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III.

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ACT

of ……. 2016,

amending Act No 281/2002 on certain measures related to the prohibition of bacteriological (biological) and toxin weapons and on amendments to the Trading Act, as amended

Parliament has adopted the following Act of the Czech Republic:

Article I

Act No 281/2002 on certain measures related to the prohibition of bacteriological (biological) and toxin weapons and on amendments to the Trading Act, as amended by Act No 186/2004, No 413/2005, No 296/2007, No 124/2008, No 223/2009, No 227/2009, No 64/2014 and No 243/2016, is amended as follows:

1. § 2, including the title and footnotes 10 to 12, shall read as follows:

„§ 2

Definition of certain terms

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

a) biological agent means any microorganism, such as bacteria, virus, mycoplasm, rickettsiae, chlamydiae or fungi, whether natural or modified, either in the form of an isolated live culture or as a substrate including living material which has been deliberately inoculated or contaminated with such culture,

b) toxin means a toxic chemical substance produced through metabolic pathways of organisms, including microorganisms, whether natural, modified, or chemically synthesised, which can cause death, disease or otherwise harm humans, animals or plants;such a chemical substance shall not be considered to be a toxin if present in a diagnostic sample or existing as a natural contaminant in another material,

c) bacteriological (biological) and toxin weapon means

   1. a weapon whose destructive effect is based on the properties of biological agents and toxins that harm the health or cause the death of humans or animals, or damage plants or cause economic damage,

   2. any device, equipment, apparatus or means designed for delivery or use of biological agents or toxins for hostile purposes or in armed conflict or a carrier of biological agents deliberately infected for hostile purposes or for use in armed conflict,

d) high-risk biological agents and toxins mean biological agents and toxins that have such properties or potential that they can be applied as a weapon;a list of high-risk biological agents and toxins shall be established in implementing legislation,

e) risky biological agents and toxins mean biological agents and toxins that may be handled under certain conditions;a list of risky biological agents and toxins shall be established in implementing legislation,
f) diagnostic kit means a veterinary medicinal product[10)] or medicinal product[11)] intended for distribution, an integral part of which is a biological agent or toxin and which is used in the diagnosis of human or animal diseases or to determine the presence of a biological agent or toxin in a sample,
g) production means the cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents or toxins,
h) handling of high-risk biological agents and toxins means the development, production, use, acquisition, retention, import, export, transport and destruction of high-risk biological agents and toxins;the handling of high-risk biological agents and toxins shall not be considered to be a service under the Free Movement of Services Act,
i) handling of risky biological agents and toxins means the development, production, use, acquisition, retention, import, export, transport and destruction of risky biological agents and toxins;the handling of risky biological agents and toxins shall not be considered to be a service under the Free Movement of Services Act,
j) international inspector means the designated representative of an international organisation conducting inspection activities to review the implementation 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')[12)],
k) prohibited information means information directly enabling the development or production of bacteriological (biological) and toxin weapons, high-risk biological agents and toxins, and
l) handling of prohibited information means collecting, for purposes other than prophylactic, protective and other peaceful purposes, providing, whether for consideration or not, or making publicly available of prohibited information.

[10)] Act No 166/1999 on veterinary care and on amendments to certain related acts (Veterinary Act), as amended.

[11)] Act No 268/2014 on medicinal products and on amendments to Act No 634/2004 on administrative fees, as amended.

[12)] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction promulgated under No 96/1975.".

2. In § 3(2)(d), point 1 shall read as follows:

"1. holders of permits issued under this Act and their professional representatives and".

3. In § 3(2), point (e) shall read as follows:

"e) keep records of
1. high-risk and risky biological agents and toxins,
2. facilities where high-risk and risky biological agents and toxins are handled, and
3. technical and technological equipment of the facilities in accordance with point 2,".

4. In § 3(2), at the end of point (e), the full stop shall be replaced by a comma and the following point (f) shall be added:

"(f) ensure international cooperation in its field of competence and provide information related to the implementation of the Convention in its field of competence.".

