DECREE No. 474/2002 Coll.

of 1 November 2002,

Implementing Act No. 281/2002 Coll., on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act

The State Office for Nuclear Safety stipulates according to Article 22 (1) of the Act No. 281/2002 Coll., on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act, (hereinafter referred to as „the Act“) to implement Article 2 (d) and (e) and Articles 9 and Article 16 (6) thereof:

Article 1

Subject of Regulation

This Regulation stipulates:

a) the list of highly hazardous biological agents and toxins which have the capability to be used as a weapon, and which can be handled only by a licensee;

b) the list of highly hazardous biological agents and toxins which can be handled under the conditions stipulated by the Act;

c) the respective study programs leading to Bachelor's, Master's or Doctoral degrees as one of the conditions determining a professional qualification.

d) particulars on the keeping of records and on the data contained in declarations.

Article 2

Lists of Highly Hazardous and Hazardous Biological Agents and Toxins

(1) The list of highly hazardous biological agents and toxins is laid down in Annex 1.

(2) The list of hazardous biological agents and toxins is laid down in Annex 2.

Article 3

Study Programs

One of the conditions determining the professional qualification for handling of highly hazardous biological agents and toxins is a university degree [1]) obtained after completion of the respective Bachelor's, Master's or Doctoral program or a foreign university degree accredited following the stipulated nostrification procedure [2])

a) in the fields of medicine or veterinary medicine and in their respective branches of study;

b) in the respective technical branches of study and in the fields of technologies or natural sciences and their respective branches of study;

---

[1]) Article 44 of the Act No. 111/1998 Coll., on Higher Education and Changes in and Amendments to other Acts (Higher Education Act).

[2]) Articles 89 and 90 of the Act No. 111/1998 Coll.

c) in the field of pharmacy and in the respective branches of study thereof; or

d) in the field of phytosanitary sciences in the respective branches of study thereof.

General Provisions on Keeping of Records

Article 4

The records of highly hazardous biological agents and toxins are maintained by an appointed employee, registered in a record book, who is responsible for entering records into the record book. The record books of highly hazardous biological agents, hazardous biological agents, highly hazardous toxins and hazardous toxins are maintained separately.

Article 5

Record Book

(1) The record book consists of separate record cards that must be bound together and numbered consecutively.

(2) The record book contains

a) on the front page

1. identification data of a natural person or legal entity in accordance with Article 11 (3) (a) or (b) of the Act or in accordance with Article 17 (2) (a) of the Act;
2. the date since when records have been kept;
3. the date of the last record entered;
4. name, address and signature of statutory body;
5. name, address and signature of an employee responsible for the keeping of records;

b) on the first page a list of recorded biological agents or toxins; a record sequence number and the page where the item is first mentioned is contained therein;

(3) Errors shall be rectified in such a manner so that the original record remains legible, and each rectification shall be signed by the employee responsible for the keeping of records. The employee shall append to his signature a date and time of rectification.

(4) In the event the total number of pages allocated to a particular record in the record book is exceeded, it is possible to allocate new consecutive pages for that particular biological agent or toxin and add this item to the list on the first page of the record book.

Article 6

Record Card

(1) A record card contains

a) name and location of a facility, wherein a recorded activity is being performed;

b) page number in a record book;

c) name of biological agent or toxin;

d) a sequence number in accordance with the list of biological agents or toxins, laid down on the first page of the record book;

e) unit of recorded amount;

f) number and date of a record and other data stipulated in Annex 3;

(2) A specimen record card is shown in Annex 3.

Article 7

Declaration of Highly Hazardous and Hazardous Biological Agents and Toxins and of Facilities Wherein They are Being Handled

(1) Declared data is submitted on forms, the specimen thereof is shown in Annex 4.

(2) Declarations shall be submitted to the State Office for Nuclear Safety in writing form with a signature of statutory body added thereto, and at the same time on a data medium.

Article 8

Effectiveness

This Act shall enter into force on 1 January 2003.

