canton:

Regional Laboratory West: FR, **GE**, NE, **VD**, VS Regional Laboratory West Central: **BE**, JU Regional Laboratory East Central: **LU**, NW, OW, SZ, UR Regional Laboratory East: AI, AR, GL, GR, SG, SH, TG, ZG, **ZH** (+ FL) Regional Laboratory North: AG, BL, **BS**, SO Regional Laboratory South: **TI**

Of note, the two cantons of Genève (GE) and Vaud (VD) share the authority over the Regional Laboratory West. The Principality of Liechtenstein (FL) participates in the Regional Laboratory East. For an explanation of abbreviations, please refer to the comprehensive map presented in paragraph 6.

The network consists of the following facilities that are described in Form A, part 2 (iii) in more detail:

Function	Authority	Facility
NRC	GDK	Labor Spiez
		Centre National de Référence pour les Infections Virales Emergentes
		Institut für Virologie und Immunologie
RL West	Canton of Genève	Laboratoire de Bactériologie
		Centre National de Référence pour les Infections Virales Emergentes
	Canton of Vaud	Laboratoires de Diagnostic de l'Institut de Microbiologie
RL West Central	Canton of Bern	Labor Spiez
RL East Central	Canton of Luzern	Institut für Medizinische Mikrobiologie
RL East	Canton of Zürich	Institut für Medizinische Mikrobiologie
		Institut für Medizinische Virologie
RL North	Canton of Basel-Stadt	Kantonales Laboratorium Basel-Stadt
RL South	Canton of Ticino	Laboratorio Microbiologia Applicata

Abbreviations: NRC: National Reference Center RL: Regional Laboratory GDK: Swiss Conference of Cantonal Ministers of Public Health

Information on the Regional Laboratory Network can also be found online (website in French): <u>https://www.bag.admin.ch/bag/fr/home/krankheiten/infektionskrankheiten-bekaempfen/labordiagnostik-infektionskrankheiten/regionallabornetzwerk.html</u>

2. State the total funding for each programme and its source.

All personnel involved in activities in relation to the Regional Laboratory Network is tasked with other civil duties. Many of these other activities, such as development of related methods, sample preparation and processing, training, etc., although at least indirectly of benefit to the activities in relation to the Regional Laboratory Network, remain unaccounted for and are not singled out as being of such nature. Furthermore, the whole network relies on existing infrastructures in use for other civil purposes. Due to these facts it is not possible to sort out personnel costs, cost of materials and consumables, as well as dedicated infrastructure costs for the program, however, it is possible to name the funding sources as follows:

- Swiss Confederation, Federal Department of Home Affairs FDHA
- All twenty-six cantons of Switzerland
- Principality of Liechtenstein

Total Funding: N/A

Funding Currency: N/A

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other nondefence facilities?

no

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

N/A

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

N/A

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



Abbreviations used in the diagram:

AWEL:	Office for Waste, Water, Energy and Air	IVI:	Institute of Virology and Immunology
BAFU:	Federal Office for the Environment	KLBE:	Cantonal Laboratory of Berne
BAG:	Federal Office of Public Health	KLBS:	Cantonal Laboratory of Basel-Stadt
Cantons:	Please refer to the map	KoKo:	Coordination Committee
CHUV:	University Hospital Center of Vaud	LAB:	Laboratory Advisory Board
CRIVE:	National Reference Center for Emerging Viral Infections	LB:	Bacteriological Laboratory
DETA:	Department for Environment, Transport and Agriculture	LMA:	Laboratory of Applied Microbiology
DGE:	Directorate-General for Environment	LS:	Spiez Laboratory
EFBS:	Swiss Expert Committee for Biosafety	LUKS:	Cantonal Hospital of Luzern
GDK:	Swiss Conference of Cantonal Ministers of Public Health	LV:	Virological Laboratory
HUG:	University Hospitals of Geneva	NRZ:	National Reference Center
IMM1:	Department of Medical Microbiology	RL:	Regional Laboratory
IMM2:	Institute of Medical Microbiology	UZH:	University of Zurich
IMUL:	Diagnostic Laboratories of the Institute of Microbiology	VBS:	Federal Department of Defense, Civil Protection and Sports
IMV:	Institute of Medical Virology		-



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and nongovernmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Please refer to Form A, part 2 (iii).

Attachments: N/A

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

Labor Spiez (Spiez Laboratory)

 Where is it located (include both address and geographical location)?
 Labor Spiez, Bundesamt f
ür Bev
ölkerungsschutz, Eidgen
össisches Departement f
ür Verteidigung, Bev
ölkerungsschutz und Sport, Austrasse, CH-3700 Spiez, Switzerland

N 46° 41' 26.32", E 7° 38' 39.41"

3. Floor area of laboratory areas by containment level:

BL 2: 483 SqM BL 3: 126 SqM BL 4: 118 SqM Of note, the BSL4 unit is operational and holds a license as follows: "Development of methods to detect and analyze viral pathogens of risk group 4 (clinical samples, environmental samples, including samples suspect of bioterrorism origin) as well as evaluation of antiviral substances, neutralizing antibodies and decontamination solutions".

Total laboratory floor area (SqM): 727

4. The organizational structure of each facility.

(i) Total number of personnel: 19

(ii) Division of personnel:Military: 0Civilian: 19

(iii) Division of personnel by category: Scientists: 10Engineers: 0Technicians: 9Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Virology, bacteriology, toxinology, biosafety and biosecurity.

Of note, as of 1 January 2019 the total number of personnel at Spiez Laboratory amounts to 99, 16 of which in the Biology Division and 3 of which in the Logistics, Quality & Security Section dealing with technical, safety and security issues related to the Biology Division.

 $(v) \mbox{ Are contractor staff working in the facility? If so, provide an approximate number.$

7

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Swiss Confederation (Federal Department of Defence, Civil Protection and Sports):

CHF 5'000'000.-

Research	15 %
Development	10 %
Test & Evaluation	5 %
Analysis / Diagnosis	15 %
Education & Training	5 %
Other activities	50 % (costs for operation, maintenance and amortization)

(vii) What are the funding levels for the following programme areas:

Research: 15 % Development: 10 % Test and evaluation: 5 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Ackermann-Gäumann R, Eyer C, Leib SL, Niederhauser C. Comparison of Four Commercial IgG-Enzyme-Linked Immunosorbent Assays for the Detection of Tick-Borne Encephalitis Virus Antibodies. Vector Borne Zoonotic Dis. 2018 Dec 4. doi: 10.1089/vbz.2018.2359. [Epub ahead of print].

Ackermann-Gäumann R, Siegrist D, Züst R, Signer J, Lenz N, Engler O. Standardized focus assay protocol for biosafety level four viruses. J Virol Methods. 2019 Feb;264:51-54. doi: 10.1016/j.jviromet.2018.12.002. Epub 2018 Dec 1.

Ackermann-Gäumann R, Tritten ML, Hassan M, Lienhard R. Comparison of three commercial IgG and IgM ELISA kits for the detection of tick-borne encephalitis virus antibodies. Ticks Tick Borne Dis. 2018 May;9(4):956-962. doi: 10.1016/j.ttbdis.2018.03.031. Epub 2018 Mar 28.

García-Nicolás O, V'kovski P, Vielle NJ, Ebert N, Züst R, Portmann J, Stalder H, Gaschen V, Vieyres G, Stoffel M, Schweizer M, Summerfield A, Engler O, Pietschmann T, Todt D, Alves MP, Thiel V, Pfaender S. The Small-Compound Inhibitor K22 Displays Broad Antiviral Activity against Different Members of the Family Flaviviridae and Offers Potential as a Panviral Inhibitor. Antimicrob Agents Chemother. 2018 Oct 24;62(11). pii: e01206-18. doi: 10.1128/AAC.01206-18. Print 2018 Nov.

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Notes:

N/A

Attachments: N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

Spiez Laboratory, which is part of the Federal Department for Civil Protection, is the Swiss Center of Expertise in NBC Protection. Its Biology Division has a range of activities including research, development, test & evaluation, training, as well as diagnosis in the fields of virology, bacteriology, toxinology and biosafety. The tasks include analysis of unknown samples, diagnostics and identification of potential biological warfare and bioterror agents, food and water analysis for the Swiss Armed Forces, and research & development in coordination with contractors. Spiez Laboratory deals with many different biological agents and toxins known to be pathogenic for humans.

Spiez Laboratory is also a National Reference Center mandated by the Swiss Federal Office of Public Health and a National Reference Laboratory mandated by the Swiss Federal Food Safety and Veterinary Office as follows:

- National Reference Center for Anthrax
 - Bacillus anthracis (anthrax)
 - Francisella tularensis (tularemia)
 - Yersinia pestis (plague)
 - Brucella spp. (brucellosis)
 - Burkholderia pseudomallei (melioidosis)
 - Clostridium botulinum (botulism)
 - other bacterial pathogens according to requirements of the national coordination committee of the

Regional Laboratory Network

- National Reference Center for Tick-Transmitted Diseases
 - Tick-borne encephalitis virus (TBE)
 - Coxiella burnetii (Q fever)
 - Borrelia burgdorferi s.l. (Lyme disease)
 - Other rare / emerging tick-transmitted pathogens
- National Reference Laboratory for Staphylococcus enterotoxins
 - Staphylococcus enterotoxin B
 - other Staphylococcus enterotoxins

In addition, Spiez Laboratory supports the National Reference Center for Emerging Viral Infections responsible for the detection of emerging and reemerging viruses of all biosafety levels, especially hemorrhagic fever viruses and variola virus.

Spiez Laboratory's Biology Division holds an accreditation by the Swiss Accreditation Service as "Testing laboratory for the detection of biological agents" (STS 0054) according to the international standard ISO/IEC 17025:2005.

For additional information please visit: https://www.labor-spiez.ch/enindex.htm

1. What is the name of the facility?

Centre National de Référence pour les Infections Virales Emergentes (National Reference Center for Emerging Viral Infections)

2. Where is it located (include both address and geographical location)?

Centre National de Référence pour les Infections Virales Emergentes, Laboratoire de Virologie, Hôpitaux Universitaires de Genève, Rue Gabrielle Perret-Gentil 4, CH-1205 Genève, Switzerland

N 46° 11' 37.20", E 6° 8' 59.92"

3. Floor area of laboratory areas by containment level:

BL 2: 29 SqM BL 3: 39 SqM BL 4: 36 SqM *Of note, the BSL4 unit is operational and holds a license for diagnostic purposes only, as follows: "Detection of viruses in clinical samples by molecular and/or serological methods".*

Total laboratory floor area (SqM): 104

4. The organizational structure of each facility.

(i) Total number of personnel: 5

(ii) Division of personnel:Military: 0Civilian: 5

(iii) Division of personnel by category:Scientists: 3Engineers: 0Technicians: 2Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Medicine, biology, microbiology, molecular biology, viral genetics, infectious diseases.