5. In § 3, the following new paragraph (3) shall be inserted after paragraph (2):

"(3) The records kept under paragraph (2)(d) shall be public.The records kept under paragraph (2)(e) shall be non-public.On request, the Office shall issue a complete or partial extract from its records kept under paragraph 2(d) to persons who can demonstrate a legal interest therein.Instead of issuing an extract, information from the information system may be provided in a manner allowing remote access.".

Paragraph (3) shall become paragraph (4).

6. § 4 shall read as follows:

„§ 4

(1) The development, production, acquisition, stockpiling, retention, processing, use, consumption, import, export, transport and distribution of bacteriological (biological) and toxin weapons or other handling of bacteriological (biological) and toxin weapons and handling of prohibited information, including the provision of support or funding for these activities, shall be prohibited.

(2) The development, production, acquisition, stockpiling, retention, import, export, distribution and other handling of technical and technological laboratory and production equipment, or the design, construction and use of facilities, for the production of bacteriological (biological) or toxin weapons and their delivery systems, including the provision of support or funding for these activities, shall be prohibited.

(3) Development, production, acquisition, stockpiling and retention of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, shall be prohibited.".

7. § 5(1) shall read as follows:

"(1) Any person who discovers materials or objects that could be assumed to be bacteriological (biological) and toxin weapons or to contain high-risk or risky biological agents or toxins or has a suspicion that prohibited information is being handled or support or funding is being provided for the activities referred to in § 4 shall, without undue delay, report them to the Police of the Czech Republic, which shall then, without undue delay, forward this information to the Office.".

8. In § 5(3), the word “immediately” shall be replaced by the words “without undue delay”.

9. In § 5, the following new paragraphs (5) and (6) shall be added after paragraph (4):

„(5) Any person who becomes aware of a loss of high-risk or risky biological agents or toxins or deliberate damage to technical or technological equipment referred to in a declaration or notified to the Office shall report this fact without undue delay to the Police of the Czech Republic, which shall, without undue delay, forward this information to the Office.

(6) The Office shall be notified within five days by any person who puts into service a facility that

a) is maintained under negative pressure against the ambient environment,
b) is equipped with a warning system to detect unacceptable changes in air pressure,
c) is using HEPA-filtered air extraction,
d) is sealable for fumigation, or
e) has a validated waste disposal system.”.

10. § 6(3), including footnote 13, shall read as follows:

“(3) No permit shall be required for the handling of

a) high-risk biological agents and toxins in the course of rescue and remedial operations[13)], if notified to the Office without undue delay,
b) diagnostic samples containing high-risk biological agents or cultures of high-risk biological agents obtained from these sample for a period of less than 30 days in a diagnostic laboratory,
c) high-risk biological agents contained in a vaccine, unless this vaccine is used for research purposes,
d) high-risk biological toxins contained in a diagnostic kit by an end-user;in this case, the procedure referred to in § 17 shall be followed, and
e) high-risk biological toxins contained in a certified reference material as referred to in the Metrology Act.

[13)] Act No 239/2000 on the integrated rescue system and on amendments to certain acts, as amended.”.

11. § 7, including the title, shall read as follows:

„§ 7

Conditions for issuing permits for the handling of high-risk biological agents and toxins

(1) Permits for the handling of high-risk biological agents and toxins (hereinafter referred to as the ‘permit’) shall be issued by the Office to a legal person or an individual under the condition that

a) the legal person's registered office or the individual's place of residence is in the Czech Republic,
b) the individual has full legal capacity and is of good repute,
c) individuals who are members of the statutory body of the legal person have full legal capacity and are of good repute,
d) the legal person and the legal person who is a member of the statutory body of the legal person are of good repute,
e) the individual acting as the representative of the legal person who is a member of the statutory body of the legal person is of good repute,
f) a professional representative has been designated who shall ensure the proper performance of the activities related to the permitted handling of high-risk biological agents and toxins;the professional representative shall have full legal capacity, be of good repute and be professionally competent,
g) the permit referred to in § 12(4)(a) and (b) has not been revoked.

(2) Compliance with the condition under paragraph (1)(a) shall not be required for legal persons with registered office or individuals with permanent residence in a Member State of the European Union.

(3) Compliance with the condition under paragraph (1)(f) shall not be required for individuals who are professionally competent.

(4) Professional representatives may act as such only for one individual or legal person.

