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

as amended by Act No. 186/2004 Coll., Act No. 413/2005 Coll., Act No. 296/2007 Coll., Act No. 124/2008 Coll., Act No. 223/2009 Coll., Act No. 227/2009 Coll., Act No. 64/2014 Coll., Act No. 243/2016 Coll., Act No. 183/2017 Coll., and Act No. 253/2017 Coll.

The Parliament has enacted this Act of the Czech Republic:

PART I
Measures related to the prohibition of bacteriological (biological) and toxin weapons

CHAPTER I
Introductory provisions

Section 1 Subject matter

This Act regulates

a) rights and obligations of natural persons and legal entities related to the prohibition of development, production, stockpiling and use of bacteriological (biological) and toxin weapons; their destruction; and the management of highly hazardous and hazardous biological agents and toxins that could be misused to violate the prohibition of bacteriological (biological) and toxin weapons; and

b) the exercise of state administration in this area.

Section 2 Definitions of certain terms

For the purposes of this Act, the following definitions shall apply:

a) biological agent means a micro-organism, namely a bacterium, virus, or fungus, whether natural or modified, either in the form of isolated live cultures or as material including living material which has been deliberately inoculated or contaminated with such culture;

b) toxin means a toxic chemical substance created by metabolic processes, whether natural or modified, or such a substance chemically synthesised and capable of causing death, disease, or in any other way detrimental to humans, animals or plants; toxin is not this chemical substance if present in a diagnostic specimen, or as a natural contaminant in any other material;

c) bacteriological (biological) weapon
   1. means a weapon whose damaging effect is based on properties of biological agents intended to harm the health of humans or animals and/or bring about their deaths and/or inflict damage on plants and/or result in economic damages;
   2. means any equipment, device, instrument and means designed or adapted to propagate or use biological agents for hostile purposes or in armed conflict or a carrier of biological agents deliberately contaminated to be used for hostile purpose or in armed conflict;

d) toxin weapon
   1. means a weapon whose damaging effect is based on properties of toxins intended to harm the health of humans or animals and/or bring about their deaths and/or inflict damage on plants and/or result in economic damages;

2. means any equipment, device, instrument and means designed or adapted to propagate or use toxins for hostile purposes or in armed conflict;

e) production means a cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents including toxins;

f) management of highly hazardous biological agents or toxins means a development, production, use, acquisition, possession, import, export, transport or disposal of a highly hazardous biological agent or toxin; management of a highly hazardous biological agent or toxin shall not be considered a service as the service defined in the Act on Free Movement of Services;

g) management of hazardous biological agents or toxins means a development, production, use, acquisition, possession, import, export, transport or disposal of a hazardous biological agent or toxin; management of hazardous biological agent or toxin shall not be considered a service as the service defined in the Act on Free Movement of Services;

h) international inspector means an authorized representative of an international organisation charged to conduct inspections aimed to make sure that the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (hereinafter referred to as the "Convention") [1)] is fulfilled;

i) classified information means a piece of information directly allowing development or production of a bacteriological (biological) or toxin weapon and/or highly hazardous biological agent or toxin, and

j) management of classified information means collecting for other than preventive, protective or other peaceful purposes, providing or publishing classified information.

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1) Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction declared under No. 96/1975 Coll.

Section 3 State administration of the prohibition of bacteriological (biological) and toxin weapons

(1) State administration for the area of the prohibition of bacteriological (biological) and toxin weapons shall be exercised through the State Office for Nuclear Safety (hereinafter referred to as the "Office"), the state administration body also acting as the National Authority responsible for the observance of the Convention.

(2) The Office shall

a) conduct control of compliance with the prohibition of bacteriological (biological) and toxin weapons;

b) conduct control over the management of highly hazardous and hazardous biological agents and toxins under this Act;

c) issue, modify and cancel a decision on the licence for the management of highly hazardous biological agents and toxins under this Act;

d) maintain register of

1. licence holders under this Act and their professional representatives, and
2. natural persons and legal entities carrying out activities involving the management of hazardous agents or toxins under Section 17;

e) maintain register of

1. highly hazardous and hazardous biological agents and toxins,
2. workplaces where activities involving the management of highly hazardous and hazardous agents and toxins are performed, and

3. technical and technological laboratory and production equipment of the workplaces under point 2;

f) ensure international cooperation within its sphere of competence.

(3) The registers maintained under paragraph (2) letter d) are public. The registers maintained under paragraph (2) letter e) are non-public. At request, the Office shall issue a full or partial extract from the registers referred to in paragraph (2) letter d) to a person who can demonstrates a legal interest. Instead of issuing an extract, information from information system may be provided in a manner allowing remote access.

(4) In pursuit of its supervisory activities the Office employs not only its own facilities but also reference laboratories earmarked for the management of highly hazardous and hazardous biological agents and toxins, operated by the Ministry of Health and the Ministry of Defence.

CHAPTER II
Prohibition of bacteriological (biological) and toxin weapons and their production facilities

Section 4

(1) Development, production, acquisition, stockpiling, possession, processing, use, consumption, import, export, transportation and distribution of bacteriological (biological) and toxin weapons or other management of bacteriological (biological) and toxin weapons and the treatment of classified information including support or funding for these activities are prohibited.

(2) Development, production, acquisition, stockpiling, possession, import, export, distribution and other activities involving management of technical and technological laboratory and production equipment for the production of bacteriological (biological) or toxin weapons and their carriers as well as design, construction and use of workplaces to produce them including support or funding for these activities are prohibited.

(3) Development, production, acquisition, stockpiling and possession of biological agents or toxins of such types and in such amounts, which do not match the need for their use for preventive, protective or other peaceful purposes, are prohibited.

Section 5

(1) Finding any material or item reasonably suspected of being a bacteriological (biological) or toxin weapon or containing highly hazardous or hazardous biological agents or toxins as well as suspicion of the treatment of classified information or suspicion of support or funding for the activities under Section 4 shall be reported without undue delay to the Police of the Czech Republic, which shall communicate such information to the Office without undue delay.