(v) Are contractor staff working in the facility? If so, provide an approximate number.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Swiss Confederation (Federal Department of Home Affairs).

2 %
55 %
15 %
20 %
1 %
7 % (costs for maintenance and administration)

(vii) What are the funding levels for the following programme areas:

Research: 2 % Development: 55 % Test and evaluation: 15 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Dissecting HIV Virulence: Heritability of Setpoint Viral Load, CD4+ T-Cell Decline, and Per-Parasite Pathogenicity. Bertels F, Marzel A, Leventhal G, Mitov V, Fellay J, Günthard HF, Böni J, Yerly S, Klimkait T, Aubert V, Battegay M, Rauch A, Cavassini M, Calmy A, Bernasconi E, Schmid P, Scherrer AU, Müller V, Bonhoeffer S, Kouyos R, Regoes RR; Swiss HIV Cohort Study. Mol Biol Evol. 2018;35(1):27-37.

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Anti-apolipoprotein A-1 autoantibodies are associated with immunodeficiency and systemic inflammation in HIV patients corresponding. N. Satta, S. Pagano, F. Montecucco, B. Gencer, F. Mach, L. Kaiser, A. Calmy, N. Vuilleumier. Journal of Infection. Feb. 2018; 76 (2):186-195.

Broad spectrum non toxic antiviral nanoparticles with a virucidal inhibition mechanism. V. Cagno, P. Andreozzi, M. D'Alicarnasso, PJ Silva, M. Mueller, M. Galloux, R. Le Goffic, ST Jones, M. Vallino, J. Hodek, J. Weber, S. Sen, EM Janeček, A. Bekdemir, B. Sanavio, C. Martinelli, M. Donalisio, MA Rameix Wetli, JF Eleouet, Y. Han, L. Kaiser, L. Vukovic, C. Tapparel, P. Král, S. Krol, D. Lembo, F. Stellacci. Nature Materials. Feb. 2018; 17 (2): 195-203.

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The National Reference Center for Emerging Viral Diseases (CRIVE/NAVI) is a national reference laboratory by order of the Federal Office of Public Health. Its task is the detection of emerging and re-emerging viruses of all biosafety levels, especially hemorrhagic fever viruses and smallpox virus. The BSL4 unit is approved for diagnostic purposes only, which does not allow any culturing or enrichment of such viruses. The National Reference Center for Emerging Viral Diseases is part of the Laboratory of Virology at the University Hospitals of Geneva. Since the 1st January 2018, the CRIVE acts also as WHO National Center for Measles and Rubella.

The Laboratory of Virology (LV) performs the analysis of many viruses impacting the human health as done in most of the hospitals (HIV, Hepatitis, CMV, EBV, respiratory and enteric viruses, etc.). LV does most of the viral analysis needed by a university hospital. LV also hosts the Swiss National Center for Influenza.

For further information please visit (website in French): <u>https://www.hug-ge.ch/laboratoire-virologie</u>

1. What is the name of the facility?

Institut für Virologie und Immunologie (Institute of Virology and Immunology)

2. Where is it located (include both address and geographical location)?

Institut für Virologie und Immunologie, Bundesamt für Lebensmittelsicherheit und Veterinärwesen, Eidgenössisches Departement des Innern, Sensemattstrasse 293, CH-3147 Mittelhäusern, Switzerland

N 46° 52' 50.20", E 7° 21' 46.81"

3. Floor area of laboratory areas by containment level:

BL 2: 210 SqM BL 3: 44 SqM ABL 3 Ag: 10446 SqM Of note, BSL3Ag facilities have special features not comparable to standard BSL3 or BSL4 facilities. The shell is considered BSL4, whereas inside the containment area BSL1, BSL2 and BSL3 space is common standard. Personnel enters through a shower barrier and is provided with suitable laboratory clothing for BSL1, 2 and 3 inside the containment area. Personnel has to shower out when leaving the containment area and has to keep a 72h quarantine (no contact to cloven hoofed animals). The IVI fulfills the requirements of the EU Minimum Biorisk Management Standards for Laboratories Working with Foot-And-Mouth Disease Virus. Due to these special features of BSL3Ag facilities, the BSL3Ag area is not limited to laboratory units only, but also includes engineering floors such as effluent treatment plant or ventilation units and animal units, which are all located within the containment area. Therefore, all maintenance work has to be done during operation – the facility has never been shut down so far. This also means that a direct comparison with BSL4 facilities is not practicable. Licenses are as follows: "Quality controls of immuno-biological products for use in applications of veterinary medicine"; "Establishment of a cell-based rapid test to determine protection provided by vaccination against foot-and-mouth disease virus"; "Validation of decontamination by H2O2"; "Diagnostics of viral pathogens causing highly contagious animal diseases".

Total laboratory floor area (SqM): 10700

4. The organizational structure of each facility.

(i) Total number of personnel: 64

(ii) Division of personnel:Military: 0Civilian: 64

(iii) Division of personnel by category: Scientists: 31Engineers: 8Technicians: 20Administrative and support staff: 5

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Virology, immunology, vaccine control, diagnostics, development and validation of methods, biosafety, engineering, animal breeding.

(v) Are contractor staff working in the facility? If so, provide an approximate number. 0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Swiss Confederation (Federal Department of Home Affairs).

Research15 %Development10 %Test & Evaluation10 %Analysis / Diagnosis25 %Education & Training10 %Other activities30 % (costs for safety, infrastructure and administration)

(vii) What are the funding levels for the following programme areas:

Research: 15 % Development: 10 % Test and evaluation: 10 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Alves, M.P., Vielle, N.J., Thiel, V., and Pfaender, S. (2018) Research models and tools for the identification of antivirals and therapeutics against Zika virus infection. Viruses-Basel 10:11, 593.

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Braun, R.O.#, Brunner, L., Wyler, K., Auray, G., García-Nicolás, O., Python, S., Zumkehr, B., Gaschen, V., Stoffel, M.H., Collin, N., Barnier-Quer, C., Bruggmann, R., and Summerfield, A. (2018) System immunology-based identification of blood transcriptional modules correlating to antibody responses in sheep. NPJ Vaccines 3, 41.

Braun, U., Janett, F., Züblin, S., von Büren, M., Hilbe, M., Zanoni, R., and Schweizer, M. (2018) Insemination with border disease virus-infected semen results in seroconversion in cows but not persistent infection in fetuses. BMC Veterinary Research 14:1, 159.

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Devinsky, O., Boesch, J.M., Cerda-Gonzalez, S., Coffey, B., Davis, K., Friedman, D., Hainline, B., Houpt, K., Lieberman, D., Perry, P., Prüss, H., Samuels, M.A., Small, G.W., Volk, H., Summerfield, A., Vite, C., Wisniewski, T., and Natterson-Horowitz, B. (2018) A cross-species approach to disorders affecting brain and behaviour. Nature Reviews Neurology 14:11, 677-686.

Englezou, P.C., Sapet, C., Démoulins, T., Milona, P., Ebensen, T., Schulze, K., Guzman, C.A., Poulhes, F., Zelphati, O., Ruggli, N., and McCullough, K.C. (2018) Self-amplifying replicon RNA delivery to dendritic cells by cationic lipids. Molecular Therapy. Nucleic acids 12, 118-134.

Fernández, M., Braun, U., Frei, S., Schweizer, M., and Hilbe, M. (2018) Border disease virus infection of bovine placentas. Veterinary Pathology 55:3, 425-433.

García-Nicolás, O., Braun, R.O., Milona, P., Lewandowska, M., Dijkman, R., Alves, M.P., and Summerfield, A. (2018) Targeting of the nasal mucosa by Japanese encephalitis virus for non-vector-borne transmission. Journal of Virology 92:24, e01091-18.

García-Nicolás, O., V'kovski, P.#, Vielle, N.J., Ebert, N., Züst, R., Portmann, J., Stalder, H., Gaschen, V., Vieyres, G., Stoffel, M., Schweizer, M., Summerfield, A., Engler, O., Pietschmann, T., Todt, D., Alves, M.P., Thiel, V., and Pfaender, S. (2018) The small compound inhibitor K22 displays broad antiviral activity against different members of the family Flaviviridae and offers potential as pan-viral inhibitor. Antimicrobial Agents and Chemotherapy 62:11, e01206-18.

Hufsky, F., Ibrahim, B., Beer, M., Deng, L., Le Mercier, P., McMahon, D.P., Palmarini, M., Thiel, V., and Marz, M. (2018) Virologists - heroes need weapons. PLoS Pathogens 14:2, e1006771.

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Kümin, D., Gsell Albert, M., and Summermatter, K. (2018) Comparison and validation of three fumigation methods to inactivate foot-and-mouth disease virus. Applied Biosafety 23:2, 70-76.

Locher, S., Schweneker, M., Hausmann, J., and Zimmer, G. (2018) Immunogenicity of propagation-restricted vesicular stomatitis virus encoding Ebola virus glycoprotein in guinea pigs. Journal of General Virology 99:7, 866-879.

Lussi, C., Sauter, K.-S., and Schweizer, M. (2018) Homodimerisation-independent cleavage of dsRNA by a pestiviral nicking endoribonuclease. Scientific Reports 8:1, 8226.

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Notes:

N/A

Attachments: N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Institute of Virology and Immunology (IVI), which is part of the Swiss Federal Food Safety and Veterinary Office, is the ISO 17025 accredited institute for the diagnosis, surveillance and control of highly contagious epizootics. In addition, the IVI pursues research both on these viruses and emerging viral diseases, as well as their potential transmission to man. The IVI is also the competent authority issuing the licenses required for the sale of veterinary immunobiological products. Basic research is carried out in the fields of immunology and virology, and involves influenza virus, foot-and-mouth disease virus, classical swine fever virus and porcine circovirus type 2. The development and diagnostics branches focus on assays and tests for classical and african swine fever, foot-and-mouth disease, avian influenza, bluetongue, and other highly contagious infectious diseases. In this domain, the IVI occupies a leading position internationally.

