ACT No. 281/2002 Coll.

of 30 May 2002

on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act

The Parliament has passed this Act of the Czech Republic:

PART I

MEASURES RELATED TO PROHIBITION OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS

SECTION ONE

INTRODUCTORY PROVISIONS

Article 1

Scope

This Act regulates:

a) rights and obligations regarding the prohibition of the development, production, stockpiling and use of bacteriological (biological) and toxin weapons and on their destruction, handling of highly hazardous ad hazardous biological agents and toxins which could be abused to violate the prohibition of bacteriological (biological) and toxin weapons;

b) performance of governmental administration in this field.

Article 2

Basic Terms

For the purposes of this Act

a) bacteriological (biological) and toxin weapons means

1. weapons, the damaging effects of which are based on the properties of biological agents and toxins; specifically designed to cause disease, death, to harm and incapacitate human beings, animals or plants or which can cause economic damage;

2. materials containing biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

3. any devices, equipment or means of delivery designed to use or to be loaded with such biological agents or toxins; or weapons specifically constructed to use or to be loaded with such biological agents or toxins for hostile purposes or in armed conflict; or vectors of biological agents deliberately infected for hostile purposes or in armed conflict;

b) biological agent means any naturally occurring or modified organism, the deliberate use of which can cause death, disease, harm and incapacitate human beings, animals or plants;

c) toxin means toxic material including micro organisms, animals or plants, whatever its origin or method of production, naturally occurring, modified or chemically synthetized which can cause death, disease, harm and incapacitate human beings, animals or plants;

d) highly hazardous biological agents or toxins means such biological agents or toxins that have the capability to be used as a weapon; the list of which is set out in the regulation;

e) hazardous biological agents or toxins means such biological agents or toxins that can be handled on specific occasions and the list of which is set out in the regulation;

f) facilities with high biological containment (BL-3 - WHO classification) and maximum biological containment (BL-4 - WHO classification) means any room or suite of rooms, laboratory(ies) or other buildings or structures which meet(s) the requirements specified in the Czech standard EN 12128 Biotechnology - Laboratories for research, development and analysis - Bio safety in Microbiological laboratories, hazard zones, rooms and technical safety requirements;

g) diagnostic facility means facility which tests samples for the purpose of diagnosis of sub clinical, clinical, or latent infection or intoxication in humans, animals or plants; or for the purpose of analysis of microbial or toxin contamination in food, water, soil and air by means of detection, isolation, and/or identification of microbial or other biological agents or toxins;

h) vaccine means preparations, including killed, live-attenuated, or otherwise modified micro organisms or components obtained from organisms, including inactivated toxins and nucleic acids, which, when introduced by any routes into a human being or animal, induces in it a specific immune response for prophylaxis or protection against infectious disease(s) or intoxication and generally safe for human beings and/or animals;

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

j) aerobiology means the study of or work with aerosols of materials comprising biological agents and toxins or simulants in a facility or open air;

k) simulants of biological agents and toxins means substances of biological, chemical or other origin which, due to their characteristics are used to carry out research of the properties of biological agents or toxins;

l) handling of stipulated highly hazardous biological agents and toxins means their development, production, use, acquisition, possession, import, export, transportation including transit and their destruction;

m) declaration means a notice in the written form containing prescribed information on highly hazardous and hazardous biological agents and toxins and objects and facilities specified in points d), e) and n) in which they are handled;

n) facilities means facilities usable for the development, production, stockpiling and use of bacteriological (biological) and toxin weapons, in particular dynamic, static or explosive aerosol chambers, fermenters, bioreactors, self-sterilizable centrifuges, spray and drum dryers, anaerobic boxes, micro encapsulation equipment, automatic DNA sequencing equipment, automatic DNA synthesizers, automatic peptide sequencing equipment, automatic peptide synthetizers, incubators, autoclaves, cabinets/chambers designed or used for rearing insects and carriers;

o) international inspector means an individual designated by international organizations carrying out inspection activities over observance of 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)]

p) prohibited information means information, enabling direct development, production and stockpiling of bacteriological (biological) and toxin weapons, highly hazardous biological agents or toxins;

r) handling of prohibited information means gathering, providing or publishing of prohibited information with or without consideration.

