MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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WAYS AND MEANS TO ENHANCE NATIONAL IMPLEMENTATION OF THE BIOLOGICAL WEAPONS CONVENTION (BWC) IN SLOVAKIA

Submitted by Slovakia

Introduction

1. Slovakia would like to make a presentation related to the first topic of this year's Meeting of Experts devoted to "Ways and means to enhance national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions". Emphasis is laid on the first part, namely "Ways and means to enhance national implementation".

2. This presentation is aimed at:

(i) Describing the process leading to enactment of a specific legislation in Slovakia to assure full domestic compliance with the Convention in the absence of a verification mechanism;

(ii) Outlining the basic philosophy and stipulations of the Act on the Prohibition of Biological Weapons; and

(iii) Contemplating the way ahead in its enforcing, strengthening the national institutions and coordination among national law enforcement institutions.

3. It is hoped that these three elements serve as an experience-sharing opportunity for those who are starting or at an early stage of ensuring full compliance with their obligation under Article IV of the Convention.

Process leading to enactment of specific legislation in Slovakia implementing Article IV of the Biological Weapons Convention

2003-2005 process

4. The 2003-2005 BWC process was launched by the topic entitled "The adoption of necessary national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation".

5. While many States Parties had at that time legislation implementing Article IV of the Biological Weapons Convention, a number of them still lacked a law that would cover the Article IV obligation comprehensively or would be pivotal in drawing together the partial legislation already in force. However, unlike them, in 2003 Slovakia was starting almost from scratch. Its legislation was well developed only as far as export control was concerned. Most elements of domestic BWC implementation were missing.

Original legislation in Slovakia[1]

6. In fact, legislation in this field had been limited to partial elements encompassed in three pieces of legislation:

(i) The 1998 Act No. 179 on Trading in Military Materials as subsequently amended stipulating that "Trade in, import, export, acquirement, mediation of trade or transportation of weapons of mass destruction nuclear, namely nuclear, chemical or biological weapons and components thereof, shall be prohibited."

(ii) The 2002 Act No. 151 on the Use of Genetic Technologies and Genetically Modified Organisms (GMO) as subsequently amended that established a Commission on BioSafety within the Ministry of Environment;

(iii) The 2002 Government Decree No. 47 on Health Protection in Handling Biological Substances, listing various biological agents such as bacteria, viruses, parasites, fungi and toxins.

Basic rationale behind the original state of affairs

7. The reasons for this state of affairs were related to the developments within the BWC itself and the process of building up a new state. Slovakia succeeded into the BWC in 1993 and took over the heritage of former Czechoslovakia. That did include the publication of the Convention in the Collection of Laws (No. 96/1976) but no specific legislation implementing its Article IV.

[1] The mentioned Acts can be found in Slovak language at www.zbierka.sk

8. In the 1990s the process to examine verification measures for the BWC was launched. Implementation of the Article IV was understood by many States Parties to be an integral component of a verification mechanism. As a result, developments in the BWC influenced thinking in Slovakia about Article IV. For a newly independent country still building its structures and courses of action, it was natural to wait for the final version of a verification mechanism that would include details of measures for domestic legislation. Such an instrument did not materialize and instead the 2003-2005 process was launched. It was necessary for each State Party to decide the best approach for itself. Slovakia got inspired by the very useful exchange of experience and views of those States Parties that had developed their national implementation of Article IV in parallel to the verification protocol. Slovakia has understood the message of the 2003 – 2005 process as embodied in a 2003 VERTIC publication, namely it is "Time to lay down the law".

Other factors precipitating the implementation of Article IV obligation

9. After 2001, the need to implement Article IV obligations became more urgent than ever. This was recognized by the elaboration of the EU Strategy Against Proliferation of Weapons of Mass Destruction in December 2003 and the adoption of the UN Security Council Resolution 1540 in April 2004.

Steps and measures taken by Slovakia to respond to the given obligations and challenges

10. The first step was to identify an institution that would lead the process of national implementation in a way that would result in adopting meaningful legislation responding properly to the requirements of the afore-said obligations and challenges. Basically two institutions were taken into consideration as a potential National Authority: First – the Ministry of Economy that performs the function of the National Authority for Chemical Weapons and deals with issues related to export control of chemical and biological goods. Second – the Ministry of Health that had generally been considered as the most appropriate institution in the field of biology. After a series of intergovernmental consultations, the Government of Slovakia approved a proposal made by the Ministry of Foreign Affairs to entrust the function of the National Authority to the Health Ministry (Government Decree No. 1050 of 10 November 2004).

Original functions of the National Authority

11. The functions of the National Authority as identified in the material accompanying the Government Decree No. 1050/2004, are to:

(i) Collect, evaluate and process information and requirements concerning domestic implementation of the Biological Weapons Convention;

(ii) Exercise, within the existing legislative framework, supervision over substances and activities that have a potential to be used for development, production and use as biological weapons;

(iii) Identify fields requiring amendments in the existing legislation of Slovakia in conformity with the commitment to strengthen the BWC through domestic measures;

(iv) Cooperate in the aforesaid identification with the Ministries of Finance, Economy, Defense, Agriculture, Justice, Education, Interior, Foreign Affairs and Environment (arranged according the Slovak alphabet);

(v) Coordinate the preparation of relevant legislative proposals related to the prohibition of biological weapons ;

(vi) Submit the relevant proposals to the Government for decision;

(vii) Process, within the Ministry of Health, the data for the annual CBMs reports and pass them on to the Ministry of Foreign Affairs;

(viii) Participate in the expert and annual sessions of the States Parties to the BWC and other relevant events related to the prohibition of biological weapons.

Elaboration of a comprehensive law

12. The main assignment of the National Authority under the afore-said governmental decree was to coordinate the elaboration of comprehensive law responding to the conclusions of the 5th BWC Review conference, the 2003 Conference of States Parties, EU WMD Strategy, UNSCR 1540 (2004), requirements posed by the fight against terrorism and other relevant commitments of Slovakia. After a process of consultation with the ministries identified above, the draft Act was prepared by the beginning of 2006. It was projected to fill in the considerable gap left by the failure to adopt a comprehensive Verification Mechanism. The proposed Act was adopted by the Government of Slovakia in January 2007. The National Council of the Slovak Republic (Parliament) approved the Act on the Prohibition of Biological Weapons on 28 March 2007. It came into force on June 1, 2007. It is promulgated in the Collection of Laws under No. 218/2007.