For further information please visit: <u>https://www.ivi.admin.ch/ivi/en/home.html</u>

1. What is the name of the facility?

Laboratoire de Bactériologie (Bacteriological Laboratory)

 Where is it located (include both address and geographical location)?
 Laboratoire de Bactériologie, Hôpitaux Universitaires de Genève, Rue Gabrielle Perret-Gentil 4, CH-1211 Genève 14, Switzerland

N 46° 11' 37.20", E 6° 8' 59.92"

3. Floor area of laboratory areas by containment level:

BL 2: 394 SqM BL 3: 74 SqM

Total laboratory floor area (SqM): 468

4. The organizational structure of each facility.

(i) Total number of personnel: 7

(ii) Division of personnel:Military: 0Civilian: 7

(iii) Division of personnel by category:Scientists: 3Engineers: 0Technicians: 4Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Medicine, biology, microbiology, molecular biology, bacterial genetics, infectious diseases.

(v) Are contractor staff working in the facility? If so, provide an approximate number. 0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Cantons of Fribourg, Genève, Neuchâtel, Valais, Vaud.

Research0 %Development5 %Test & Evaluation40 %Analysis / Diagnosis40 %Education & Training13 %Other activities2 % (costs for maintenance and administration)

(vii) What are the funding levels for the following programme areas:

Research: 0 % Development: 5 % Test and evaluation: 40 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

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Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Bacteriological Laboratory, which is part of the University Hospitals of Geneva, is the Regional Competence Center for the primary analysis of bacteriological samples suspicious of a bioterror-related background. Protocols for the detection of bacteria causing anthrax, plague, tularemia and brucellosis have been established in close collaboration with the National Reference Center for Anthrax. Furthermore, there is a strong link between the Bacteriological Laboratory and the Genomic Research Laboratory that is almost exclusively executing basic and applied research projects under joint leadership. Translational research is actively promoted through this channel of cooperation.

For further information please visit (website in French): <u>https://www.hug-ge.ch/laboratoire-bacteriologie</u>

1. What is the name of the facility?

Laboratoires de Diagnostic de l'Institut de Microbiologie (Diagnostic Laboratories of the Institute of Microbiology)

2. Where is it located (include both address and geographical location)?

Laboratoires de Diagnostic de l'Institut de Microbiologie, Département de Pathologie et Médecine de Laboratoire, Centre Hospitalier Universitaire Vaudois, Rue du Bugnon 48, CH-1011 Lausanne, Switzerland

N 46° 31' 30.57", E 6° 38' 29.15"

3. Floor area of laboratory areas by containment level:

BL 3: 77 SqM

Total laboratory floor area (SqM): 77

4. The organizational structure of each facility.

(i) Total number of personnel: 13

(ii) Division of personnel:Military: 0Civilian: 13

(iii) Division of personnel by category:Scientists: 6Engineers: 0Technicians: 7Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Bacteriology, mycology, parasitology, virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number. 0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Cantons of Fribourg, Genève, Neuchâtel, Valais, Vaud.

Research0 %Development5 %Test & Evaluation5 %Analysis / Diagnosis70 %Education & Training20 %Other activities0 %

(vii) What are the funding levels for the following programme areas:

Research: 0 % Development: 5 % Test and evaluation: 5 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Added Value of Xpert MTB/RIF Ultra for Diagnosis of Pulmonary Tuberculosis in a Low-Prevalence Setting. Opota O, Zakham F, Mazza-Stalder J, Nicod L, Greub G, Jaton K. J Clin Microbiol. 2019 Jan 30;57(2).

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Role of bi-weekly serum galactomannan screening for the diagnosis of invasive aspergillosis in haematological cancer patients. Couchepin J, Brunel AS, Jaton K, Meylan P, Bochud PY, Lamoth F. Mycoses. 2018 Jun;61(6):350-354.

A cluster of multidrug-resistant Mycobacterium tuberculosis among patients arriving in Europe from the Horn of Africa: a molecular epidemiological study. Walker TM, Merker M, Knoblauch AM, Helbling P, Schoch OD, van der Werf MJ, Kranzer K, Fiebig L, Kröger S, Haas W, Hoffmann H, Indra A, Egli A, Cirillo DM, Robert J, Rogers TR, Groenheit R, Mengshoel AT, Mathys V, Haanperä M, Soolingen DV, Niemann S, Böttger EC, Keller PM; MDR-TB Cluster Consortium. Lancet Infect Dis. 2018. Apr;18(4):431-440.

Notes: N/A

Attachments: N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Diagnostic Laboratories of the Institute of Microbiology, which are part of the University Hospital of Lausanne, are the Regional Competence Center for the primary analysis of samples suspicious of a bioterror-related background. Due to its other diagnostic activities, it is able to cover the whole spectrum of microbiology.

Of note, in 2017, the Diagnostic Laboratories of the Institute of Microbiology obtained the necessary funds for an upgrade and expansion of its BSL3 laboratory. The construction started in February 2017 and will be finished in May 2019. During this period all these activities are carried out in the research BSL3 laboratory of the Institute according to the good laboratories practices recommended.

The new BSL3 laboratory will be the reference BSL3 laboratory of the hospital (CHUV) for the diagnosis and manipulation of BSL3 samples, strains, microorganisms that may be encountered in the daily work as well as environmental samples for the Regional Laboratory Network.

For further information please visit: <u>https://www.chuv.ch/en/microbiologie/imu-home/diagnostics/</u>

1. What is the name of the facility?

Institut für Medizinische Mikrobiologie (Department of Medical Microbiology)

2. Where is it located (include both address and geographical location)?

Institut für Medizinische Mikrobiologie, Zentrum für LaborMedizin, Luzerner Kantonsspital, Luzerner Kantonsspital Haus 47, Spitalstrasse, CH-6000 Luzern 16, Switzerland

N 47° 3' 32.45", E 8° 18' 1.17"

3. Floor area of laboratory areas by containment level:

BL 2: 716 SqM BL 3: 62 SqM

Total laboratory floor area (SqM): 778

4. The organizational structure of each facility.

(i) Total number of personnel: 8

(ii) Division of personnel:Military: 0Civilian: 8

(iii) Division of personnel by category: Scientists: 3Engineers: 0Technicians: 4Administrative and support staff: 1

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Clinical microbiology (all disciplines; diagnostics and applied research).

(v) Are contractor staff working in the facility? If so, provide an approximate number.

0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Cantons of Luzern, Nidwalden, Obwalden, Schwyz, Uri.

Research0 %Development0 %Test & Evaluation15 %Analysis / Diagnosis75 %Education & Training10 %Other activities0 %

(vii) What are the funding levels for the following programme areas:

Research: 0 % Development: 0 % Test and evaluation: 15 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

No publicly available papers or reports published in 2018.

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Department of Medical Microbiology, as part of the Zentrum für LaborMedizin, Luzerner Kantonsspital, is accredited (ISO / EN 17025) for clinical bacteriology, mycology, mycobacteriology, parasitology, molecular diagnostics, serology. The current focus of applied research activities is on specific bacteriological / molecular testing topics. In addition, it is the Regional Competence Center for primary analyses of samples suspicious of a bioterror-related background.

For further information please visit (website in German): <u>https://www.luks.ch/standorte/luzern/kliniken/zentrum-fuer-labormedizin/institut-fuer-medizinische-mikrobiologie.html</u>

1. What is the name of the facility?

Institut für Medizinische Mikrobiologie (Institute of Medical Microbiology)

2. Where is it located (include both address and geographical location)? Institut für Medizinische Mikrobiologie, Medizinische Fakultät, Universität Zürich, Gloriastrasse 30/32, CH-8006 Zürich, Switzerland

N 47° 22' 36.20", E 8° 33' 11.18"

3. Floor area of laboratory areas by containment level: BL 3: 20 SqM

Total laboratory floor area (SqM):

20

4. The organizational structure of each facility.

(i) Total number of personnel: 3

(ii) Division of personnel:Military: 0Civilian: 3

(iii) Division of personnel by category: Scientists: 2Engineers: 0Technicians: 1Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Microbiology (bacteriology / mycology).

 $(v) \mbox{ Are contractor staff working in the facility? If so, provide an approximate number.$

0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Cantons of Appenzell Ausserrhoden, Appenzell Innerrhoden, Glarus, Graubünden, Sankt Gallen, Schaffhausen, Thurgau, Zug, Zürich, and the Principality of Liechtenstein.

Research0 %Development0 %Test & Evaluation10 %Analysis / Diagnosis80 %Education & Training10 %Other activities0 %

(vii) What are the funding levels for the following programme areas:

Research: 0 % Development: 0 % Test and evaluation: 10 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Ribosome levels selectively regulate translation and lineage commitment to human hematopoiesis. Khajuria RK, Munschauer M, Ulirsch JC, Fiorini C, Ludwig LS, McFarland SK, Abdulhay NJ, Specht H, Keshishian H, Mani DR, Jovanovic M, Ellis SR, Fulco CP, Engreitz JM, Schütz S, Lian J, Gripp KW, Weinberg OK, Pinkus GS, Gehrke L, Regev A, Lander ES, Gazda HT, Lee Wy, Panse VG, Carr SA, Sankaran VG (2018) Cell 173: 90-103.

A cluster of multidrug-resistant Mycobacterium tuberculosis among patients arriving in Europe from the Horn of Africa: a molecular epidemiological study. Walker TM, Merker M, Knoblauch AM, Helbling P, Schoch OD, van der Werf MJ, Kranzer K, Fiebig L, Kröger S, Haas W, Hoffmann H, Indra A, Egli A, Cirillo DM, Robert J, Rogers TR, Groenheit R, Mengshoel AT, Mathys V, Haanperä M, Soolingen DV, Niemann S, Böttger EC, Keller PM; MDR-TB Cluster Consortium (2018) Lancet Infect Dis 18: 431-440.

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Detection limit of Mycobacterium chimaera in water samples for monitoring medical device safety: insights from a pilot experimental series. Schreiber PW, Köhler N, Cervera R, Hasse B, Sax H, Keller PM (2018) J Hosp Infect 99: 284-289.

Detection of respiratory bacterial pathogens causing atypical pneumonia by multiplex Lightmix® RT-PCR. Wagner K, Springer B, Imkamp F, Opota O, Greub G, Keller PM. (2018) Int J Med Microbiol 308: 317-323.

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A novel RT-PCR for the detection of Helicobacter pylori and identification of clarithromycin resistance mediated by mutations in the 23S rRNA gene. Redondo JR, Keller PM, Zbinden R, Wagner K. (2018) Diagn Microbiol Infect Dis 90: 1-6.

High-throughput screening of bacterial pathogens in clinical specimens using 16S rDNA qPCR and fragment analysis. Wagner K, Springer B, Pires VP, Keller PM (2018) Diagn Microbiol Infect Dis: Epub ahead of print.