Article 3

Governmental Administration in the Field of Observance of the Bacteriological (Biological) and Toxin Weapons Prohibition

(1) Governmental administration in the field of the observance of bacteriological (biological) and toxin weapons prohibition is performed by The State Office for Nuclear Safety (hereinafter referred to as "the Office") which is also The National Office responsible for the observance of the Convention.

(2) The Office

a) is responsible for supervision of the observance of bacteriological (biological) and toxin weapons prohibition;

b) is responsible for supervision of highly hazardous biological agents and toxins handling pursuant to this Act;

c) issues, alters and cancels decisions on the handling of highly hazardous biological agents and toxins licensing pursuant to this Act;

d) keeps records

1. of holders of licences issued pursuant to this Act, and

2. of those natural persons and legal entities which handle highly hazardous biological agents or toxins pursuant to Article 17;

e) keeps records of highly hazardous and hazardous biological agents, toxins and facilities and elaborates a declaration thereof.

(3) During supervision the Office uses reference laboratories for highly hazardous and hazardous biological agents or toxins operated by the Ministry of Health and the Ministry of Defence in addition to its own facility.

SECTION TWO

PROHIBITION OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND FACILITIES USED FOR THEIR PRODUCTION

Article 4

(1) It is prohibited to develop, produce, stockpile, possess, process, use, consume, import, export, transport and transfer, trade in and otherwise handle bacteriological (biological) and toxin weapons and handle prohibited information.

[1)] the 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) It is prohibited to develop, produce, stockpile, possess, import, export, trade in and otherwise handle facilities for the bacteriological (biological) and toxin weapons and the carriers thereof or to design, build and use operational premises for the production thereof.

Article 5

(1) Any person who finds material or article which he believes to be a bacteriological (biological) or toxin weapon or to contain highly hazardous biological agents or toxins or where there is any suspicion of handling of prohibited information, shall be required to report the matter forthwith to the Police of the Czech Republic or to the territorially competent Public Prosecutor's Office and to the Office.

(2) In case of finding a facility, the provisions of paragraph (1) shall apply.

(3) Any person who does not hold the licence issued by the Office pursuant to Article 6 (1) and isolates or detects highly hazardous biological agents or toxins by chance shall be required to report the matter forthwith to the Office.

(4) The Office is responsible for disposal of materials, articles and facilities laid down in paragraphs (1) to (3). Appropriate expenses are reimbursed by the state. This is without prejudice to the damage liability governed by separate regulations.

SECTION THREE

USE OF HIGHLY HAZARDOUS BIOLOGICAL AGENTS AND TOXINS

Article 6

Handling of Highly Hazardous Biological Agents and Toxins

(1) Handling of highly hazardous biological agents and toxins on the Czech Republic territory shall be possible only with licence issued by The Office

a) for industrial, agriculture, research, medical, pharmaceutical and other peaceful purposes;

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

c) for the prevention, identification, diagnosis and treatment of diseases caused by biological agents or toxins;

d) for the transit thereof pursuant to Article 15.

(2) The licences issued by the Office under this Act do not substitute licences issued pursuant to separate regulations.[2])

(3) Any person who determines a loss of stipulated highly hazardous biological agents or toxins or damage of facilities shall be required to report the matter to the Office without delay.

[2)] Such as Act No. 258/2000 Coll. on Protection of Public Health and Amendment to Some Related Acts; as Subsequently Amended.

Article 7

Licensing Conditions for Handling of Highly Hazardous Biological Agents and Toxins

(1) The Office shall issue licence for handling of highly hazardous biological agents and toxins (hereinafter referred to as "licence") to the natural person or legal entity on condition that

a) a legal entity has its seat or a natural person has place of residence on the territory of the Czech Republic;

b) members of a statutory body or representatives of a legal entity to whom the licence is to be issued must have reached the age of 21, be competent to perform legal acts and be persons of probity;

c) it appoints its responsible representative, responsible for the proper performance of practices related to the licensed handling; responsible representative must be competent to perform legal acts, be a person of probity and professionally qualified; he cannot be member of this legal entity's supervisory board or another control body; the responsible representative may exercise his function only for one legal entity;

d) the natural person to whom the licence is to be issued, and his responsible representative, if any, have reached the age of 21, are competent to perform legal acts, are persons of probity and professionally qualified;

e) if the licence pursuant to the Article 12 (3) (a) and (b) was not terminated;

(2) It is not required of legal entities with a seat and of natural persons with a place of residence on the territory of a European Union member state to comply with the condition under paragraph 1 (a).

