The full wording
Act No. 167/1998 Coll.,
on dependency producing substances and on amending certain other acts, as follows from amendments brought by
Act No. 354/1999 Coll., Act, No. 117/2000 Coll., Act No. 132/2000 Coll., Act No. 57/2001 Coll., Act No. 185/2001 Coll., Act No. 407/2001 Coll., Act No. 320/2002 Coll., Act No. 223/2003 Coll., and Act No. 362/2004 Coll., Act No. 228/2005 Coll., Act No. 74/2006 Coll., Act No. 124/2008 Coll., Act No. 141/2009 Coll., Act No. 291/2009 Coll., Act No. 41/2009 Coll., Act No. 281/2009 Coll., Act No. 106/2011 Coll., Act No. 341/2011 Coll., Act No. 375/2011 Coll., Act No. 167/2012 Coll., Act No. 18/2012 Coll., Act No. 50/2013 Coll., Act No. 167/2012 Coll., Act No. 273/2013 Coll.

as at 31 August 2015

PART ONE
CHAPTER I
INTRODUCTORY PROVISIONS

Section 1
Subject of Regulation

(1) This Act regulates

a) the handling of dependency producing substances, their export and import, and transit operations with them;

b) the handling of preparations containing dependency producing substances, preparations containing dependency producing substances and scheduled substances of category 1 pursuant to a directly applicable European Union regulation governing drug precursors[1)] (hereinafter referred to as "scheduled substances of category 1") and medical preparations containing scheduled substances of category 1, their export and import, and transit operations with them; and

c) the cultivation of poppy, cannabis, and coca bush, and the export, import, and destruction of poppy straw.

(2) This Act has been notified pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information related to technical standards and regulations for information society services, as amended.

Section 2
Definition of Terms

For the purposes of this Act

a) dependency producing substances mean narcotic drugs and psychotropic substances listed in Annexes of Government Regulation Concerning a List of Dependency Producing Substances,

b) preparation is a solution or mixture in any physical state containing a dependency producing substance or a dependency producing substance and scheduled substance of category 1 or a medical preparation pursuant to the Act on Pharmaceuticals containing a scheduled substance of category 1,

c) poppy straw means all above-ground parts (except the seeds) of opium poppy (Papaver somniferum L.), as well as their crushed products after the harvest, with the exception of whole poppy plants, including pods for decorative purposes,

d) cannabis means the flowering or fruiting tops of a plant of the genus Cannabis or the aboveground part of a plant of the genus Cannabis that includes the top,

e) coca bush means all species of the genus Erythroxylon and coca leaf means the leaf of the coca bush, except a leaf from which all ecgonine, cocaine and other ecgonine alkaloids have been removed,[2a)]

f) export or import of dependency producing substances and preparations containing them and poppy straw means their physical transfer from one country to another country.[2a), 2c)]

CHAPTER II

HANDLING OF DEPENDENCY PRODUCING SUBSTANCES AND PREPARATIONS

Section 3
Handling of Dependency producing substances and Preparations

(1) Handling of dependency producing substances and preparations means

a) the research, manufacture, processing, withdrawal, storage, supply and use of dependency producing substances and preparations,

b) the purchase and sale of dependency producing substances and preparations, as well as the acquisition and alienation of other property or contractual rights connected therewith, mediating in such agreements and representation in their execution.

(2) Dependency producing substances listed in Annex No. 3 or 4 of Government Regulation Concerning a List of Dependency Producing Substances and preparations containing them may be used only for limited research, scientific and very limited therapeutic purposes defined in the handling permit. Other dependency producing substances and preparations may be used only for therapeutic, scientific, educational and veterinary purposes and also for other purposes on the basis of a permit granted by the Ministry of Health.

Section 3
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Section 4
Handling Permit

A handling permit is required for handling of dependency producing substances, preparations and precursors, unless stipulated otherwise in this Act.

Section 5
Handling of Dependency producing substances and Preparations without Handling Permit

(1) Without a handling permit, dependency producing substances set forth in Annex No. 1, 2, 5, 6 or 7 of Government Regulation Concerning a List of Dependency Producing Substances and preparations containing them, or medical preparations containing a scheduled substance of category 1, may be

a) acquired, alienated and stored by persons operating a pharmacy,[2e)] exclusively for the purposes of operation of the pharmacy,

b) disposed of, without storage, by persons authorized thereto pursuant to the special law,[3)]

c) to be prepared in pharmaceutical form in pharmacies by pharmacists or pharmaceutical assistants under the supervision of a pharmacist.

(2) Without a handling permit, preparations containing dependency producing substances set forth in Annex No. 1, 2, 5, 6 or 7 of Government Regulation Concerning a List of Dependency Producing Substances and medical preparations containing a scheduled substance of category 1 may be

a) acquired, alienated and stored by persons operating a health-care facility or persons providing in-patient social services, exclusively for the purposes of providing health care,

b) acquired, alienated and stored by natural or legal persons authorized to perform professional veterinary activities, exclusively for the purposes of providing veterinary care,

c) prescribed by physicians within the provision of health care in health-care facilities and facilities providing social services,

d) used for therapeutic purposes by physicians and other health-care workers in in-patient and outpatient health-care facilities and in facilities providing inpatient social services or physicians who have an agreement on the prescription of pharmaceuticals concluded with a health insurance fund,

e) prescribed and used by veterinary doctors for the purposes of veterinary care,[4)]

f) prepared and dispensed by pharmacists in pharmacies on the basis of a prescription form duly completed and signed by a physician (hereinafter a "prescription") or on the basis of an order of natural and legal persons authorized to provide health care or veterinary care (hereinafter an "order"),

g) accepted in pharmacies by pharmacists or pharmaceutical laboratory technicians under the pervision of a pharmacist,

h) acquired, even by proxy, on the basis of a prescription issued by a physician, kept and used by natural persons for their own needs pursuant to the issued prescription,

i) acquired, even by proxy, on the basis of a prescription issued by a veterinary doctor, or acquired from a natural or legal person authorized to perform veterinary activities, stored and used pursuant to the issued prescription or pursuant to the set diagnosis by natural and legal persons for the purposes of providing veterinary care,

j) acquired, alienated, stored, transported and used by contractors and examiners during preparation and performance of clinical trial of human medicaments pursuant to the special law,[5)]

k) acquired, alienated, stored, transported or used by contractors or examiners during preparation or performance of clinical trial of veterinary medicaments pursuant to the special regulation,[5a)]

(3) A handling permit shall not be required for transport of dependency producing substances, preparations and precursors performed for a person who is authorized to manage dependency producing substances, preparations and precursors.

(4) Limited amounts of preparations containing dependency producing substances set forth in Annex No. 2, 6 or 7 of Government Regulation Concerning a List of Dependency Producing Substances or medical preparations containing a scheduled substance of category 1 may be transported without a handling permit in means of transport intended for international transport for the purposes of providing first aid and for urgent cases.

(5) A handling permit shall not be required for the acquisition, storage, and processing of cannabis plants, which may have a maximum content of substances of the tetrahydrocannabinol group

of 0.3%, provided that such cannabis is used only for industrial, technical, and horticultural purposes, or for trade in cannabis for those purposes.

(6) A handling permit shall not be required for activities of governmental bodies within their competence, for activities of territorial self-governing units within their delegated competence and in providing for local matters of public order within their independent competence, and for activities of the Army of the Czech Republic, Police of the Czech Republic, the Prison Service of the Czech Republic and the Customs Administration of the Czech Republic in performance of their tasks.

(7) A handling permit shall not be required for activities of legal or natural persons that establish forensic toxicological laboratories, laboratories of health-care institutes, specialized diagnostic, scientific and research, and educational workplaces of universities, and specialized diagnostic, scientific and research workplaces of the Academy of Sciences of the Czech Republic, whose list shall be stipulated by the Ministry of Health in a decree. An application for inclusion in the above list and an application for a change in the information stated in the list shall be lodged on a form issued by the Ministry of Health.

(8) A person included in the list shall announce any changes in the information stated in the list pursuant to paragraph (7) to the Ministry of Health in writing without undue delay.

