ACT 281 / 2002 Coll.

of 30 May 2002

on Some Measures Related to a Ban on Bacteriological (Biological) and Toxin Weapons and on Amendments to the Trades Licensing Act

Amendment: 186 / 2004 Coll.;
Amendment: 413 / 2005 Coll.;
Amendment: 296 / 2007 Coll.;
Amendment: 124 / 2008 Coll.;
Amendment: 223 / 2009 Coll.;
Amendment: 227 / 2009 Coll.
Amendment: 64 / 2014 Coll.

The Parliament has passed this Act of the Czech Republic:

PART I

MEASURES RELATED TO A BAN ON BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS

SECTION I

INTRODUCTORY PROVISIONS

Article 1

Scope

This Act regulates:

a) rights and obligations of natural persons and legal entities as associated with the ban on development, production, stockpiling and use of bacteriological (biological) and toxin weapons; their disposal; and the handling of highly hazardous and hazardous agents and toxins that could be abused to violate the ban on bacteriological (biological) and toxin weapons; and

b) the execution of governmental administration in this area.

Article 2

Definitions of some terms

As used in this Act,

a) the term of bacteriological (biological) and toxin weapons shall cover:
   1 weapons whose damaging effect is based on properties of biological agents and 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 materials containing biological agents or toxins of any origin or process of production; their types and quantities not justifiably adequate for prophylactic, protective or other peaceful purposes;
   3 any pieces of equipment, devices, instruments and manners of their propagation designed to be filled by with such biological agents or toxins and/or weapons designed specifically as suitable to be filled with the biological agents or toxins and used against enemies or in

armed conflicts; the same applies to carriers of biological agents purposefully contaminated to be used for hostile purposes or in armed combat.

b) the term of biological agent shall cover any organism, natural or modified, whose intentional use can cause death, disease and/or incapacitate people and animals and/or kill animals or damage plants;

c) the term of toxin shall designate a substance generated by any organisms, including microorganisms, animals or plants, and manufactured by any process, natural or modified; or a substance synthesized chemically and capable of causing death, disease, or in any other way detrimental to humans, animals or plants;

d) the term of highly hazardous biological agents and toxins shall describe biological agents and toxins whose properties and capabilities make it possible to use the agents / toxins as weapons; such agents and toxins are listed in the relevant Decree;

e) the term of hazardous biological agents and toxins shall depict biological agents and toxins allowed to be handled if specific preconditions are met; such agents and toxins are listed in the relevant Decree;

f) the term of facilities with engineered safety levels of BL 3 WHO and BL 4 WHO shall mean premises, particularly a room or several rooms, laboratories or any other buildings or structures fulfilling requirements applicable to the relevant level of engineered safety as set forth in the standard of ČSN - EN 12128 - Laboratories for Research, Development and Analyses - Levels of Safety in Microbiological Laboratories; Hazard Zones; Premises and Technical Safety Requirements;

g) the term of diagnostic facility shall depict a facility engaged in testing samples in an attempt at diagnosing subclinical, clinical or latent infections or intoxications in humans, animals or plants, or analyzing microbial or toxin contamination of food, water, soil and air through detecting, isolating and identifying microbial or any other biological agents or toxins;

h) the term of vaccine shall cover a range of preparations, including killed, weakened or otherwise modified live micro-organisms or components obtained from microorganisms, including deactivated toxins and nucleic acids which, when introduced by any route into human or animal bodies, will induce in them a specific immune response acting as prophylaxis or protection against communicable diseases or intoxication, and generally effective and safe for people and/or animals;

i) the term of production shall describe a process through which biological agents are cultivated and reproduced using any means, e.g. synthesis, biosynthesis and the extraction of non-replicative biological agents or toxins;

j) the term of aerobiology shall cover the study of or work with aerosols containing biological agents and toxins or their simulants in facilities or in the open air;

k) the term of simulants of biological agents and toxins shall depict substances of biological, chemical or other origins whose characteristics make them usable for the research of properties encountered in the biological agents or toxins;

l) the term of handling the established highly hazardous and hazardous biological agents and toxins shall be understood to cover their development, production, use, acquisition, possession, import, export, transportation and disposal; the management of the established highly hazardous and hazardous biological agents and toxins shall not be considered a service as the service is defined in the Act on Free Movement of Services;