(2) The provisions of paragraph (1) shall apply similarly to finding any equipment.

(3) Whoever, in pursuit of his/her activity, incidentally isolates or detects highly hazardous biological agents or toxins without being granted a licence by the Office under Section 6(1), is obliged to notify the Office thereof without undue delay.

(4) The office ensures the distruction of materials, items and devices referred to in paragraphs (1) to (3). The costs are borne by the state. This is without prejudice to liability for damages under special legislation.

(5) Whoever becomes aware of a loss of a highly hazardous or hazardous biological agent or toxin or intentional damage to the technical or technological equipment referred to in the declaration under Section 16 or 17 or reported to the Office, is obliged to notify the Police of

the Czech Republic thereof without undue delay, which shall communicate such information to the Office without undue delay.

(6) Every person is obliged to notify the Office within 5 days of putting into operation a workplace, which
   a) is maintained under negative pressure to the surroundings;
   b) is equipped with an alarm system fitted to detect unacceptable air pressure changes;
   c) has the extracted air filtered through the filters allowing high-efficiency particulate absorption (HEPA filters);
   d) is sealable to permit fumigation, and
   e) has a validated waste disposal system.

CHAPTER III
Using highly hazardous biological agents and toxins

Section 6 Management of highly hazardous biological agents and toxins

(1) The activities involving the management of highly hazardous biological agents and toxins may be performed within the Czech Republic only on the basis of the licence granted by the Office
   a) for industrial, agricultural, research, medical, pharmaceutical and any other peaceful purposes;
   b) for protective purposes directly related to the protection against bacteriological (biological) or toxin weapons;
   c) for prevention, identification, diagnostics and treatment of diseases caused by biological agents or toxins.

(2) A licence granted by the Office under this Act shall not be a substitute for the licences issued under special legislation. [2)]

(3) Licence is not required for the management of
   a) highly hazardous biological agent or toxin in rescue and disposal activities [10)];
   b) diagnostic specimen containing the highly hazardous biological agents or the culture of highly hazardous biological agent obtained from this specimen after a period of less than 30 days in the reference or diagnostic laboratory under special legislation [11)];
   c) highly hazardous biological agent contained in the vaccine if the vaccine is not being used for research purposes;
   d) highly hazardous toxin contained in the diagnostic kit by the end user; diagnostic kit means a veterinary preparation [12)] or a medical device [13)] intended for distribution, whose integral part is a biological agent or toxin and which is used in the diagnosis of disease of humans or animals or for determining the presence of a biological agent or toxin in the specimen taken; in such activities involving the management, Section 17 to 17c shall apply analogically, and
   e) highly hazardous toxin contained in the certified reference material according to the Metrology Act.

(4) Implementing legislation sets out a list of highly hazardous biological agents and toxins.

(5) Whoever without licence performs activities involving the management of a highly hazardous biological agent or toxin under paragraph (3) letter a) is obliged to notify the Office of such activities involving management without undue delay.

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2) For example, Act No. 258/2000 Coll., on Public Health Protection and on Amendment to Certain Related Acts, as amended.

10) Act No. 239/2000 Coll., on Integrated Rescue System and on Amendment to Certain Related Acts, as amended.

11) For example, Act No. 166/1999 Coll., on Veterinary Care and on Amendment to Certain Related Acts (Veterinary Act), as amended, Act No. 258/2000 Coll., on Public Health Protection and on Amendment to Certain Related Acts, as amended, Act No. 147/2002 Coll., on the Central Institute for Supervising and Testing in Agriculture and on Amendment to Certain Related Acts (Act on the Central Institute for Supervising and Testing in Agriculture), as amended, Act No. 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended, Act No. 373/2011 Coll., on Specific Medical Services, as amended.

12) Act No. 166/1999 Coll., on Veterinary Care and on Amendment to Certain Related Acts (Veterinary Act), as amended.

13) Act No. 268/2014 Coll., on Medical Devices and on Amendment to Act No. 634/2004 Coll., on Administrative Fees, as amended.

Section 7 Licensing conditions for the management of a highly hazardous biological agent or toxin

(1) The Office shall grant a licence for the management of highly hazardous biological agent and toxin (hereinafter referred to as the "licence") to a legal entity or a natural person on condition that

a) the applicant, if a legal entity, has its seat or, if a natural person, has his/her residence on the territory of the Czech Republic;
b) the applicant, if a natural person, has full legal capacity and good repute;
c) natural persons, who are members of the statutory body of the applicant, have full legal capacity and good repute;
d) the applicant, if a legal entity, and a legal entity who is a member of the statutory body of the applicant, have good repute;
e) the natural person, who is a representative of the legal entity, who is a member of the statutory body of the applicant, has full legal capacity and good repute;
f) appoints a professional representative who is obliged to ensure the proper performance of the activities associated with licensed management of highly hazardous biological agent or toxin; the professional representative must have full legal capacity, good repute and must be professionally competent;
g) a licence has not been cancelled under Section 12(4) letter a) and b).

(2) The fulfilment of the condition specified in paragraph (1) letter a) shall not be required for legal entities with their seat and for natural persons with their residence on the territory of the EU Member State.

(3) The fulfilment of the condition specified in paragraph (1) letter f) shall not be required for a natural person who is professionally competent.

(4) The function of the professional representative can be performed always only for one person.

Section 8 Good repute

(1) For the purposes of this Act, a person shall be considered to be of good repute if he/she has not been finally convicted of a criminal infraction committed by negligence, the constituent elements of which are related to the licensed activity, or committed intentionally.

(2) Proof demonstrating good repute shall be

a) an extract from the Criminal Records Register of a person, to whom the condition of good repute under Section 7(1) applies, or
b) an equivalent document on good repute issued by the competent authority of the EU Member State of which the natural person, statutory body, member of statutory body or professional representative is a national or on whose territory the legal person has its seat; in the event that this State does not issue such documents, they can be replaced by an affidavit made before the competent authority or a notary established in this State; a foreigner, who is or was a national of another EU Member State or has or had his/her address of residence in another EU Member State, can demonstrate his/her good repute by presenting an extract from the criminal records with the annex containing the information that is recorded in the register of criminal records of another EU Member State instead of the document providing a proof of good repute issued by the competent authority of another EU Member State [2a)].