(9) A handling permit shall not be required for persons operating a pharmacy, who acquire, alienate and store dependency producing substances set forth in Annexes Nos. 3 and 4 of Government Regulation Concerning a List of Dependency Producing Substances for the purposes of their supply to persons set forth in paragraph 7 above.

(10) The dependency producing substances listed in Annex 3 or Annex 4 of Government Regulation Concerning a List of Dependency Producing Substances and any preparations containing them may be destroyed without a handling permit, if they are not being stored, by a person pursuant to a consent granted by a Regional Authority[3)]. The Regional Authority that issued the consent shall inform the Ministry of Health of the issuance of the consent. This notification shall be made on a form issued by the Ministry of Health.

Section 6
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Section 7

The Ministry of Health may stipulate in a decree other cases where a handling permit is not required for handling of dependency producing substances.

Section 8
Issuing Handling Permits

(1) The Ministry of Health shall issue handling permits. Handling permit shall be no entitlement to if a person fails to comply with requirements for a request under paragraph (6).

(2) A handling permit provides authorization only for activities stipulated therein and, with respect to a manufacture permit, it may stipulate the highest permissible amount of manufactured dependency producing substances or preparations.The former handling permit shall expire upon issuance of a new handling permit.

(3) A permit to handle dependency producing substances and preparations shall be issued for a term of no more than 5 years.

(4) A handling permit shall not be transferable.

(5) A handling permit may be issued only to a legal or natural person who has appointed a responsible person. This shall not apply if a natural person who is an entrepreneur proves that he meets the requirements imposed on a responsible person by this Act.

(6) An application for a handling permit shall be lodged on a form issued by the Ministry of Health. The following documents shall be submitted along with an application

a) the original, a duplicate, or an officially verified copy of a decision documenting a permit to handle pharmaceuticals pursuant to the Act on Pharmaceuticals or a certificate of compliance with the conditions for performing veterinary medical and preventative activities, pursuant to the Act on the Chamber of Veterinary Doctors,

b) proof of having a clean record, if it is not possible to proceed in line with Section 8a (4),

c) permit to engage in business,

d) documentation of the consent of the owner of a real property, concerning the activities listed in the Application,

e) agreement on specialised veterinary activities, if such activities are to be performed,

f) document appointing a responsible person, pursuant to paragraph (5),

g) document of medical competence, pursuant to Section 18,

h) document of specialised competence, pursuant to Section 19 (1),

i) declaration of the applicant that in the case of activities in which direct contact is made with dependency producing substances and preparations, an appropriate method of securing such substances and preparations will be chosen, pursuant to Sections 10 and 11,

j) description of the technology of the intended production, in the case of application for a permit to produce dependency producing substances and preparations.

(7) A person, whose handling permit is about to expire and who intends to continue the handling of dependency producing substances and preparations, shall be obliged to submit to the Ministry of Health an application for a new handling permit at the latest 6 weeks prior to expiry of the former handling permit.

(8) A person, to whom a handling permit has been issued, shall be obliged to notify the Ministry of Health forthwith in writing of any changes in the details specified in the application for a handling permit.

(9) In the event of a change in the information stated in the application for a handling permit, where the change pertains to

(a) the activities already permitted, or their expansion,

(b) the name, registered seat, legal form, or identification number of the person, in the case of a legal person, or

(c) the residence and place of business, if other than the place of residence, in the case of a natural person, the person intending to make the change shall submit a new application for a handling permit to the Ministry of Health.

(10) In case of breach of duties following from this Act or from a decision issued on the basis thereof, as well as in the case of disclosure of false or incomplete data in the application for a handling permit, the Ministry of Health may resolve to revoke a handling permit. The Ministry of Health shall revoke a handling permit if the holder of the permit has been validly convicted of a crime, whose merits are related to this activity.[5d)]

(11) If a natural or legal person ceases to perform an activity, for which a handling permit was issued, it shall notify the Ministry of Health forthwith of this fact; the Ministry of Health shall cancel the handling permit through its decision. An application for canceling a handling permit shall be lodged on a form issued by the Ministry of Health.

(12) If the Ministry of Health makes a decision on revoking a handling permit or fails to issue a new handling permit or cancels a handling permit through its decision, it shall specify in the relevant decision a deadline for performance of acts connected with cessation of the activity and the manner of andling of the dependency producing substances nd preparations.

(13) A person to whom a new handling permit has been issued shall return the invalid handling permit to the Ministry of Health within 14 days of the effective date of the new handling permit. This obligation applies even to persons whose handling permit is expiring pursuant to paragraph (7) and who do not intend to continue to handle dependency producing substances and preparations; the period for returning the invalid handling permit shall be 14 days after the expiration of the handling permit.

Section 8a

Clean Record Evidence

(1) A handling permit may only be issued to a natural person who has a clean record and a permanent residence in the Czech Republic, or to a legal person that has a clean record and its registered seat in the Czech Republic. The condition of having a permanent residence or registered seat in the Czech Republic shall not apply in the case of a person who has a permanent residence permit or residence, place of business, registered seat, central administration, chief place of business, or an organisational unit in another European Union Member State, a contractual state of the European Economic Area Agreement, or the Swiss Confederation.

(2) For the purpose of this Act, a person with a clean record shall be a person who has not been finally convicted for an intentional or negligent criminal act committed in connection with the handling of dependency producing substances or preparations.

(3) A clean record evidence shall be documented by

a) an excerpt from the Criminal Registry records not older than 3 months
1. for a natural person whose permanent or other residence is in the Czech Republic,
2. for a natural person who is or was a national of another European Union Member State or has or had his/her residence in another European Union Member State,
3. for a legal person that has its registered seat in the Czech Republic,

b) a document similar to an excerpt from the Criminal Registry record
1. for a natural person whose permanent or other residence is outside of the Czech Republic and for a natural person who has had in the last 5 years a continuous stay more than 6 months outside of the Czech Republic; such a document must be issued by the authorised body of the country of the person's permanent or other residence, the countries in which the person stayed continuously for more than 6 months in the last 5 years, and the country that is not the country of the person's permanent or other residence, of which the person is a national,
2. for a legal person having its registered seat outside of the Czech Republic; such a document must be issued by the authorised body of the country of the person's registered seat,
(c) sworn declaration as to a clean record

1. for a natural person, if the country of the person's permanent or other residence or the country in which the natural person stayed continuously in the last 5 years does not issue the document referred to in paragraph (b); such a sworn declaration must be made before a notary or an authorised body of the country of the person's permanent or other residence and of the countries in which the person stayed continuously for more than 6 months in the last 5 years,
2. for a legal person, if the country of the legal person's registered seat does not issue the document referred to in paragraph (b); such a sworn declaration must be made before a notary or an authorised body of the country of the person's registered seat.

(4) For the documentation of a clean record of persons referred to in paragraph (3) a) subparagraphs (1) and (3), the Ministry of Health shall obtain an excerpt from the Criminal Registry record pursuant to a special legal regulation[5f)]. An application for an excerpt from the Criminal Registry record and an excerpt from the Criminal Registry record shall be submitted in electronic form, by means allowing for remote access. The Ministry of Health may also obtain other background documents, if required for verifying information learned pursuant to paragraph (3).

Section 9
Responsible Person

(1) A person who manages dependency producing substances and preparations on the basis of a handling permit must appoint a responsible person for the entire term of the handling permit. This shall not apply if, at the time of issuance of the handling permit, the requirement for appointing a responsible person was waived pursuant to the second sentence of Section 8 (5) hereof.

(2) The responsible person shall be responsible for

a) keeping records and documentation prescribed by this Act,

b) fulfillment of notification duties prescribed by this Act.

(3) A natural person with a permanent address in the territory of the Czech Republic may be appointed as a responsible person. The precondition of permanent address in the Czech Republic shall not apply to a national of a Member State of the European Union or a national of the Czech Republic who does not have his place of residence in the territory of the Czech Republic. This person must comply with the requirements for general, health and professional qualification for handling of dependency producing substances.