m) the term of declaration shall mean a written notification of data required to be communicated on the highly hazardous and hazardous biological agents and toxins, and on facilities and premises specified under d), e) and n), where such agents / toxins are handled;

n) the term of facility shall describe premises suitable to be used to develop, produce, stockpile and apply bacteriological (biological) and toxin weapons, particularly dynamic / static / explosive aerosol chambers, fermentors, bioreactors, self-sterilizable centrifuges, spray and drum dryers, anaerobic boxes, micro-encapsulation equipment, automated DNA sequencing equipment, automated DNA synthesizers, peptide sequencers and synthesizers, incubators, autoclaves, chambers used to rear insects and carriers;

o) the term of international inspector shall depict an authorized representative of an international organization 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 [1)] (only the "Convention" hereinafter) is duly observed;

p) the term of classified information shall describe a piece of information possibly misused to directly develop or produce a bacteriological (biological) or toxin weapon, highly hazardous agents or toxins;

r) the term of handling a classified piece of information shall cover gathering, providing or publishing such information, for consideration or free of charge.

Article 3

Governmental administration of the ban on bacteriological (biological) and toxin weapons

(1) The Government administers the ban on bacteriological (biological) and toxin weapons through the State Office for Nuclear Safety (only the "Office" hereinafter), an authority also acting as the National Agency responsible for the observance of the Convention.

(2) The Office

a) supervises the observance of ban on the bacteriological (biological) and toxin weapons;

b) supervises the management of highly hazardous and hazardous biological agents and toxins for compliance with this Act;

c) issues, modifies and cancels permissions to handle highly hazardous biological agents and toxins as envisaged in this Act;

d) keeps records on

1 the licensees granted licenses pursuant to this Act, and on

2 the natural persons and legal entities handling hazardous agents or toxins in accordance with Article 17;

e) keeps files on highly hazardous and hazardous biological agents, toxins and facilities, and makes a declaration on them;

(3) In pursuit of its supervisory activities the Office employs not only its own facilities but also reference laboratories earmarked to handle highly hazardous and hazardous biological agents and toxins as such premises are operated by the Ministry of Health and the Ministry of Defense.

SECTION II

BAN ON BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND THEIR PRODUCTION FACILITIES

Article 4

(1) It is prohibited to develop, produce, stockpile, possess, process, use, import, export, transport (incl. the transit transportation), deal in and in any other way handle bacteriological (biological) and toxin weapons and the classified information.

(2) It is prohibited to develop, produce, stockpile, posses, import, export, deal in and in any other way handle equipment used to manufacture bacteriological (biological) or toxin weapons and their carriers and/or to design, build and operate premises suitable for their manufacture.

Article 5

(1) Any person finding materials or articles reasonably suspected of being bacteriological (biological) or toxin weapons or containing highly hazardous agents or toxins, or being materials / articles possibly containing highly hazardous biological agents or toxins, or persons becoming aware of any cases of handling classified information, shall be obliged to forthwith report their findings to the Czech Republic Police or to the territorially competent Public Prosecutor's Office or to the Office.

(2) In case a facility / piece of equipment is found, the provisions of paragraph (1) shall apply.

(3) Whoever, in pursuit of their activities, incidentally isolates or detects highly hazardous biological agents or toxin without being granted by the Office the permission envisaged in Article 6, par. 1, shall be obliged to report this fact to the Office without any undue delay.

(4) The Office shall see to it that the materials / articles / equipment / facilities specified in paragraphs 1 through 3 are disposed of at the Government's expenses without any prejudice to the liability for damages as stipulated in special acts of legislation.

SECTION III

USING HIGHLY HAZARDOUS BIOLOGICAL AGENTS AND TOXINS

Article 6

Handling highly hazardous biological agents and toxins

(1) Highly hazardous biological agents and toxins can be handled within the Czech Republic solely when so licensed by the Office

a) to serve industrial, agricultural, research, health-care, pharmaceutical and any other peaceful purposes;

b) to achieve protective purposes directly related to the protection against bacteriological (biological) or toxin weapons;

c) to prevent, identify, diagnose and treat diseases caused by biological agents or toxins.

(2) A license granted by the Office in adherence to this Act shall not be a substitute for licenses issued according to special acts of legislation [2)].

(3) Whoever becomes aware of a loss of established highly hazardous biological agents or toxins or a damage done to a facility shall be obliged to report the fact to the Office without any undue delay.