(5) The provisions of paragraph (1) and paragraph (2) shall apply mutatis mutandis to organisational units of the state and their designated employees.".

12. In § 8(2)(a), the word "responsible" shall be replaced by the word "professional" and the words "legal persons" shall be added after the word "individuals,".

13. In § 8(2), point (b) shall read as follows:

"b) similar proof of good repute issued by the competent authority of a Member State of the European Union of which the individual, statutory body, member of statutory body or professional representative is a national or in whose territory the legal person is established;where the competent authorities of the state do not issue such documents, these may be substituted by a solemn declaration made before the competent authority or a notary of a Member State of the European Union.Foreign nationals who are or were nationals of another Member State of the European Union or whose place of residence is or was in another Member State of the European Union may use an extract from the Criminal Records Register with a supplement containing the information entered in the criminal register of another Member State of the European Union[2a)] in place of proof of good repute issued by the competent authority of a Member State of the European Union.".

14. In § 8, the following new paragraph shall be inserted after paragraph (2):

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

Paragraph (3) shall become paragraph (4).

15. § 9, including the title, shall read as follows:

„§ 9

Professional competence

(1) Professional competence means experience in the field of at least three years and duly completed higher education in a study programme on

a) general medical practice or pharmacology,
b) veterinary medicine or veterinary hygiene,
c) chemistry, biology, ecology and the environment,
d) teaching, with a focus on chemistry or biology, or
e) agriculture or food industry.

(2) In the recognition of professional qualifications 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 § 7(1)(f), the Office shall proceed in accordance with the Recognition of Professional Qualifications Act.The Office's decision recognising professional qualifications shall serve as proof of professional competence under this Act.

(3) In accordance with other legislation, evidence of education issued abroad shall be accompanied by a nostrification clause and evidence of higher education shall be accompanied by a certificate of recognition of equivalence.

(4) The obligation to present evidence accompanied by a nostrification clause or certificate of recognition of equivalence referred to in paragraph (3) shall not apply to evidence of education issued in, or presented by an individual from, 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.

(5) Where a permit applicant, 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 to be permitted on a temporary or occasional basis, the Office shall carry out verification of the applicant's professional qualifications under the conditions laid down in the Recognition of Professional Qualifications Act.".

16. § 10(1) shall read as follows:

"(1) The permit application shall include

a) the personal number, if assigned, or date of birth of the individual, who is
   1. the applicant,
   2. a member of the statutory body of an applicant who is a legal person, or
   3. a representative of a legal person that is a member of the statutory body of an applicant who is a legal person,
b) the name, quantity and purpose and description of handling high-risk biological agents or toxins,

c) the place of performance of the activity to be permitted, if other than the applicant's registered office or place of residence.".

17. In § 10(2)(a), the word "responsible" shall be replaced by the word "professional".

18. In § 10(2)(b), the word "equipment" shall be replaced by the words "technical and technological laboratory and production equipment".

19. In § 10(2)(d), the words:"and that a bankruptcy filing has not been rejected due to the fact that the person's property is not sufficient to cover the costs of bankruptcy proceedings" shall be deleted.

20. In § 10, the following new paragraph (3) shall be inserted after paragraph (2):

"(3) The permit application shall be filed on a form.The standard permit application form shall be set out by the Office in implementing legislation.".

21. In § 11(3)(a) and (b), the words "personal number" shall be deleted.

22. In § 11(3)(b), the word "responsible" shall be replaced by the word "professional".

23. In § 11, paragraph (4), including footnote 4, shall be deleted.Paragraph (5) shall become paragraph (4).

24. § 12, including the title, shall read as follows:

„§ 12

New decision to issue a permit and revocation and lapse of a permit

(1) The Office shall commence new proceedings and issue a new permit decision

a) on a reasoned request of the permit holder, or
b) if the facts on the basis of which the original permit was issued have changed.

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

(3) In the proceedings under paragraph (1)(b), the party to the proceedings shall submit on request of the Office documents necessary to issue the new decision providing proof of a change in the facts based on which the original decision was issued and compliance with the conditions laid down by law.

(4) The Office shall revoke a permit whose holder

a) has obtained the permit on the basis of false or incomplete information,
b) fails to fulfil the obligations laid down by this Act or fails to remedy deficiencies found by the Office,

c) no longer satisfies the conditions relevant to the issue of the permit, or
d) has requested revocation of the permit.