(3) Proof of good repute referred to in paragraph (2) letter b) shall not be older than 3 months.

(4) In order to demonstrate the good repute, the Office shall request the extract from the Criminal Records Register in accordance with special legislation [2a)]. The application for the issue of an extract from the Criminal Records Register and the extract from the Criminal Records Register shall be transmitted in electronic form, in a manner allowing remote access.

2a) Act No. 269/1994 Coll., on Penal Register, as amended.

Section 9 Professional competence

(1) Professional competence means an experience in the field of at least 3 years and a completion of higher education in a degree programme in the field of
a) general medicine or pharmacy;
b) veterinary medicine or veterinary hygiene;
c) chemistry or biology, ecology and the environment;
d) teaching with a focus on chemistry or biology, or
e) agriculture or food industry.

(2) When recognising professional qualification obtained in another Member State of the European Union, another State that is a contracting party to the Agreement on the European Economic Area or in the Swiss Confederation for the performance of activities referred to in Section 7(1) f), the Office shall proceed in accordance with the Act on Recognition of Professional Qualifications.

(3) Evidence of education and training issued abroad shall be accompanied by a nostrification clause and evidence of higher education shall be accompanied by a certificate of recognition of equivalence of education in accordance with special legislation.

(4) The obligation to present evidence accompanied by a nostrification clause or certificate of recognition of equivalence of education referred to in paragraph 3 shall not apply to evidence of education and training issued in a Member State of the European Union, in another State that is a contracting party to the Agreement on the European Economic Area or in Swiss Confederation or presented by a natural person from that State.

(5) If the applicant for licence, who is a national of a Member State of the European Union, another State that is a contracting party to the Agreement on the European Economic Area or the Swiss Confederation, intends to perform the activity subject to the licence on a

temporary or occasional basis, the Office shall verify his/her professional competence under the conditions laid down in the Act on Recognition of Professional Qualifications.

Section 10 Licensing application

(1) A licensing application shall contain
   a) personal identification number, if assigned, or date of birth of the natural person who is
      1. an applicant,
      2. a member of the statutory body of the applicant, who is a legal person, or
      3. a representative of the legal person who is a member of the statutory body of the applicant who is a legal person,
   b) the name of highly hazardous biological agent or toxin, its quantity, and the purpose and a description of activities involving the management thereof;
   c) the location of licensed activity, if different from the seat or permanent residence of the applicant.

(2) The licensing application shall be accompanied by
   a) a document certifying the professional competence of the natural person and that of professional representatives;
   b) technical documentation including construction plans, specifications of the premises and technical and technological laboratory and production equipment installed therein, and the Final Inspection Approval (*a.k.a. certificate of occupancy or certificate of practical completion*);
   c) a report approved by a public health authority competent over the location of activity under special legislation; [3)]
   d) a declaration that no decision on bankruptcy has been issued in respect of the legal entity's assets;
   e) other documents as requested by the Office;
   f) if the applicant's good repute is demonstrated by a document under Section 8(2) letter b), such document shall be enclosed with the application.

(3) The licensing application shall be submitted on the form. The specimen of the licensing application shall be established by implementing legislation.

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3) For example Decree No. 89/2001 Coll., establishing conditions of works categorization, limit indicators of biological exposure tests and particulars of reporting on works with asbestos and biological items.

Section 11 Decision on the issue of licence

(1) The administrative procedure for granting a licence conducted by the Office shall be independent of the procedure conducted by another administrative authority. The applicant shall be the sole party to the procedure.

(2) The Office shall decide on granting a licence within 90 days of the date of initiation of the procedure.

(3) The decision on granting a licence issued by the Office shall specify
   a) business name or trade name, seat and ID number of the legal entity applying for the licence, and name and surname, residence of a person or persons positioned as the statutory body or its members;
   b) name and surname, personal identification number and residence of a natural person, and name and surname and residence of his/her professional representative, if any;
   c) subject matter and scope of the licence for management;

d) kinds and quantities of highly hazardous biological agents or toxins whose management is being licensed;
e) conditions under which activities involving the management of highly hazardous biological agents or toxins can be performed.

(4) The application for licence shall be refused if the applicant fails to comply with the conditions laid down by this Act or when to do so would result in exceeding the overall quantity of highly hazardous biological agent or toxin on the territory of the Czech Republic for a certain period; the overall quantity of highly hazardous biological agent or toxin on the territory of the Czech Republic for a certain period, which may not be exceeded, shall be stipulated by the implementation legislation.

Section 12 New decision on the issue of a licence and cancellation and lapse of a licence

(1) In the event of a change in any of the data referred to in the decision on the licence or other facts relevant for the performance of licensed activities, the Office shall issue a new decision on request of the licence holder.

(2) The original decision shall be cancelled by the new decision issued in accordance with paragraph (1).

(3) If the Office becomes aware about a change of the data referred to in the decision on the licence or other facts relevant for the performance licensed activities and the licence holder has not filed an application for a new decision, the Office shall call the licence holder to submit an application and shall set a period of time for the application, which shall not be less than 5 working days from the date of delivery of the call up

(4) The Office shall cancel the licence if the licence holder
a) has obtained it on the grounds of untrue or incomplete information;
b) fails in his/her obligations laid down by this Act or fails to remedy the deficiencies identified by the Office;
c) no longer satisfies the conditions relevant for the issue of the licence ;
d) requests in writing that it be cancelled, or
e) despite the call up of the Office under paragraph (3) did not apply for a new decision.

(5) If the licence holder does not intend to continue to perform the licensed activity, he/she shall notify the Office thereof without undue delay and concurrently request cancellation of the licence.

(6) The licence shall lapse
a) on the date of dissolution or death of the licence holder;
b) by declaring bankruptcy of the licence holder, or
c) by decision of the Office to cancel the licence.