Article 7

Licensing conditions for handling highly hazardous biological agents and toxins

(1) The Office shall grant a license for handling highly hazardous biological agents and toxins (only the "license" hereinafter) to a natural person or a legal entity on condition that

a) the person or the entity is domiciled in the Czech Republic;

b) natural persons positioned as statutory bodies or members of statutory bodies applying for the license are competent to perform acts in law and of unimpeachable character;

c) legal entities appoint their representatives responsible for proper performance of all activities associated with the licensed handling; such a representative shall be a person of unimpeachable character, competent to carry out acts in law, professionally qualified and not a member of Supervisory Board or any other surveillance body of the relevant legal entity; he/she may be positioned as a representative of only a single legal entity at a time.

d) natural persons applying for the license and their responsible representatives, if any are appointed, are persons of unimpeachable character, competent to perform acts in law and professionally qualified.

e) a license granted in conformity with Article 12, par. 3), letters a) and b) has not been canceled.

(2) Condition specified in paragraph (1), letter e), is not obligatory for legal entities and natural persons domiciled in a Member State of the European Union.

(3) If the facts specified under paragraph 1 undergo a change, the relevant legal entity shall be obliged to forthwith report the change to the Office.

(4) The provisions included in paragraphs 1 and 2 shall hold good for also the Governmental agencies and their assigned employees.

Article 8

Unimpeachability of character

(1) As the term is used herein, a person shall be considered of unimpeachable character if not conclusively sentenced for a negligence-related criminal offence whose factual content is in any way linked with the activity to be licensed, or for a criminal offence committed with intent.

(2) Documents accepted as a proof of character unimpeachability shall include:

a) an extract from Penal Register of a natural person; of a person positioned as a statutory body; of a member of a statutory body; and of a responsible representative of such persons, or possibly

b) another equivalent document on the unimpeachability of character issued by the relevant agency of the EU Member State of which the natural person; the statutory body; the member of statutory body; or the responsible representative is a national; in case the relevant agency does not issue such documents on principle, they can be replaced by an affidavit made before the relevant agency or a notary established in an EU Member State.

(3) To substantiate the unimpeachability of character, the Office, proceeding in accordance with a special act of legislation, shall apply for the extract from Penal Register. Both the application and the incoming extract itself shall change hands in the electronic form and in a manner making remote access possible.

Article 9
Professional qualification

Professionally qualified to carry out activities associated with handling highly hazardous biological agents and toxins shall be persons having accomplished university education in the relevant specialism and having terminated 3 years of relevant practice; the range of specialized educational programs shall be specified by the Office in an implementing legal regulation.

Article 10
Licensing application

(1) Specified in a written Licensing Application shall be:

a) business name or firm, registered office and identification number (only "ID" hereinafter) of a legal entity applying for the license; name, surname, Birth Number, citizenship and fixed address of a person or persons positioned as the entity's statutory body or its members;

b) name, surname, Birth Number, citizenship and address of a natural person applying for the license; name, surname, Birth Number, citizenship and address of the person's responsible representative, if any is established;

c) name of a highly hazardous biological agent or toxin, its quantity, purpose, the manner of handling and its final destination;

d) purpose for which highly hazardous biological agents or toxins are imported.

(2) Enclosed with the Licensing Application shall be:

a) a document proving professional qualification of the natural person and that of his/her responsible representatives;

b) engineering documentation, including construction plans; specifications of the premises and equipment therein installed; and the Final Inspection Decree (*a.k.a. occupancy permit* or *certificate of practical completion*);

c) a report approved by a public health-protection agency having authority over the site of envisaged activity in conformity with a special act of legislation [3)];

d) a declaration saying that no decision on bankruptcy has been announced against the legal entity's possessions and no petition for insolvency procedure has been dismissed for lack of funds, not sufficient to cover the cost of the insolvency proceedings;

e) other documents as possibly requested by the Office;

f) a document on the unimpeachability of character in case the applicant's unimpeachability of character is required to be supported by a document prescribed in Article 8, par. 2, letter b) - such document shall be enclosed with the application.

Article 11
Deciding on the License issue

(1) When deciding about the license application, the administrative procedure carried out by the Office shall be independent of proceedings instituted by any other administrative agency. The applicant shall be positioned as the sole participant in the procedure.

(2) The Office shall pass the resolution on the license within 90 days of when the procedure was commenced.