(3) A legal entity shall communicate to the Office without delay any changes that may occur in the facts specified in paragraph (1);

(4) The provisions of paragraphs (1) and (2) shall also apply to the state organizational components and to authorized employees thereof.

Article 8

Probity

(1) For the purpose of this Act, a person is considered to be of probity, if he has not been legally sentenced for a criminal offence involving negligence, where the facts of the case are associated with licensed activities, or for a criminal offence committed with intent.

(2) As a document proving probity serves

a) an extract from the Crimes Register of a natural person who is member of a statutory body and an extract from the crimes register of a responsible representative; or

b) analogous document proving probity issued by an appropriate body of the European Union member state of which a natural person, statutory body or responsible representative is a national; in countries where these official bodies do not issue such a document, an affidavit made before a notary public of the European Union member state should be obtained.

Article 9

Professional Qualification

Professional qualification for practices related to handling of highly hazardous biological agents and toxins means a university graduate in the respective field of specialisation and a minimum of three years on-job experience in the field; the respective fields of specialization shall be set forth in an implementing regulation issued by the Office.

Article 10

Licence Application

(1) A written licence application shall contain:

a) business firm or a name, seat, registration number in the Companies Register of a legal entity applying for the licence, name and surname, birth registration number, citizenship, permanent residential address of person or persons who constitute its statutory body;

b) for a natural person: name and surname, birth registration number, citizenship and residential address, name and surname, birth registration number, citizenship and residential address of a responsible representative, if appointed;

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

d) purpose of import or export of highly hazardous biological agents or toxins;

(2) The following documents shall be attached to a licence application:

a) a document proving probity pursuant to Article 8 (2), that must not be older than 3 months;

b) a document proving professional qualification of a natural person and professional qualification of responsible representatives;

c) technical documentation including building construction plan, operational premises and installed equipment specification and an occupancy permit;

d) a report approved by the public health protection authority appropriate to the place of activity pursuant to separate regulation; [3])

e) several variants of proposed place of entry in the Czech Republic and place of exit from the Czech Republic in the event of a licence application for transit of highly hazardous biological agents or toxins ;

f) declaration that the bankruptcy of a legal entity has not been adjudicated or that bankruptcy has not been refused due to a lack of assets;

g) other documents depending on the Office requirements.

Article 11

Decision on Licence Issue

(1) In administrative proceedings, the Office shall proceed independently of the

[3])Such as 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.

proceedings of any other administrative body. The applicant shall be the only participant in the proceeding.

(2) The Office shall take a decision on the issue of a licence within 60 days from commencement of licence proceedings.

(3) In a decision on the issue of a licence, the Office shall specify

a) business firm or a name, seat, registration number in the Companies Register of a legal entity applying for the licence, name and surname, birth registration number, permanent residential address of person or persons who constitute its statutory body;

b) name and surname, birth registration number and residential address of a natural person, and name and surname, birth registration number and residential address of a responsible representative, if appointed;

c) the subject and scope of the handling practices being licensed;

d) type and quantity of highly hazardous biological agents or toxins the handling of which is being licensed;

e) conditions for the handling of highly hazardous biological agents or toxins;

f) the period for which a licence is issued.

(4) A licence is not required for relief work averting an emergency situation or for liquidation of emergency situation consequences;[4]) such actions shall be communicated to the Office without delay.

(5) An application shall be dismissed if the applicant fails to comply with the conditions of this Act or if the total amount of highly hazardous biological agent or toxin within a certain period of time on the Czech Republic territory would be exceeded; the total amount of highly hazardous biological agent or toxin within a certain period of time on the Czech Republic territory which must not be exceeded, shall be set forth in an implementing regulation issued by the Office.

Article 12

Modification of Conditions, Alteration, Cancellation and Expiration of Licence

(1) Without a previous written approval provided by the Office based on the application of a licensee, no installation modifications or other technical or organisational changes impacting provisions of this Act may be performed.

(2) The Office may decide to modify the licence

a) on the basis of a well-justified application of a licensee;

b) in the event of a change in the facts on the basis of which the licence has been issued.