(5) Permit holders not intending to continue to perform the permitted activity shall notify the Office of this fact without undue delay and, at the same, request revocation of the permit.

(6) A permit shall lapse

a) on the date of dissolution of the legal person or death of the individual,
b) upon declaration of the permit holder's bankruptcy, or
c) on the date the Office's decision to revoke the permit becomes final.

(7) After the revocation of the permit becomes final, the permit holder shall, without undue delay, cease to perform the permitted activity in accordance with this Act.

(8) Appeals against decisions to revoke a permit shall not have suspensory effect.".

25. In § 13(b), the word ", lost" shall be inserted after the words "be misused" and the words "and undertake the security arrangements referred to in § 14a" shall be inserted after the words "or stolen".

26. In § 13(c), the words "set time limits" shall be replaced by the words "set time limit".

27. § 13)(d) shall read as follows:

"d) allow access to the facility by the Office's inspectors, international inspectors and persons invited by the Office and provide a briefing on the scope of activities being carried out and the security arrangements necessary to exercise control,"

28. In § 13, at the end of point (f), the full stop shall be replaced by a comma and the following points (g) to (n) shall be added:

"g) inform, without undue delay, the Office of a change of the professional representative, if designated, and other important changes that have occurred in respect of performing the permitted activity, in particular
   1. changes in the conditions for the issue of the permit,
   2. organisational changes,
   3. changes in the facility's technical or technological equipment,
h) notify the Office of any planned changes in the performance of the permitted activity in accordance with point (g) no later than 30 days before implementing them,
i) when destroying high-risk biological agents and toxins, proceed in a manner that does not pose a risk to human or animal health or to the environment,
j) provide high-risk biological agents and toxins only to holders of a permit under § 6(1), unless, in exceptional circumstances and for a limited period of time, the Office decides otherwise and unless the purpose of this Act is being jeopardised,
k) inform carriers of high-risk biological agents and toxins of the nature and safe handling of the goods in their custody and make a record that this information has been provided,
l) lay down through internal rules the requirements for ensuring the proper performance of activities related to the permitted handling of high-risk biological agents and toxins,

including the obligation to ensure that the professional representative maintains a constant overview of the status of performance of these activities,

m) when the permit is revoked or lapsed, ensure, without undue delay, that high-risk biological agents and toxins are handed over to another permit holder or destroyed, and

n) notify the Office of a release of high-risk biological agents and toxins into the environment without undue delay.".

29. § 13a, including the title and footnote 14, shall read as follows:

"§ 13a

Transport

(1) High-risk biological agents and toxins may only be transported in transport packaging, in the manner laid down in special legislation[14)].

(2) Carriers shall ensure that shipments containing high-risk biological agents and toxins are transported, stored whilst in transit and transferred to the recipient in such a way as to prevent theft, misuse or loss and shall ensure that unauthorised persons do not come into contact with them.

[14)] For example,European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) No 64/1987, as amended.".

30. In § 14(2), the words "to the State Parties to the Convention and only" shall be deleted and the words "paragraph (1)" shall be added at the end of the paragraph.

31. In § 14(3), the words "from the State Parties to the Convention and only" shall be deleted and the words "paragraph (1)" shall be added at the end of the paragraph.

32. § 14(5) shall read as follows:

"(5) Permit holders shall notify the Office within five days of high-risk biological agents and toxins entering or leaving the territory of the Czech Republic.The notification shall be transmitted electronically.".

33. In § 14, the following new paragraphs (6) to (8) shall be added after paragraph (5):

"(6) The notification referred to in paragraph (5) shall include

a) the type and quantity of high-risk biological agents and toxins imported or exported,

b) first name, surname, telephone number and e-mail address of the individual arranging for the import or export for the permit holder,

c) the business name or name and registered office of the legal person or first name, surname, date of birth and place of residence of the individual who is the supplier or recipient abroad of high-risk biological agents and toxins,

d) the date of import or export,

e) the business name or name and identification number of the carrier, and

f) the customs office conducting the import or export customs procedure.