(3) The resolution document issued by the Office shall specify:

a) business name or firm, registered office, ID of the legal entity applying for the license; name, surname, Birth Number, citizenship and fixed address of a person or persons positioned as the entity's statutory body or its members;

b) name, surname, Birth Number, citizenship and address of a natural person applying for the license; name, surname, Birth Number, citizenship and address of the person's responsible representative, if any is established;

c) subject matter and scope of the handling license;

d) kinds and quantities of highly hazardous biological agents or toxins whose handling is being licensed;

e) conditions in which highly hazardous agents and toxins can be handled.

(4) The license is not required for rescue operations taken to avoid an emergency or for removal jobs conducted to remedy the consequences of an emergency; [4)] - such operations / jobs shall be forthwith reported to the Office.

(5) If the applicant fails to meet conditions specified herein, or provided that granting the application results in temporarily exceeding the overall quantities of highly hazardous biological agents or toxins at a Czech Republic site, the application shall be refused; the overall quantities of highly hazardous biological agents or toxins forbidden to be even temporarily exceeded shall be stipulated by the Office in an implementation legal regulation.

Article 12

Modified conditions; license change, revocation or expiration

(1) Facilities shall not undergo any modifications or other engineering or organizational changes having legal relevance without first being approved by the Office in response to the licensee's application.

(2) The Office may institute a change in the license

a) when so asked by the licensee in a duly substantiated request;

b) when the facts change that were used as a background for the license award.

(3) The Office shall revoke the license in case

a) the licensee has obtained it on the grounds of untrue or incomplete information;

b) the licensee fails to fulfill his/her obligations as established in this Act, or he/she does not remedy deficiencies identified by the Office;

c) the licensee's responsible representative ceases operating as such, and the licensee does not forthwith appoint a new responsible representative and does not ask the Office for a change in the license;

d) the licensee has ceased to meet conditions decisive for the license award or he/she asked that the license be revoked.

(4) The license shall become null and void

a) on the day when the legal entity winds up or the natural person dies or is declared dead;

b) when a bankruptcy petition is filed.

(5) Resolution on a change in the license or a revocation of it shall have no suspensive effect.

Article 13
Obligations of licensees

The licensees shall be obliged particularly:

a) to handle highly hazardous biological agents and toxins within what is permitted in the license;

b) to handle highly hazardous biological agents and toxins so that they cannot be abused or stolen;

c) to submit to the Office their declarations by specified deadlines;

d) to allow access to their facilities and provide information on the range of activities being currently pursued in them and on safety measures that the Office's inspectors / international inspectors / other persons invited by the Office to participate may need to conduct their examination activities;

e) to allow the inspectors to dispose round the facilities monitoring instrumentation required to follow highly hazardous biological agents and toxins and take their analytical samples;

f) to notify the Office without any undue delay in case that insolvency proceedings are initiated.

Article 13a
Transportation

The highly hazardous and hazardous biological agents or toxins can only be transported in dedicated packages in a manner specified in a special act of legislation [5a)].

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

(1) Highly hazardous biological agents and toxins can be exported from the Czech Republic solely by properly licensed persons / entities. This license does not replace a license issued in accordance with a special act of legislation [6)].

(2) The licensees are allowed to export highly hazardous biological agents and toxins only to the member states of the Convention, and exclusively for purposes specified in Article 6.

(3) The licensees are allowed to import highly hazardous biological agents and toxins only from the member states of the Convention, and exclusively for purposes specified in Article 6.

(4) Highly hazardous biological agents and toxins shall not be exported or imported in consignments addressed to depositories; to custom warehouses; to free custom warehouses; to free customs zones; or to addresses of any other persons than those specified in the license.

(5) Licensee granted the license pursuant to Article 11 shall see to it that every carrier assigned to transport highly hazardous biological agents within the Czech Republic or in its close vicinity cooperate with the customs authority charged to supervise or [6a)] inspect the consignment and will:

a) give the authority an authenticated copy of the relevant license granted by the Office;

b) report to the authority in writing all cases of entry or exit of the consignment to/from the Czech Republic - such report shall identify the licensee; quote the names and quantities of highly hazardous biological agents and toxins being transported; specify ID data on their recipient, the names of the exporting and importing countries, and the dates of the consignment entry or exit;

c) submit to the authority an authenticated copy of a license awarded in accordance to a special act of legislation, [6b)] or, in case such license is not required by law, the carrier shall present:

1 Sales Contract concluded by and between the exporter or the importer and their foreign contractual partners wherein the inspected highly hazardous biological agents or toxins are specified, including their quantities;

2 a declaration by the foreign end-user promising that the highly hazardous biological agents and toxins being exported will not be used to develop or manufacture biological weapons - their particular purpose and application shall be specified;

3 a declaration promising that highly hazardous biological agents or toxins will not be re-exported without first obtaining a re-export permission from the exporting country;

4 a declaration by the end-user accompanied by a written statement promising that the specified imported highly hazardous agents and toxins will be used solely for the permitted purposes.