(4) The health qualification of a responsible person shall be demonstrated by medical assessment, which may not be older than 3 months on the date of appointment of the responsible person. The medical assessment of health qualification shall be carried out by the assessing physician on the basis of the result of a medical inspection and other professional examinations, as appropriate. A person, with respect to whom there is a justified suspicion that his health or life could be endangered in performance of the duties of a responsible person or that health or life of other persons could be endangered in performance of the duties of the responsible person in connection with the state of health of this person, may not be considered to have the required health qualification.

(5) Only an employee with set weekly working hours, or a partner of a partnership, unlimited partner of a limited partnership company, executive of a limited company, member of the board of directors of a joint-stock company or cooperative, member of the executive board of a generally beneficial company or a corporate agent may be appointed as a responsible person.

(6) The person to whom a handling permit has been issued shall ensure that activities that require a handling permit shall not be carried out without the consent of a responsible person.

(7) The responsible person shall countersign

a) the application for a handling permit,

b) the application for an export permit or import permit,

c) reports submitted in the framework of fulfillment of the notification duty hereunder.

(8) A responsible person who is not an employee may resign from this position by means of a written notice addressed to the person, for whom he performs the duties of a responsible person.

(9) If a responsible person or a person performing his duties pursuant to Section 8 (5) is temporarily incapable of performing his duties, the person, to whom a handling permit was issued, shall forthwith appoint a deputy responsible person. Appointment of the deputy responsible person and termination of his duties must be forthwith notified in writing on a form issued by the Ministry of Health. The deputy responsible person must comply with the requirements for general, health and professional qualification stipulated by this Act for a responsible person.

(10) If a responsible person ceases to meet the set requirements or, for some other reasons, is permanently incapable of performing his duties, or resigns, the person to whom a handling permit was issued, shall be obliged to appoint a new responsible person within 10 days and apply to the Ministry of Health for an amendment to the handling permit. The application for an amendment to a handling permit shall be lodged on a form issued by the Ministry of Health and shall be countersigned by the newly appointed responsible person.

Section 10
Storage

(1) Dependency producing substances and preparations must be stored in locked rooms, whose walls, ceilings, floors, windows and doors are made from a material that makes it difficult to gain access to the stored substances, or in stationary lockable steel containers or in a specially manufactured lockable device which is inseparably fastened to a wall, ceiling or floor made of a solid material (e.g. bricks or concrete panels).

(2) Keys to rooms, where dependency producing substances and preparations are stored, may be provided only to designated persons and must be stored separately from keys to other rooms in the building.

(3) The stored dependency producing substances and preparations, as well as equipment used for their manufacture or growing, must be protected against loss, theft and misuse, particularly by means of continuous presence of a guard and suitable technical means (fence, electronic alarm, etc.).

(4) The duties stipulated in the previous paragraphs need not be complied with in storage, for which a handling permit is not required. However, in these cases, storage must be implemented so that unauthorized persons do not have access to the stored substances. In health-care facilities, facilities providing social services and in premises of persons authorized to provide veterinary care, dependency producing substances set forth in Annex No. 1, 3, 4 or 5 of Government Regulation Concerning a List of Dependency Producing Substances and preparations containing them must be stored in stationary lockable metal boxes.

Section 11
Transport

(1) Dependency producing substances set forth in Annex No. 1, 3, 4 or 5 of Government Regulation Concerning a List of Dependency producing Substances and preparations containing them

may be transported only in lockable metal containers or in specially constructed baggage equipped with a locking mechanism or in an enclosed compartment of vehicles that must be adapted so that these substances cannot move outside the enclosed area. Continuous guard must be ensured during their loading, transport and unloading. The transport routes must be changed irregularly and must not be disclosed to the public.

(2) During transport, dependency producing substances listed in Annex No. 1, 3, 4 or 5 of Government Regulation Concerning a List of Dependency Producing Substances and preparations containing them must be marked so that it can be ascertained that the relevant substances and preparations or precusors are involved, where the marking must be made in a manner ensuring that unauthorized persons cannot ascertain the object of transport.

Section 12
Trade

Dependency producing substances and preparations may only be provided or sold to persons authorised to handle them. The same applies to the transfer of other rights connected with dependency producing substances and preparations.

Section 13
Prescription Forms and Order Forms with Blue Stripe

(1) A medical preparation pursuant to the Act on Pharmaceuticals (hereinafter referred to as "medical preparation") containing a dependency producing substance or a scheduled substance of category 1 may only be issued at a pharmacy to a person who has not been granted a handling permit, on the basis of a prescription or application, or, if without a prescription, then with the limitations pursuant to the Act on Pharmaceuticals.[6a)] A medical preparation containing a dependency producing substance listed in Annex 1 or Annex 5 of the Government Regulation Concerning a List of Dependency Producing Substances may only be issued on the basis of a prescription or application labelled with a blue stripe running from the bottom left-hand corner to the top right-hand corner, or exclusively on the basis of an electronic prescription, if the Act on Pharmaceuticals so stipulates.[6)] A medical preparation containing a dependencyproducing substance listed in Annex 1 or Annex 5 of the Government Regulation Concerning a List of Dependency Producing Substances, which is at the same time listed in Annex 8 of the Government Regulation Concerning a List of Dependency Producing Substances, may be issued at a pharmacy on the basis of a prescription or application not labelled with a blue stripe.

(2) Records shall be kept of prescription forms and order forms with a blue stripe, including specification of the serial number of the form and the code of the municipal authority of the municipality with extended competence that issued them.

(3) Only persons set forth in Section 5 (2) a) and b) hereof may order and obtain prescription forms and order forms with a blue stripe from the locally competent municipal authority of a municipality with extended competence through their appointed representatives. These persons shall keep records of further use thereof.

(4) Municipal authorities of municipalities with extended competence shall provide for printing and distribution of prescriptions and orders with a blue stripe.

(5) Municipal authorities of municipalities with extended competence shall keep records of provision, return and destruction of the returned prescriptions and orders with a blue stripe.

(6) The persons set forth in Section 5 (2) a) and b) hereof shall be obliged to submit destroyed prescription forms or order forms with a blue stripe to the municipal authority of a municipality withextended competence that issued them.

(7) Persons who have ceased to meet the preconditions set forth in Section 5 (2) a) and b)hereof shall be obliged to submit, through their authorized representatives, unused or destroyed prescription forms or order forms with a blue stripe within 5 days to the municipal authority of a municipality with extended competence that issued them. The municipal authority of a municipality with extended competence shall issue a receipt for the submitted forms.

(8) In case of death of a person, to whom prescription forms or order forms with a blue stripe have been provided by the authorized representative or directly by the municipal authority of a municipality with extended competence, the person who has lived with the deceased person in a common household, shall be obliged to submit these forms within 10 days of the date of death to the authorized representative, if the relevant person performed activities within employment or similar relationship, or, in other cases, to the municipal authority of the municipality with extended competence.

(9) The distribution, returning, destruction and keeping records of prescriptions and orders with a blue stripe shall be regulated by a special regulation.[6b)]

(10) A medical preparation containing a dependency producing substance or a scheduled substance of category 1 must not be issued repeatedly on the basis of a single prescription.

(11) The Ministry of Defense and the Ministry of Finance shall issue prescription forms and order forms with a blue stripe, including specification of the code of the relevant ministry, for healthcare and veterinary facilities belonging to their competence. The provisions of paragraphs 2 to 8 above shall apply to management of these forms mutatis mutandis provided that, instead of the municipal authority of a municipality with extended competence, the relevant activities shall be performed by the Ministry of Defense or Ministry of Finance.

Section 14
Disposal of Wastes and of Excessive and Unusable Dependency producing substances, and Preparations

(1) Unusable dependency producing substances and preparations, as well as waste containing them, must be disposed of. A person destroying unused dependency producing substances and preparations and any waste containing them shall make a record thereof.