(7) A standard form for the notification referred to in paragraph (5) shall be set out by the Office in implementing legislation.

(8) When high-risk biological agents and toxins are exported, the permit holder shall keep a written declaration of the foreign end-user that the high-risk biological agents and toxins will not be used for the production or development of biological weapons giving the specific purpose of using them.”.

34. § 14a shall be inserted after § 14, which shall, including the title, read as follows:

“§ 14a

Security of high-risk biological agents and toxins

(1) Permit holders shall protect high-risk biological agents and toxins and equipment for the production thereof against loss, theft and misuse, in particular by technical means or by means of surveillance.

(2) Permit holders shall store high-risk biological agents and toxins in a locked room with walls, ceiling, floor, windows and doors that are made of a penetration-proof material, or in a non-portable lockable box or a special lockable laboratory cabinet designed for this purpose.

(3) Permit holders shall ensure that only persons designated by them enter unaccompanied the room where high-risk biological agents and toxins stored.Keys or other means of access to this room shall be kept separately from the keys or other means of access to other rooms.

(4) Permit holders shall compile and keep up-to-date a list of persons who have access to high-risk biological agents and toxins.

(5) Permit holders operating a facility referred to in § 5(6), where high-risk biological agents and toxins are handled, shall compile a list of persons who have access to this facility.

(6) Permit holders shall ensure that any person who has access to high-risk biological agents and toxins receives annual training on securing high-risk biological agents and toxins against misuse, loss or theft.”.

35. In § 16(1), the words “the records shall be archived for a period of 10 years from the lapse of the permit to handle high-risk biological agents or toxins” shall be deleted.

36. In § 16(2), the words “facilities in which” shall be replaced by the words “facilities where”.

37. In § 16(4), the words “and estimate data for the following calendar year by 31 August of the given year” shall be deleted.

38. § 16(5) shall read as follows:

"(5) The declaration shall include

a) the type and quantity of all high-risk biological agents and toxins handling of which is permitted,
b) the name and location of the facility where the declared activity is carried out,
c) technical and technological laboratory and production equipment of the facility referred to in (b) and
d) information as to whether the handling of high-risk biological agents or toxins is part of national defence or security research.".

39. In § 16(6), the words ", the period of retention of the records" shall be inserted after the words "record-keeping".

40. The following paragraph (7) shall be added in § 16:

"(7) A standard form for the declaration shall be set out by the Office in implementing legislation.".

41. § 17, including the group heading, shall read as follows:

"Risky biological agents and toxins

§ 17

(1) Risky biological agents and toxins may be handled within the territory of the Czech Republic only for

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

(2) Individuals or legal persons handling risky biological agents and toxins shall report to the Office data for the preceding calendar year by 31 January of the following year in the form of a declaration.

(3) The declaration shall include

a) the type and quantity of all notified risky biological agents and toxins,
b) the facility where the declared activity is carried out,
c) technical and technological laboratory and production equipment of the facilities referred to in (b) and
d) information as to whether the handling of risky biological agents and toxins is part of national defence or security research.".

(4) Individuals or legal persons intending to handle risky biological agents and toxins for the first time shall comply with the notification obligation no later than 14 days prior to handling them.

(5) The notification obligation under paragraph (4) shall not apply to the handling of

a) risky biological agents and toxins in the course of rescue and remedial operations[13)], provided that these are notified to the Office without undue delay,
b) diagnostic samples containing risky biological agents or cultures of risky biological agents obtained from these sample for a period of less than 30 days in a diagnostic laboratory,
c) risky biological agents contained in a vaccine, unless this vaccine is used for research purposes,
d) risky biological toxins contained in a certified reference material as referred to in the Metrology Act.

(6) The notification referred to in paragraph (4) shall include

a) the type of the risky biological agent and toxin, and
b) the data referred to in paragraph (2)(b) and (c).".

42. New § 17a and § 17b shall be inserted after § 17, which shall, including the title, read as follows:

"§ 17a

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

(2) Standard forms for the declaration referred to in § 17(2) and the notification referred to in § 17(4) shall be set out by the Office in implementing legislation.

(3) The provisions of § 16 shall apply mutatis mutandis to record-keeping of risky biological agents and toxins.The details of record-keeping, the period of retention of records and the data to be included in the declaration shall be set out by the Office in implementing legislation.