Signed:

Chairwoman: M.Sc. Drábová

List of Highly Hazardous Biological Agents and Toxins (Article 2 (d) of the Act)

1. Human pathogens and animal pathogens transmissible to humans

1.1 Viruses

1. Herpesvirus simiae (B virus);
2. Sin Nombre virus;
3. White pox virus;
4. Dengue fever virus;
5. Ebola virus;
6. Hantaan virus;
7. Lassa fever virus;
8. Rift Valley fever virus;
9. Chikungunya virus;
10. Japanese encephalitis virus;
11. Junin virus;
12. Congo-Crimean haemorrhagic fever virus;
13. Lymphocytic choriomeningitis virus (neurotropic strains);
14. Machupo virus;
15. Marburg virus;
16. Monkey pox virus;
17. Variola virus;
18. Russian Spring-Summer encephalitis virus;
19. Venezuelan equine encephalitis virus;
20. Eastern equine encephalitis virus;
21. Western equine encephalitis virus;
22. Yellow fever virus.

1.2 Bacteria

1. Bacillus anthracis;
2. Brucella melitensis (except biovar Canis);
3. Burkholderia mallei (Pseudomonas mallei);
4. Burkholderia pseudomallei (Pseudomonas pseudomallei);
5. Clostridium botulinum;
6. Francisella tularensis;

7. Chlamydia psittaci;
8. Salmonella typhi;
9. Shigella dysenteriae Type 1;
10. Vibrio cholerae;
11. Yersinia pestis.

1.3 Rickettsiae

1. Bartonella quintana (Rochalimea quintana, Rickettsia quintana);
2. Coxiella burnetii;
3. Rickettsia prowazekii;
4. Rickettsia rickettsii.

2. Animal Pathogens

2.1 Viruses

1. African swine fever virus;
2. Porcine herpes virus (Aujeszky`s disease);
3. Avian influenza virus, as follows:
    a. Uncharacterised virus; or
    b. Defined as virus having high pathogenicity, as follows:
        1. Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1,2; or
        2. Type A viruses H5 or H7 suptype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin;
4. Bluetongue virus;
5. Swine fever virus (Hog cholera virus);
6. Peste des petits ruminants virus;
7. Rinderpest virus;
8. Newcastle disease virus;
9. Foot and mouth disease virus;
10. Teschen disease virus;
11. Porcine enterovirus type 9 (Swine vesicular disease virus);
12. Vesicular stomatitis virus;
13. Lyssa virus;
14. Sheep and Goat pox virus.

2.2 Mycoplasma

Mycoplasma mycoides var. mycoides SC.

3. Plant Pathogens

Fungi

1. Cochliobolus miyabeanus (Helminthosporium oryzae);
2. Magnaporthe grisea (pyricularia grisea/pyricularia oryzae);
3. Microcyclus ulei (syn. Dothidella ulei).

4. Toxins

1. Abrin;
2. Aflatoxins;
3. Anatoxin (neurotoxin of Cyanobacteriae);
4. Botulinum toxins;
5. Bungarotoxin;
6. Ciguatoxin;
7. Conotoxin;
8. Cholera toxin;
9. Microcystin (Cyanginosin);
10. Modecin;
11. Ricin;
12. Saxitoxin;
13. Shiga toxin (Shiga-like toxin, verotoxin);
14. Tetrodotoxin;
15. Clostridium perfringens toxins;
16. Staphylococcus aureus toxins;
17. Trichothecene toxins;
18. Viscumin;
19. Volkensin.

5. Genetically-modified organisms

5.1 The above listed microorganisms which have been genetically modified.

5.2. Other genetically modified organisms or genetic material that contain nucleic acid sequences derived from any of the listed microorganisms, or that contain nucleic acid

sequences associated with pathogenicity of the listed microorganisms; or that contain nucleic acid sequences coding for any of the listed toxins.

List of Hazardous Biological Agents and Toxins (Article 2 (e) of the Act)

I. Viruses

1. Equine morbilli virus;
2. Flexal virus;
3. Guanarito;
4. Hendra and Nipah;
5. Sabia;
6. Murray Valley Encephalitis virus;
7. St. Louis Encephalitis;
8. Everglades virus;
9. Hepatitis B virus;
10. Hepatitis C virus;
11. Hepatitis D (Delta) virus;
12. Hepatitis E virus;
13. Hepatitis G virus;
14. Hepatitis viruses not yet identified;
15. Kyasanur Forest ;
16. Oropouche virus;
17. Tick-borne encephalitis viruses
18. Mayaro virus;
19. Mucambo virus;
20. Omsk haemorragic fever virus;
21. Powassan;
22. Rocio;
23. Seoul virus;
24. SIV;
25. Tonate virus;
26. Louping ill;
27. Wesselbron virus;
28. West Nile fever virus.