(3) The Office shall withdraw the licence if

a) the licensee acquired it on the basis of false or incomplete statements;

b) the licensee fails to fulfil his obligations as established in this Act or does not remove deficiencies identified by the Office;

[4]) Act No. 239/2000 Coll., on Integrated Rescue System and on Amendments to Certain Acts

c) the responsible representative of the licensee ceases to perform his function and the licensee does not appoint without delay another responsible representative and does not apply at the Office for the licence alteration;

d) the licensee has ceased to fulfil the obligations on the basis of which the licence has been issued or has applied in writing for a withdrawal.

(4) A licence shall terminate

a) on the date a legal person ceases to exist or in case of a natural person, if a natural person dies or is declared to be dead;

b) upon adjudication of bankruptcy;

c) on expiry of the period for which it was issued;

(5) The Alteration or Cancellation Decision does not have suspensory effect.

Article 13

Obligations of Licensees

A licensee is in particular obliged to

a) handle highly hazardous biological agents and toxins in the scope appropriate to the particular licence;

b) handle highly hazardous biological agents and toxins in such a manner that they cannot be misused or stolen;

c) submit a declaration to the Office within set time limits;

d) allow access to a facility, conduct training on the scope of activities conducted in a facility and on security measures required for the inspection activities performed by the Office's inspectors, international inspectors and persons called upon by the Office;

e) allow inspectors to place monitoring devices to monitor highly hazardous biological agents and toxins and to collect samples for analysis;

f) transport highly hazardous biological agents and toxins only in special transport packaging and in a manner laid down by separate regulation,[5])

g) inform the Office without undue delay of adjudication of bankruptcy or refusal of bankruptcy due to a lack of assets.

Article 14

Export and Import of Highly Hazardous Biological Agents and Toxins

(1) Highly hazardous biological agents and toxins may be exported from or imported to the Czech Republic only by a licensee. The licence does not substitute a licence or authorisation issued under separate regulation.[6])

[5]) Such as Decree No. 64/1987 Coll., on the European Agreement on International Highway Transport of Dangerous Goods (ADR).

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

(2) A licensee may export highly hazardous biological agents and toxins only to the Member States of the Convention and for the purposes laid down in Article 6.

(3) A licensee may import highly hazardous biological agents and toxins only from the Member States of the Convention and for the purposes laid down in Article 6.

(4) It is prohibited to export and import highly hazardous biological agents and toxins in the form of consignments addressed to a depository, customs warehouse, free customs warehouse, free customs zone or to the address of any person other than specified in a licence.

Article 15

Transit of Highly Hazardous Biological Agents and Toxins

(1) Transit of highly hazardous biological agents and toxins through the territory of the Czech Republic is only possible on the basis of a licence issued by the Office, with the place of entry in the Czech Republic and the place of exit from the Czech Republic specified therein.

(2) Before crossing the border, the transporter holding the licence issued by the Office is obliged to report the entry in the Czech Republic and the exit from the Czech Republic to the border Customs Office.

Article 16

Records Keeping and Declaration of Highly Hazardous Biological Agents and Toxins

(1) A licensee shall keep records associated with handling of highly hazardous biological agents and toxins and shall submit them on request to the Office; the records are archived for 10 years after the expiration of the licence for handling of highly hazardous biological agents or toxins.

(2) The records are kept according to the facility wherein the recorded activity is being conducted, the type and quantity of particular highly hazardous biological agents or toxins.

(3) Upon the expiration or cancellation of the licence the licensee shall pass the records associated with handling of highly hazardous biological agents or toxins to the Office.

(4) A licensee shall submit to the Office a declaration for the previous calendar year not later than January 31 of the following year and the anticipated data for the following calendar year until August 31.

(5) A declaration shall contain the following information

a) business firm or a name, seat, legal entity's registration number in the Companies Register, name and surname, birth registration number, citizenship, residential address of person or persons who constitute its statutory body or name and surname, birth registration number, citizenship and residential address of a natural person;

b) type and quantity of highly hazardous biological agents or toxins;

c) facilities wherein the declared activity is being performed.

(6) Particulars on records keeping and the data contained in a declaration shall be set forth in an implementing regulation issued by the Office.

SECTION FOUR

USE OF HAZARDOUS BIOLOGICAL AGENTS AND TOXINS

Article 17

Hazardous biological agents and toxins

(1) A natural person or legal entity who handles highly hazardous biological agents or toxins specified in Article 2 (e), shall in the form of a declaration report to the Office data for the previous calendar year until January 31of the following year and the anticipated data for the following calendar year until August 31.