Regulations of the Act

13. The Act creates a new legal and administrative framework for comprehensive and effective surveillance over relevant biological items with a view to preventing their abuse for activities prohibited under the BWC, UNSCR 1540 and other international instruments, including those dealing with the issue of terrorism.

14. It regulates:

(i) The rights and duties of individuals, natural-person entrepreneurs, and legal entities as regards the prohibition of the development, production, stockpiling, keeping and use of biological weapons and their destruction, when handling them and detecting highly hazardous biological agents and toxins that might be used in a manner infringing the prohibition of biological weapon;

(ii) The conditions for handling highly hazardous biological agents;

(iii) The role of the State Administration in the field of compliance with the prohibition of biological weapons;

and it introduces criminal sanctions into the Criminal Code (Collection of Laws No. 300/2005 as subsequently amended).

The heart of the Act

15. The heart of the Act lies in specifying high-risk biological agents and toxins that have the potential to be used contrary to the BWC and other international instruments. Simultaneously, it represents a certain parallel to the Act on the Prohibition of Chemical Weapons of 1998 (Collection of Laws No. 129/1998 as subsequently amended).

Structure of the Act and brief description of the main stipulations

16. The Act is comprised of 7 Parts, 25 Articles and 2 Annexes.

17. Part I is composed of 25 Articles as described below.

18. Parts II-IV stipulate some technical amendments of other Acts that were influenced by adopting the Act on the Prohibition of Biological Weapons.

19. Part V is of specific importance since it amends the Criminal Code by adding to it stipulations prosecuting the activities performed contrary to the prohibition of biological weapons as stipulated in the Article I of the Act. It supplements the relevant provisions of the Criminal Act, namely on:

(i) The illegal armament and trading in military material with the words “biological weapons”,

(ii) The illegal production and keeping of nuclear materials, radioactive substances, highly hazardous chemical substances with the words “and highly hazardous biological agents and toxins”

20. Part VI amends the new Act on Dual-Use Goods and Technologies (Collection of Laws No. 21/2007).

21. Part VII determines 1 June 2007 as the date when the Act becomes effective.

22. Annex No. 1 lists highly hazardous biological agents and toxins that may be used as biological weapons.

23. Annex No. 2 lists highly hazardous biological agents and toxins that are subject to issuing an opinion by the (Public Health Care) Authority.

Stipulations of the Act

24. Brief description:

(i) § 1 - stipulates scope of the Act in three areas: rights and obligations regarding the prohibition of biological weapons; conditions for handling highly hazardous biological agents and toxins; and exercise of State Administration in relation to the afore-said issues.

(ii) § 2 - introduces basic definitions of the terms used so as ensure their unified interpretation.

(iii) § 3 - stipulates prohibitions of biological weapons and the facilities designed to produce them, including financing of related activities.

(iv) § 4 - stipulates the obligations in case of finding materials that can be presumed to be exploited as a biological weapon or to contain highly hazardous biological agents or toxins, or discovering the leakage of such biological agents and toxins.

(v) § 5 – 6 - stipulate basic obligations in handling highly hazardous biological agents and toxins, obligations of license holders and sanctions in case of their violation.

(vi) § 7 – 10 – specify: basic parameters of the system of State Administration in the field of biological weapons prohibition consisting of the Ministry of Health (National Authority), Public Health Authority of the Slovak Republic and Regional Public Health Authority based in Banská Bystrica; and roles of the State Administration.

(vii) § 11 – 13 - determine conditions for granting of a license for handling highly hazardous biological agents and toxins.

(viii) § 14 – 15 - provide details of requirements related to: the application for granting of a license; decision for granting of a license; and specify cases when license is not required.

(ix) § 16 - stipulates change of conditions, amendments, revocation and termination of a license for handling highly hazardous biological agents and toxins.

(x) § 17 - stipulates procedure for cases when a license related to export or import of certain highly hazardous biological agents and toxins is issued by another authority (i.e. Ministry of Economy) under special regulation.

(xi) § 18 - stipulates conditions for issuing a binding opinion under the Act on Land Planning and Building Regulations for cases of building facilities that may serve for any kind of handling with highly hazardous biological agents and toxins.

(xii) § 19 - imposes obligation to license holders to keep records with regard to the handling with highly hazardous biological agents and toxins, enumerates the details of the records and statements which license holder is obliged to provide to the Authority in given timeframes.

(xiii) § 20 - stipulates the functions of supervisory body in its exercising the supervision over compliance with the Act.

(xiv) § 21 - specifies corrective measures in case any deficiencies in the activities undertaken by the inspected person.

(xv) § 22 - defines cooperation with State Administration authorities.

(xvi) § 23 – 24 - identify misdemeanors and sanctions and criteria for their imposition.

(xvii) § 25 - contains joint and interim provisions.

Way ahead in enforcing the national implementation, including strengthening the national institutions and coordination among national law enforcement institutions

Basic prerequisites

25. The 2007 BWC Meeting of Experts provides an excellent opportunity for all States Parties to share the experience within the given topics. Slovakia would like to use it fully in order to continue the process of assuring an effective functioning of the system focused against the abuse of advances in biological sciences for military or terrorist purposes.

26. Slovakia finds herself in the initial phase of the process of legislation enforcement. Strengthening the national institutions and coordination among national law enforcement institutions represent important tasks that have to be accomplished effectively and without delay. The burden of this task lies primarily on the Ministry of Health/National Authority. Its interaction and coordination of the institution identified above is crucial. Moreover, this time it will be necessary to involve in the process much broader scope of subjects, including research, development, scientific, educational and others.

Conclusion

27. The Delegation of Slovakia will listen carefully the presentations of other States Parties, especially those whose experience has the potential to be beneficial for achieving the abovementioned goals. We hope we will be able to report on progress in this process at the next Meeting of States Parties in December this year.

Annex I

"218 ACT of 28 March 2007 on the Prohibition of Biological Weapons and on Amendments and Supplements to Certain Acts
(unofficial translation)

The National Council of the Slovak Republic has passed the following act:

Part I

Article 1

Subject of the Act

This Act stipulates

a) the rights and duties of individuals, natural-person entrepreneurs, and legal entities as regards the prohibition of the development, production, stockpiling, keeping and use of biological weapons and their destruction, when handling them and detecting highly hazardous biological agents and toxins that might be used in a manner infringing the prohibition of biological weapons,

b) conditions for handling highly hazardous biological agents,

c) the exercise of State administration in the field of compliance with the prohibition of biological weapons.