II. Bacteria

1. Brucella melitensis, biovar Canis;
2. Clostridium tetani;

3. Legionella pneumophilia;
4. Mycobacterium africanum;
5. Mycobacterium bovis (except BCG strain);
6. Mycobacterium leprae;
7. Mycobacterium microti;
8. Mycobacterium tuberculosis;
9. Mycobacterium ulcerans;
10. Xanthomonas albilineans;
11. Xanthomonas campestris pv. citri including strains referred to as Xanthomonas campestris pv. citri typu A, B, C, D, E or otherwise classified as Xanthomonas citri, Xanthomonas campestris pv. aurantifolia or Xanthomonas campestris pv. citrumelo;
12. Yersinia pseudotuberculosis.

III. Rickettsiae

1. Rickettsia akari;
2. Rickettsia canada;
3. Rickettsia montana;
4. Rickettsia tsutsugamushi;
5. Rickettsia typhi (Rickettsia mooseri);
6. Ricktettsia conorii.

IV. Toxins

1. Tetanus toxin.

V. Genetically-modified organisms

V.I. The above listed microorganisms, which have been genetically modified.

V.II. Other genetically modified organisms or genetic material that contain nucleic acid sequences derived from any of the listed microorganisms, or that contain nucleic acid sequences associated with pathogenicity of any listed microorganism; or that contain nucleic acid sequences coding for any of the listed toxins.

Annex 3 to Decree No. 474/2002 Coll.

Record card

Name(s) of facility _____ page number

(wherein the declared activity is being performed) _____ (in the record book)

Name of biological agent (toxin) _____ sequence number (according to first page of the record book)

Unit of recorded amount _____

Record number	Record date	Receipt (amount)	Delivery (amount)	Stock (amount)	Supplier - Receiver (name, seat, registration number in the Companies Register)	Type and number of a document (delivery note, release order)	Receiver's signature	Note
1	2	3	4	5	6	7	8	9

DECLARATION OF HIGHLY HAZARDOUS AND HAZARDOUS BIOLOGICAL AGENTS AND TOXINS [1] AND OF FACILITIES WHEREIN THEY ARE BEING HANDLED

Form No. 1 - <u>Basic declaration form</u>

Business firm or a name of a legal entity:	
Seat:	
Registration number in the Companies Register (if allocated):	
Natural person	
Name and surname:	
Birth registration number (if allocated, otherwise date of birth):	
Citizenship:	
Residential address:	
Responsible representative:	
Name and surname:	
Birth registration number (if allocated, otherwise date of birth):	
Citizenship:	
Residential address:	
Statutory body or members thereof:	
Name and surname:	
Birth registration number (if allocated otherwise date of birth):	
Citizenship:	
Residential address:	
Name and surname:	

Birth registration number (if allocated otherwise date of birth):	
Citizenship:	
Residential address:	

[1] DELETE AS APPROPRIATE

Form No. 2 - <u>Type and amount of highly hazardous and hazardous biological agents and toxins</u>

List of highly hazardous and hazardous biological agents and toxins that have been handled in your facility (or shall be handled)

Name
Amount that have been handled (or shall be handled)
Purpose
Way of handling
Final destination

Name
Amount that have been handled (or shall be handled)
Purpose
Way of handling
Final destination

Name
Amount that have been handled (or shall be handled)
Purpose
Way of handling
Final destination

Name
Amount that have been handled (or shall be handled)
Purpose
Way of handling
Final destination

Name
Amount that have been handled (or shall be handled)
Purpose
Way of handling
Final destination

Name
Amount that have been handled (or shall be handled)
Purpose
Way of handling
Final destination

Form No. 3 - Facilities, wherein the declared activity is being performed

1. Name(s) of facility ----------
2. Responsible public or private organization or company ----------
   ----
3. Location and postal address ----------

   ----
4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
   ----
5. Number of maximum containment units (BL-4) within the facility, with an indication of their respective size (m^2)
   ----
6. If no maximum containment unit (BL-4), indicate highest level of protection
   ----
7. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate
   ----

   ----
8. Type of a facility (research centre, laboratory, production unit,) ----------
9. List of facilities pursuant to Article 2 (f) and (n) of the Act No. 281/2002 Coll.:

a) Chambers designed for aerosol challenge testing with micro organisms or toxins

static NO/YES-total volume thereof---------- m^3

dynamic NO/YES-total volume thereof---------- m^3

explosive NO/YES-total volume thereof---------- m^3

b) Fermenters capable of cultivation of pathogenic micro organisms, viruses, or for toxin production, without the propagation of aerosols and having a total capacity of 100 litres or more YES/NO