(2) A declaration shall contain the following information

a) business firm or a name, seat, registration number in the Companies Register of a legal entity which has a reporting duty, name and surname, birth registration number, citizenship, residential address of person or persons who constitute its statutory body or name and surname, birth registration number, citizenship and residential address of a natural person which has a reporting duty pursuant to paragraph 1.

b) type and quantity of highly hazardous biological agents or toxins;

c) facilities wherein the reported activity is to be performed.

(3) If a natural person or legal entity intends to handle hazardous biological agents or toxins for the first time or in the event that changes occur in anticipated data for the following calendar year, the natural person or legal entity shall perform its reporting duty not later than 14 days before the handling or the changes occur.

(4) A reporting duty shall apply also to the installation of new devices.

(5) In the event that changes occur in anticipated data for the following calendar year, a natural person or a legal entity stated in Article 17 (1) shall perform its reporting duty no later than 14 days before the changes occur.

(6) For keeping records of hazardous biological agents and toxins the provisions under Article 16 shall apply analogously.

(7) Import and export of hazardous biological agents and toxins is only possible on the basis of, within the scope and under the conditions stipulated by a separate regulation.[6])

SECTION FIVE

SUPERVISION OF THE COMPLIANCE WITH THE ACT

Article 18

Supervision

(1) The Office shall perform supervision of the compliance with this Act and subsequent regulations issued pursuant to it (hereinafter referred to as “supervision”).

(2) The Office shall perform supervision

a) over persons who have been granted a licence for handling of highly hazardous biological agents or toxins under Article 11;

b) over persons who handle highly hazardous biological agents or toxins under Article 17;

c) over persons, who are under a well-founded suspicion, that they handle highly hazardous biological agents and toxins without a licence;

(hereinafter referred to as "the inspected persons").

The Office shall also perform supervision over keeping records and submitting declarations from the timeliness and correctness point of view.

(3) The supervision is performed by the Chairman of the Office and the inspectors of the Office (hereinafter referred to as "the inspectors"); the inspectors shall be appointed by the Chairman of the Office.

(4) The Chairman of the Office and the inspectors are authorised to

a) enter operational premises and facilities of the inspected persons and perform inspection therein, request explanations from the employees of the inspected persons, check appropriate documentation, collect and analyze samples and perform other operations, necessary for the purposes of supervision;

b) request information and documents including those subject to trade secret or industrial rights protection, if necessary for the purposes of supervision;

(5) The Chairman of the Office and the inspectors are not obliged to announce a commencement of supervision to the inspected person.

(6) The inspected person shall have the right to retain part of the collected samples and be present at the analysis thereof either on the place or at a control laboratory; such right shall not be enjoyed by a person who handles highly hazardous biological agents or toxins illegally.

(7) Should the Chairman of the Office and the inspectors discover that the inspected person handles highly hazardous biological agents or toxins without a licence or performs activities violating the prohibition of bacteriological (biological) and toxin weapons, they shall report the matter forthwith to the Police of the Czech Republic or to the territorially competent Public Prosecutor's Office.

(8) If, in order to prove the compliance with the provisions of this Act and international treaties which are legally binding on the Czech Republic, the inspectors require submitting data and documentation subject to classified information or trade secret protection, such data may be conveyed under the conditions stipulated by a separate regulation.[7])

(9) Unless otherwise stated in this Act, the procedure for inspection activities shall be governed by a separate regulation.[8])

[7]) Such as Act No. 148/1998 Coll., on Protection of Classified Information and on Amendment to Certain Acts; as Subsequently Amended. Act No. 513/1991 Coll., Commercial Code, as Subsequently Amended.

[8]) Act No. 552/1991 Coll., on state inspection, as Subsequently Amended.

Article 19

Cooperation with Ministries and Other Administrative Bodies

(1) Ministries and other administrative bodies shall without delay inform the Office of epidemics and infectious diseases in humans, animals and plants under suspicion that they originate from the highly hazardous biological agents or toxins release or misuse thereof, and they shall take measures for early detection and release restriction thereof within the scope of their competencies.

(2) Ministries and other administrative bodies shall, on request, convey to the Office data, necessary for the performance of supervision.