Article 2

Definition of basic terms

For the purposes hereof

a) biological weapons mean:

1. weapons whose destructive effects are based on the properties of biological agents and toxins that cause death or impair the health of humans or animals, or cause plants to die or damage them,

2. materials containing biological agents or toxins of any origin or production mode that are of such type or in such quantities which do not correspond to utilisation for prophylactic, safety or peaceful purposes,

3. equipment filled with such biological agents or toxins which are intended to be exploited for terrorism, criminal activities, hostile purposes or for an armed conflict, and are capable of causing death or disease or impairing the health of humans or animals, or causing plants to die or damaging

them; the same applies to carriers of biological agents intentionally infected so that they can be used for terrorism, criminal activities, hostile purposes or for an armed conflict, and are capable of causing death or disease or impairing the health of humans or animals, or causing plants to die or damaging them,

b) biological agent means any natural or modified organism whose intentional use might cause death or disease or impair the health of humans or animals, or cause plants to die or damage them,

c) toxin means a substance originating in any organisms, including micro-organisms, animals or plants, of any production mode, natural or chemically synthesised, that might cause death or disease or impair the health of humans or animals, or cause plants to die or damage them,

d) highly hazardous biological agents and toxins mean biological agents and toxins whose properties or capabilities make it possible for them to be exploited as biological weapons; the biological agents and toxins capable of being used as biological weapons are listed in Annex 1,

e) diagnostic equipment means a facility used to test samples for the purpose of diagnosing sub-clinical, clinical or latent infections or intoxication of humans, animals or plants, or for the purpose of analysing microbial or toxin contamination of foodstuff, water, soil and air by detecting, isolating or identifying microbial or other biological agents or toxins,

f) vaccine means a preparation, including killed, weakened or otherwise modified live microorganisms, or a component derived from microorganisms, including deactivated toxins and nucleic acids, which, after being put into a human or animal body in whatever way, induce a specific immune response in the body, and are intended for the prophylaxis of infectious diseases or intoxications, and are provably efficient and harmless to humans or animals,

g) production means cultivation of reproducible biological agents or synthesis, biosynthesis and isolation of non-reproducible biological agents or toxins,

h) aerobiological study means any work with aerosols containing biological agents and toxins,

i) handling of specified highly hazardous agents and toxins in the Slovak Republic means the research, development, production, use, acquisition, keeping, trading in, import, export, transport including transit, and disposal of such agents and toxins,

j) statement means a written statement of required information on highly hazardous biological agents and toxins and on objects and facilities pursuant to letters c), d) and e), in which they are handled,

k) facility means an apparatus, mechanism or equipment designed for the production, assembling, keeping, and utilisation of biological weapons, in particular aerosol chambers, dynamic, static, explosive fermenters, bioreactors, continually operated industrial sterilisation centrifuges which are intended to be employed for work with infectious or toxic materials, industrial tangential filtrating equipment, aerosol driers designed for drying infectious or toxic materials, industrial lyophylisators, biological material micro-encapsulation equipment, autoclaves, insect growing chambers and carriers,

l) infection carriers mean coelenterates carrying infections.

Article 3

Prohibition of biological weapons and their production facilities

(1) It is prohibited to research, develop, produce, stockpile, keep, process, trade in, use, consume, import, export, transport (including transit) or otherwise handle biological weapons or finance such activities.

(2) It is prohibited to research, develop, produce, stockpile, keep, import, export, trade in or use facilities designed to produce biological weapons and their carriers in another manner, or to design their construction or put such production facilities into operation or finance such activities.

Article 4

(1) Anyone finding materials or things that can be presumed to be exploited as a biological weapon or to contain highly hazardous biological agents or toxins, or discovering the leakage of such biological agents and toxins into the air and the environment shall be obliged to notify this fact without undue delay to the Police Force, the emergency call operation centre[2], the Public Health Care Authority of the Slovak Republic[3] (hereinafter referred to as the "Authority") or the Regional Public Health Care Authority in Banská Bystrica[4] (hereinafter referred to as the "Regional Authority"). The State authority that has received such notification shall without unnecessary delay inform the other State authorities referred to in the preceding sentence and the Slovak Intelligence Service accordingly. If finding such materials or things to be contained in a postal consignment, the notification duty shall be performed by the universal service provider[5], with the consignor being held accountable for the content of the postal consignment itself.[6]

(2) When finding a facility or ascertaining the loss of highly hazardous biological agents or toxins, the provision of paragraph 1 shall be applied.

[2] Article 10 of Act No. 129/2002 Coll. on Integrated Rescue System as subsequently amended.
[3] Article 3 par. 1 letter b) of Act No. 126/2006 Coll. on Public Health Care and on Amendments and Supplements to Certain Acts.
[4] Article 3. par. 1 letter c) of Act No. 126/2006 Coll.
[5] Article 16 par. 1 of Act No. 507/2001 Coll. on Postal Services as subsequently amended.
[6] Article 28 par. 3 and Article 29 par. 3 of Act No. 507/2001 Coll. as amended.

(3) A person who does not hold a licence for handling highly hazardous biological agents and toxins that has been issued by the Authority (hereinafter referred to as the "Licence") or a licence pursuant to a special regulation[7] and, when carrying out their activities, isolates or detects highly hazardous biological agents or toxins shall be obliged to notify the Regional Authority thereof without undue delay.

Article 5

Handling highly hazardous biological agents and toxins

(1) Highly hazardous biological agents and toxins shall be allowed to be handled in the Slovak Republic only based on the Licence or a licence pursuant to a special regulation[6] for

a) industrial, agricultural, research, health care, pharmaceutical and other peaceful purposes,

b) safety purposes which are directly related to protection against biological weapons,

c) training purposes and for testing the existing means of protection and detection and those being developed for the needs of the armed forces of the Slovak Republic.

(2) The Licence shall not be required for rescue work aimed at averting an emergency[8], nor for removal work aimed at eliminating the consequences brought about by an emergency; the performance of such work must be notified to the Authority.

(3) A Licence holder shall be obliged to transport highly hazardous biological agents and toxins only in transport packaging bearing an individually verifiable seal so that any handling of the transported package during the transport does not result in breaking the seal. Likewise, the packaging of a highly hazardous biological agent or toxin itself must be safe enough to ensure that no biological agent can be taken without the packaging having been apparently damaged or the protective component of a repeatedly usable lock having been broken. A Licence holder shall be required to indicate on the transport packaging and individual packages that they contain highly hazardous biological agents and toxins, adding a warning that substances highly hazardous to human life and health are concerned and that in the event of any finding the authorities referenced in Article 4 par. 1 must be notified thereof, and to refrain from any handling of the transport packaging, its content or individual packages. A Licence holder shall be obligated to ensure that highly hazardous biological agents and toxins are transported in such a manner as to prevent them from leaking into the environment or to prevent human and animals' lives and health from being threatened or plants from being damaged.