(2) Disposal of unusable dependency producing substances and preparations, as well as waste containing them, that are a medical substance, shall be governed by a special regulation.[6c)]

(3) Disposal of unusable dependency producing substances ans preparations, as well as waste containing them, that are not a medical substance pursuant to a special law[6)] may be carried out only at the presence of a representative of the regional authority. A person carrying out the disposal shall draw up a protocol thereof, which shall be signed by the participating representative of the regional authority.

(4) The handling of unused dependency producing substances and preparations and any waste containing them shall proceed identically to the handling of dangerous waste, including keeping a record thereof, pursuant to the act governing the handling of waste.

Section 15
Prohibitions

It shall be prohibited to

a) place dependency producing substances and preparations in customs warehouses, free customs zones and free customs warehouses,[7)]

b) send dependency producing substances and preparations
1. by mail as normal consignments,
2. by means of post office boxes, or
3. to persons who are not authorized to handle them,

c) submit in any manner whatsoever to another persons mushrooms of the genus Psilocybe,

d) produce opium from opium poppy (Papaver somniferum L),

e) produce cannabis resin and substances of the tetrahydrocanabiol group from a cannabis plant (the Cannabis genus), which shall not prejudice the obtaining of such substances for medical use or scientific purposes subject to the conditions stipulated by this Act and the Act on Pharmaceuticals[6)],

f) advertising of dependency producing substances and preparations not focused on industry professionals, pursuant to an act governing advertising regulation.

Section 16
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CHAPTER III
ELIGIBILITY FOR HANDLING

Section 17
General Qualification

(1) Activities, for which a handling permit is required, as well as activities set forth in Section 5 (1) a), (2) a) and b), and (6), during which there is a direct contact with dependency producing substances, preparations and precursors, may be performed only by natural persons with no criminal record that enjoy legal capacity and that are over 18 years of age. A clean record shall be documented pursuant to Section 8a.

(2) The requirements stipulated in paragraph 1 above must also be met by natural persons who directly manage activities set forth in paragraph 1 above.

Section 18
Health Qualification

(1) Activities, for which a handling permit is required, as well as activities set forth in Section 5 (1) a), (2) a) to g) and (6), during which there is a direct contact with dependency producing substances, preparations and precursors, may not be performed by natural persons, whose organism contains a dependency producing substance, unless the dependency producing substance is present as a consequence of treatment prescribed by a physician.

(2) The requirements stipulated in paragraph 1 above must also be met by natural persons who directly manage activities set forth in paragraph 1 above.

(3) Employees of persons performing activities set forth in paragraphs 1 and 2 above shall be obliged, on request of the employer, to undergo a medical inspection aimed at ascertaining the presence of a dependency producing substance in the organism.

Section 19
Professional Qualification

(1) A natural person may be appointed as a responsible person if he/she has graduated from a masters programme in any of the following areas

a) pharmacology,

b) general medicine, dental medicine, or stomatology,

c) chemistry, or

d) veterinary medicine.

(2) Every person who performs activities, for which a handling permit is required, as well as activities set forth in Section 5 (1) a) and (2) a) and b), during which there is a direct contact with dependency producing substances, preparations and precursors, shall be obliged to ensure that natural persons, who come to direct contact with dependency producing substances, preparations and precursors during these activities or who directly manage these activities, obtain knowledge of the nature and effects of these substances and on handling thereof.

CHAPTER IV
EXPORT, IMPORT AND TRANSIT OPERATIONS

Section 20
Export of Dependency producing substances and Preparations

(1) Each individual export of dependency producing substances and preparations requires a permit of the Ministry of Health (hereinafter an "export permit"). This permit shall not replace an export license pursuant to special regulations.

(2) An export permit shall not be required

a) for export of mass-produced medicinal preparations containing dependency producing substances set forth in Annex No. 1, 2, 5, 6, 7 or 8 to Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1, if they are exported by a physician for the purpose of providing first aid or by a veterinary doctor for the purpose of providing urgent veterinary care during transport of animals, or by a natural person for his own needs in an amount and type corresponding to the duration of the trip and the state of health according to the set diagnosis,

b) for export of preparations set forth in Annex No. 8 of Government Regulation Concerning a List of Dependency Producing Substances or medical preparations containing a scheduled substance of category 1, if the export is performed by a person, to whom a permit has been issued for handling of preparations set forth in Annex No. 8 of Government Regulation Concerning a List of Dependency Producing Substances or medical preparations containing a scheduled substance of category 1,

c) for export of a limited amount of preparations containing dependency producing substances set forth in Annex No. 2, 5, 6, 7 or 8 of Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1 in means of transport intended for international transport for the purpose of providing first aid or assistance in urgent cases,

d) for export of mass-produced medicinal preparations containing dependency producing substances set forth in Annex No 1, 2, 5, 6, 7 or 8 of Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1, if they are exported for the needs of health-care and veterinary services provided by corps of the Army of the Czech Republic active abroad,

e) for the export of cannabis plants, which may have a maximum content of substances of the tetrahydrocannabinol group of 0.3%, for industrial, technical, and horticultural purposes.

(3) An export permit may be issued only after submission of an import permit issued by the country, to which the export is to be performed, or the consent of the competent governmental body of the country, to which the export is to be performed, if the relevant country does not require an import permit; the limit stipulated by the International Narcotics Control Board for the country of import[8a)] may not be exceeded.

(4) The Ministry of Health shall send one counterpart of the export permit to the competent body of the country, to which the export is performed.

(5) One counterpart of the export permit must be submitted to the customs authority that makes a decision on releasing the goods contained in the consignment. This customs authority shall state the details of the goods in the consignment in the submitted counterpart.

Section 20a
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Section 20b
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Section 21
Import of Dependency producing substances and Preparations

(1) Each individual import of dependency producing substances and preparations requires a permit of the Ministry of Health (hereinafter an "import permit").

(2) An import permit shall not be required

a) for import of mass-produced medicinal preparations containing dependency producing substances set forth in Annex No. 1, 2, 5, 6, 7 or 8 to Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1, if they are imported by a physician for the purpose of providing first aid or by a veterinary doctor for the purpose of providing urgent veterinary care during transport of animals or by a natural person for his own needs in an amount and type corresponding to the duration of the trip and the state of health according to the set diagnosis,

b) for import of preparations set forth in Annex No. 8 of Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1, if the import is performed by a person, to whom a permit has been issued for handling of preparations set forth in Annex No. 8 of Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1.

c) for import of a limited amount of preparations containing dependency producing substances set forth in Annex No. 2, 5, 6, 7 or 8 of Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1, in means of international transport for the purpose of providing first aid or assistance in urgent cases,

d) for the import of cannabis plants, which may have a maximum content of substances of the tetrahydrocannabinol group of 0.3%, for industrial, technical, and horticultural purposes,

e) for import of mass-produced medicinal preparations produced containing dependency producing substances set forth in Annex No. 1, 2, 5, 6, 7 or 8 of Government Regulation Concerning a List of Dependency Producing Substances, or medical preparations containing a scheduled substance of category 1, if they are imported by corps of the Army of the Czech Republic after cessation or limitation of their activities abroad as a remainder of stocks provided for their activities.

(3) The customs authority that makes a decision on releasing the goods in the consignment shall state on a counterpart of the import permit information on the goods in the consignment and the date of their releasing and send it to the Ministry of Health.

(4) After completion of the import, the Ministry of Health shall return the export permit to the country that issued it, including a note on the amount of actually imported dependency producing substances and preparations.

Section 22
Joint Provisions on Export and Import

(1) There shall be no entitlement to an export permit or import permit. An export permit or import permit shall not be transferable and shall not pass to a legal successor.

(2) An application for an export permit or for an import permit shall be lodged on a form issued by the Ministry of Health. The relevant natural or legal person shall be obliged to notify the Ministry of Health of any change in the details specified in the application for an export permit or import permit at the latest within 5 days of the date of the change.

(3) An import permit shall be issued for a term of 3 months or, on request of the importer, it may also be issued for a shorter term. The Ministry of Health shall stipulate the term of an export permit according to the term of the import permit of the country, to which the export is to be performed, unless the exporter requests a shorter term. If the export or import is not performed within this term, the person, to whom the export permit or import permit was issued, shall be obliged to notify the Ministry of Health forthwith in writing of this fact and return to the Ministry of Health all counterparts of the export permit or import permit that he possesses. The Ministry of Health shall return the export permit to the country that issued it, including a note that the import has not taken place, or notify the country, to whose territory export was permitted by the Ministry of Health of the fact that the export has not taken place.