(4) Legal persons and individuals handling risky biological agents and toxins shall notify the Office within fives days of risky biological agents and toxins entering or leaving the territory of the Czech Republic.The notification shall be transmitted electronically.

(5) The notification referred to in paragraph (4) shall include

a) the type and quantity of risky biological agents and toxins imported or exported,
b) first name, surname, telephone number and e-mail address of the individual arranging for the import or export for the person handling risky biological agents and toxins,
c) the business name or name and registered office of the legal person or first name, surname, date of birth and place of residence of the individual who is the supplier or recipient abroad of risky biological agents and toxins,
d) the date of import or export,
e) the business name or name and identification number of the carrier, and
f) the customs office conducting the import or export customs procedure.

(6) A standard form for the notification referred to in paragraph (4) shall be set out by the Office in implementing legislation.

(7) When risky biological agents and toxins are exported, the person handling the risky biological agents and toxins shall keep a written declaration of the foreign end-user that the risky biological agents and toxins will not be used for the production or development of biological weapons giving the specific purpose of using them.

(8) Risky biological agents and toxins may only be transported in transport packaging, in the manner laid down in special legislation[14)].

§ 17b

Securing risky biological agents and toxins

Any person handling risky biological agents and toxins shall

c) ensure that risky biological agents and toxins are secured against loss, misuse or theft, in particular by technical means,
d) ensure that high-risk biological agents and toxins are destroyed in a manner that does not pose a risk to human or animal health or to the environment,
e) notify the Office without undue delay of a release of risky biological agents and toxins into the environment,
f) ensure that persons who have access to risky biological agents and toxins receive annual training on securing risky biological agents and toxins against misuse, loss and theft, and
g) inform the Office without undue delay of changes in the performance of the notified activity, in particular organisational changes and changes in technical or technological equipment of the facility.".

43. In the heading of TITLE V, the word "supervision" shall be replaced by the word "control".

44. The title of § 18 shall read:"Control".

45. In § 18(1), the words "(hereinafter referred to as 'supervision')" shall be deleted.

46. In § 18(3), the word "Supervision" shall be replaced by the word "Control".

47. The following paragraph (4) shall be added in § 18:

"(4) The inspector's authority to conduct control shall have the form of an identification card issued by the Office.The identification card shall contain

a) name or, if applicable, names 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 identification card, and
f) the name and address of the seat of the Office.".

48. In § 19(1), the word “immediately” shall be replaced by the words “without undue delay”.

49. In § 19(1), the words “or risky” shall be inserted after the words “high-risk”.

50. In § 19, paragraph (2) shall be deleted and paragraph (1) shall become unnumbered.

51. In § 20, the words “chairperson of the Office” shall be deleted.

52. In § 20(b), the words “equipment or parts, system or sets thereof” shall be replaced by the words “technical and technological laboratory and production equipment”.

53. New heading “Offences” shall be inserted before § 21.

54. § 21 shall read as follows:

„§ 21

(1) Individuals, legal persons or sole traders will commit an offence by

a) breaching the prohibition of development, production, acquisition, stockpiling, retention, processing, use, consumption, import, export, transport or distribution of bacteriological (biological) and toxin weapons or other handling of bacteriological (biological) or toxin weapons, or handling of prohibited information, including the provision of support or funding for these activities, as referred to in § 4(1),
b) breaching the prohibition of development, production, acquisition, stockpiling, retention, import, export, distribution or other handling of technical and technological laboratory and production equipment, or the design, construction and use of facilities, for the production of bacteriological (biological) or toxin weapons and their delivery systems, including the provision of support or funding for these activities, as referred to in § 4(2),
c) breaching the prohibition of development, production, acquisition, stockpiling and retention of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, as referred to in § 4(3),
d) failing to inform the Police of the Czech Republic of any of the facts referred to in § 5(1) or (5),
e) failing to inform the Office of any of the facts referred to in § 5(3),
f) failing to inform the Office of any of the facts referred to in § 5(6), or
g) handling high-risk biological agents or toxins without a permit from the Office as referred to in § 6.