Increased Pathogen Identification in Vascular Graft Infections by the Combined Use of Tissue Cultures and 16S rRNA Gene Polymerase Chain Reaction. Ajdler-Schaeffler E, Scherrer AU, Keller PM, Anagnostopoulos A, Hofmann M, Rancic Z, Zinkernagel AS, Bloemberg GV, Hasse BK; and the VASGRA Cohort (2018) Front Med (Lausanne) 5: 169.

A cluster of scedosporiosis in lung transplant candidates and recipients: The Zurich experience and review of the literature. Abela IA, Murer C, Schuurmans MM, Schmitt JW, Muller F, Imkamp F, Mueller NJ, Benden C (2018) Transpl Infect Dis 20: e12792.

Ureaplasma and Mycoplasma in kidney allograft recipients-A case series and review of the literature. Gerber L, Gaspert A, Braghetti A, Zwahlen H, Wüthrich R, Zbinden R, Mueller N, Fehr T (2018) Transpl Infect Dis 20: e12937.

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Membrane transporter research in times of countless structures. Seeger MA (2018) Biochim Biophys Acta 1860: 804-808.

The Role of Antibiotic-Target-Modifying and Antibiotic-Modifying Enzymes in Mycobacterium abscessus Drug Resistance. Luthra S, Rominski A, Sander P (2018) Front Microbiol 9: 2179.

Acanthamoeba and Dictyostelium as cellular models for Legionella infection. Swart AL, Harrison CF, Eichinger L, Steinert M, Hilbi H (2018) Front Cell Infect Microbiol 8: 61.

Improving the quality and workflow of bacterial genome sequencing and analysis: paving the way for a Switzerland-wide molecular epidemiological surveillance platform. Egli A, Blanc DS, Greub G, Keller PM, Lazarevic V, Lebrand A, Leib S, Neher RA, Perreten V, Ramette A, Schrenzel J, Stephan R, Wagner K, Wuethrich D, Xenarios I (2018) Swiss Med Wkly 148: w14693.

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Analysis of Legionella metabolism by pathogen vacuole proteomics. Manske C, Finsel I, Hoffmann C, Hilbi H (2018) In Meth. Mol. Biol. 1841, Microbial proteomics. Becher, D. (ed.), Springer Press; pp. 59-76.

Notes:

N/A

Attachments: N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Institute of Medical Microbiology at the University of Zurich is the Regional Competence Center for the primary analysis of bacteriological samples suspicious of a bioterror-related background. This represents an additional and not a continuous task of the diagonstics laboratory proficient in bacteriology, mycology and serology.

For further information please visit (website in German): http://www.imm.uzh.ch/index.html

1. What is the name of the facility? Institut für Medizinische Virologie (Institute of Medical Virology)

 Where is it located (include both address and geographical location)?
 Institut f
ür Medizinische Virologie, Medizinische Fakult
ät, Universit
ät Z
ürich, Winterthurerstrasse 190, CH-8057 Z
ürich, Switzerland

N 47° 23' 52.08", E 8° 33' 01.92"

3. Floor area of laboratory areas by containment level:

BL 3: 25 SqM Of note, the Institute of Medical Virology holds a BSL4 license for diagnostic purposes only, as follows: "Inactivation of environmental samples and of potentially highly pathogenic viruses for diagnostic purposes within the framework of the Regional Laboratory Network".

Total laboratory floor area (SqM):

25

4. The organizational structure of each facility.

(i) Total number of personnel: 2

(ii) Division of personnel:Military: 0Civilian: 2

(iii) Division of personnel by category:Scientists: 1Engineers: 0Technicians: 1Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Microbiology (virology).

(v) Are contractor staff working in the facility? If so, provide an approximate number.

0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Cantons of Appenzell Ausserrhoden, Appenzell Innerrhoden, Glarus, Graubünden, Sankt Gallen, Schaffhausen, Thurgau, Zug, Zürich, and the Principality of Liechtenstein.

Research	0 %
Development	0 %
Test & Evaluation	10 %
Analysis / Diagnosis	50 %
Education & Training	10 %
Other activities	30 % (costs for maintenance and amortization)

(vii) What are the funding levels for the following programme areas:

Research: 0 % Development: 0 % Test and evaluation: 10 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Metagenomic virome sequencing in living donor-recipient kidney transplant pairs revealed JC Polyomavirus transmission. Schreiber PW, Kufner V, Hübel K, Schmutz S, Zagordi O, Kaur A, Bayard C, Greiner M, Zbinden A, Capaul R, Böni J, Hirsch HH, Mueller TF, Mueller NJ, Trkola A, Huber M. Clin Infect Dis. 2018 Dec 2. doi: 10.1093/cid/ciy1018.

Inferring the age difference in HIV transmission pairs by applying phylogenetic methods on the HIV transmission network of the Swiss HIV Cohort Study. Kusejko K, Kadelka C, Marzel A, Battegay M, Bernasconi E, Calmy A, Cavassini M, Hoffmann M, Böni J, Yerly S, Klimkait T, Perreau M, Rauch A, Günthard HF, Kouyos RD; Swiss HIV Cohort Study. Virus Evol. 2018 Sep 18;4(2):vey024. doi: 10.1093/ve/vey024. eCollection 2018 Jul. Review.

Tracing HIV-1 strains that imprint broadly neutralizing antibody responses. Kouyos RD, Rusert P, Kadelka C, Huber M, Marzel A, Ebner H, Schanz M, Liechti T, Friedrich N, Braun DL, Scherrer AU, Weber J, Uhr T, Baumann NS, Leemann C, Kuster H, Chave JP, Cavassini M, Bernasconi E, Hoffmann M, Calmy A, Battegay M, Rauch A, Yerly S, Aubert V, Klimkait T, Böni J, Metzner KJ, Günthard HF, Trkola A; Swiss HIV Cohort Study. Nature. 2018 Sep;561(7723):406-410. doi: 10.1038/s41586-018-0517-0. Epub 2018 Sep 10.

Quantifying the drivers of HIV transmission and prevention in men who have sex with men: a population modelbased analysis in Switzerland. Kusejko K, Marzel A, Hampel B, Bachmann N, Nguyen H, Fehr J, Braun DL, Battegay M, Bernasconi E, Calmy A, Cavassini M, Hoffmann M, Böni J, Yerly S, Klimkait T, Perreau M, Rauch A, Günthard HF, Kouyos RD; Swiss HIV Cohort Study. HIV Med. 2018 Nov;19(10):688-697. doi: 10.1111/hiv.12660. Epub 2018 Jul 26.

The Cumulative Impact of Harm Reduction on the Swiss HIV Epidemic: Cohort Study, Mathematical Model, and Phylogenetic Analysis. Marzel A, Kusejko K, Weber R, Bruggmann P, Rauch A, Roth JA, Bernasconi E, Calmy A, Cavassini M, Hoffmann M, Böni J, Yerly S, Klimkait T, Perreau M, Günthard HF, Kouyos RD; Swiss HIV Cohort Study . Open Forum Infect Dis. 2018 May 19;5(5):ofy078. doi: 10.1093/ofid/ofy078. eCollection 2018 May.

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Dissecting HIV Virulence: Heritability of Setpoint Viral Load, CD4+ T-Cell Decline, and Per-Parasite Pathogenicity. Bertels F, Marzel A, Leventhal G, Mitov V, Fellay J, Günthard HF, Böni J, Yerly S, Klimkait T, Aubert V, Battegay M, Rauch A, Cavassini M, Calmy A, Bernasconi E, Schmid P, Scherrer AU, Müller V, Bonhoeffer S, Kouyos R, Regoes RR; Swiss HIV Cohort Study. Mol Biol Evol. 2018 Jan 1;35(1):27-37. doi: 10.1093/molbev/msx246.

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Institute of Medical Virology at the University of Zurich is the Regional Competence Center for the primary analysis of viral samples suspicious of a bioterror-related background. This represents an additional and not a continuous task of the viral diagnostics laboratory.

For further information please visit: https://www.virology.uzh.ch/index_en.html

1. What is the name of the facility?

Kantonales Laboratorium Basel-Stadt (Cantonal Laboratory of Basel-Stadt)

2. Where is it located (include both address and geographical location)?

Kantonales Laboratorium Basel-Stadt, Bereich Gesundheitsschutz, Gesundheitsdepartement des Kantons Basel-Stadt, Kannenfeldstrasse 2, CH-4056 Basel, Switzerland

N 47° 33' 43.48", E 7° 34' 26.85"

3. Floor area of laboratory areas by containment level: BL 2: 14 SqM BL 3: 36 SqM

Total laboratory floor area (SqM): 50

4. The organizational structure of each facility.

(i) Total number of personnel: 4

(ii) Division of personnel:Military: 0Civilian: 4

(iii) Division of personnel by category:Scientists: 2Engineers: 0Technicians: 2Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Microbiology, molecular biology, chemistry, inspection.

(v) Are contractor staff working in the facility? If so, provide an approximate number. 0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Cantons of Aargau, Basel-Landschaft, Basel-Stadt, Solothurn.

Research	0 %
Development	15 %
Test & Evaluation	40 %
Analysis / Diagnosis	40 %
Education & Training	5 %
Other activities	0 %

(vii) What are the funding levels for the following programme areas:

Research: 0 % Development: 15 % Test and evaluation: 40 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Transmission of ESBL-producing Enterobacteriaceae and their mobile genetic elements-identification of sources by whole genome sequencing: study protocol for an observational study in Switzerland. Stadler T, Meinel D, Aguilar-Bultet L, Huisman JS, Schindler R, Egli A, Seth-Smith HMB, Eichenberger L, Brodmann P, Hübner P, Bagutti C, Tschudin-Sutter S. BMJ Open. 2018 Feb 17;8(2):e021823.

Notes:

N/A

Attachments: N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Cantonal Laboratory of Basel-Stadt is the Regional Competence Center for the primary analysis of samples suspicious of a bioterror-related background. The Regional Laboratory North is also appointed reference laboratory by the Federal Office of Environment for the two following fields of activities: Analysis of samples taken in and around laboratories subjected to the Containment Ordinance, and analysis of samples taken in the environment for the surveillance of the Release Ordinance.

The Cantonal Laboratory of Basel-Stadt has been co-author for the "Chemical Inactivation of Organisms in Liquids - Guidelines for the chemical inactivation of organisms in liquid cultures or supernatants with proof of efficacy and safe disposal" and is working out specific SOP for chemical inactivation of microorganisms attn. Federal Office of Public Health FOPH.

Microbiological and molecular biological methods have been established for the identification of a wide range of microorganisms in environmental samples, including relevant pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Bacillus anthracis*, as well as adenoviruses and lentiviruses. Further methods for the detection of bioterror agents have been implemented according to the Regional Laboratory Network.