[7] Article 8 of Act No. 21/2007 Coll. on Dual-Use Goods and Technologies and on Amendments and Supplements to Certain Acts.
[8] Articles 11 and 31 of Act No 126/2006.

Article 6

Obligations of a Licence holder

A Licence holder or a holder of a licence under a special regulation[6] shall be obliged to

a) handle highly hazardous biological agents and toxins only to the extent stipulated by the Licence or a licence under a special regulation,[6]

b) handle highly hazardous agents and toxins in such a manner as to prevent them from being misused or stolen,

c) submit a statement to the Authority,

d) enable inspectors to enter a facility, and inform them on the scope of inspection activities being carried out in the facility and on safety measures necessary for the performance of inspection activities by inspectors of the Regional Authority, international inspectors and persons invited by State authorities having charge of compliance with the prohibition of biological weapons, and implement remedial measures pursuant to Article 21,

e) enable inspectors to install monitoring devices to monitor highly hazardous biological agents and toxins and to take samples to be analysed,

f) transport highly hazardous biological agents and toxins in such manner as stipulated in Article 5 par. 3 and in the manner set out in a special regulation[9],

g) notify the Authority without unnecessary delay of a bankruptcy order or rejection of a bankruptcy petition due to a lack of property,

h) perform obligations concerning the protection of employees and other inhabitants under a special regulation.[10]

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[9] Article 19 of Act No 264/1999 Coll. on Technical Requirements for Products and on Conformity Assessment and on Amendments and Supplements to Certain Acts as amended.
Article 26 of Act No. 163/2001 Coll. on Chemical Substances and Chemical Preparations as amended.
Articles 16d, 24 and 30 of Act No. 140/1998 Coll. on Medicines and Medical Aids and on Amendments to Act No. 455/1991 Coll. on Trade Enterprise (Trade Licensing Act) as amended and on Amendments and Supplements to Act of the National Council of the Slovak Republic No. 220/1996 Coll. on Advertising as amended.
European Agreement on the International Carriage of Dangerous Items by Road (ADR) (Decree of the Ministry of Foreign Affairs No. 64/1987 Coll.). Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Notice No. 60/1995 Coll. as amended by Notice No. 132/2000 Coll.).
[10] Ordinance of the Government of the Slovak Republic No. 338/2006 Coll. on Protection of the Health of Employees from Hazards related to Exposure to Biological Factors at Work .

Article 7

State administration authorities in the field of compliance with the prohibition of biological weapons

State administration in the field of compliance with the prohibition of biological weapons shall be exercised by

a) the Ministry of Health of the Slovak Republic (hereinafter referred to as the "Ministry"),

b) the Authority,

c) the Regional Authority.

Article 8

The Ministry shall

a) in liaison with other central bodies of State administration, prepare methodological and conceptual procedures for protection against bio-terrorism, and shall act as a State authority which is in charge of performance of the Convention on the Prohibition of the Development, Production and Stockpiling of Biological Weapons and on Their Destruction (hereinafter referred to as the "Convention"),[11]

b) decides on remedies against decisions of the Authority,

c) prepares international treaties or agreements with State or international organisations having charge of the prohibition of biological weapons,

d) publishes a list of the States Parties to the Convention in the Ministry bulletin.

Article 9

The Authority shall

a) regulate the exercise of supervision by the Regional Authority,

b) issue binding opinions pursuant to Article 18,

c) issue, amend or cancel a Licence-granting decision or affirmative opinion concerning the handling of highly hazardous biological agents and toxins (hereinafter referred to as "affirmative opinion") under this Act,

[11] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (Decree of the Ministry of Foreign Affairs No. 96/1975 Coll.).

d) order the destruction of a biological weapon, highly hazardous biological agents and toxins which are being handled at variance with this Act,

e) impose fines for violation of this Act.

Article 10

(1) The Regional Authority shall

a) prepare supporting and background documentation for decisions and measures to be taken by the Authority,

b) exercise the supervision of compliance with the prohibition of biological weapons under this Act,

c) exercise the supervision of the handling of highly hazardous biological agents and toxins under this Act,

d) carry out the microbiological diagnostics of highly hazardous biological agents and toxins listed in the annex hereto as well as laboratory examinations within environmental microbiology, environmental biology and medical microbiology,

e) keep records to the extent provided for by Article 19 par. 3.

(2) The Regional Authority shall provide for disposal of materials, things and facilities quoted in Article 4 par. 1; the thereto-related costs shall be chargeable to the individual, natural-person entrepreneur or legal entity to whom/which it has been proved that the found material, thing or device originates from their activities. If no such originator is established, the costs shall be covered by the State budget.

Article 11

Conditions for the granting of a Licence

(1) A Licence shall be granted by the Authority to an applicant, provided

a) an individual has his permanent or temporary residence, a natural-person entrepreneur has his place of business and a legal entity has its registered office, in the Slovak Republic,

b) a natural person who is a statutory body or member of a statutory body of a legal entity to which the Licence shall be granted has attained the age of at least 21 years and possesses full legal capacity and meets the integrity and professional competence requirements,

c) a legal entity has appointed its responsible representative to be in charge of the due performance of all activities associated with permitted handling; the responsible representative shall have attained the age of at least 21 years and shall possess full legal capacity and meet the integrity and professional competence

requirements, and must not be a member of the supervisory board or other auditing body of that legal entity; the office of responsible representative may at all times be held only for one legal entity or natural-person entrepreneur,

d) a natural-person entrepreneur to whom the Licence shall be granted has attained the age of at least 21 years and possesses full legal capacity and meets the integrity and professional competence requirements, or has appointed his or her responsible representative to be in charge of the due performance of all activities associated with permitted handling; the responsible representative shall have attained the age of at least 21 years and shall possess full legal capacity and meet the integrity and professional competence requirements; the office of the responsible representative may at all times be held only for one natural-person entrepreneur or legal entity,

e) an individual to whom the Licence shall be granted possesses full legal capacity and meets the integrity and professional competence requirements and has attained the age of at least 21 years,

f) their Licence has not been revoked pursuant to Article 16 par. 3, letters a) and b).

(2) The condition set out in par. 1 letter a) shall not be required to be satisfied where concerning an individual having his or her permanent or temporary residence, a natural-person entrepreneur having his or her place of business or a legal entity having its registered office, in another EU member State.

(3) Any change in the details laid down in paragraph 1 must be notified by an individual, natural-person entrepreneur or legal entity without undue delay to the Authority.