(2) Fines of up to the following amounts may be imposed for the offences under paragraph (1)

a) CZK 50 000 000, for the offences referred to in paragraph (1)(a) to (c),
b) CZK 10 000 000, for the offence referred to in paragraph (1)(g),
c) CZK 500 000, for the offence referred to in paragraph (1)(f), or

d) CZK 100 000, for the offences referred to in paragraph (1)(d) or (e).".

55. The following new § 21a to § 21e shall be inserted after § 21:

"§ 21a

(1) Individuals, legal persons or sole traders who are holders of the permit under this Act, will commit an offence by

a) handling high-risk biological agents or toxins in a scope other than that defined in the permit,
b) handling high-risk biological agents or toxins in such a way that they can be misused, lost or stolen or by failing to undertake the security arrangements in accordance with § 13(b),
c) failing to present to the Office the declaration referred to in § 13(c) within the set time limit,
d) failing to provide assistance to the Office in accordance with § 13(d) or (e),
e) failing to inform the Office without undue delay of any of the facts referred to in § 13(f) to (h) or (n), or in § 14(5),
f) proceeding contrary to § 13(i) when destroying high-risk biological agents or toxins,
g) providing high-risk biological agents or toxins to a person contrary to § 13(j),
h) failing to inform carriers of high-risk biological agents or toxins of the facts referred to in § 13(k) or failing to make a record that this information has been provided,
i) failing to lay down through internal rules the requirements referred to in § 13(l),
j) failing to hand over to another permit holder or destroy high-risk biological agents or toxins without undue delay when the permit is revoked or lapsed as referred to in § 13(m), or
k) transporting high-risk biological agents or toxins contrary to § 13a(1).

(2) Individuals, legal persons or sole traders who are holders of the permit under this Act, will commit an offence by

a) exporting or importing high-risk biological agents or toxins for a purpose other than those referred to in § 14(2) or (3),
b) failing to keep the written declaration of the foreign end-user referred to in § 14(8) when exporting a risky biological agent or toxin,
c) failing to ensure protection of high-risk biological agents or toxins or equipment for the production thereof against loss, theft and misuse as referred to in § 14a(1),
d) failing to store high-risk biological agents or toxins in accordance with § 14a(2),
e) failing to ensure that only persons designated by the permit holder enter unaccompanied the room where high-risk biological agents and toxins stored or failing to ensure that the keys or other means of access are stored in accordance with § 14a(3),
f) failing to compile or keep up-to-date a list of persons who have access to high-risk biological agents or toxins as referred to in § 14a(4),
g) failing to compile or keep up-to-date a list of persons who have access to a facility holding high-risk biological agents or toxins as referred to in § 14a(5), or
h) failing to ensure that persons who have access to high-risk biological agents or toxins receive annual training in accordance with § 14a(6).

(3) Individuals, legal persons or sole traders who are holders of the permit under this Act, will commit an offence by

a) failing to keep record of the handling of high-risk biological agents or toxins or failing to present the records on the Office's request in accordance with § 16(1),
b) failing to hand over all records of the handling of high-risk biological agents or toxins to the Office upon the lapse or revocation of the permit in accordance with § 16(3), or
c) failing to present to the Office the declaration referred to in § 16(4).

(4) Fines of up to the following amounts may be imposed for the offences under paragraphs (1) to (3)

a) CZK 10 000 000, for the offence referred to in paragraph (2)(a),
b) CZK 1 000 000, for the offences referred to in paragraph (1)(a), (b), (d), (i) to (k), paragraph (2)(c) to (e) or paragraph (3)(a),
c) CZK 500 000, for the offence referred to in paragraph (1)(c), (e) to (h) or paragraph 2(f) to (h), or paragraph(3)(b) or (c), or
d) CZK 100 000, for the offence referred to in paragraph (2)(b).