(7) After a lapse of licence, the licence holder shall discontinue licensed activity in accordance with this Act without undue delay

(8) An appeal against a decision to cancel a licence shall not have suspensory effect.

Section 13 Obligations of licence holder

The licence holder shall in particular
a) perform activities involving the management of highly hazardous biological agents and toxins in the scope provided for in the licence;
b) enable Office inspectors, international inspectors and the persons invited by the Office to enter the workplace and to provide them with information about the scope of the activities being performed and about the safety measures needed in order to carry out inspection;

c) enable the inspectors to install monitoring instrumentation required to monitor highly hazardous biological agents and toxins and to collect their specimens for analysis;
d) inform the Office about the initiation of insolvency proceedings without undue delay;
e) inform the Office about a change of the professional representative, if any, and about another important change that has occurred in the performance of the licensed activity without undue delay, in particular about
   1. a change in the facts relevant for the issue of a licence,
   2. a change in organisational structure ,
   3. a change in the technical or technological laboratory and production equipment of the workplace;
f) notify the Office about a planned change in the performance of the licensed activity under letter e) at least 30 days prior to its implementation;
g) in the event of the disposal of highly hazardous biological agent or toxin, to follow the procedure that presents no risk to human or animal health or to the environment;
h) provide a highly hazardous biological agent or toxin only to the licence holder under Section 6(1) unless provided otherwise in the decision made by the Office in exceptional, duly justified cases, for a limited period and provided that it does not jeopardise the purpose of this Act at the same time;
i) inform the carrier of highly hazardous biological agent or toxin about the nature of the goods entrusted to it and about the safe method of management and to document this information;
j) lay down the requirements in the internal regulations to ensure the proper performance of the activities associated with the licensed management of highly hazardous biological agent or toxin including the obligation to ensure a systematic overview of the professional representative on the status of the implementation of these activities;
k) in case of cancellation and lapse of the licence, to ensure without undue delay the handover of a highly hazardous biological agent or toxin to another licence holder or its disposal of, and
l) notify the Office of any release of a highly hazardous biological agent or toxin into the environment without undue delay.

Section 13a Transport

(1) Highly hazardous biological agent and toxin can be transported only in a transport container and in the manner laid down in special legislation governing the transport of dangerous goods [14)].

(2) The carrier must ensure that the consignment, which includes highly hazardous biological agents or toxins, is transported, stored during transport and handed over to the recipient in a manner preventing the theft, misuse and loss, and must ensure that no unauthorised person comes into contact with that consignment.

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14) Act No. 111/1994 Coll., on Road Transport, as amended.
European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), declared under No. 64/1987 Coll.
Act No. 266/1994 Coll., on Railway, as amended.
Convention concerning International Carriage by Rail (COTIF), declared under No. 8/1985 Coll.
Act No. 114/1995 Coll., on Inland Navigation, as amended.
Decree No. 222/1995 Coll., on Waterways, Shipping Traffic in Ports, Common Accident and Transportation of Dangerous Goods, as amended.

Act No. 49/1997 Coll., on Civil Aviation and on Amendment and Supplement to Act No. 455/1991 Coll., on Licensed Trade (Trade Licensing Act), as amended.
European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), declared under No. 102/2011 Coll.

Section 14 Export and import of highly hazardous biological agents and toxins

(1) Highly hazardous biological agents and toxins can be exported from and imported to the Czech Republic solely by a licence holder. This licence does not replace the licence issued in accordance with special legislation. [6)]

(2) Export of highly hazardous biological agents and toxins by licence holder is possible only for the purposes referred to in Section 6(1).

(3) Import of highly hazardous biological agents and toxins by licence holder is possible only for the purposes referred to in Section 6(1).

(4) It is prohibited to export and import highly hazardous biological agents and toxins in the form of the consignments addressed to depositories, custom warehouses, free zones or to addresses of any other person than those specified in the licence.

(5) The licence holder is obliged to notify the Office of the entry of highly hazardous biological agents or toxins into the Czech Republic or their exit from the Czech Republic within 5 days from the date of the entry or exit. The notification shall be transmitted electronically.

(6) The notification under paragraph (5) shall contain
a) kinds and quantities of imported or exported highly hazardous biological agents or toxins;
b) name, surname, telephone number and email address of the natural person who ensures import or export for the licence holder;
c) business name or trade name and seat of the legal entity or name, surname, date of birth and place of residence of the natural person who is a supplier of highly hazardous biological agents or toxins or their recipient abroad;
d) the date of import or export;
e) business name or trade name and identification number of the carrier, and
f) the customs office, which conducted the clearance procedures for import or export.

(7) The specimen of notification under paragraph (5) shall be established by implementing legislation.

(8) The export of highly hazardous biological agents or toxins requires the licence holder to hold a written declaration of the foreign end user that highly hazardous biological agents or toxins will not be used for the production or development of bacteriological (biological) or toxin weapons, indicating specific purpose of their use.

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6) Act No. 21/1997 Coll., on Control of Exports and Imports of Goods and Technologies Subject to International Control Regimes.

Section 14a Security of highly hazardous biological agent and toxin

(1) The licence holder shall ensure security of highly hazardous biological agents and toxins and production equipment for its production from loss, theft and misuse, especially by technical means or physical security.

(2) The licence holder shall store highly hazardous biological agents and toxins in a locked room, whose walls, ceiling, floor, windows and doors are made of a material preventing the intrusion, in a stationary lockable container or in special lockable laboratory equipment designated for this purpose.

(3) The licence holder shall ensure that the room, where highly hazardous biological agent or toxin is stored, is individually entered only by the persons designated by the licence holder. Keys and means of access to this room must be stored separately from keys and means of access to other rooms.

(4) The licence holder shall draw up and update a list of persons who have access to highly hazardous biological agent or toxin.

(5) The licence holder, who operates the workplace under Section 5(6), where activities involving the management of highly hazardous biological agents or toxin are performed, is obliged to draw up a list of persons who have access to this workplace.