Article 12

Integrity

(1) For the purposes hereof, a person of integrity shall be deemed an individual not having been lawfully convicted of a criminal offence against life or health or for a criminal offence that is universally dangerous or committed against the environment.

(2) Deemed a certificate of integrity shall be

a) an abstract from the criminal record of an individual, natural-person entrepreneur, natural person acting in the capacity of statutory body or member of a statutory body of a legal entity, and abstract from the criminal record of their responsible representative,

b) in case of a person who is not a Slovak citizen, a similar document certifying integrity that has been issued by the relevant authority in the home country of which an individual, natural-person entrepreneur, statutory body or member of a statutory body of a legal entity or their responsible representative is a national; the certificate of integrity must be submitted along with an officially authenticated translation into the State language.

Article 13

Professional competence

Professional competence to perform activities connected with the handling of highly hazardous biological agents and toxins shall be understood as completed university education of the second degree in such field of study as medicine, public health care, veterinary medicine, pharmacy, biology or chemistry, with a minimum of three years of experience in any of the above fields of study.

Article 14

Licence application

(1) A written licence application must contain

a) business name, registered office and identification number of a legal entity applying for a Licence, name and surname, birth registration number, nationality and permanent or temporary residence of a person/persons who acts/act as its statutory body or member thereof or as its responsible representative,

b) in case of a natural-person entrepreneur, his or her name and surname, place of business, identification number, nationality, and permanent or temporary residence, and the name and surname, birth registration number, nationality and permanent or temporary residence of a responsible representative if appointed,

c) in case of an individual, his or her name and surname, birth registration number, nationality and permanent or temporary residence,

d) the name of one or several kinds of highly hazardous biological agents or toxins, their quantity, purpose and method of handling and final use,

e) designation of the final user of highly hazardous biological agents or toxins.

(2) A licence application shall be accompanied by

a) a certificate of integrity pursuant to Article 12 par. 2, dated no more than three months prior,

b) a certificate of professional competence of an individual or a responsible representative of a legal person or natural-person entrepreneur if appointed,

c) binding opinion pursuant to Article 18, technical documentation including a project implementation plan, specification of the course and installation of a laboratory facility and a certificate of occupancy,

d) a document certifying the ownership or lease of premises or other legal title to the premises where highly hazardous biological agents and toxins are to be handled,

e) affirmative decision of the public health care authority[12] stating that the premises meet the public health protection requirements for putting into operation,[13]

f) a statement that a natural-person entrepreneur or legal entity has not been adjudicated bankrupt or that no bankruptcy petition has been rejected due to a lack of their property.

Article 15

Decision on the granting of a Licence

(1) The grant of a Licence shall be decided by the Authority within 60 days following the completion of a Licence application.

(2) In the Licence-granting decision, the Authority shall, *inter alia*, indicate

a. business name, registered office and identification number of a legal entity applying for a Licence, name and surname, birth registration number, permanent or temporary residence of a person/persons who acts/act as its statutory body or member thereof or as its responsible representative,

b. the name and surname, birth registration number, and permanent or temporary residence of an individual, the name and surname, identification number and place of business of a natural-person entrepreneur, and the name and surname, birth registration number, and permanent or temporary residence of their responsible representative if appointed,

c. subject matter and scope of the Licence,

d. kind and quantity of highly hazardous biological agents or toxins that are permitted to be handled as well as the method of handling such materials,

e. terms and conditions upon which highly hazardous biological agents and toxins are permitted to be handled,

f. a period for which the Licence is granted.

(3) No Licence shall be granted for longer than five years.

(4) A Licence application shall be rejected by the Authority if this would result in exceeding the total volume of highly hazardous biological agents and toxins set for a certain period in the Slovak Republic. The total volume of highly hazardous biological agents and toxins for a certain period in the Slovak Republic, which must not be exceeded, shall be set by the Ministry in a generally binding legal regulation.

[12] Article 3, par. 1 of Act No. 126/2006 Coll.
[13] Article 10, par. 4, letter a) of Act No. 126/2006 Coll.

Article 16

Change of conditions, amendment, revocation and termination of the Licence

(1) No facility modifications or other technical or organisational changes may be made except with the prior written consent of the Authority granted at the request of a Licence holder.

(2) The Authority may decide on amending the Licence

a. based on a reasonable request by the License holder, the Authority to issue a binding opinion,

b. if there occurs a change in the circumstances on the basis of which the Licence was granted.

(3) The Authority shall revoke the Licence if

a. the Licence has been granted to the Licence holder on the basis of false or incomplete information,

b. the Licence holder does not fulfil their obligations provided for herein or fails to rectify the identified shortcomings within a period set by the Authority or the Regional Authority,

c. the Licence holder's responsible representative no longer exercises their office and the Licence holder fails to ask the Authority to amend the Licence without delay,

d. the Licence holder no longer meets the requirements for the granting of the Licence or has asked for the Licence to be revoked, e) so necessitated by the security interests of the Slovak Republic.

(4) The Licence shall terminate

a. upon the death of an individual or upon proclaiming them to be dead, or upon the conclusion of a natural-person entrepreneur or legal entity that was a Licence holder,

b. upon the expiry of the period for which it was granted.

(5) An appeal against a decision on amending or revoking of the Licence shall have no deferment effect.

Article 17

Affirmative opinion

(1) A licence under a special regulation[6] for the export or import of highly hazardous biological agents and toxins listed in Annex 2 may only be granted on the basis of an affirmative opinion.

(2) A person given an affirmative opinion shall, within 100 days from the date of issue of the affirmative opinion,[6] submit to the Authority a licence under a special regulation. Failure to do so within the said period causes the affirmative opinion to become void and null upon the expiry of this period. In substantiated cases, upon a proposal by the applicant, the Authority may extend this period by a maximum of 30 days.

(3) To the actions of the Authority issuing a reasoned affirmative opinion, the provisions of this Act regarding the grant of licences shall be applied *mutatis mutandis*.

Article 18

Binding opinion

A Licence applicant shall, in advance, ask[14] in a proposal (2) The Authority may decide on amending the Licence for land planning procedure, issuance of a final inspection decision and for alterations in the utilisation of a structure in which highly hazardous biological agents and toxins shall be handled.

Article 19

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

(1) A Licence holder or a person holding a licence under a special regulation[6] shall be obliged to keep records with regard to the handling of highly hazardous biological agents and toxins, and to submit them upon request to the Authority or the Regional Authority.

(2) Records shall be kept at the facility where the recorded activities are performed, by kind and quantity of highly hazardous biological agents and toxins.

