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

Amendment: 74/2013 Coll.

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 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 fields of technical science and technologies or natural science in the branches of study that relate to the handling of biological agents and toxins;

---

[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 or toxicology and in the respective branches of study thereof; or

d) in the field of phytosanitary or agricultural 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 person, 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 a person 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 person responsible for the keeping of records, and who shall append to his signature a date 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) The declarations shall be submitted to the State Office for Nuclear Safety in an electronic form signed with a recognized electronic signature, unless the declaration is delivered via a data box, or in a documentary form with a signature of the statutory body and, at the same time, in an electronic form.

Article 8

Effectiveness

This Act shall enter into force on 1 January 2003.

Signed:

Chairwoman: M.Sc. Drábová

Annex 1 to Decree No. 474/2002 Coll.

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

1. Human pathogens and zoonoses

1.1 Viruses

1. Andes virus;
2. Dengue fever virus;
3. Ebola virus;
4. Hantaan virus;
5. Rift Valley fever virus;
6. Chikungunya virus;
7. Japanese encephalitis virus;
8. Junin virus;
9. Congo-Crimean haemorrhagic fever virus;
10. Lassa fever virus;
11. Lujo virus;
12. Lymphocytic choriomeningitis virus;
13. Machupo virus;
14. Marburg virus;
15. Monkey pox virus;
16. Variola virus;
17. Sin Nombre virus;
18. Venezuelan equine encephalitis virus;
19. Eastern equine encephalitis virus;
20. Western equine encephalitis virus;
21. Yellow fever virus;

1.2 Bacteria

1. Bacillus anthracis;
2. Brucella abortus;
3. Brucella melitensis;
4. Brucella suis;
5. Burkholderia mallei (Pseudomonas mallei);
6. Burkholderia pseudomallei (Pseudomonas pseudomallei)
7. Clostridium botulinum;
8. Clostridium perfringens epsilon toxin producing types;
9. Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes*;*
10. Francisella tularensis;
11. Chlamydia psittaci;

12. Salmonella typhi;
13. Shigella dysenteriae Type 1;
14. Vibrio cholerae;
15. 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 horse sickness virus;
2. African swine fever virus;
3. Porcine herpes virus (Aujeszky's disease);
4. 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;
5. Bluetongue virus;
6. Classical swine fever virus;
7. Peste des petits ruminants virus;
8. Rinderpest virus;
9. Sheeppox virus;
10. Goatpox virus;
11. Newcastle disease virus;
12. Lumpy skin disease virus;
13. Foot-and-mouth disease virus;
14. Teschen disease virus;
15. Swine vesicular disease virus;
16. Vesicular stomatitis virus;
17. Lyssavirus;

2.2 Mycoplasma

1. Mycoplasma mycoides subspecies mycoides SC (small colony);
2. Mycoplasma capricolum subspecies capripneumoniae.

3. Plant Pathogens

3.1 Viruses

1. Potato Andean latent tymovirus;
2. Potato spindle tuber viroid;

3.2 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. Conotoxins;
8. Cholera toxin;
9. Microcystin (Cyanginosin);
10. Modecin;
11. Ricin;
12. Saxitoxin;
13. Shiga toxin (Verotoxin and shiga-like ribosome inactivating proteins);
14. Tetrodotoxin;
15. Clostridium perfringens toxins;
16. Staphylococcus aureus toxins;
17. Trichothecene toxins;
18. Viscumin;
19. Volkensin.

5. Genetic elements and genetically modified organisms

5.1 Genetic elements that contain nucleic acid sequences associated with the pathogenicity of organisms specified in 1 - 3.

5.2 Genetic elements that contain nucleic acid sequences coding for any of the toxins specified in 4 or coding for sub-units of toxins specified in 4.

5.3 Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of organisms specified in 1 - 3.

5.4 Genetically modified organisms that contain nucleic acid sequences coding for any of the toxins specified in 4 or coding for sub-units of toxins specified in 4.