Article 15
Canceled

Article 16

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

(1) The licensee shall be obliged to continually keep records of how the highly hazardous biological agents have been handled, and when so asked the licensee shall submit the records to the Office; the records shall be retained for 10 years from when the license for handling highly hazardous biological agents and toxins expires.

(2) The records shall be kept in consideration of the facility wherein the activity being recorded is pursued and in view of the different kinds and quantities of highly hazardous biological and toxins.

(3) When the license expires or is canceled, the licensee shall be obliged to pass to the Office all records on handling highly hazardous biological agents and toxins.

(4) The licensee shall submit to the Office the declaration covering the previous calendar year no later than on 31 January of the following year together with data expected for the ensuing calendar year until 31 August thereof.

(5) The declaration shall specify:

a) business name or firm, its registered office and ID as a legal entity; name, surname, Birth Number, citizenship and address of a person or persons positioned as the entity's statutory body or its members; for natural persons the declaration shall specify name, surname, Birth Number, citizenship and address;

b) kinds and quantities of highly hazardous biological agents or toxins;

c) facilities wherein the activity being thus declared is conducted.

(6) Detailed requirements for how the records should be kept and what items of information they should contain will be specified by the Office in the relevant implementing legal regulation.

SECTION IV

USING HAZARDOUS BIOLOGICAL AGENTS and TOXINS

Article 17

Hazardous biological agents and toxins

(1) Natural persons or legal entities handling hazardous biological agents or toxins specified in Article 2, letter e), shall be obliged to declare to the Office data concerning the past calendar year no later than on 31 January of the next year together with data expected for the ensuing calendar year always until 31 August thereof.

(2) The declaration shall specify:

a) business name or firm, its registered office and ID as a legal entity bound by the reporting duty and name, surname, Birth Number, citizenship and address of a person or persons positioned as the entity's statutory body or its members; for natural persons the declaration shall specify name, surname, Birth Number, citizenship and address of the person bound by the reporting duty pursuant to paragraph 1;

b) kinds and quantities of highly hazardous biological agents or toxins;

c) facilities wherein the activities being thus declared are conducted.

(3) In case a natural person or a legal entity intended to handle hazardous biological agents or toxins for the first time, or if it happens that the data expected for the subsequent calendar year change, the person / entity shall be obliged to report the intention no later than 14 days before such handling or change happen.

(4) The reporting duty shall apply to also the installation of new facilities / devices.

(5) In the event that data expected for the next calendar year are supposed to undergo a change, natural persons or legal entities specified in Article 17, par. 1, shall be obliged to report the change no later than 14 days before the change materializes.

(6) Records kept on hazardous biological agents and toxins shall also be governed by analogy with Article 16.

(7) Hazardous biological agents and toxins can only be imported and exported in accordance with the related special act of legislation, in the scope and under conditions therein specified.

(8) Legal entities or natural persons shall see to it that their carriers of hazardous biological agents or toxins assigned to transport the substances from / to the Czech Republic cooperate with the customs authorities in their supervision or [6a)] inspections of the consignments, and that they shall:

a) submit to the authority an authenticated copy of the relevant license granted by the Office;

b) report to the authority in writing all cases of entry or exit of the consignment to/from the Czech Republic - such report shall identify the legal entity or the natural person; quote the names and quantities of hazardous biological agents and toxins being transported; specify ID data on their recipient, the names of the exporting and importing countries, and the dates of the consignment entry or exit;

c) submit to the authority an authenticated copy of a license awarded in accordance with a special act of legislation, [6b)] or, in case such license is not required by law, the carrier shall present a Sales Contract concluded by and between the exporter or the importer and their foreign contractual partners wherein the inspected hazardous biological agents or toxins are specified, including their quantities, particular purpose and application.