(3) Upon the termination or revocation of a Licence or a licence pursuant to a special regulation[6] the licence holder shall be required to hand over to the Authority all records concerning the handling of highly hazardous biological agents and toxins. Such records shall be kept by the Authority to such extent as stipulated in par. 6 and shall be retained for a period of ten years following the termination or revocation of the Licence or the licence under a special regulation.[6]

[14] Article 140b of Act No. 50/1976 Coll. on Land Planning and Building Regulations (Building Act) as amended.

(4) Upon the termination or revocation of a Licence or a licence pursuant to a special regulation[6] the licence holder shall be bound to hand over biological agents and toxins without delay to the Regional Authority for disposal.

(5) A Licence holder or a person holding a licence under a special regulation[6] shall be obliged to submit to the Authority a statement for the past calendar year no later than 31 January and anticipated data for the next calendar year by 31 August of the given year.

(6) The statement must contain

a. the business name, registered office and identification number of a legal entity, the name and surname, birth registration number, nationality and permanent or temporary residence of a person/persons who acts/act as its statutory body or member thereof or as its responsible representative, the name and surname, identification number and place of business of a natural-person entrepreneur or the name and surname, birth registration number, nationality and permanent or temporary residence of an individual and their responsible representative if appointed,

b. kind and quantity of highly hazardous biological agents and toxins,

c. facility in which activities listed in the statement are performed.

Article 20

Supervision over compliance with the Act

(1) The Regional Authority shall exercise supervision over compliance with this Act and the related implementing regulations (hereinafter referred to as “supervision”).

(2) The supervisory body pursuant to par. 1 shall exercise supervision over

a. the fulfilment of obligations imposed by this Act on persons who are granted a Licence or a licence under a special regulation[6])-and who are reasonably suspected of handling highly hazardous biological agents and toxins without a licence (hereinafter referred to as “inspected person”),

b. the timeliness and accuracy of records kept and statements submitted.

(3) Supervision shall be exercised by inspectors of the supervisory body (hereinafter referred to as “inspectors”) who identify themselves by a card issued by the Authority; inspectors shall be appointed and recalled by the director of the Regional Authority. Inspectors shall be authorised to

a) enter the operational premises and facilities of inspected persons and inspect them, demand that persons performing the inspected activities identify themselves and accompany them where necessary, require employees of inspected persons to provide explanations, inspect the relevant documentation, take and analyse

samples of substances and take actions necessary to ensure the exercise of supervision,

b) require inspected persons to provide the necessary information and documentation including those which are subject to business secrecy or industrial right protection if necessary for the purposes of the exercise of supervision.

(4) Inspectors shall not be obliged to advise any inspected person of the commencement of the exercise of supervision.

(5) An inspected person shall be entitled to retain all control samples taken and to be present in the analysis of such samples on the spot or in the control laboratory; any person that is reasonably suspected of handling highly hazardous biological agents and toxins contrary to this Act shall have no such entitlement.

(6) Whenever inspectors exercising supervision find an inspected entity to be handling highly hazardous biological agents or toxins without a licence or to be performing activities infringing the prohibition of biological weapons, they shall inform the Police Force and the Slovak Intelligence Service thereof without undue delay. Should human or animal life and health be endangered or plants be damaged, the inspectors shall also report it to the emergency call operation centre of the integrated rescue system.

(7) The provisions of a special regulation[15] shall apply *mutatis mutandis* to the exercise of supervision.

Article 21

Corrective measures

(1) If the inspectors identify any deficiencies in the activities undertaken by the inspected person, they shall be authorised, depending on the nature of the deficiency identified,

a. to demand that the inspected person take corrective action, or

b. to order the inspected person to undertake a technical check, revision or examination of the fitness and suitability of the facility and its components, system or its files.

(2) In the event of danger in delay or upon the occurrence of undesirable circumstances that are essential in the light of safety, the Authority shall be entitled to issue a measure to be implemented by the inspected person in order to restrict or ban the handling of highly hazardous biological agents and toxins.

[15] Articles 8 to 16 of Act of the National Council of the Slovak Republic No. 10/1996 Coll. on Inspection in State Administration as amended.

Article 22

Cooperation with State administration authorities

(1) The ministries and other State administration authorities shall without undue delay advise the Regional Authority of the occurrence of an epidemic or infection among humans, animals and plants if they find, within their scope of competence, suspicion that they have occurred as a result of the leakage of highly hazardous biological agents and toxins or their misuse, and shall take measures, within the purview of their competence, to detect them in time and limit their leakage.

(2) The ministries and other State administration authorities shall provide the supervisory body upon request with information required for the exercise of supervision.

(3) The ministries, the Authority, the Regional Authority and supervisory body inspectors shall supply the Slovak Intelligence Service with information gained through the exercise of State administration and supervision, including data from records and files kept, which is necessary for the performance of duties and tasks of the Slovak Intelligence Service. If so necessitated by the protection of the constitutional establishment, internal order and State security, the supervisory body shall also invite an officer of the Slovak Intelligence Service to participate in the exercise of supervision.

Article 23

Misdemeanours

(1) Under this Act, an individual shall be deemed to have perpetrated a misdemeanour if

a. they are in breach of the obligation set forth in Article 4,

b. they are in breach of the prohibition of the development, stockpiling, keeping and use of biological weapons,

c. without a licence granted by the Authority, they handled the designated highly hazardous biological agents and toxins,

d. they are in breach of the obligations set forth in Article 6, fail to take corrective action pursuant to §2, or violate the prohibition set out in Article 16 par. 1,

e. they frustrate or hinder the exercise of supervision, distort or conceal facts that are fundamental to the exercise of supervision, or do not cooperate during an inspection.

(2) For the misdemeanours set forth in par. 1, the Authority shall impose

a) material forfeiture or a fine of up to SKK 20,000 for a misdemeanour committed pursuant to par. 1 letter a),

b) material forfeiture or a fine amounting from SKK 1,000,000 to SKK 10,000,000 for a misdemeanour committed pursuant to par. 1 letter b),

c) material forfeiture or a fine amounting from SKK 100,000 to SKK 5,000,000 for a misdemeanour committed pursuant to par. 1 letter c),

d) material forfeiture or a fine amounting from SKK 100,000 to SKK 2,000,000 for a misdemeanour committed pursuant to par. 1 letter d).

(3) For a misdemeanour committed pursuant to par. 1 letter e), the Authority shall impose a fine amounting from SKK 20,000 to SKK 200,000 on an individual or natural person who acts as the statutory body of a legal entity or as its member and on a responsible representative, and a fine amounting from SKK 10,000 to SKK 50,000 on employees of an inspected entity who failed to fulfil the obligations set forth in Article 4 par. 1 and 2.