5.5 De novo chemically synthesized genetic material and artificially produced organisms that contain nucleic acid sequences associated with the pathogenicity of organisms specified in 1 - 3.

5.6 De novo chemically synthesized genetic material and artificially produced organisms that contain nucleic acid coding for any of the toxins specified in 4 or coding for sub-units of toxins specified in 4.

Notes:

1) Microorganisms specified in 1.2 9 shall include in particular serogroup strains O26, O45, Q91, O103, O104, O111, O113, O121, O145, O157 and other shiga toxin producing strains or strains carrying genes encoding their production. "Shiga toxin producing Escherichia coli (STEC)" is also known as "verotoxin producing Escherichia coli (VTEC)."

2) The rules for handling with toxins do not apply to botulinum toxins (4.4) or conotoxins (4.7) contained in medical products authorized by a state authority under the Act on Pharmaceuticals.

3) Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons and vectors whether genetically modified or unmodified.

4) Nucleic acid sequences associated with the pathogenicity of organisms specified in 1 - 3 means any sequence specific for any of the above mentioned micro-organisms that

   a) in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health,

   b) is known to enhance the ability of a specified micro-organism, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health.

5) For microorganisms specified in 1.2 9 "genetic elements and genetically modified organisms" in paragraph 5 shall apply only to nucleic acid sequences that encode shiga toxin (verotoxin) and shiga-like ribosome inactivating proteins or their sub-units.

Annex 2 to Decree No. 474/2002 Coll.

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

I. Viruses

1. Murray Valley encephalitis virus;
2. Dobrava-Belgrade virus;
3. St. Louis encephalitis virus;
4. Flexal virus
5. Guanarito virus;
6. Hendra virus (Equine morbilli virus);
7. Kyasanur Forest virus;
8. Chapare virus;
9. Choclo virus;
10. Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus);
11. Laguna Negra virus;
12. Nipah virus;
13. Oropouche virus;
14. Omsk hemorrhagic fever virus;
15. Powassan virus;
16. Puumala virus;
17. Rocio virus;
18. Sabia virus;
19. Seoul virus;
20. Louping ill virus;
21. West Nile virus.

II. Bacteria

1. Clostridium perfringens epsilon toxin producing types;
2. Clostridium tetani;
3. Legionella pneumophila;
4. Mycobacterium bovis (except BCG strain);
5. Mycobacterium tuberculosis (multiresistant strains);
6. Xanthomonas albilineans;
7. 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;
8. Yersinia pseudotuberculosis.

III. Fungi

1. Coccidioides immitis;

2. Coccidioides posadasii;
3. Colletotrichum coffeanum var. Virulans (Colletotrichum kahawae);
4. Puccinia graminis (syn. Puccinia graminis f. sp. tritici);
5. Puccinia striiformis (syn. Puccinia glumarum).

IV. Toxins and their sub-units

1. Tetanus toxin.

V. Genetic elements and genetically modified organisms

1 Genetic elements that contain nucleic acid sequences associated with the pathogenicity of organisms specified in I - III.

2 Genetic elements that contain nucleic acid sequences coding for any of the toxins specified in IV or coding for sub-units of toxins specified in IV.

3 Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of organisms specified in I - III.

4 Genetically modified organisms that contain nucleic acid sequences coding for any of the toxins specified in IV or coding for sub-units of toxins specified in IV.

5 De novo chemically synthesized genetic material and artificially produced organisms that contain nucleic acid sequences associated with the pathogenicity of organisms specified in I - III.

6 De novo chemically synthesized genetic material and artificially produced organisms that contain nucleic acid coding for any of the toxins specified in IV or coding for sub-units of toxins specified in IV.

Notes:

Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons and vectors whether genetically modified or unmodified.

Nucleic acid sequences associated with the pathogenicity of organisms specified in I - III means any sequence specific for any of the above mentioned micro-organisms that

a) in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health,

b) is known to enhance the ability of a specified micro-organism, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health.