(6) The licence holder shall ensure that all persons, who have access to highly hazardous biological agent or toxin, have been trained, every year, in the field of security of highly hazardous biological agent and toxin against misuse, loss and theft.

Section 15 Cancelled

Section 16 Record-keeping and declaration of highly hazardous biological agents and toxins

(1) The licence holder shall continuously keep records of the management of highly hazardous biological agents or toxins and to submit the records to the Office on request.

(2) The records shall be kept in consideration of the workplace where the activity recorded is being performed and in view of the different kinds and quantities of highly hazardous biological agents or toxins.

(3) When the licence is lapsed or cancelled, the licence holder is obliged to pass to the Office all records on the management of highly hazardous biological agents or toxins.

(4) The licence holder shall submit to the Office the declaration covering the previous calendar year no later than on 31 January of the following year.

(5) The declaration shall specify

a) kinds and quantities of all highly hazardous biological agents and toxins, the management of which is being licensed;
b) name of the workplace, where the declared activity is being performed and its location;
c) technical and technological laboratory and production equipment of the workplace referred to in letter b), and
d) information, whether the management of highly hazardous biological agents or toxins is included in the national defence or security research.

(6) Detailed requirements for keeping the records, their retention periods and information contained in the declaration shall be set out in implementing legislation.

(7) The specimen of declaration shall be established by implementing legislation.

CHAPTER IV
Using hazardous biological agents and toxins

Hazardous biological agents and toxins

Section 17

(1) The activities involving the management of hazardous biological agents and toxins may be performed within the Czech Republic only

a) for industrial, agricultural, research, medical, pharmaceutical and any other peaceful purposes;
b) for protective purposes directly related to the protection against bacteriological (biological) or toxin weapons, or
c) for prevention, identification, diagnostics and treatment of diseases caused by biological agents or toxins.

(2) A natural person or a legal entity, which performs activities involving the management of hazardous biological agent or toxin, is obliged to notify data to the Office in the form of a declaration covering the previous calendar year no later than on 31 January of the following year.

(3) The declaration shall specify
a) kinds and quantities of all reported hazardous biological agents and toxins;
b) workplaces where the activity declared is being performed;
c) technical and technological laboratory and production equipment of the workplaces referred to in letter b), and
d) information, whether the management of hazardous biological agent and toxin is included in the national defence or security research.

(4) Section 16 shall apply, analogically, to the records kept on hazardous biological agents and toxins.

(5) Implementing legislation shall establish a list of hazardous biological agents and toxins.

(6) Detailed requirements for keeping the records, their retention periods, information contained in the declaration, and the specimen of declaration shall be set out in implementing legislation.

Section 17a

(1) In case a natural person or a legal entity intends to perform activities involving the management of hazardous biological agent or toxin for the first time, the person / entity is obliged to notify the Office of the intention 14 days before the date of such activities involving management.

(2) The duty of notification shall also apply to the installation of new technical and technological laboratory and production equipment.

(3) The notification under paragraph (1) shall contain
a) kind of hazardous biological agent or toxin, and
b) information under Section 17(3) letter b) and c).

(4) The duty of notification under paragraph (1) shall not apply to the management of
a) hazardous biological agent or toxin in rescue and disposal activities[10)];
b) diagnostic specimen containing the hazardous biological agents or the culture of hazardous biological agent obtained from this specimen after a period of less than 30 days in the reference or diagnostic laboratory under special legislation [11)];
c) hazardous biological agent contained in the vaccine if the vaccine is not being used for research purposes, or
d) hazardous toxin contained in the certified reference material according to the Metrology Act.

(5) Whoever without previous notification performs activities involving the management of a hazardous biological agent or toxin under paragraph (4) letter a) is obliged to notify the Office of such activities involving management without undue delay.

(6) The specimen of notifications under paragraphs (1) and (2) shall be established by implementing legislation.

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10) Act No. 239/2000 Coll., on Integrated Rescue System and on Amendment to Certain Related Acts, as amended.

11) For example, Act No. 166/1999 Coll., on Veterinary Care and on Amendment to Certain Related Acts (Veterinary Act), as amended, Act No. 258/2000 Coll., on Public Health Protection and on Amendment to Certain Related Acts, as amended, Act No. 147/2002 Coll., on the Central Institute for Supervising and Testing in Agriculture and on Amendment to Certain Related Acts (Act on the Central Institute for Supervising and Testing in Agriculture), as amended, Act No. 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended, Act No. 373/2011 Coll., on Specific Medical Services, as amended.

Section 17b

(1) Legal entities or natural persons, who perform activities involving the management of hazardous biological agent or toxin, shall notify the Office of the entry of hazardous biological agent or toxin into the Czech Republic or its exit from the Czech Republic within 5 days from the date of the entry or exit. The notification shall be transmitted electronically.

(2) The notification under paragraph (1) shall contain
   a) kinds and quantities of imported or exported hazardous biological agents or toxins;
   b) name, surname, telephone number and email address of the natural person who ensures import or export for the person performing activities involving the management of hazardous biological agent or toxin;
   c) business name or trade name and seat of the legal entity or name, surname, date of birth and place of residence of the natural person who is a supplier of hazardous biological agent or toxin or its recipient abroad;
   d) the date of import or export;
   e) business name or trade name and identification number of the carrier, and
   f) the customs office, which conducted the clearance procedures in case of import or export.

(3) The specimen of notification under paragraph (1) shall be established by implementing legislation.

(4) The export of hazardous biological agent or toxin requires the person, who performs activities involving the management of hazardous biological agent or toxin, to hold a written declaration of the foreign end user that hazardous biological agents or toxins will not be used for the production or development of bacteriological (biological) or toxin weapons, indicating specific purpose of their use.