Article 20

Remedial Measures

(1) Should the Chairman of the Office and the inspectors identify deficiencies of activities of the inspected person, they are authorised, depending on the nature of the identified discrepancy, to

a) require the inspected person to remedy the situation, within a set time period; or

b) charge the inspected person to perform technical inspections, reviews or testing of function condition of the installation, its parts, system or its assemblies.

(2) The Office is authorised, in the event of a hazard arising from delay or an occurrence of undesirable situations with an impact on safety, to issue a provisional measure imposing on the inspected person the obligation to reduce or suspend handling of highly hazardous biological agents and toxins.

Article 21

Penalties, imposing thereof and other sanctions

(1) The Office shall impose a penalty, up to the sum of

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

b) CZK 50 million on a person who have been handling stipulated highly hazardous biological agents and toxins without a licence issued by the Office;

c) CZK 5 million on a licensee violating obligations set forth in Article 16 or a prohibition set forth in Article 12 (1);

d) CZK 10 million on a person violating obligations set forth in Articles 14 and 15;

e) CZK 5 million on a person violating obligations set forth in Article 5 (3) or in Article 1;

f) CZK 200,000 on persons who are members of a statutory body and to a responsible representative, and CZK 100,000 on employees of an inspected person for distortion or concealment of facts important for performance of an inspection or for non-cooperation

during an inspection or on persons who have not fulfilled the obligation set forth in Article 5 (1) and (2);

(2) A penalty may be imposed within three years after the date on which the Office identified the violation of an obligation, but no later then 10 years after the occurrence of the violation.

(3) The amount of the penalty shall reflect the seriousness, significance and time period of the illegal activity and the extent of consequences that were caused, and early and efficient cooperation in removing the deficiencies; in the event that the deficiencies are removed immediately following the identification of the breach of the obligations and the Office has been provided with efficient cooperation, and neither persons nor the environment have suffered any damage, the Office may decide to refrain from imposing a penalty.

(4) Penalties are collected and exacted by the Office. Penalties shall constitute an income to the State budget.

(5) The exaction of imposed penalties shall be governed by separate regulations.[9])

(6) Imposing penalties pursuant to paragraph 1 does not obstruct the proceedings pursuant to Article 12 (3) (a) and (b) and Article 20 (1) and (2).

SECTION SIX

GENERAL, TEMPORARY AND FINAL PROVISIONS

Article 22

(1) The Office shall issue regulations to implement Article 2 (d) and (e) and Articles 9, 11 (5) and Article 16 (6).

(2) Proceedings under this Act shall be governed by Administrative Procedure Code, unless otherwise specified by this Act.

(3) Pursuant to this Act, natural persons or legal entities performing activities regulated by this Act in accordance with hitherto regulations shall submit a licence application as well as perform their reporting duty by submitting a declaration to the Office no later than 1 month from the date on which this Act enters into force.

(4) By performing a reporting duty the right to handle hazardous biological agents and toxins shall be preserved.

(5) Legal entity or natural person who has been handling highly hazardous biological agents or highly hazardous toxins on the basis of a trade licence prior to the date of this Act entering into force, can continue in performing its business activities within 6 months from the date on which this Act enters into force at the latest.

(6) Legal entity or natural person who has been handling highly hazardous biological agents or highly hazardous toxins on the basis of a trade licence prior to the date of this Act entering into force, can continue in performing its business activities on condition of complying with the reporting duty pursuant to Article 17.

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[9]) Such as Act No. 337/1992 Coll., on Administration of Taxes and Fees, as Subsequently Amended.

PART II

AMENDMENTS TO TRADES LICENSING ACT

Article 23

Act No. 455/1991 Coll., on engaging in a trade (the Trades Licensing Act), in the wording of Act No. 231/l992 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/l997 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/l999 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; in Article 3(3), at the end of subparagraph (ae) the full stop shall be substituted by a comma and a new point (af) shall be added thereto, which, together with the footnote No.23m), shall read as follows:

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

[23m]) Act No. 281/2002 Coll., on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act

PART III

EFFECTIVENESS

Article 24

This Act shall enter into force on the day of its promulgation except for the provisions under Article 7 (2) and Article 8(2) (b), which shall enter into force on the day on which the Treaty on the accession of the Czech Republic to the European Union comes into force.

Signed:

Klaus

Havel

Rychetský