(4) With respect to both import and export, the consignment must always be accompanied by an export permit, unless an export permit is not required pursuant to the legislation of the country of origin of the consignment or if a different official procedure is prescribed. In case of breach of this duty, the consignment shall be seized[9)] or confiscated.[10)]

(5) In case of export of dependency producing substances and preparations, the customs declaration for releasing the goods into the export procedure shall be submitted to the locally competent customs authority pursuant to the place of residence or place of business of the natural person or registered office of the legal person. An export permit pursuant to Section 20 hereof shall be also submitted, if required pursuant to this Act.

(6) In case of import of dependency producing substances and preparations, the customs declaration for releasing the goods into free circulation or a procedure with economic effects shall be submitted to the locally competent customs authority pursuant to the place of residence or place of business of the natural person or registered office of the legal person. An import permit pursuant to Section 21 hereof shall be also submitted, if required pursuant to this Act.

(7) The Ministry of Health shall make a decision on rejecting an application for an export permit or import permit, on suspension, revoking or canceling an export permit or import permit in case of

a) illicit traffic pursuant to international agreements binding the Czech Republic,

b) statement of false data or failure to supplement incomplete data in the application for an export permit or import permit within the set deadline,

c) breach of duties following from this Act or from a decision issued on the basis thereof, or

d) the holder of registration being validly convicted of a criminal offense, whose merits are related to this activity, unless the relevant person is considered not to be convicted.

Section 23
Transit Operations

(1) A transit operation may not be performed without submitting an export permit and the consignment must always be accompanied by an export permit, unless an export permit is not required pursuant to the legislation of the country of origin of the consignment or if a different official procedure is prescribed. In case of breach of this duty, the consignment shall be seized[9)] or confiscated.[10)]

(2) The consignment may not be unloaded from the vehicle during transport.

(3) The duty stipulated in paragraph 2 above need not be fulfilled in case of a transit operation performed by air transport, if the aircraft does not land on the territory of the Czech Republic.

CHAPTER V

CANNABIS, COCA, POPPY, and POPPY STRAW

Section 24
Cannabis, Coca, and Poppy

(1) It shall be prohibited to

a) to cultivate kinds and varieties of cannabis plants (genus Cannabis) that may have a content of substances of the tetrahydrocannabinol group in excess of 0.3%, with the exception of cultivation on the basis of a licence granted pursuant to this Act; the ban shall not apply to the cultivation of varieties of the cannabis plant (genus Cannabis) for research purposes, for the cultivation of new varieties, and for the maintenance of genetic diversity by scientific and research workplaces established by law or by the state, specified in the handling permit.

b) cultivate plants of the genus Erythroxylon (coca bush),

c) to cultivate poppy (Papaver somniferum L.) varieties the dry matter of whose pods may have a morphine content in excess of 0.8%; the ban does not pertain to the cultivation of poppy (Papaver somniferum L.) varieties for research and testing purposes, for the cultivation of new varieties of plants, and for the maintenance of genetic diversity by scientific and research workplaces.

(2) A person cultivating poppy (Papaver somniferum L.) or a person processing or storing poppy straw, shall also immediately inform the locally competent department of the Police of the Czech Republic of any suspicious circumstances, in particular the entry of an unauthorised person into the stand, the cutting of poppy pods, the theft of poppy pods, and any unusual orders that indicate that poppy straw may be abused for the illegal production of dependency producing substances.

(3) Poppy straw produced in the Czech Republic must be exported or destroyed or processed such that the dependency producing substances contained therein could not be used or derived by any technological means.

Section 24a

(1) Cannabis may only be grown for medical use by a legal entity or individual engaged in business that has been granted a licence for that activity by the State Institute for Drug Control. A licence holder may commence the growing of cannabis for medical use only if it has been granted a permit for handling with dependency producing substances and preparations.

(2) For the granting of a licence, the State Institute for Drug Control shall organise a tender which shall be carried out pursuant to another legal regulation.[14)] The tender shall have two rounds. For the first round, the qualification requirements, the tendering documentation, and the technical conditions shall be set, including the rules of the correct growing practice, and an applicant shall advance to the second round upon compliance with these. Only a person who has documented his ability to ensure that cannabis is grown according to the standardised procedure resulting in the defined contents of the effective substances in cannabis and a constant quality of cannabis grown may advance. The basic evaluating criterion in the second round of the tender shall be the price for which cannabis produced is offered, whose weight in the determination of the tendering conditions for evaluating the offers must be at least 75% in relation to other sub-evaluation criteria. The tendering conditions may specify the maximum number of persons to whom a licence will be granted. The State Institute for Drug Control shall not grant a licence to any of the applicants if the price offered plus the expected costs specified in the last sentence of Section 24b (2) exceed the price of cannabis for medical use that is available from other countries. In order to conduct a market survey, the State Institute for Drug Control shall make, prior to the second round of the tender, inquiries in countries that are may export cannabis for medical use, the parameters of which inquiry shall correspond to those of the tender in terms of the amount of cannabis and the contents of effective substance.

(3) Following the tender, a licence shall be granted for 5 years. In the licence, the State Institute for Drug Control shall set out the area on which cannabis is to be grown. If a licence is about to expire or in the event of a shortage of cannabis grown for medical use, a new tender shall be called and a licence may be granted repeatedly.

(4) A person to whom a licence has been granted for the growing of cannabis for medical use shall

a) ensure that it is grown and processed in covered premises suited for that purpose,

b) secure the premises on which the growing, harvesting, and processing take place, to prevent abuse,

c) ensure that a protocol is drawn of all of the activities related to growing, harvesting, and processing,

d) enable the State Institute for Drug Control at any time to inspect any of the premises used for growing and processing without prior notice, and make available to it protocols of activities and other relevant documentation; the rights and obligations of the inspectors and the persons inspected shall be governed mutatis mutandins by another legal regulation.[15)]

e) ensure that all vegetable waste is stored in the manner set out in Sec. 10 and destroyed at the expense of that person in the manner set out in Sec. 14; vegetable waste shall include any cannabis that does not comply with the tendering documentation and the technical conditions set in line with paragraph 2,

f) comply with the conditions set in paragraph 2.

(5) If the State Institute for Drug Control finds a breach of the obligation imposed pursuant to paragraph 4 on a person to whom a licence has been granted for the growing of cannabis for medical use, it shall withdraw its licence.

Section 24b

(1) The person to whom a licence has been granted shall transfer cannabis grown and harvested in line with the conditions set out in Sec. 24a (2) exclusively to the State Institute for Drug Control. For this transfer, it shall present a certificate of quality issued by a control laboratory which has been granted a permit to operate pursuant to the Act on pharmaceuticals.[6)] The State Institute for Drug Control shall buy cannabis harvested within 4 months of its harvesting. A written purchase agreement shall be entered into for the transfer, the particulars of which shall include a precise specification of cannabis harvested for medical use, its amount, quality, and purchase price, which shall not exceed the price offered in the second round of the tender and which shall correspond to the extent to which the technical conditions of the tender set out in Sec. 24a (2) have been met. A protocol shall be made of the handing over of cannabis.

(2) During the carriage of cannabis harvested, it shall be ensured that the shipment is not abused in any way and it shall be delivered exclusively to a pharmacy operator for the preparation of medical preparation. The State Institute for Drug Control and the pharmacy operator shall enter into a written purchase agreement for the transfer, the particulars of which shall be governed mutatis mutandis by paragraph (1) and a protocol shall also be made of the handing over of cannabis. The purchase price in the transfer to the pharmacy operator shall be subject to factual price control pursuant to another legal regulation.[16)] It shall be based on the purchase price for which cannabis was purchased from the person to whom a licence has been granted. The purchase price in the transfer to the pharmacy operator shall be non-profit, and may only be increased by the costs related to the carriage of cannabis from the person to whom a licence has been granted, the costs of the carriage of cannabis and its protection against abuse during carriage, the costs related to its storage, and the costs related to the handover of cannabis to the pharmacy operator.