Section 17c Security and transport of hazardous biological agent and toxin

(1) Everyone, who performs activities involving the management of hazardous biological agent or toxin, shall
   a) ensure security of hazardous biological agent or toxin against the loss, misuse or theft, in particular by technical means;
   b) ensure the disposal of hazardous biological agent or toxin in the manner that presents no risk to human or animal health or to the environment;
   c) notify, without undue delay, the Office in the event of leakage of a hazardous biological agent or toxin into the environment;

d) ensure that the person, who has access to hazardous biological agent or toxin, has been trained, every year, in the field of security of hazardous biological agents and toxins against misuse, loss and theft, and
e) inform without undue delay the Office about a change that has occurred in the performance of the reported activity, in particular about organisational change and change in the technical or technological laboratory and production equipment of the workplace.

(2) Hazardous biological agent or toxin can be transported only in a transport container and in the manner laid down in special legislation governing the transport of dangerous goods [14)].

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14) Act No. 111/1994 Coll., on Road Transport, as amended.
European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), declared under No. 64/1987 Coll.
Act No. 266/1994 Coll., on Railway, as amended.
Convention concerning International Carriage by Rail (COTIF), declared under No. 8/1985 Coll.
Act No. 114/1995 Coll., on Inland Navigation, as amended.
Decree No. 222/1995 Coll., on Waterways, Shipping Traffic in Ports, Common Accident and Transportation of Dangerous Goods, as amended.
Act No. 49/1997 Coll., on Civil Aviation and on Amendment and Supplement to Act No. 455/1991 Coll., on Licensed Trade (Trade Licensing Act), as amended.
European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), declared under No. 102/2011 Coll.

CHAPTER V
Compliance control

Section 18 Control

(1) The Office shall conduct control of compliance with this Act and other legal regulations issued on the basis of the Act.

(2) The Office shall control
a) persons licensed to perform activities involving the management of highly hazardous biological agents or toxins under Section 11;
b) persons performing activities involving the management of hazardous biological agents or toxins under Section 17, or
c) persons in respect of whom there are reasonable grounds for believing that they perform activities involving the management of highly hazardous biological agents or toxins without licence.

(3) The control shall be carried out by the Office's Chairperson and inspectors (hereinafter referred to as the “inspectors”); the inspectors shall be appointed and dismissed by the Office's Chairperson.

(4) The authorisation of the inspector to conduct control shall have the form of an identity card issued by the Office. The identity card shall contain
a) name(s) and surname of the inspector;
b) the date and place of birth of the inspector;
c) a photograph or other form of visual identification of the inspector;
d) the inspector’s signature;
e) the date of issue of the identity card , and
f) the name and address of the seat of the Office.

(5) cancelled

(6) cancelled

(7) cancelled

(8) cancelled

(9) cancelled

Section 19 Cooperating with ministries and other administrative authorities

Ministries and other administrative authorities shall notify the Office without undue delay of epidemics and infections encountered in people, animals and plants and suspected to be caused by leakages of highly hazardous or hazardous biological agents or toxins or by their misuse; acting within their own scopes of responsibility, the ministries / authorities shall take measures to ensure early detection of the agents and toxins and to minimize their leakages.

Section 20 Corrective measures

If the Inspectors find a deficiency in the activities of inspected person, they shall proceed in consideration of the deficiency and either

a) require that the inspected person remedies the deficiency within the prescribed period, or
b) order the inspected persons to carry out technical checks, reviews or tests of operational capability of the technical and technological laboratory and production equipment.

Infractions

Section 21

(1) A natural person, legal entity or self-employed natural person commits an infraction by

(a) disrespecting the prohibition of development, production, acquisition, stockpiling, possession, processing, use, consumption, import, export, transport or distribution of bacteriological (biological) or toxin weapons or other management of bacteriological (biological) or toxin weapons or the treatment of classified information including support or funding for these activities under Section 4(1);

(b) disrespecting the prohibition of development, production, acquisition, stockpiling, possession, import, export, distribution or other activities involving management of technical and technological laboratory and production equipment for the production of bacteriological (biological) or toxin weapons or their carriers as well as design, construction or use of workplaces to produce them including support or funding for these activities under Section 4(2);

(c) disrespecting the prohibition of development, production, acquisition, stockpiling or possession of biological agents or toxins of such types or in such amounts, which do not match the need for their use for preventive, protective or other peaceful purposes under Section 4(3);

d) failing to inform the Police of the Czech Republic about the facts referred to in Section 5(1) or (5);
e) failing to inform the Office about the facts referred to in Section 5(3);
f) failing to inform the Office about the facts referred to in Section 5(6), or
g) performing activities involving the management of highly hazardous biological agent or toxin without Office’s licence under Section 6.

(2) A penalty may be imposed for an infraction under paragraph (1) in the maximum amount of
   a) CZK 50,000,000 for an infraction under paragraph (1) letter a) to c);
   b) CZK 10,000,000 for an infraction under paragraph (1) letter g);
   c) CZK 500,000 for an infraction under paragraph (1) letter f), or
   d) CZK 100,000 for an infraction under paragraph (1) letter d) or e).

Section 21a

(1) A natural person, legal entity or self-employed natural person, who is the holder of a licence under this Act or was the holder of such licence and this licence has expired or has been revoked, commits an infraction by
   a) performing activities involving the management of highly hazardous biological agent or toxin in the scope not provided for in the licence;
   b) failing to provide the Office with cooperation under Section 13 letter b) or c);
   c) failing to inform the Office without undue delay of the facts referred to in Section 13 letter d) to f) or l) or referred to in Section 14(5);
   d) in case of the disposal of highly hazardous biological agent or toxin, acting contrary to Section 13 letter g);
   e) providing highly hazardous biological agent or toxin to a person contrary to Section 13 letter h);
   f) failing to inform the carrier of highly hazardous biological agent or toxin about the facts referred to in Section 13 letter i) or failing to document such information;
   g) failing to set out the requirements in the internal regulation under Section 13 letter j);
   h) failing to ensure, upon expiration or revocation of the licence, without undue delay handover of a highly hazardous biological agent or toxin to another holder of the licence or its disposal in accordance with Section 13 letter k), or
   i) transporting a highly hazardous biological agent or toxin contrary to Section 13a(1).