For further information please visit (website in German): <u>https://www.kantonslabor.bs.ch/</u>

1. What is the name of the facility?

Laboratorio Microbiologia Applicata (Laboratory of Applied Microbiology)

2. Where is it located (include both address and geographical location)?

Laboratorio Microbiologia Applicata, (Edificio dell'Istituto Cantonale di Microbiologia), Dipartimento Ambiente Costruzioni e Design, Scuola Universitaria Professionale della Svizzera Italiana, Via Mirasole 22A, CH-6500 Bellinzona, Switzerland

N46° 11' 53.50", E9° 1' 10.25"

3. Floor area of laboratory areas by containment level:

BL 2: 185 SqM BL 3: 38 SqM

Total laboratory floor area (SqM): 223

4. The organizational structure of each facility.

(i) Total number of personnel: 5

(ii) Division of personnel:Military: 0Civilian: 5

(iii) Division of personnel by category:Scientists: 4Engineers: 0Technicians: 1Administrative and support staff: 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Bacteriology, mycology, molecular microbiology, microbial ecology, entomology, vector biology.

(v) Are contractor staff working in the facility? If so, provide an approximate number. 0

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Canton of Ticino.

Research	10 %
Development	10 %
Test & Evaluation	30 %
Analysis / Diagnosis	30 %
Education & Training	5 %
Other activities	15 % (administrative and maintenance costs)

(vii) What are the funding levels for the following programme areas:

Research: 10 % Development: 10 % Test and evaluation: 30 %

(viii) Briefly describe the publication policy of the facility:

Publication in open literature.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Danza, F., Ravasi, D., Storelli, N., Roman, S., Luedin, S., Bueche, M. & Tonolla, M. (2018) Bacterial diversity in the water column of meromictic Lake Cadagno and evidence for seasonal dynamics. PLoS ONE, vol. 13 (12).

Ravasi, D., De Respinis, S. & Wahli, T. (2018) Multilocus sequence typing reveals clonality in Saprolegnia parasitica outbreaks. Journal of Fish Diseases.

Lüdin, S., Pothier, J., Danza, F., Storelli, N., Frigaard, N.-U., Wittwer, M. & Tonolla, M. (2018) Complete genome sequence of "Thiodictyon syntrophicum" sp. nov. strain Cad16T, a photolithoautotrophic purple sulfur bacterium isolated from the alpine meromictic Lake Cadagno. Standards in Genomic Sciences, vol. 13 pp.14-14.

De Marchi, R., Koss, M., Ziegler, D., De Respinis, S. & Petrini, O. (2018) Fungi in water samples of a full-scale water work. Mycological Progress, vol. 17 (4) pp.467-478.

Ravasi, D., Guidi, V., Flacio, E., Lüthy, P., Perron, K., Lüdin, S. & Tonolla, M. (2018) Investigation of temperature conditions in Swiss urban and suburban microhabitats for the overwintering suitability of diapausing Aedes albopictus eggs. Parasites & vectors, vol. 11 pp.212-212.

Lange, K., Bruder, A., Matthaei, C., Brodersen, J.& Paterson, R. (2018) Multiple-stressor effects on freshwater fish: Importance of taxonomy and life stage. Fish and Fisheries, vol. 0 (0).

Pozzoni, M., Bruder, A., Bulgheroni, M., Pera Ibarguren, S., Scapozza, C., Rioggi, S., Domenici, M. & Colombo, L. (2018) Lago Nero: monitoraggio della risposta di un ecosistema all'inquinamento atmosferico e ai cambiamenti ambientali. Bollettino della Società ticinese di Scienze naturali.

Wagner, S., Guidi, V., Torgerson, P., Mathis, A. & Schaffner, F. (2018) Diversity and seasonal abundances of mosquitoes at potential arboviral transmission sites in two different climate zones in Switzerland. Medical and Veterinary Entomology.

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms $\frac{9}{2}$ and/or toxins studied, as well as outdoor studies of biological aerosols.

The Laboratory of Applied Microbiology is the Regional Competence Center South of the Alps responsible for the primary analysis of samples suspicious of a bioterror-related background.

For further information please visit (website in Italian): <u>http://www.supsi.ch/lma</u>

Confidence-Building Measure "B"

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

At the Third Review Conference it was agreed that States Parties continue to implement the following:

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

- When the cause of the outbreak cannot be readily determined or the causative agent $\frac{10}{10}$ is difficult to diagnose,

- When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,

- When the causative agent is exotic to a given geographical region,

- When the disease follows an unusual pattern of development,

- When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,

- When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form **B**

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern¹¹

Human diseases

1. Time of cognizance of the outbreak: N/A

2. Location and approximate area affected:

N/A

N/A

3. Type of disease/intoxication: N/A

4. Suspected source of disease/intoxication: N/A

5. Possible causative agent(s): N/A

6. Main characteristics of systems: N/A

7. Detailed symptoms, when applicable N/A

- Respiratory: N/A

- Circulatory: N/A

- Neurological/behavioural: N/A

- Intestinal: N/A

- Dermatological:

N/A

- Nephrological: N/A

- Other:

N/A

8. Deviation(s) from the normal pattern as regards

- Type:

N/A

- Development:

N/A

- Place of occurrence: N/A

- Time of occurrence:

- Symptoms: N/A

- Virulence pattern: N/A

- Drug resistance pattern: N/A

- Agent(s) difficult to diagnose: N/A

- Presence of unusual vectors: N/A

- Other: N/A

9. Approximate number of primary cases: N/A

10. Approximate number of total cases: N/A

11. Number of deaths:

12. Development of the outbreak:

13. Measures taken: N/A

Notes:

The Swiss Federal Office of Public Health (FOPH) is responsible for the surveillance and reporting of human diseases. A nationwide notification system is regulated by the Ordinance on the Declaration of Observations of Communicable Human Diseases (*RS 818.101.126 Ordonnance du DFI du 1 décembre 2015 sur la déclaration d'observations en rapport avec les maladies transmissibles de l'homme*), which is based on the Federal Act on the Control of Communicable Human Diseases (*RS 818.101 Loi fédérale du 28 septembre 2012 sur la lutte contre les maladies transmissibles de l'homme*). Every medical practitioner and laboratory is obliged to report the occurrence or identification of certain notifiable diseases. The current situation is accessible online and data is transmitted to the World Health Organization (WHO):

 $\label{eq:https://www.bag.admin.ch/bag/fr/home/zahlen-und-statistiken/zahlen-zu-infektionskrankheiten/meldepflichtige-infektionskrankheiten---woechentliche-fallzahlen.html$

No outbreaks of infectious diseases or similar occurrences that seemed to deviate from the normal pattern in terms of human diseases were observed during the reporting period.

Attachments:

N/A

Animal diseases 1. Time of cognizance of the outbreak: N/A 2. Location and approximate area affected: N/A N/A 3. Type of disease/intoxication: N/A 4. Suspected source of disease/intoxication: N/A 5. Possible causative agent(s): N/A 6. Main characteristics of systems: N/A 7. Detailed symptoms, when applicable N/A - Respiratory: N/A - Circulatory: N/A - Neurological/behavioural: N/A - Intestinal: N/A - Dermatological: N/A - Nephrological: N/A - Other: N/A 8. Deviation(s) from the normal pattern as regards - Type: N/A - Development: N/A - Place of occurrence: N/A - Time of occurrence:

- Symptoms:

N/A

- Virulence pattern:

N/A

- Drug resistance pattern: N/A

- Agent(s) difficult to diagnose: N/A

- Presence of unusual vectors: N/A

- Other:

N/A

9. Approximate number of primary cases: N/A

10. Approximate number of total cases: N/A

11. Number of deaths:

12. Development of the outbreak:

13. Measures taken: N/A

- - - - -

Notes:

The Swiss Federal Food Safety and Veterinary Office (FSVO) is responsible for the surveillance and reporting of animal diseases. According to the Federal Law on Animal Epidemics (*RS 916.40 Loi du 1er juillet 1966 sur les épizooties*) and the corresponding ordinance (*RS 916.401 Ordonnance du 27 juin 1995 sur les épizooties*), notifiable animal diseases have to be reported to the FSVO which in turn is responsible for the reporting to the World Organization for Animal Health (OIE). The current situation is accessible online: http://www.infosm.blv.admin.ch/public/bulletin/aktuell

No outbreaks of infectious diseases or similar occurrences that seemed to deviate from the normal pattern in terms of animal diseases were observed during the reporting period.

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Attachments:

N/A

Plant diseases and pests

1. Time of cognizance of the outbreak: N/A

2. Location and approximate area affected:

N/A

N/A

3. Type of disease/intoxication: N/A 4. Suspected source of disease/intoxication: N/A 5. Possible causative agent(s): N/A 6. Main characteristics of systems: N/A 7. Detailed symptoms, when applicable N/A - Respiratory: N/A - Circulatory: N/A - Neurological/behavioural: N/A - Intestinal: N/A - Dermatological: N/A - Nephrological: N/A - Other: N/A 8. Deviation(s) from the normal pattern as regards - Type: N/A - Development: N/A - Place of occurrence: N/A - Time of occurrence: - Symptoms: N/A - Virulence pattern: N/A - Drug resistance pattern: N/A

- Agent(s) difficult to diagnose: N/A

- Presence of unusual vectors: N/A

- Other:

N/A

9. Approximate number of primary cases: N/A

10. Approximate number of total cases: N/A

11. Number of deaths:

12. Development of the outbreak:

13. Measures taken:

N/A

Notes:

The Swiss Federal Plant Protection Service (FPPS) is responsible for any kind of phytosanitary measures in order to prevent the introduction and spread of particularly harmful pests and diseases that affect plants and plant products. The FPPS is run jointly by the Swiss Federal Office for Agriculture (FOAG) and the Swiss Federal Office for the Environment (FOEN). The FOAG is responsible for the sector of agricultural and horticultural crops, whereas the FOEN is responsible for forest plants, wood and wood products, including invasive plants. According to the Federal Law on Agriculture (*RS 910.1 Loi fédérale du 29 avril 1998 sur l'agriculture*) and the corresponding ordinance (*RS 916.20 Ordonnance du 27 octobre 2010 sur la protection des végétaux*), notifiable plant diseases and pests are reported to either the FOAG or the FOEN that transmit reports to the European and Mediterranean Plant Protection Organization (EPPO). Reporting of invasive plants to the FOEN, which then communicates with the EPPO, is primarily regulated in the Ordinance on the Release of Organisms into the Environment (*RS 814.911 Ordonnance du 10 septembre 2008 sur l'utilisation d'organismes dans l'environnement*).