SECTION V

SUPERVISING THE ACT'S OBSERVANCE

Article 18

Supervision

(1) The Office shall supervise the observance of this Act and other legal regulations that the Act may entail (only the "supervision" hereinafter).

(2) The Office shall supervise:

a) persons licensed to handle highly hazardous biological agents or toxins according to Article 11;

b) persons handling hazardous biological agents or toxins according to Article 17;

c) persons justifiably suspected of handling highly hazardous biological agents or toxins without being licensed to do so;

(3) The supervision shall be carried out by the Office's chairperson and inspectors (only the "inspectors" hereinafter); the inspectors shall be appointed to their positions and suspended from them by the Office's chairperson;

Article 19

Cooperating with ministries and other administrative agencies

(1) Ministries and other administrative agencies shall notify the Office forthwith of epidemics and infections encountered in people, animals and plants and suspected to be caused by leaks of highly hazardous biological agents or toxins or by their abuse; acting within their own scopes of responsibility, the ministries / agencies shall take measures to ensure early detection of the agents and toxins and to minimize their leaks.

(2) In January and July the customs authorities shall give the Office information specified in Article 14, par. 5, and Article 17, par. 8, as always applicable to the six previous months. Should the customs authorities reveal any deficiencies in the activities of persons inspected pursuant to Article 14 or Article 17, they shall be obliged to detain the highly hazardous or hazardous biological agents or toxins being transported, and to notify the Office immediately.

Article 20

Remedial measures

In case the chairperson or the inspectors of the Office disclose any deficiencies in the activities of inspected persons, they shall proceed in consideration of the deficiency and either

a) require that the inspected person remedies the deficiency within an agreed span of time, or

b) order the inspected persons to carry out technical checks, reviews or tests of operational capability of their installation, its parts, systems or assemblies.

Article 21

Penalties, their imposition and other sanctions

(1) The Office may impose penalties as high as

a) CZK 100 million on those who disrespect the ban on development, production, stockpiling and use of bacteriological (biological) and toxin weapons;

b) CZK 50 million on a person handling the specified highly hazardous biological agents and toxins without being authorized by the Office to do so;

c) CZK 5 million on a licensee found in breach of duties specified in Article 16 or the ban specified in Article 12, par. 1;

d) CZK 10 million on a person found in breach of duties specified in Article 14;

e) CZK 5 million on a person found in breach of duties specified in Article 5, par. 3, or Article 17;

f) CZK 200 thousand on persons positioned as statutory bodies or their members and to the responsible representative, and CZK 100 thousand on employees of the inspected person / entity for misrepresenting or concealing facts important for the process of supervision or for failing to offer cooperation in the supervisory activities, or on persons failing in their duty specified in Article 5, par. 1 and par. 2.

(2) Such penalties can be imposed within 3 years of the date when the Office disclosed the breach of duties, but no later than in 10 years of when the breach of duty occurred.

(3) When deciding on the penalty fee, the Office shall consider the gravity, importance and duration of the illicit conduct and the scope of its consequences; moreover, it shall take into account whether the offender offered timely and effective cooperation in remedying the misconduct. In case a breach of duty is remedied immediately after it has been disclosed and the Office is lent effective assistance and no harm is done to persons or the environment, the Office may decide to waive the penalty.

(4) The penalties are collected and enforced by the Office and added to the state budget as its income.

(5) The imposed penalties are collected in conformity with special acts of legislation [9)].

(6) Penalties imposed pursuant to paragraph 1 shall not make it impossible to proceed in accordance with Article 12, par. 3, letters a) and b), and Article 20.

SECTION VI

GENERAL, TEMPORARY and FINAL PROVISIONS

Article 22

(1) The Office shall release decrees aimed to implement Article 2, letters d) and e); Article 11, par. 5; and Article 16, par. 6.

(2) Unless this Act stipulates otherwise, proceedings instituted pursuant hereto shall follow the rules of administrative procedure.

(3) Legal entities and natural persons engaged in activities regulated by this Act in adherence to the current regulations shall submit to the Office their license application and reporting declaration no later than 1 month from when this Act assumes effectivity.

(4) With the reporting duty fulfilled, the right of handling the hazardous biological agents and toxins shall be retained.

(5) Legal entities or natural persons who, on the date when this Act became effective, handled highly hazardous biological agents or highly hazardous toxins in conducting business based on a trade license, may continue to do so for no longer than 6 months from when this Act assumed effectivity.