(4) Where a natural person commits a misdemeanour repeatedly, the Authority shall impose a fine up to a two-multiple of the fines imposable under par. 2 and 3, or shall order the forfeiture of material.

(5) Misdemeanours and the trying thereof shall be subject to a general regulation on misdemeanour.

Article 24

Administrative delicts

(1) The Authority shall impose material forfeiture or a fine amounting

a) from SKK 20,000,000 to SKK 100, 000,000 on a natural-person entrepreneur and legal person for a breach of the prohibition of the development, production, stockpiling, keeping and use of biological weapons,

b) from SKK 1,000,000 to SKK 50,000,000 on a natural-person entrepreneur and legal person having handled highly hazardous biological agents and toxins without a licence granted by the Authority,

c) from SKK 100,000 to SKK 2,000,000 on a natural-person entrepreneur and legal person for a breach of the obligations set forth in Article 6, failure to implement a corrective measure pursuant to Article 21 or for a violation of the prohibition under Article 16 par. 1.

(2) A fine or material forfeiture shall be imposable within three years from the day when the Authority became aware of a breach of obligations, but within no longer than 10 years from the occurrence of such breach.

(3) When determining the amount of a fine, account shall be taken of the gravity, significance and duration of unlawful conduct and the extent of caused implications and whether prompt and efficient cooperation is provided in the rectification of shortcomings.

(4) A fine and material forfeiture shall be imposed by a decision of the Authority.

(5) The management and disposal of forfeited material, which is the property of the State, shall be ensured by the Regional Authority.

(6) Fines shall be deemed a State budget revenue.

Article 25

Joint and interim provisions

(1) The actions of State administration authorities under this Act shall be subject to general regulations on administrative procedure, unless otherwise stipulated by this Act, except for

a. the issuance of an affirmative opinion under Article 17 and a binding opinion pursuant to Article 18,

b. the issuance of a corrective measure pursuant to Article 21.

(2) A licence and affirmative opinion shall be non-transferable and shall not be subject to any transfer or assignment of rights, distraint proceedings,[16] bankruptcy proceedings[17] or inheritance proceedings.[18]

(3) In the case of those performing activities under this Act based on a trade licence, their licence shall expire on 30 September 2007.

(4) Those whose licence expired pursuant to par. 3 shall be obliged to handover over highly hazardous biological agents and toxins without delay to the Regional Authority.

Part II

Act No. 50/1976 Coll. on Land Planning and Building Regulations (Building Act) as amended by Act No. 139/1982 Coll., Act No. 103/1990 Coll., Act No. 262/1992 Coll., Act of the National Council of the Slovak Republic No. 136/1995 Coll., Act of the National Council of the Slovak Republic No. 199/1995 Coll., Finding of the Constitutional Court of the Slovak Republic No. 286/1996 Coll., Act No. 229/1997 Coll., Act No. 175/1999 Coll., Act No. 237/2000 Coll., Act No. 416/2001 Coll., Act No. 553/2001 Coll., Finding of the Constitutional Court of the Slovak Republic No. 217/2002 Coll., Act No. 103/2003 Coll., Act No. 245/2003 Coll., Act No. 417/2003 Coll., Act No. 608/2003 Coll., Act No. 541/2004 Coll., Act No. 290/2005 Coll., Act No. 479/2005 Coll. and Act No. 24/2006 Coll. shall be supplemented as follows:

In Article 126 par. 1, the words “on fire protection” shall be followed by the words “on the prohibition of biological weapons,”.

[16] Act of the National Council of the Slovak Republic No. 233/1995 Coll. on Court Distrainers and Distraining Activities (Distraint Procedure Code) an on Amendments and Supplements to other Acts as amended.
[17] Act No. 7/2005 Coll. on Bankruptcy and Restructuring and on Amendments and Supplements to Certain Acts as amended.
[18] Article 460 et seq. of the Civil Code.

Part III

Act No. 455/1991 Coll. on Trade Enterprise (Trade Licensing Act) as amended by Act of the National Council of the Slovak Republic No. 231/1992 Coll., Act No.. 600/1992 Coll., Act of the National Council of the Slovak Republic No. 132/1994 Coll., Act of the National Council of the Slovak Republic No. 200/1995 Coll., Act of the National Council of the Slovak Republic No. 216/1995 Coll., Act of the National Council of the Slovak Republic No. 233/1995 Coll., Act of the National Council of the Slovak Republic No. 123/1996 Coll., Act of the National Council of the Slovak Republic No. 164/1996 Coll., Act of the National Council of the Slovak Republic No. 222/1996 Coll., Act of the National Council of the Slovak Republic No.. 289/1996 Coll., Act of the National Council of the Slovak Republic No. 290/1996 Coll., Act No. 288/1997 Coll., Act No. 379/1997 Coll., Act No. 70/1998 Coll., Act No. 76/1998 Coll., Act No. 126/1998 Coll., Act No. 129/1998 Coll., Act No. 140/1998 Coll., Act No. 143/1998 Coll., Act No. 144/1998 Coll., Act No. 161/1998 Coll., Act No. 178/1998 Coll., Act No. 179/1998 Coll., Act No. 194/1998 Coll., Act No. 263/1999 Coll., Act No. 264/1999 Coll., Act No. 119/2000 Coll., Act No. 142/2000 Coll., Act No. 236/2000 Coll., Act No. 238/2000 Coll., Act No. 268/2000 Coll., Act No. 338/2000 Coll., Act No. 223/2001 Coll., Act No. 279/2001 Coll., Act No. 488/2001 Coll., Act No. 554/2001 Coll., Act No. 261/2002 Coll., Act No. 284/2002 Coll., Act No. 506/2002 Coll., Act No. 190/2003 Coll., Act No. 219/2003 Coll., Act No. 245/2003 Coll., Act No. 423/2003 Coll., Act No. 515/2003 Coll., Act No. 586/2003 Coll., Act No. 602/2003 Coll., Act No. 347/2004 Coll., Act No. 350/2004 Coll., Act No. 365/2004 Coll., Act No. 420/2004 Coll., Act No. 533/2004 Coll., Act No. 544/2004 Coll., Act No. 578/2004 Coll., Act No. 624/2004 Coll., Act No. 650/2004 Coll., Act No. 656/2004 Coll., Act No. 725/2004 Coll., Act No. 8/2005 Coll., Act No. 93/2005 Coll., Act No. 331/2005 Coll., Act No. 340/2005 Coll., Act No. 351/2005 Coll., Act No. 470/2005 Coll., Act No. 473/2005 Coll., Act No. 491/2005 Coll., Act No. 555/2005 Coll., Act No. 567/2005 Coll., Act No. 124/2006 Coll., Act No. 126/2006 Coll., Act No. 17/2007 Coll., Act No. 99/2007 Coll. and Act No. 193/2007 Coll. shall be supplemented as follows:

Article 3, paragraph 2 shall be supplemented by the letters zv), which shall read as follows:

"zv) handling a highly hazardous biological agent and toxin."