(2) A natural person, legal entity or self-employed natural person, who is the holder of a licence under this Act or was the holder of such licence and this licence has expired or has been revoked, commits an infraction by
   a) exporting or importing a highly hazardous biological agent or toxin for any purpose other than referred to in Section 14(2) or (3);
   b) failing to hold a written statement of the foreign end user under Section 14(8) for export of a hazardous biological agent or toxin;
   c) failing to ensure the protection of a highly hazardous biological agents or toxins and/or production equipment to produce them against loss, theft or misuse under Section 14a(1);
   d) failing to store a highly hazardous biological agent or toxin under Section 14a(2).
   e) failing to ensure that the room, where a highly hazardous biological agent or toxin is stored, is individually entered only by the persons designated by the licence holder or failing to store the keys or means of access under Section 14a(3);
   f) failing to draw up or update a list of persons who have access to highly hazardous biological agent or toxin under Section 14a(4);
   g) failing to draw up a list of persons who have access to the workplace with highly hazardous biological agent or toxin under Section 14a(5); or
   h) failing to ensure that the person with access to a highly hazardous biological agent or toxin has been trained every year under Section 14a(6).

(3) A natural person, legal entity or self-employed natural person, who is the holder of a licence under this Act or was the holder of such licence and this licence has expired or has been revoked, commits an infraction by
   a) failing to keep records on the management of highly hazardous biological agents or toxins or failing to provide the Office with the records on request under Section 16(1);
   b) failing to submit, upon expiration or revocation of the licence, the entire records of the management of highly hazardous biological agents or toxins to the Office under Section 16(3), or
   c) failing to submit to the Office the declaration under Section 16(4).

(4) A penalty may be imposed for an infraction under paragraphs (1) to (3) in the maximum amount of
   a) CZK 10,000,000 for an infraction under paragraph (2) letter a);
   b) CZK 1,000,000 for an infraction under paragraph (1) letter a), b), g) to i), paragraph (2) letter c) to e), or paragraph (3) letter a);
   c) CZK 500,000 for an infraction under paragraph (1) letter c) to f), paragraph (2) letter f) to h), or paragraph (3) letter b) or c), or
   d) CZK 100,000 for an infraction under paragraph (2) letter b).

Section 21b

(1) A natural person, legal entity or self-employed natural person, who performs activities involving the management of hazardous biological agents or toxins, commits an infraction by
   a) failing to notify the Office of the facts referred to in Section 17(2), Section 17b(1) or Section 17c(1) c);
   b) failing to fulfil the duty of notification under Section 17a(1) or (2);
   c) failing to keep records on the management of hazardous biological agent or toxin under Section 17(4);
   d) failing to hold a written statement of the foreign end user under Section 17b(4) for export of a hazardous biological agent or toxin;
   e) transporting a hazardous biological agent or toxin contrary to Section 17c(2);
   f) failing to ensure the protection of a hazardous biological agent or toxin against the loss, misuse or theft under Section 17c(1) letter a);
   g) failing to ensure the disposal of a hazardous biological agent or toxin under Section 17c(1) letter b);
   h) failing to ensure that the person with access to a hazardous biological agent or toxin has been trained every year under Section 17c(1) letter d), or
   i) failing to inform, without undue delay, the Office about organisational change or change in the technical or technological equipment of the workplace under Section 17c(1) letter e).

(2) A penalty may be imposed for an infraction under paragraph (1) in the maximum amount of
   a) CZK 500,000 for an infraction under paragraph (1) letter a) to c), e) to g) or i);
   b) CZK 200,000 for an infraction under paragraph (1) letter h), or
   c) CZK 100,000 for an infraction under paragraph (1) letter d).

Section 21c

(1) A natural person, legal entity or self-employed natural person, who is the carrier of highly hazardous biological agents or toxins, commits an infraction by failing to ensure that

a) any shipment containing a highly hazardous biological agent or toxin has been transported, stored in transport or forwarded to the recipient in a manner preventing the theft, misuse or loss under Section 13a(2), or
b) an unauthorised person comes into contact with a shipment containing a highly hazardous biological agent or toxin under Section 13a(2).

(2) A penalty in the maximum amount of CZK 100,000 may be imposed for an infraction under paragraph (1).

Section 21d

(1) The limitation period shall be 5 years. If the limitation period is interrupted, the responsibility for the infraction shall expire no later than 8 years from its commission.

(2) Infractions under this Act are dealt with by the Office.

(3) Fines for infractions are collected by the Office.

(4) The rate of the penalty for an infraction under this Act is increased to double if the same infraction is committed repeatedly. The infraction is committed repeatedly if a period of one year has not passed from the date when the decision on imposition of penalty for the same infraction became final.

Section 21e Use of data for the exercise of State Authority in the area of the prohibition of bacteriological (biological) and toxin weapons

(1) For the exercise of the responsibilities in the area of the prohibition of bacteriological (biological) and toxin weapons, the Office uses
a) reference data from the basic population register,
b) data from the population register information system,
c) data from the information system on foreign nationals.

(2) The data used under paragraph (1) letter a) shall include
a) surname,
b) name(s) ,
c) date, place and district of birth; in the case of data subjects born abroad, date, place and State of birth,
d) permanent address,
e) date, place and district of death; in the case of the data subject's death outside the territory of the Czech Republic, the date of death and the place and State in which the death occurred; if a court decision on the declaration of death has been issued, the date stated in the decision as the date of death or the date which the data subject declared dead did not survive, and the date on which this decision became final,
f) state citizenship or citizenships, if applicable.

(3) The data used under paragraph (1) letter b) shall include
a) name(s), surname and name at birth,
b) date of birth,
c) sex,
d) place and district of birth; State of birth of the foreign national,
e) personal (identification) number,
f) state citizenship or citizenships, if applicable,
g) date, place and district of death; in the case of death outside the territory of the Czech Republic, the date of death and the place and State in which the death occurred.