(6) Legal entities or natural persons who, on the date when this Act became effective, handled hazardous biological agents or hazardous toxins in conducting business based on a trade license, may continue to do so for, provided they satisfy the reporting obligation imposed upon them in Article 17 within 14 days from when this Act assumed effectivity.

PART II

Amendments to the Trades Licensing Act

Article 23

Act 455/1991 Coll., on trade-licensed enterprising (the Trades Licensing Act) as amended by Act 231/1992 Coll., Act 591/1992 Coll., Act 600/1992 Coll., Act 273/1993 Coll., Act 303/1993 Coll., Act 38/1994 Coll., Act 42/1994 Coll., Act 136/1994 Coll., Act 200/1994 Coll., Act 237/1995 Coll., Act 286/1995 Coll., Act 94/1996 Coll., Act 95/1996 Coll., Act 147/1996 Coll., Act 19/1997 Coll., Act 49/1997 Coll., Act 61/1997 Coll., Act 79/1997 Coll., Act 217/1997 Coll., Act 280/1997 Coll., Act 15/1998 Coll., Act 83/1998 Coll., Act 157/1998 Coll., Act 167/1998 Coll., Act 159/1999 Coll., Act 356/1999 Coll., Act 358/1999 Coll., Act 360/1999 Coll., Act 363/1999 Coll., Act 27/2000 Coll., Act 29/2000 Coll., Act 121/2000 Coll., Act 122/2000 Coll., Act 123/2000 Coll., Act 124/2000 Coll., Act 149/2000 Coll., Act 151/2000 Coll., Act 158/2000 Coll., Act 247/2000 Coll., Act 249/2000 Coll., Act 258/2000 Coll., Act 309/2000 Coll., Act 362/2000 Coll., Act 409/2000 Coll., Act 458/2000 Coll., Act 61/2001 Coll., Act 100/2001 Coll., Act 120/2001 Coll., Act 164/2001 Coll., Act 256/2001 Coll., Act 274/2001 Coll., Act 477/2001 Coll., Act 478/2001 Coll., Act 501/2001 Coll., Act 86/2002 Coll., Act 119/2002 Coll. a Act 174/2002 Coll., the full stop used at Article 3, par. 3, at the end of letter ae) shall be replaced by a comma and the af) letter, together with a footnote #23m, worded as follows:

"af) handling of highly hazardous and hazardous biological agents and toxin. [23m)]

[23m)] Act 281/2002 Coll., on Some Measures Related to a Ban on Bacteriological (Biological) and Toxin Weapons and on Amendments to the Trades Licensing Act.".

PART III

EFFECTIVENESS

Article 24

This Act of law shall become effective on the day of its promulgation with the exception of Article 7, par. 2 and Article 8, par. 2, letter b) - the two latter items shall enter into force on the day when the Treaty on Accession of the Czech Republic to the European Union assumes effectivity.

Klaus (*autograph*)

Havel (*autograph*)

(*by proxy*) Rychetský (*autograph*)

Article XLV of Act 223/2009 Coll.

Temporary provision

Proceedings started before this Act assumed effectivity and not finished by that day shall be finalized and the rights and obligations they entail shall be assessed in adherence to the hitherto legal regulations.

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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 published under No. 96/1975 Coll.

2) For example Act 258/2000 Coll. on Public Health Protection and Amendment to Several Related Acts, as amended.

2a) Act 269/1994 Coll., on Penal Register, as amended.

3) For example Decree 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.)

4) Act 239/2000 Coll., on the integrated rescue system and on amendments to certain acts.

5a) For example the European Agreement on international highway transport of dangerous goods (ADR) concluded in Geneva on 30 September 1957, promulgated under 4/1987 Coll., as later modified by Amendments 159/1997 Coll. No. 186/1998 Coll. No. 54/1999 Coll. No. 93/2000 Coll. of International Treaties, No. 6/2002 Coll. of I. T. and No 65/2003 Coll. of I.T.

6) Act 21/1997 Coll., on the control of exports and imports of goods and technologies subject to international control regimes.

6a) Art. 4/13 of Council Regulation 2913/92 of 12 October 1992 establishing the Community Customs Code, as amended.

6b) For example Act 21/1997, on the control of exports and imports of goods and technologies subject to international control regimes.

9) For example Act 337/1992 Coll., on the administration of taxes and fees, as later amended.