Part IV

Act No. 575/2001 Coll. on the Organisation of Activities of the Government and on the Organisation of Central State Administration as amended by Act No. 143/2002 Coll., Act No. 411/2002 Coll., Act No. 465/2002 Coll., Act No. 139/2003 Coll., Act No. 453/2003 Coll., Act No. 523/2003 Coll., Act No. 215/2004 Coll., Act No. 351/2004 Coll., Act No. 405/2004 Coll., Act No. 585/2004 Coll., Act No. 654/2004 Coll., Act No. 78/2005 Coll., Act No. 172/2005 Coll., Act No. 474/2005 Coll., Act No. 231/2006 Coll., Act No. 678/2006 Coll. and Act No. 103/2007 Coll. shall be supplemented as follows:

Article 19 shall be supplemented by letter q), which shall read as follows:

"g) check of the prohibition of biological weapons."

Part V

Act No. 300/2005 Coll. Criminal Act as amended by Act No. 650/2005 Coll. and Act No. 692/2006 Coll. shall be supplemented as follows:

1. In Article 232 par. 3 letter c), the word “substances” shall be followed by a comma and the words “highly hazardous biological agents and toxins”.

2. In Article 295 par. 2 letter b), the following words shall be added at the end “or biological weapons.”

3. The heading above Article 298 shall read as follows:

> “Illegal production and keeping of nuclear materials, radioactive substances, highly hazardous chemical substances and highly hazardous biological agents and toxins”.

4. In Article 298 par. 1, the word “substance” shall be followed by the words “or a highly hazardous biological agent or toxin,” and the word “its” shall be replaced by the word “their”.

5. In Article 299 par. 1, the words “chemical substance” shall be followed by the words “or highly hazardous biological agent and toxin”.

Part VI

Act No. 21/2007 Coll. on Dual-Use Goods and Technologies and on Amendments and Supplements to Certain Acts

1. In Article 4, paragraph 1 shall be supplemented by the letter f), which shall read as follows:

> “f) comply with the obligations stipulated by a special regulation[4a] with regard to the export of highly hazardous biological agents and toxins.”

Footnote to reference 4a shall read as follows:

> “[4a] Act No. 218/2007 Coll. on the Prohibition of Biological Weapons and on Amendments and Supplements to Certain Acts.”

2. In Article 9 par. 6 letter d), the words “the opinion of the Ministry of Health” shall be replaced by the words “the affirmative opinion of the Public Health Care Authority of the Slovak Republic[22a] (hereinafter referred to as the “Public Health Care Authority”)”

Footnote to reference 22a shall read as follows:

> “[22a] Article 17 of Act No. 218/2007 Coll.”

3. In Article 13 par. 4 letter d), the words “the opinion of the Ministry of Health” shall be replaced by the words “the affirmative opinion of the Public Health Care Authority[22a]”. Acts shall be supplemented as follows:

4. In Article 20 par. 3 letter c), the words “the opinion of the Ministry of Health” shall be replaced by the words “the affirmative opinion of the Public Health Care Authority[22a]”.

Part VII

This Act shall enter into force as of 1 June 2007.

Ivan Gašparovič, signed
Pavol Paška, signed
Robert Fico, signed

Annex No. 1
to Act No. 218/2007 Coll.

LIST OF HIGHLY HAZARDOUS BIOLOGICAL AGENTS AND TOXINS THAT CAN BE USED AS BIOLOGICAL WEAPONS

A. Human and animal pathogenic viruses:

1. Crimean-Congo hemorrhagic fever virus
2. Ebola virus
3. Sin Nombre virus (serotype of Hanta virus)
4. Junin virus
5. Lassa virus
6. Machupo virus
7. Marburg virus
8. Rift Valley fever virus.
9. Tick-borne encephalitis virus
10. Variola virus
11. Venezuela horse encephalitis virus
12. Eastern horse encephalitis virus
13. Yellow fever virus
14. Monkey smallpox virus

B. Bacteria:

1. Bacillus anthracis
2. Brucella melitensis
3. Brucella suis
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Francisella tularensis
7. Yersinia pestis
8. Coxiella burnetti
9. Rickettsia prowazekii
10. Rickettsia rickettsii

C. Protozoa:

1. Naegleria fowleri

D. Animal pathogens:

1. African swine plague virus
2. African horse plague virus
3. Catarrhal sheep fever virus, blue tongue
4. Foot-and-mouth disease virus
5. Poultry pseudoplague virus
6. Beef-cattle plague virus

E. Plant pathogens:

1. Colletotrichum coffeanum var. virulans
2. Dothistroma pini (Scirrhia pini)
3. Erwinia amylovora
4. Peronospora hyoscyami f. tabacina
5. Ralstonia solanacearum
6. Fiji csugar cane virus
7. Tilletia indica
8. Xanthomonas albilineans

F. Toxins:

Bacteria toxins:

1. Botulotoxin
2. Clostridium perfringens toxin
3. Staphylococ enterotoxin
4. Shigatoxin

G. Phycotoxins

1. Anatoxin
2. Ciguatoxin
3. Saxitoxin

H. Mycotoxins:

1. Trichotecentoxin

I. Phytotoxins:

1. Abrin
2. Rhicin

J. Zootoxins:

1. Bungarotoxin

Annex No. 2
to Act No. 218/2007 Coll.

LIST OF HIGHLY HAZARDOUS BIOLOGICAL AGENTS AND TOXINS ON WHICH THE AUTHORITY IS TO ISSUE AN OPINION

Protozoa:

1. Naegleria fowleri

Plant pathogens:

1. Dothistroma pini (Scirrhia pini)
2. Erwinia amylovora
3. Peronospora hyoscyami f. tabacina
4. Ralstonia solanacearum
5. Fiji sugar cane virus
6. Tilletia indica

Phycotoxins

1. Anatoxin
2. Ciguatoxin

Mycotoxins:

1. Trichotecentoxin

Zootoxins:

1. Bungarotoxin”

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