Section 25
Export and Import of Poppy Straw

(1) A permit for export of poppy straw or a permit for import of poppy straw shall be required for export or import, respectively, of poppy straw. An application for an export permit or an import permit shall be lodged on a form issued by the Ministry of Health.

(2) A permit to export poppy straw and a permit to import poppy straw shall be issued by the Ministry of Health, which shall also be authorized to revoke an issued permit, if there is a justified suspicion that duties following from this Act or from a decision issued on the basis thereof have been breached or that illicit traffic pursuant to international agreements binding the Czech Republic is involved. A permit to export poppy straw may be issued for a term specified therein for several exports. A permit to import poppy straw may be issued for a term specified therein for several imports. Otherwise, issuing and revoking permits to export poppy straw and permits to import poppy straw shall be subject to the provisions of Part Four.

CHAPTER VI
NOTIFICATION DUTIES AND RECORDS

Section 26
Notification Duty on the Basis of Handling Permit

(1) Persons who are authorized to manage dependency producing substances and preparations on the basis of a handling permit shall be obliged to submit to the Ministry of Health, on forms issued by

the Ministry of Health, in writing or in electronic form signed by a guaranteed electronic signature pursuant to the special regulation[10a)]

a) by the end of February, for the previous calendar year, a report on manufacture, growing and consumption of dependency producing substances and preparations bout destruction, on trade therein and trends in stocks thereof, if those persons did not handle the substances in the previous calendar year, it suffices to announce that fact to the Ministry of Health in writing,

b) by the end of April, an estimate of the production, cultivation, and import of dependency producing substances and preparations in the next calendar year; for preparations listed in Annex 8 of the Government Regulation Concerning a List of Dependency Producing Substances, only the estimate of production shall be stated; in the event that the original estimate of the production and import is expected to be exceeded, the persons concerned shall increase the estimate of production and import without delay; these estimates may be modified[10b)] by the International Narcotics Control Board,[2a)]

c) by the fifteenth day of the subsequent month, a monthly report on import and export of dependency producing substances, preparations and precursors for the previous calendar month, except for preparations set forth in Annex No. 8 or medical preparations containing a scheduled substance of category 1.

(2) The notification duty shall also apply to persons managing dependency producing substances, preparations and precursors set forth in Section 5 (7). These persons shall be obliged to submit to the Ministry of Health information set forth in paragraph 1 above.

(3) Persons who are authorized to manage dependency producing substances, preparations and precursors on the basis of a handling permit and persons, for whose activity a permit for handling of dependency producing substances, preparations and precursors is not required pursuant to Section 5 (7), shall be obliged to notify the Ministry of Health forthwith

a) of any theft of dependency producing substances, preparations and precursors,

b) of any special circumstances, e.g. of unusual orders and transactions in these substances,

c) on its request, of other details concerning activities that are the subject of the handling permit.

(4) Upon cessation of an activity, for which a handling permit is required, or with respect to persons pursuant to Section 5 (7), the person who has performed the activity shall be obliged to submit an extraordinary report within the scope stipulated in paragraph 1 (a) above within 30 days of the cessation of the activity. Upon the death of a natural person who was engaged in business, for whom a handling permit had been issued, the obligation to file an extraordinary report pursuant to paragraph (1) a) shall transfer to the responsible person or his/her representative, and if those persons are unable to meet that obligation, it shall transfer to the estate executor.

Section 27

Notification Duty of Persons Operating Pharmacy

(1) Persons operating a pharmacy shall be obliged to submit to the regional authority by the end of February an annual report for the previous calendar year describing the state of and trends in stocks of dependency producing substances set forth in Annex No. 1 or 5 of Government Regulation Concerning a List of Dependency Producing Substances, as well as preparations containing them, except for preparations set forth in Annex No. 8 of Government Regulation Concerning a List of Dependency Producing Substances. The annual report shall be submitted on a form issued by the Ministry of Health in writing or in electronic form signed by a guaranteed electronic signature pursuant to the special regulation.[10a)] If those persons did not handle the substances in the previous calendar year, it suffices to announce that fact to the State Drug Control Institute in writing.

(2) Upon cessation of activities of a pharmacy[10c)] the person, who has operated this activity shall be obliged to submit, within 30 days of cessation of this activity, to the regional authority an extraordinary report within the scope stipulated in paragraph 1 above.

Section 27a

(1) Persons operating a pharmacy and distributors of medical substances[10d)] shall be obliged, at the latest by January 10 of each calendar year, to report to the the Institute for State Control of Veterinary Bio-Preparations and Pharmaceuticals (hereinafter referred to as the "Veterinary Institute") withdrawal of preparations containing dependency producing substances set forth in Annexes Nos. 1 and 5 of Government Regulation Concerning a List of Dependency Producing Substances, except for preparations set forth in Annex No. 8 hereof, by veterinary doctors during the previous calendar year. The report shall be submitted to the Veterinary Institute on a form issued by it.

(2) The Veterinary Institute shall be obliged to submit to the Ministry of Health, by the end of February of each calendar year, a report for the previous calendar year describing the consumption of preparations containing dependency producing substances set forth in Annexes Nos. 1 and 5 hereof, except for preparations set forth in Annex No. 8 hereof, by veterinary doctors.

Section 28
Deleted

Section 29
Notification Duty of Persons Cultivating Opium Poppy or Cannabis

Persons cultivating opium poppy or cannabis on a total area exceeding 100 m^2 shall be obliged to submit a report to the locally competent customs body pursuant to the place of cultivation, in writing or in electronic form signed by a guaranteed electronic signature pursuant to the special regulation[10a)]

a) by the end of May
1. the area of land on which poppy or cannabis is sown for harvesting in the relevant calendar year, including the name of the variety used,[10g)] the parcel numbers, name and number of the cadastral district,[10h)] or the land block identification number, or the identification number of a section of a land block in the soil registry,[10i)]
2. estimate of the area of land where opium poppy or cannabis will be cultivated during the next calendar year,

b) during the vegetation period and during harvest or during the liquidation of harvested poppy straw, information about the area of the land and about the method of destruction of poppy, poppy straw left on the land or harvested, or cannabis, including the name of the registered variety used[10g)], the parcel numbers, name and number of the cadastral district[10h)], or the land block identification number, or the identification number of a section of a land block, the soil registry[10i)], no later than 5 days prior to their destruction; if the person cultivating poppy does not take back the poppy straw from cleansed seed, the obligation to file a report on the destruction of poppy straw shall transfer to the person that cleaned the poppy seeds,

c) by the end of December of the relevant calendar year
1. the area of land that was sown with opium poppy or cannabis, the area of land, where opium poppy or cannabis was harvested, including the name of the registered variety,[10g)] the number of the lot, and the name and number of the cadastral territory,[10h)] or the identification number of a section of a land block in the soil registry,[10i)]
2. the amount of harvested poppy straw, cannabis, seeds of opium poppy and seeds of cannabis,

3. weight, year of harvest poppy or cannabis sold or otherwise transferred and the identification of a new acquirer.

Section 30
Notification Duty in Export and Import of Poppy Straw

Every person who has exported or imported poppy straw shall be obliged to submit to the Ministry of Health, by the fifteenth day of the first month of a calendar quarter, a quarterly report on export or import of poppy straw during the previous quarter. The quarterly report shall be submitted on a form issued by the Ministry of Health in writing or in electronic form signed by a guaranteed electronic signature pursuant to the special regulation.[10a)]

Section 31
Report Form

(1)Reports shall be submitted on forms issued by the Ministry of Health, except for reports pursuant to Section 27, which shall be submitted on forms issued by the State Institute for Drug Control, except for reports pursuant to Section 27a, which shall be submitted on forms issued by the Veterinary Institute, and except for reports pursuant to Section 29, in writing or in electronic form signed by a guaranteed electronic signature pursuant to the special regulation.[10a)]

(2) The Ministry of Finance and Ministry of Agriculture shall stipulate in a Decree a sample form for reports submitted by persons cultivating opium poppy or cannabis (Section 29) and the manner of filling out and handling the relevant form.