§ 21b

(1) Individuals, legal persons or sole traders handling risky biological agents or toxins will commit an offence by

a) failing to report to the Office any of the facts referred to in § 17(2), § 17a(4) or § 17b(c),
b) failing to comply with the notification obligations referred to in § 17(4) or § 17a(1),
c) failing to keep record of the handling of risky biological agents or toxins in accordance with § 17a(3),
d) failing to keep the written declaration of the foreign end-user referred to in § 17a(7) when exporting a risky biological agent or toxin,
e) transporting risky biological agents or toxins contrary to § 17a(8),
f) failing to ensure that risky biological agents and toxins are secured against loss, misuse or theft in accordance with § 17b(a),
g) failing to destroy risky biological agents or toxins in accordance with § 17b(b),
h) failing to ensure that persons who has access to risky biological agents or toxins receive annual training in accordance with § 17b(d), or
i) failing to inform the Office without undue delay of any organisational changes or changes in technical or technological equipment of the facility.

(2) Fines of up to the following amounts may be imposed for the offences under paragraph (1)

a) CZK 500 000, for the offences referred to in paragraph (1)(a) to (c), (e) to (g) or (i),
b) CZK 200 000, for the offence referred to in paragraph (1)(h), or
c) CZK 100 000, for the offence referred to in paragraph (1)(d).

§ 21c

(1) Individuals, legal persons or sole traders who are carriers of high-risk biological agents or toxins will commit an offence by failing to ensure that

a) shipments containing high-risk biological agents or toxins are transported, stored whilst in transit or transferred to the recipient in such a way as to prevent theft, misuse or loss in accordance with § 13a(2), or
b) no unauthorised persons come into contact with a shipment containing high-risk biological agents or toxins in accordance with § 13a(2).

(2) A fine of up to CZK 100 000 may be imposed for the offences referred to in paragraph (1).

§ 21d

(1) The limitation period shall be five years.Where the limitation period has been interrupted, the liability for the offence shall not lapse before 10 years after it was committed.

(2) Offences under this Act shall be dealt with by the Office.

(3) Fines for offences shall be collected by the Office.

(4) The amounts of fines for offences under this Act shall be doubled where the same offence has been committed repeatedly.An offence shall be deemed to have been committed repeatedly if less than one year has passed since the date on which the decision imposing a fine for the same offence became final.

§ 21e

Use of data to exercise state authority in the area of the prohibition of bacteriological (biological) and toxin weapons

(1) The Office shall use the following data to exercise state authority in the area of the prohibition of bacteriological (biological) and toxin weapons

a) reference data from the basic population register,
b) data from the population register information system and
c) data from the information system on foreign nationals.

(2) The data used under paragraph 1(a) shall include

a) surname,
b) name or, if applicable, names,
c) date, place and district of birth; in the case of data subjects born abroad, date, place and country of birth,
d) address of the place of residence,
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 country 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) citizenship or, if applicable, citizenships.

(3) The data used under paragraph 1(b) shall include

a) name or, if applicable, names, surname and name at birth,
b) date of birth,
c) gender,
d) place and district of birth; in the case of individuals born abroad, the country of birth,
e) personal number,
f) citizenship or, if applicable, citizenships,
g) date, place and district of death; in the case of the individual's death outside the territory of the Czech Republic, the date of death and the place and country in which the death occurred.

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

a) name or, if applicable, names, surname and name at birth,
b) date of birth,

c) gender,
d) place and country of birth of the foreign national,
e) personal number,
f) citizenship or, if applicable, citizenships,
g) type and address of the place 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 country in which the death occurred and the date of death and the date stated in the 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.".

56. § 22(1) shall read as follows:

"(1) The Office shall issue an implementing decree to implement § 2(d) and (e), § 10(3), § 11(4), and § 14(7), § 16(6) and (7), § 17a(2), (3) and (6)".

57. In § 22, paragraph (2) shall be deleted.

Paragraphs (3) to (6) shall become paragraphs (2) to (5).

Article II

Transitional provisions

1. Legal persons or individuals handling high-risk biological agents and toxins or risky biological agents and toxins as of the date of entry into force of this Act shall adapt their legal arrangements to Act No 281/2002 as in force from the date of entry into force of this Act within six months of the date of entry into force of this Act.

2. For persons who are handling high-risk biological agent and toxins on the date of entry into force of this Act on the basis of a permit exclusively for the purpose referred to in § 6(3)(d) and who, in accordance with § 6(3), no longer need a permit for this activity, the notification obligation referred to in § 17(3) shall be considered fulfilled.

Article III

Notification

This Act was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Article IV

Entry into force

This Act shall enter into force on 1 January 2018.