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern in terms of plant diseases and pests that occurred during the reporting period is provided in the form of short descriptions of notifications made by the National Plant Protection Organisation of Switzerland to the EU Commission by means of the EUROPHYT-Outbreak system as follows:

26.01.2018
Closing: Update no 2. Finding (confirmed) of Xylella
fastidiosa in Switzerland
Eradication of the regulated pest in Switzerland
Xylella fastidiosa
Coffea
https://gd.eppo.int/reporting/article-6277

2.	Date of approval Title Short description Pest Infested plant / material	14.02.2018 First Outbreak (confirmed) of Aproceros leucopoda in Switzerland (Bassersdorf) Non-regulated pest of elm trees Aproceros leucopoda Ulmus glabra
3.	Date of approval Title Short description Pest Infested plant / material EPPO Reporting	23.02.2018 Closing: Update no 1. Outbreak (confirmed) of Anoplophora glabripennis in Switzerland Eradication of the regulated pest at one site (Brünisried) Anoplophora glabripennis Acer pseudoplatanus https://gd.eppo.int/reporting/article-6273
4.	Date of approval Title Short description Pest Infested plant / material EPPO Reporting	23.02.2018 First Finding (confirmed) of Brenneria goodwinii in Switzerland (Muttenz) Non-regulated pests of oak trees (Brenneria goodwinii, Gibbsiella quercinecans, and Rahnella victoriana) Brenneria goodwinii Quercus https://gd.eppo.int/reporting/article-6298
5.	Date of approval Title Short description Pest Infested plant / material	28.03.2018 First Outbreak (confirmed) of Pseudococcus comstocki in Switzerland (Canton of Valais) Non-regulated pest of fruit trees Pseudococcus comstocki Prunus armeniaca, Pyrus, Malus
6.	Date of approval Title Short description Pest Infested plant / material EPPO Reporting	12.07.2018 Closing: Update no 1. Finding (confirmed) of Pomacea sp. in Switzerland (Ettiswil) Eradication of the regulated pest in Switzerland Pomacea sp. Artificial pond https://gd.eppo.int/reporting/article-6294
7.	Date of approval Title Short description Pest Infested plant / material EPPO Reporting	09.10.2018 Closing: Update no 2. Outbreak (confirmed) of Ralstonia solanacearum race 1 in Switzerland (Cantons of Bern, Solothurn and Zurich) Eradication of the regulated pest in Switzerland Ralstonia solanacearum race 1 Rosa, Strelitzia, Olea europaea https://gd.eppo.int/reporting/article-6395

8.	Date of approval Title Short description Pest	09.10.2018 First Outbreak (confirmed) of Rhexocercosporidium carotae in Switzerland Non-regulated pest of carrots Rhexocercosporidium carotae
	Infested plant / material	Daucus carota
9.	Date of approval	14.11.2018
	Title	Update no 1. Finding (confirmed) of Grapevine flavescence dorée in Switzerland (Canton of Fribourg)
	Short description	First outbreak of the regulated pest in a nursery in Northern Switzerland
	Pest	Grapevine flavescence dorée
	Infested plant / material	Vitis vinifera
10	Data of approval	10.12.2018
10.	Title	Presence (confirmed) of Globodera nallida in Switzerland
	1 IIIC	(Canton of Bern)
	Short description	The regulated pest was found during official survey in a field
	Short desemption	that was planned to be used for seed potato production
	Pest	Globodera pallida
	Infested plant / material	l Soil
	1	
11		10.12.2010
11.	. Date of approval	19.12.2018
	Ittle	Switzerland (Conten of Dem)
	Short description	The regulated past was found during official survey in a field
	Short description	that was planned to be used for seed potato production
	Pest	Globodera rostochiensis
	Infested plant / material	l Soil

Attachments:

N/A

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

At the Third Review Conference it was agreed that States parties continue to implement the following:

Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research.

Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.

2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, inter alia, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.

3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Comments:

Switzerland does not impose any restrictions on the publication of basic and applied research in biosciences related to the Convention:

• CBM "A":

No restrictions implemented on the publication of research carried out within the frameworks of the National Biological Defense Program and the Regional Laboratory Network as well as their contractors.

• CBM "B":

No restrictions implemented on the publication of research. Full cooperation with international organizations (WHO, OIE, EPPO) in their respective frameworks.

• CBM "G":

Public institutions (universities, institutes, hospitals, state-run facilities): No restrictions implemented on the publication of research.

Private companies: Publication of research is encouraged, however, companies are responsible for their own publication policy that are in line with the protection of any commercial interests.

Publishers of scientific and medical journals and other publications based in Switzerland:

Birkhäuser Verlag AG, Basel: <u>https://www.springer.com/birkhauser</u> EMH Schweizerischer Ärzteverlag AG, Muttenz: <u>https://www.emh.ch/en/read</u> Frontiers Media SA, Lausanne: <u>https://www.frontiersin.org/</u> Inderscience Publishers, Genève: <u>https://www.inderscience.com/</u> MDPI AG, Basel: <u>https://www.mdpi.com/</u> S. Karger AG, Basel: <u>https://www.karger.com/</u> SciPress Ltd., Bäch: <u>https://www.scipress.com/</u> WHO Press, Genève: <u>http://apps.who.int/bookorders</u>

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

(a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

(b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

(c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation Regu	lations	Other measures ¹²	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	yes y	ves	yes	yes
(b) Exports of micro-organisms $\frac{13}{2}$ and toxins	yes y	ves	yes	yes
(c) Imports of micro-organisms $\frac{13}{2}$ and toxins	yes y	ves	yes	yes
(d) Biosafety $\frac{14}{14}$ and biosecurity $\frac{15}{15}$	yes y	ves	yes	yes

Additional information to Form E:

Switzerland adheres to a monistic system, i.e. treaties of international law become effective upon ratification and are part of the Swiss Federal Legislation. This fact is reflected as follows:

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (*RS 0.515.07 Convention du 10 avril 1972 sur l'interdiction de la mise au point, de la fabrication et du stockage des armes bactériologiques (biologiques) ou à toxines et sur leur destruction*)

https://www.admin.ch/opc/fr/classified-compilation/19720074

Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (*RS 0.515.105 Protocole du 17 juin 1925 concernant la prohibition d'emploi à la guerre de gaz asphyxiants, toxiques ou similaires et de moyens bactériologiques*) https://www.admin.ch/opc/fr/classified-compilation/19250020

Legislation and regulations concerned with the implementation of the Convention in Switzerland is detailed as follows:

Federal Constitution of the Swiss Confederation (RS 101 Constitution fédérale de la Confédération suisse du 18 avril 1999)

https://www.admin.ch/opc/fr/classified-compilation/19995395

Federal Act on Measures Ensuring Homeland Security (*RS 120 Loi fédérale du 21 mars 1997 instituant des mesures visant au maintien de la sûreté intérieure*) https://www.admin.ch/opc/fr/classified-compilation/19970117

Ordinance on the Intelligence Service (*RS 121.1 Ordonnance du 16 août 2017 sur le Service de renseignement*) https://www.admin.ch/opc/fr/classified-compilation/20162430

Ordinance on Information and Storage Systems of the Intelligence Service of the Confederation (*RS 121.2* Ordonnance du 16 août 2017 sur les systèmes d'information et les systèmes de stockage de données du Service de renseignement de la Confédération)

https://www.admin.ch/opc/fr/classified-compilation/20162429

Federal Act on the Prohibition of « al-Qaeda » and « Islamic State » Groups and related Organizations (*RS 122 Loi fédérale du 12 décembre 2014 interdisant les groupes « Al-Qaïda » et « État islamique » et les organisations apparentées*)

https://www.admin.ch/opc/fr/classified-compilation/20142993

Ordinance on the Federal Expert Commission for Biosafety (*RS 172.327.8 Ordonnance du 20 novembre 1996 sur la Commission fédérale d'experts pour la sécurité biologique*) https://www.admin.ch/opc/fr/classified-compilation/19960584

Establishes the roles of the Federal Commission of Experts for Biological Security to ensure the protection of the Swiss population against transmissible diseases, the health of workers, and the protection of animals and plants and their environments.

Swiss Criminal Code (*RS 311.0 Code pénal suisse du 21 décembre 1937*) https://www.admin.ch/opc/fr/classified-compilation/19370083

Swiss Code of Criminal Procedure (*RS 312.0 Code de procédure pénale suisse du 5 octobre 2007*) https://www.admin.ch/opc/fr/classified-compilation/20052319

Ordinance on the Communication of Penal Decisions Taken by Cantonal Authorities (*RS 312.3 Ordonnance du 10 novembre 2004 réglant la communication des décisions pénales prises par les autorités cantonales*) https://www.admin.ch/opc/fr/classified-compilation/20041752

Military Criminal Code (*RS 321.0 Code pénal militaire du 13 juin 1927*) https://www.admin.ch/opc/fr/classified-compilation/19270018

Federal Act on International Legal Aid in Criminal Cases (*RS 351.1 Loi fédérale du 20 mars 1981 sur l'entraide internationale en matière pénale*) https://www.admin.ch/opc/fr/classified-compilation/19810037

Federal Act on Main Offices of Criminal Investigation Departments of the Confederation (*RS 360 Loi fédérale du 7 octobre 1994 sur les Offices centraux de police criminelle de la Confédération*) https://www.admin.ch/opc/fr/classified-compilation/19940242 Ordinance on the Information System of the Federal Criminal Police (*RS 360.2 Ordonnance du 15 octobre 2008 sur le système informatisé de la Police judiciaire fédérale*) https://www.admin.ch/opc/fr/classified-compilation/20081753

Ordinance on the National Central Bureau Interpol Bern (*RS 366.1 Ordonnance du 21 juin 2013 concernant le Bureau central national Interpol Bern*) https://www.admin.ch/opc/fr/classified-compilation/20130208

Ordinance on the Coordinated Medical Service (*RS 501.31 Ordonnance du 27 avril 2005 sur le Service sanitaire coordonné*) https://www.admin.ch/opc/fr/classified-compilation/20041336

Federal Act on the Army and the Military Administration (*RS 510.10 Loi fédérale du 3 février 1995 sur l'armée et l'administration militaire*) https://www.admin.ch/opc/fr/classified-compilation/19950010

Ordinance on Measures Taken by the Army against Human and Animal Epidemics (*RS 510.35 Ordonnance du 2. octobre 1955 concernant les mesures à prendre par l'armée contre les épidémies et épizooties*) https://www.admin.ch/opc/fr/classified-compilation/19550188

Ordinance on Domestic Disaster Management by the Army (*RS 513.75 Ordonnance du 21 novembre 2018 sur l'aide militaire en cas de catastrophe dans le pays*) https://www.admin.ch/opc/fr/classified-compilation/20181341

Federal Act on War Material (*RS 514.51 Loi fédérale du 13 décembre 1996 sur le materiel de guerre*) <u>https://www.admin.ch/opc/fr/classified-compilation/19960753</u>

Prohibits the development, production, indirect transfer, acquisition, import, export, transit and stockpiling of nuclear, biological or chemical weapons under Article 7. It prohibits any action committed by any person who has any connection to the acquisition of WMD. This article also applies to offences committed abroad if they are in violation of international law which is binding on Switzerland.