Specify the volume of the largest fermenter ----------m^3

Technical Note: Fermenters include bioreactors, chemo stats and continuous-flow systems.

c) Centrifugal separators and decanters, capable of continuous or semi-continuous separation without the propagation of aerosols, having a flow rate exceeding 100 litres per hour, and capable of *in-situ* steam sterilisation in a closed state YES/NO

d) Dryers: spray YES/NO

drum YES/NO

the main purpose of their use----------

e) Steam sterilisable freeze-drying equipment with a condensor capacity greater than 10 kg of ice in 24 hours and less than 1000 kg of ice in 24 hours YES/NO

f) Cross (tangential) flow filtration equipment, capable of continuous separation without the propagation of aerosols, equal to or greater than $5m^2$; and capable of *in-situ* sterilization;

YES/NO

g) Anaerobic chambers YES/NO

h) Equipment designed for micro encapsulation of live organisms, the products or components thereof including toxins or biological material YES/NO

i) Cell destruction (disruption) equipment including ultra sound equipment capable of continuous operation without the release of aerosols with a flow rate greater than 10 litres per hour

YES/NO

j) Equipment used in molecular biology

Equipment for: Automatic DNA sequencing YES/NO

Automatic DNA synthesis YES/NO

Automatic peptide sequencing YES/NO

Automatic peptides synthesis YES/NO

k) Chambers designed or used for rearing insects YES/NO

Total volume thereof---------- m^3

l) Autoclaves designed to sterilize infectious material with internal volume equal to 0.5 m^3 or greater YES/NO

m) Shaking incubators with a total flask capacity greater than 5 litres

YES/NO

n) Air input and output through aerosol filter (HEPA) YES/NO

o) Positive pressure air-fed protective suits or self-contained respirators for other than fire-fighting purposes. YES/NO

Form No. 3.1 - Facilities, wherein the declared activity is being performed:

Declaration of vaccine production facility

1. Name of facility:

2. Location (mailing address):

3. General description of the types of diseases covered:

Form No. 4 - Purpose of Handling of Highly Hazardous or Hazardous Biological Agents or Toxins

National biological defence research and development programme Declaration

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

Yes/No

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

Form No. 4.1 - Purpose of Handling of Highly Hazardous or Hazardous Biological Agents or Toxins

National biological defence research and development programme

Description

1. State the objectives and funding of the 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.
2. State the total funding for the programme and its source.
3. Are aspects of this programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes/No

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.
6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).
7. Provide a declaration in accordance with Form 4.2, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of this resources devoted to the national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Form No. 4.2 - <u>Purpose of Handling of Highly Hazardous or Hazardous Biological Agents or Toxins</u>

National biological defence research and development programme

Facilities, wherein the declared activity is being performed:

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?

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

3. Floor area of laboratory areas by containment level:

   BL2 ……. (m^2)

   BL3 ……. (m^2)

   BL4 ……. (m^2)

   Total laboratory floor area ……. (m^2)

4. The organizational structure of each facility.

   (i) Total number of personnel ……..

   (ii) Division of personnel:

   Military ……..

   Civilian ……..

   (iii) Division of personnel by category:

   Scientists ……..

   Engineers ……..

   Technicians ……..

   Administrative and support staff ……..

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

   (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?

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

Research ……..

Development ……..

Test and evaluation ……..

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

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

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms ∗ and/or toxin studied, as well as outdoor studies of biological aerosols.

∗ Including viruses and prions.

Form No. 5 - Encouragement of publication of results and promotion of use of knowledge

1. List of the most important publication, which appeared during the year, is enclosed

2. List of (conferences, seminars) during the year

Form No.6 - Active promotion of contacts

1. **<u>Planed international conferences, symposia, seminars and other similar forums for exchange</u>**

   For each such event, the following information should be provided:

   - name of the conference, etc. ……
   - arranging organization(s), etc. ……
   - time ……
   - place ……
   - main subject(s) for the conference, etc. ……
     ……
   - conditions for participation ……
     ……
   - point of contact for further information, registration, etc. ……
     ……
     ……

2. **Information regarding other opportunities**

   ……
   ……
   ……