Section 32
Records and Documentation

(1) Records shall be kept in the set manner[10j)] of handling of dependency producing substances and preparations, as well as of their import and export. Records must be kept by persons who perform activities, for which a handling permit, export permit or import permit is required, persons who operate a health-care facility, persons providing facility in-patient social services, persons who provide veterinary care and persons set forth in Section 5 (6) and (7).

(2) The Ministry of Health shall stipulate, in a decree, the requisites and contents of the records and documentation, their types, forms of keeping documentation and the manner of maintaining and verifying thereof.

Section 33
Maintaining Documentation

(1) Documentation relating to handling of dependency producing substances, and preparations and export and import thereof must be maintained for a period of 5 years.

(2) The Ministry of Health shall stipulate the details of the manner and period of maintaining documentation in a decree.

CHAPTER VII
CONTROL

Section 34
Inspectors

(1) Control of adherence to the obligations arising from this Act and decisions issued pursuant to it shall be carried out by

a) authorised employees of
1. the Ministry of Health,
2. the State Institute for Drug Control, in matters concerning pharmacies and the handling of cannabis for medical use,
3. regions, who are employees of the Regional Authority, except for inspections of pharmacies, and also in matters concerning control pursuant to Section 13 and 14,
4. the Veterinary Institute,

b) officers of
1. the Police of the Czech Republic,
2. the Customs Administration of the Czech Republic, in matters pertaining to the cultivation of poppy and cannabis and in matters related to adherence to obligations arising from Section 11,

(hereinafter referred to as "Inspectors").

(2) Inspectors shall be authorized to carry out unannounced inspections.

(3) Within control activities, inspectors shall be obliged to prove their identity by means of an identity card issued by one of the bodies set forth in paragraph 1 above.

(4) Within control activities, inspectors shall be authorized

a) to enter properties, buildings and rooms,

b) to request explanations of ascertained facts and submission of instruments and documents,

c) to make copies of instruments and documents and excerpts therefrom, and, where this is not possible and it is simultaneously required for performance of control, to seize the instruments and documents,

d) to an extent essential for performing control, to take samples.

(5) If requested in writing by the controlled person, the control body shall provide compensation for the taken samples in an amount of the costs of manufacture or acquisition.

(6)The inspector shall discuss with the controlled persons any shortcomings ascertained during control and the manner of and the deadline for a ensuring a remedy. The inspector shall draw up a protocol of the course and result of control.

(7) Controlled persons shall be obliged to endure control and provide collaboration required for the performance thereof.

(8) For the purposes of control of cultivation of opium poppy or cannabis, the cadastral authorities shall provide the customs authority with information from the land registry free-of-charge.

Section 35
Control upon Acceptance

Each person shall be obliged to verify, upon acceptance of dependency producing substances, preparations and precursors, whether their amount and type corresponds to the accompanying documents, and report any ascertained material shortcomings immediately to the Police of the Czech Republic and the Ministry of Health.

CHAPTER VIII
ADMINISTRATIVE TORTS

Section 36
Administrative Offences

(1) A legal person or a natural person engaged in business commits an administrative offence if he/she/it

a) in violation of Section 4, engages in an activity that requires a handling permit while not having the permit,

b) in violation of Section 5 (8), fails to inform the Ministry of Health about a change of information stated in the list,

c) in violation of Section 8 (2), produces dependency producing substances or preparations in excess of the highest permissible volume set in the handling permit,

d) states incorrect or incomplete information in an application for a handling permit filed pursuant to Section 8 (6),

e) in violation of Section 8 (7), fails to submit a written application to the Ministry of Health for the issuance of a new handling permit no later than 6 weeks before the expiration of the existing handling permit,

f) in violation of Section 8 (8), fails to inform the Ministry of Health in writing about a change in the information stated in an application for a handling permit,

g) fails to apply for the issuance of a new handling permit in the case of any of the changes of information stated in an application for a handling permit referred to in Section 8 (9),

h) in violation of Section 8 (11), fails to report the discontinuation of the activity for which a handling permit has been issued,

i) in violation of Section 8 (13), fails to return an invalid handling permit to the Ministry of Health within 14 days of the day on which a new handling permit took effect,

j) in violation of Section 9 (9), fails to inform the Ministry of Health in writing of the appointment of a representative of a responsible person or the discontinuation of his office,

k) in violation of Section 9 (10), fails to appoint a new responsible person within the time-period set or fails to request that the Ministry of Health change its/his/her handling permit,

l) in violation of Section 10, stores dependency producing substances and preparations, and equipment for their production or cultivation,

m) in violation of Section 11, transports dependency producing substances stated in Annexes 1, 2, 3, or 5 of the Government Regulation Concerning a List of Dependency Producing Substances and preparations containing them,

n) in violation of Section 12, provides or sells dependency producing substances and preparations or other rights connected with dependency producing substances and preparations,

o) as a natural person or a legal person listed in Section 5 (2) a) or b), fails to hand over destroyed prescription forms or application forms with a blue stripe to the Municipal Authority of a municipality with extended powers, pursuant to Section 13 (6),

p) as a natural person or legal person who no longer complies with the conditions set in Section 5 (2) a) or b), fails to hand over unused or destroyed prescription forms or application forms with a blue stripe to the Municipal Authority of a municipality with extended powers, pursuant to Section 13 (7), within 5 days,

q) in violation of Section 14 (1), fails to destroy unused dependency producing substances and preparations or waste containing them,

r) in violation of Section 15 (a), places dependency producing substances and preparations in customs warehouses, custom-free zones, or custom-free warehouses,

s) breaches any of the bans stated in Section 15 b),

t) in violation of Section 20 (1), exports dependency producing substances or preparations without an export permit,

u) in violation of Section 21 (1), imports dependency producing substances or preparations without an import permit,

v) states incorrect or incomplete information in an application for an export or import permit submitted pursuant to Section 22 (2),

w) fails to return an export or import permit to the Ministry of Health, pursuant to Section 22 (3),

x) breaches the ban on the cultivation of kinds and varieties of the cannabis plant (Cannabis genus) that may have a content of substances of the tetrahydrocannabinol group in excess of 0.3%, pursuant to Section 24 (1) a), or

y) breaches the ban on the cultivation of a poppy variety the dry matter of the pods of which may have a morphine content in excess of 0.8%, pursuant to Section 24 (1) c).

(2) Furthermore, a legal person or a natural person engaged in business commits an administrative offence if he/she/it

a) as a natural person cultivating poppy or a natural person processing or storing poppy straw, fails to notify the Police of the Czech Republic without delay of the circumstances referred to in Section 24 (2),

b) in violation of Section 24 (3), destroys or ploughs-under poppy straw produced in the Czech Republic,

c) in violation of Section 25 (1), imports or exports poppy straw without an import or export permit,

d) in an application for a permit for the export of poppy straw or permit for the import of poppy straw, pursuant to Section 25 (1), states incorrect or incomplete information,

e) as a natural person entitled to handle dependency producing substances and preparations pursuant to a handling permit, fails to comply with any of the notification obligations set out in Section 26 (1) or (3) or states incorrect or incomplete information in a report,

f) as anatural person whose activities do not require a permit to handle dependency producing substances and preparations pursuant to Section 5 (7), fails to comply with any of the notification obligations pursuant to Section 26 (2),

g) in violation of Section 30, fails to provide to the Ministry of Health, by the fifteenth day of the first month of the next calendar quarter, a quarterly report on the export or import of poppy straw in the last quarter, or states incorrect or incomplete information in a report,

h) fails to comply with any obligation pursuant to Section 32 (1) or Section 33 (1),

i) fails to comply with the control or notification obligation pursuant to Section 35, or

j) fails to use names of dependency producing substances and preparations pursuant to Section 42.