Ordinance on War Material (*RS 514.511 Ordonnance du 25 février 1998 sur le matériel de guerre*) <u>https://www.admin.ch/opc/fr/classified-compilation/19980112</u>

Regulates the initial authorisation and the specific authorisations that are required for the manufacture, the brokerage, the import, the export and the transit of war materials, as well as the conclusion of contracts to transfer incorporeal property, including know-how and the concession of related rights. Applies in Switzerland customs area, to Swiss customs warehouses and Swiss customs enclaves.

Federal Act on the Protection of the Population and Civil Protection (*RS 520.1 Loi fédérale du 4 octobre 2002 sur la protection de la population et sur la protection civile*) https://www.admin.ch/opc/fr/classified-compilation/20011872

Ordinance on the Federal Staff Civil Protection (*RS 520.17 Ordonnance du 2 mars 2018 sur l'État-major fédéral Protection de la population*) https://www.admin.ch/opc/fr/classified-compilation/20171280

Ordinance on the National Emergency Operations Centre (*RS 520.18 Ordonnance du 17 octobre 2007 sur la Centrale nationale d'alarme*) https://www.admin.ch/opc/fr/classified-compilation/20063371

Federal Act on Customs (*RS 631.0 Loi du 18 mars 2005 sur les douanes*) https://www.admin.ch/opc/fr/classified-compilation/20030370

Ordinance on Customs (*RS 631.01 Ordonnance du 1er novembre 2006 sur les douanes*) https://www.admin.ch/opc/fr/classified-compilation/20052713 Ordinance on the Transportation of Hazardous Goods on the Road (*RS 741.621 Ordonnance du 29 novembre 2002 relative au transport des marchandises dangereuses par route*)

https://www.admin.ch/opc/fr/classified-compilation/20022136

Regulates the transport of dangerous materials by automobiles or other mediums of transport on roads open to those same vehicles.

Ordinance on Hazardous Goods Representatives for the Transportation of Hazardous Goods on the Road, by Air or by Sea (*RS 741.622 Ordonnance du 15 juin 2001 sur les conseillers à la sécurité pour le transport de marchandises dangereuses par route, par rail ou par voie navigable*) https://www.admin.ch/opc/fr/classified-compilation/20001699

Determines the appointment, tasks, training and examination of persons charged with reducing risks to people, property and the environment during transportation of hazardous goods or packaging operations, shipment or loading and unloading associated with this transport.

Ordinance on the Transportation of Hazardous Goods by Railway and Aerial Railway (*RS 742.412 Ordonnance du 31 octobre 2012 sur le transport de marchandises dangereuses par chemin de fer et par installation à câbles*) <u>https://www.admin.ch/opc/fr/classified-compilation/20121700</u>

Federal Act on Surveillance of Postal Mail and Telecommunications (*RS 780.1 Loi fédérale du 18 mars 2016 sur la surveillance de la correspondance par poste et télécommunication*) https://www.admin.ch/opc/fr/classified-compilation/20122728

Ordinance on Surveillance of Postal Mail and Telecommunications (*RS 780.11 Ordonnance du 15 novembre 2017 sur la surveillance de la correspondance par poste et télécommunication*) https://www.admin.ch/opc/fr/classified-compilation/20172173

Ordinance on the Transplantation of Organs, Tissues and Cells of Animal Origin (*RS 810.213 Ordonnance du 16 mars 2007 sur la transplantation d'organes, de tissus et de cellules d'origine animale*) https://www.admin.ch/opc/fr/classified-compilation/20051808

Ordinance on Clinical Trials with Therapeutic Products (*RS 810.305 Ordonnance du 20 septembre 2013 sur les essais cliniques dans le cadre de la recherche sur l'être humain*) https://www.admin.ch/opc/fr/classified-compilation/20121176

Ordinance on Pharmaceuticals (*RS 812.212.21 Ordonnance du 21 septembre 2018 sur les médicaments*) https://www.admin.ch/opc/fr/classified-compilation/20173471

Regulates: a. authorization of medicines on the market ready for use, b. authorization processes of surface treatment of labile blood products, c. classification criteria for categories of delivery, d. distribution restrictions, e. authorization of mail order drugs, f. market surveillance and vigilance.

Federal Act on the Protection against Dangerous Substances and Preparations (*RS 813.1 Loi fédérale du 15 décembre 2000 sur la protection contre les substances et les préparations dangereuses*) <u>https://www.admin.ch/opc/fr/classified-compilation/19995887</u> *Protects the lives and health of human beings from the harmful effects of substances or preparations.*

Ordinance on Good Laboratory Practice (RS 813.112.1 Ordonnance du 18 mai 2005 sur les bonnes pratiques de laboratoire)

https://www.admin.ch/opc/fr/classified-compilation/20031589

Fixes the principles of good laboratory practices, guarantees the quality of studies and regulates the verification of these requirements.

Ordinance on Marketing and Handling Biocidal Products (RS 813.12 Ordonnance du 18 mai 2005 concernant la mise sur le marché et l'utilisation des produits biocides)

https://www.admin.ch/opc/fr/classified-compilation/20021524

Regulates marketing of biocidal products and their active substances, particularly the various types and licensing procedures, the use of data from previous requests for the benefit of new applicants, and the classification of packaging, labelling and safety data sheets.

Federal Act on the Protection of the Environment (*RS 814.01 Loi fédérale du 7 octobre 1983 sur la protection de l'environnement*)

https://www.admin.ch/opc/fr/classified-compilation/19830267

Ordinance on the Protection against Major Accidents (RS 814.012 Ordonnance du 27 février 1991 sur la protection contre les accidents majeurs)

https://www.admin.ch/opc/fr/classified-compilation/19910033

Covers activities involving the contained use of genetically modified organisms and pathogenic organisms in laboratories, production facilities, greenhouses and premises housing animals.

Ordinance on Waste Management (RS 814.600 Ordonnance du 4 décembre 2015 sur la limitation et l'élimination des déchets)

https://www.admin.ch/opc/fr/classified-compilation/20141858

Federal Act on non-Human Genetic Engineering (RS 814.91 Loi fédérale du 21 mars 2003 sur l'application du génie génétique au domaine non humain)

https://www.admin.ch/opc/fr/classified-compilation/19996136

Protects humans, animals and the environment against the abuse of genetic engineering, and ensures that applications of genetic engineering serve humans, animals and the environment.

Ordinance on the Release of Organisms into the Environment (*RS 814.911 Ordonnance du 10 septembre 2008 sur l'utilisation d'organismes dans l'environnement*)

https://www.admin.ch/opc/fr/classified-compilation/20062651

Protects humans, animals and the environment, as well as biodiversity and sustainable use of its components against the dangers and outrages associated with the use of organisms, their metabolites and their waste.

Ordinance on the Contained Use of Organisms (RS 814.912 Ordonnance du 9 mai 2012 sur l'utilisation des organismes en milieu confiné)

https://www.admin.ch/opc/fr/classified-compilation/20100803

Protects people and the environment and in particular communities of animals and plants and their habitats, against harmful effects or nuisances of the contained use of organisms. Contributes to the maintenance of biodiversity and soil fertility. Regulates the contained use of organisms, in particular genetically modified or pathogenic organisms.

Ordinance on Transborder Traffic of Genetically Modified Organisms (*RS 814.912.21 Ordonnance du 3 novembre 2004 sur les mouvements transfrontières des organismes génétiquement modifiés*) https://www.admin.ch/opc/fr/classified-compilation/20031535

Regulates the transborder transport of GMOs. Does not apply to medicines for human use which contain GMOs.

Federal Act on Foods and Commodities (*RS 817.0 Loi fédérale du 20 juin 2014 sur les denrées alimentaires et les objets usuels*) https://www.admin.ch/opc/fr/classified-compilation/20101912

Ordinance on Foods and Commodities (*RS 817.02 Ordonnance du 16 décembre 2016 sur les denrées alimentaires et les objets usuels*)

https://www.admin.ch/opc/fr/classified-compilation/20143388

Ordinance on Maximum Levels of Pesticide Residues Present in or on Products of Vegetable or Animal Origin (*RS 817.021.23 Ordonnance du DFI du 16 décembre 2016 sur les limites maximales applicables aux résidus de pesticides présents dans ou sur les produits d'origine végétale ou animale*) https://www.admin.ch/opc/fr/classified-compilation/20143405

Ordinance on Genetically Modified Foods (*RS 817.022.51 Ordonnance du DFI du 23 novembre 2005 sur les denrées alimentaires génétiquement modifiées*) https://www.admin.ch/opc/fr/classified-compilation/20050176

Ordinance on Hygiene when Handling Food (*RS 817.024.1 Ordonnance du DFI du 16 décembre 2016 sur l'hygiène dans les activités liées aux denrées alimentaires*) https://www.admin.ch/opc/fr/classified-compilation/20143394

Ordinance on the Enforcement of the Legislation on Foods (*RS 817.042 Ordonnance du DFI du 16 décembre 2016 sur l'exécution de la législation sur les denrées alimentaires*) https://www.admin.ch/opc/fr/classified-compilation/20143389

Ordinance on Animal Slaughter and Meat Control (*RS 817.190 Ordonnance du 16 décembre 2016 concernant l'abattage d'animaux et le contrôle des viandes*) https://www.admin.ch/opc/fr/classified-compilation/20162765

Ordinance on Animal Slaughter Hygiene (*RS 817.190.1 Ordonnance du DFI du 23 novembre 2005 concernant l'hygiène lors de l'abattage d'animaux*) https://www.admin.ch/opc/fr/classified-compilation/20051438

Federal Act on the Control of Communicable Human Diseases (*RS 818.101 Loi fédérale du 28 septembre 2012 sur la lutte contre les maladies transmissibles de l'homme*) https://www.admin.ch/opc/fr/classified-compilation/20071012

Regulates fight against diseases transmissible to man by stating that the Confederation and the cantons take the necessary measures, including biosafety precautions, to protect human beings against pathogens including those genetically modified. Regulates identification of laboratories through permits delivered by the Swiss Institute of Therapeutic Products. Regulates the trade in pathogenic agents and requires an authorisation from every person disseminating pathogens for research or commerce. Entitles the Federal Council to regulate the transport, importation, exportation and the transit of pathogens, to limit or to ban the use of certain pathogens, to fix the conditions for persons using pathogens. Outlines the provisions for quarantine, vaccination, and disease surveillance and reporting requirements. Provides for imprisonment or fines anyone who intentionally or by negligence does not respect the prescriptions of the Federal Act.