(4) The data used under paragraph (1) letter c) shall include

a) name(s), surname and name at birth,
b) date of birth,
c) sex,
d) place and State of birth of the foreign national,
e) personal (identification) number,
f) state citizenship or citizenships, if applicable,
g) type and the address of residence in the territory of the Czech Republic,
h) date, place and district of death; in the case of death outside the territory of the Czech Republic, the State in which the death occurred and the date of death, as well as the date stated in a court decision on the declaration of death as the date of death or, if applicable, the date the foreign national declared dead did not survive.

(5) The data maintained in the basic population register as reference data shall be obtained from the population registration information system or the information system on foreign nationals only if they are in the format preceding the currently applicable format.

(6) In each particular case, the data provided may be used only to the extent necessary to accomplish the given task.

CHAPTER VI
Common, transitional and final provisions

Section 22

(1) The Office shall issue a decree for the implementation of Section 6(4), Section 10(3), Section 11(4), Section 14(7), Section 16(6) and (7), Section 17(5) and (6), Section 17a(6) and Section 17b(3).

(2) Legal entities and natural persons engaged in activities regulated by this Act in adherence to the current regulations are obliged to submit to the Office their licence applications as well as compliance with the duty of notification by presenting a declaration under this Act no later than 1 month from the date of entry into force of this Act.

(3) With the duty of notification fulfilled, the right of the management of hazardous biological agents and toxins shall be retained.

(4) Legal entities or natural persons who, on the date of entry into force of this Act, carried out activities involving the management of highly hazardous biological agents or highly hazardous toxins in conducting business activities based on a trade licence, may do so no longer than 6 months from the date of entry into force of this Act.

(5) Legal entities or natural persons who, on the date of entry into force of this Act, carried out activities involving the management of hazardous biological agents or hazardous toxins in conducting business activities based on a trade licence, may continue to do so provided they meet their duty of notification under Section 17 within 14 days from the date of entry into force of this Act.

PART II
Amendments to the Trade Licensing Act

Section 23

In Act No. 455/1991 Coll., on Licensed Trade (Trade Licensing Act), as amended by Act No. 231/1992 Coll., Act No. 591/1992 Coll., Act No. 600/1992 Coll., Act No. 273/1993 Coll., Act No.

303/1993 Coll., Act No. 38/1994 Coll., Act No. 42/1994 Coll., Act No. 136/1994 Coll., Act No. 200/1994 Coll., Act No. 237/1995 Coll., Act No. 286/1995 Coll., Act No. 94/1996 Coll., Act No. 95/1996 Coll., Act No. 147/1996 Coll., Act No. 19/1997 Coll., Act No. 49/1997 Coll., Act No. 61/1997 Coll., Act No. 79/1997 Coll., Act No. 217/1997 Coll., Act No. 280/1997 Coll., Act No. 15/1998 Coll., Act No. 83/1998 Coll., Act No. 157/1998 Coll., Act No. 167/1998 Coll., Act No. 159/1999 Coll., Act No. 356/1999 Coll., Act No. 358/1999 Coll., Act No. 360/1999 Coll., Act No. 363/1999 Coll., Act No. 27/2000 Coll., Act No. 29/2000 Coll., Act No. 121/2000 Coll., Act No. 122/2000 Coll., Act No. 123/2000 Coll., Act No. 124/2000 Coll., Act No. 149/2000 Coll., Act No. 151/2000 Coll., Act No. 158/2000 Coll., Act No. 247/2000 Coll., Act No. 249/2000 Coll., Act No. 258/2000 Coll., Act No. 309/2000 Coll., Act No. 362/2000 Coll., Act No. 409/2000 Coll., Act No. 458/2000 Coll., Act No. 61/2001 Coll., Act No. 100/2001 Coll., Act No. 120/2001 Coll., Act No. 164/2001 Coll., Act No. 256/2001 Coll., Act No. 274/2001 Coll., Act No. 477/2001 Coll., Act No. 478/2001 Coll., Act No. 501/2001 Coll., Act No. 86/2002 Coll., Act No. 119/2002 Coll. and Act No. 174/2002 Coll., the full stop at the end of letter ae) in Section 3(3) shall be replaced by a comma and letter af) shall be added, together with footnote 23m) worded as follows:
“af) management of highly hazardous and hazardous biological agent and toxin. 23m)

23m) Act No. 281/2002 Coll., on Some Measures Related to the Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to the Trade Licensing Act, as amended.”.

PART III
Entry into force

Section 24

This Act of law shall become effective on the date of its promulgation +) with the exception of Section 7(2) and Section 8(2) b) - the two latter items shall enter into force on the date of entry into force of the Treaty of Accession of the Czech Republic to the European Union. ++)

Klaus (autograph), Havel (autograph), (by proxy) Rychetský (autograph)

+) 28/06/2002
++) 01/05/2004

Article XLV
of Act No. 223/2009 Coll.,
amending certain acts in connection with the adoption of the Act on Free Movement of Services

Transitional provision

Proceedings initiated before the date of entry into force of this Act and not finished by that date shall be completed including associated rights and obligations in adherence to existing legislation.

Article II
of Act No. 253/2017 Coll.,
amending Act No. 281/2002 Coll., on Some Measures Related to the Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to the Trade Licensing Act, as amended

Transitional provisions

1. Who on the date of entry into force of this Act performed activities involving the management of highly hazardous biological agent or toxin and/or hazardous biological agent or toxin under Act No. 281/2002 Coll., in the version in force before the date of entry into force of this Act, is obliged to harmonise the legal situation with Act No. 281/2002 Coll., in the version in force from the date of entry into force of this Act, within 6 months from the date of entry into force of this Act.

2. The obligation to notify the State Office for Nuclear Safety of the first management of highly hazardous biological agent or toxin under Section 6(3) d) of Act No. 281/2002 Coll., in the version in force before the date of entry into force of this Act, shall be deemed to be fulfilled in case of a person who performed activities involving the management of this highly hazardous biological agent or toxin solely for the purpose referred to in that provision on the date of entry into force of this Act on the basis of a licence under Act No. 281/2002 Coll., in the version in force before the date of entry into force of this Act.