Ordinance on the Control of Communicable Human Diseases (*RS 818.101.1 Ordonnance du 29 avril 2015 sur la lutte contre les maladies transmissibles de l'homme*) https://www.admin.ch/opc/fr/classified-compilation/20133212

Ordinance on the Declaration of Observations of Communicable Human Diseases (*RS 818.101.126 Ordonnance du DFI du 1 décembre 2015 sur la déclaration d'observations en rapport avec les maladies transmissibles de l'homme*)

https://www.admin.ch/opc/fr/classified-compilation/20151622

Ordinance on Microbiological Laboratories (*RS 818.101.32 Ordonnance du 29 avril 2015 sur les laboratoires de microbiologie*) https://www.admin.ch/opc/fr/classified-compilation/20143116

Ordinance Relating to the Act of Labour (RS 822.114 Ordonnance 4 du 18 août 1993 relative à la loi sur le travail)

https://www.admin.ch/opc/fr/classified-compilation/19930255

Ordinance on the Protection of Workforce against Microbiological Risks (*RS 832.321 Ordonnance du 25 août 1999 sur la protection des travailleurs contre les risques liés aux micro-organismes*) https://www.admin.ch/opc/fr/classified-compilation/19994946

Defines micro-organisms and genetically modified micro-organisms and techniques for genetic modification. Requires the regular identification and evaluation of the risks to which workers are exposed and the notification of the "Bureau de Biotechnologie de la Confédération" by employers. Defines general security measures for the protection of the workers by employers. Covers activities involving the contained use of genetically modified organisms and pathogenic organisms in laboratories, production facilities, greenhouses and premises housing animals.

Federal Act on Agriculture (*RS 910.1 Loi fédérale du 29 avril 1998 sur l'agriculture*) https://www.admin.ch/opc/fr/classified-compilation/19983407

Ordinance on the Coordination of Controls on Agricultural Farms (*RS 910.15 Ordonnance du 23 octobre 2013 sur la coordination des contrôles dans les exploitations agricoles*) https://www.admin.ch/opc/fr/classified-compilation/20130217

Ordinance on Primary Production (*RS 916.020 Ordonnance du 23 novembre 2005 sur la production primaire*) https://www.admin.ch/opc/fr/classified-compilation/20051718

Ordinance on the Release of Phytopharmaceutical Products (*RS 916.161 Ordonnance du 12 mai 2010 sur la mise en circulation des produits phytosanitaires*)

https://www.admin.ch/opc/fr/classified-compilation/20100203

Ensures that plant protection products lend themselves well in their intended use and as those are used in accordance with the requirements preventing unacceptable side effects on the health of humans, animals and the environment.

Ordinance on Plant Protection (*RS 916.20 Ordonnance du 27 octobre 2010 sur la protection des végétaux*) https://www.admin.ch/opc/fr/classified-compilation/20101847

Protects plants of all sorts against the nuisances of dangerous organisms, and protects agriculture and horticulture fields from the same organisms.

Ordinance on the Control of Milk (*RS 916.351.0 Ordonnance du 20 octobre 2010 sur le contrôle du lait*) https://www.admin.ch/opc/fr/classified-compilation/20100941

Ordinance on the Milk Production Hygiene (*RS 916.351.021.1 Ordonnance du DFI du 23 novembre 2005 réglant l'hygiène dans la production laitière*) https://www.admin.ch/opc/fr/classified-compilation/20051436

Federal Act on Animal Diseases (*RS 916.40 Loi du 1er juillet 1966 sur les épizooties*) https://www.admin.ch/opc/fr/classified-compilation/19660145

Ordinance on the Control of Animal Diseases (*RS 916.401 Ordonnance du 27 juin 1995 sur les épizooties*) https://www.admin.ch/opc/fr/classified-compilation/19950206

Designates new contagious animal diseases and defines the measures of control of and the organization of the fight against animal diseases, as well as the compensation of animal keepers.

Ordinance on the Disposal of Animal Side Products (RS 916.441.22 Ordonnance du 25 mai 2011 concernant l'élimination des sous-produits animaux)

https://www.admin.ch/opc/fr/classified-compilation/20101486

Ensures that animal by-products do not endanger human and animal health and do not harm the environment. Allows as much as possible the recovery of animal by-products. Ensures that the infrastructure for the disposal of animal by-products is available. Ordinance on Import, Transit and Export of Animals and Animal Products Exchanged with Third Countries (*RS* 916.443.10 Ordonnance du 18 novembre 2015 réglant les échanges d'importation, de transit et d'exportation d'animaux et de produits animaux avec les pays tiers)

https://www.admin.ch/opc/fr/classified-compilation/20151237

Regulates the import, transit and export of animals, animal by-products and animal products.

Ordinance on Import, Transit and Export of Animals and Animal Products Exchanged with EU Member States, Iceland and Norway (*RS 916.443.11 Ordonnance du 18 novembre 2015 réglant les échanges d'importation, de transit et d'exportation d'animaux et de produits animaux avec les Etats membres de l'UE, l'Islande et la Norvège*)

https://www.admin.ch/opc/fr/classified-compilation/20151238

Regulates the import, transit and export of animals, animal by-products and animal products.

Federal Act on the Control of Goods Suitable for Civilian and Military Purposes and Specific Military Goods (*R. 946.202 Loi fédérale du 13 décembre 1996 sur le contrôle des biens utilisables à des fins civiles et militaires et des biens militaires spécifiques*)

https://www.admin.ch/opc/fr/classified-compilation/19960740

Regulates, inter alia, the import, export and transit of microorganisms and toxins. Applies to dual-use goods and specific military goods which are the subject of international agreements. Also outlines the responsibilities of the Federal Council in this regard including licensing and reporting requirements and surveillance measures for import, export, transit, production, storage, transfer and use of goods.

Ordinance on the Control of Goods Suitable for Civilian and Military Purposes, Specific Military Goods and Strategic Goods (*RS 946.202.1 Ordonnance du 3 juin 2016 sur le contrôle des biens utilisables à des fins civiles et militaires, des biens militaires spécifiques et des biens stratégiques*) https://www.admin.ch/opc/fr/classified-compilation/20151950

Regulates the export, import and transit of goods usable for civilian and military purposes, specific military goods and strategic goods which are the subject of international control measures not binding pursuant to international law. Applies in Swiss customs area to Swiss customs warehouses and Swiss customs enclaves.

Ordinance on the Control of Chemicals Suitable for Civilian and Military Purposes (*RS 946.202.21 Ordonnance du 21 août 2013 sur le contrôle des produits chimiques utilisables à des fins civiles et militaires*) https://www.admin.ch/opc/fr/classified-compilation/20121582

Ordinance Establishing Measures against Persons and Entities Linked to Osama bin Laden, the al-Qaeda Group or the Taliban (*RS 946.203 Ordonnance du 2 octobre 2000 instituant des mesures à l'encontre de personnes et entités liées à Oussama ben Laden, au groupe «Al-Qaïda» ou aux Taliban*) https://www.admin.ch/opc/fr/classified-compilation/19996052

Federal Act on Sanctions on Trade with Foreign Countries (*RS 946.231 Loi fédérale du 22 mars 2002 sur l'application de sanctions internationales*) https://www.admin.ch/opc/fr/classified-compilation/20000358

Ordinance of the Swiss Financial Market Supervisory Authority on Combatting Money Laundering and Financing of Terrorism in the Financial Sector (*RS 955.033.0 Ordonnance de l'Autorité fédérale de surveillance des marchés financiers du 3 juin 2015 sur la lutte contre le blanchiment d'argent et le financement du terrorisme dans le secteur financier*)

https://www.admin.ch/opc/fr/classified-compilation/20143112

Ordinance on the Reporting Bureau in Matters of Money Laundering (*RS 955.23 Ordonnance du 25 août 2004 sur le Bureau de communication en matière de blanchiment d'argent*) https://www.admin.ch/opc/fr/classified-compilation/20031873 Titles in English are inofficial translations that are provided for information purposes only and have no legal force. To access legal documents please consult the Swiss Federal Legislation in either French (links above), German or Italian. Some additional information may also be obtained in the framework of UNSCR 1540 at: https://www.un.org/en/sc/1540/national-implementation/national-reports.shtml

Confidence-Building Measure "F"

Declaration of past activities in offensive and/or defensive biological research and development programmes

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

Form F

Declaration of past activities in offensive and/or defensive biological research and development programmes

1. Date of entry into force of the Convention for the State Party.

Tuesday, May 4, 1976

2. Past offensive biological research and development programmes:

- no

- Period(s) of activities

N/A

- Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

N/A

3. Past defensive biological research and development programmes:

- yes

- Period(s) of activities

1997 to present.

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

Please refer to Form A, part 2 (ii) as well as past CBM declarations.

Confidence-Building Measure "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Form G

Declaration of vaccine production facilities

1. Name of facility:

Janssen Vaccines, Branch of Cilag International GmbH

2. Location (mailing address): Rehhagstrasse 79, CH-3018 Bern, Switzerland

- 3. General description of the types of diseases covered:
- 1. Disease(s) targeted Ebola virus disease Name of vaccine Ad26.ZEBOV License Trial Phase 2/3
- 2. Disease(s) targeted Bacteremia (extraenous pathogenic *E. coli*) Name of vaccine ExPEC Multivalent License Trial Phase 1/2a
- 3. Disease(s) targeted Irritable bowel syndrome Name of vaccine Ve-202 License Trial Phase 1
- 4. Disease(s) targeted Influenza Name of vaccine Ad26.FLU License Trial Phase 1

1. Name of facility: **PaxVax Berna GmbH**

2. Location (mailing address): Oberriedstrasse 68, CH-3174 Thörishaus, Switzerland

3. General description of the types of diseases covered:

1. Disease(s) targeted Typhoid fever Name of vaccine Vivotif License Yes

Notes

1. World Health Organization

2. World Organization for Animal Health.

3. The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

4. For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

5. In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

6. Microorganisms pathogenic to humans and/or animals

7. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

8. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

9. Including viruses and prions.

10. It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

11. See paragraph 2 of the chapeau to Confidence-Building Measure B.

12. Including guidelines.

13. Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

14. In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

15. In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.