(3) Furthermore, a legal person or a natural person engaged in business who is providing pharmaceutical medical services commits an administrative offence if he/she/it

a) in violation of Section 27 (1), fails to submit to the State Institute for Drug Control , by the end of February, an annual report for the previous calendar year about the state and movement of the stock of dependency producing substances listed in Annex 1 or 5 of the Government Regulation Concerning a List of DependencyProducing Substances, including preparations containing them, with the exception of preparations listed in Annex 8 of the Government Regulation Concerning a List of Dependency Producing Substances;

b) in violation of Section 27 (1), states incorrect or imprecise information in an annual report for the previous calendar year about the state and movement of the stock of dependency producing substances listed in Annex 1 or 5 of the Government Regulation Concerning a List of Dependency Producing Substances, including preparations containing them, with the exception of preparations listed in Annex 8 of the Government Regulation Concerning a List of Dependency Producing Substances, or

c) in violation of Section 27 (2), at the time of the discontinuation of the operation of a pharmacy, fails to submit to the State Institute for Drug Control an extraordinary report on the state and movement of the stock of dependency producing substances listed in Annex 1 or 5 of Government Regulation Concerning a List of Dependency Producing Substances, including preparations containing them, with the exception of preparations listed in Annex 8 of Government Regulation Concerning a List of Dependency Producing Substances, or states incorrect or incomplete information in the report.

(4) A legal person or a natural person engaged in business that provides pharmaceutical medical services or distributes pharmaceuticals commits an administrative offence if he/she/it

a) in violation of Section 27a (1), fails to report, by 10 January of a calendar year, to the Veterinary Institute, the purchase of preparations containing dependency producing substances listed in Annex 1 or 5 of Government Regulation Concerning a List of Dependency Producing Substances, with the exception of preparations listed in Annex 8 of Government Regulation Concerning a List of Dependency Producing Substances, by veterinary doctors in the previous calendar year, or

b) in violation of Section 27a (1), states incorrect or incomplete information in a report on the purchase of preparations containing dependency producing substances listed in Annex 1 or 5 of Government Regulation Concerning a List of Dependency Producing Substances, with the exception of preparations listed in Annex 8 of Government Regulation Concerning a List of Dependency Producing Substances, by veterinary doctors in the previous calendar year.

(5) Furthermore, a legal person or a natural person engaged in business cultivating poppy or cannabis on an aggregate area exceeding 100 m2 commits an administrative offence if he/she/it

a) in violation of Section 29, fails to comply with a notification obligation, or

b) states incorrect or incomplete information in reports pursuant to Section 29.

(6) Furthermore, a legal person or a natural person engaged in business that has been granted a licence forthe cultivation of cannabis for medical use commits an administrative offence if he/she/it breaches an obligation pursuant to Section 24a (4) a), b), c), d), e), or f) or pursuant to Section 24b (1).

Section 37
Fines

1) A fine up to the amount stated below shall be imposed for an administrative offence pursuant to Section 36 (1)

a) CZK 500,000 in the event of an administrative offence pursuant to paragraph b), c), e) to h), j) to q), (u), x), or y),

b) CZK 1,000,000 in the event of an administrative offence pursuant to paragraph d), i), t), v), or w),

c) CZK 10,000,000 in the event of an administrative offence pursuant to paragraph a), r), or s).

(2) A fine up to CZK 500,000 shall be imposed for an administrative offence pursuant to Section 36 (2).

(3) A fine up to the amount stated below shall be imposed for an administrative offence pursuant to Section 36 (3)

a) CZK 500,000, for administrative torts pursuant to subparagraph a) and c),

b) CZK 1,000,000, for administrative torts pursuant to subparagraph b).

(4) A fine up to the amount stated below shall be imposed for an administrative offence pursuant to Section 36 (4)

a) CZK 500,000, for administrative torts pursuant to subparagraphs a),

b) CZK 1.000,000, for administrative torts pursuant to subparagraphs b).

(5) A fine up to the amount stated below shall be imposed for an administrative offence pursuant to Section 36 (5)

a) CZK 500,000 in the event of an administrative offence pursuant to paragraph b)

b) CZK 1.000,000 in the event of an administrative offence pursuant to paragraph a).

6) A fine of up to CZK 1.000,000 shall be imposed for an administrative offence pursuant to Section 36 (6).

Section 38
Forfeiture of an Item

The forfeiture of dependencyproducing substances and preparations and of equipment and materials required for their production or cultivation may be imposed for an administrative offence pursuant to Section 36, provided that those items belong to the person who has committed the administrative offence, and

(a) were intended for the commission of the administrative offence,

(b) were used in the commission of the administrative offence,

(c) were obtained through the commission of the administrative offence, or

(d) were acquired in exchange for an item obtained through the administrative offence.

Section 38a
Confiscation of an Item

If the forfeiture of an item has not been imposed pursuant to Section 38, a decision may be made to confiscate the item if it belongs to an offender who cannot be prosecuted for the administrative offence or if it does not fully belong to that the offender, and should it be required for the sake of the safety of persons or property or due to another general interest.

Section 39
Offenses

(1) A natural person cultivating opium poppy or cannabis on a land with a total area exceeding 100 m^2 commits a misdemeanor in that he

a) fails to fulfill the notification duty pursuant to Section 29,

b) states false or incomplete data in reports pursuant to Section 29.

(2) A fine of up to CZK 100,000 may be imposed for an offence pursuant to paragraph (1) a), and a fine of up to CZK 200,000 may be imposed for an offence pursuant to paragraph (1) b). In an on-the-spot procedure, a fine of up to CZK 5,000 may be imposed for an offence pursuant to paragraph (1).

Section 40
Joint Provisions on Penalties

(1) A legal person shall not be liable for an administrative tort if it demonstrates that it used all efforts, that could be requested from this person, to prevent the breach of the legal duty.

(2) The seriousness of the administrative tort and, in particular, the manner of committing thereof and its consequences, and the circumstances, under which it was committed, shall be taken into account in determining the amount of the fine imposed on a legal person.

(3) The liability of a legal person for an administrative tort shall expire if the competent administrative authority does not commence proceedings thereon within 5 years of the date when it learnt of the tort and, at the latest, 10 years after the date of committing the administrative tort.

(4) Administrative offences pursuant to Section 36 (1) and (2), with the exception of administrative offences pursuant to Section 36 (1) l) and q), committed at a medical institution, including a pharmacy, and administrative offences pursuant to Section 36 (1) m), o), p), r), x), and y), and pursuant to Section 36 (2) a), b), h), and i), shall be heard by the Ministry of Health at first instance.

(5) Administrative offences pursuant to Section 36 (1) l), o), p), and q) and pursuant to Section 36 (2) h), and i), committed in a medical institution except for a pharmacy, shall be heard by the Regional Court at first instance.

(6) Administrative offences pursuant to Section 36 (1) l) and q) and pursuant to Section 36 (2) h) and i) committed at a pharmacy, and administrative offences pursuant to Section 36 (3) a), b), and c) and pursuant to Section 36 (6), shall be heard by the State Drug Control Institute at first instance.

(7) Administrative offences pursuant to Section 36 (1) m), r), x), and y), Section 36 (2) a) and b), and pursuant to Section 36 (5) a) and b), and offences pursuant to Section 39 (1) a) and b), shall be heard by the Customs Administration of the Czech Republic at first instance.

(8) Administrative offences pursuant to Section 36 (4) a) and b) shall be heard by the Veterinary institute.

(9) Provisions of the Act on liability and punishment of legal persons shall apply to liability for any conduct occurred within business activities of a natural person[10p)] or in direct relation thereto.

(10) Fines shall be collected and exacted by the body that imposed them. A decision on imposing a fine may be enforced within 5 years from expiry of the deadline for payment thereof.

(11) Income from fines imposed by the Ministry of Health, customs bodies, State Institute for Drug Control or by the Veterinary Institute shall be an income for the state budget. Income from fines imposed by a regional authority shall be an income for the relevant region.

CHAPTER IX
JOINT, TRANSITORY AND CONCLUDING PROVISIONS

Section 41

Relation to Special Regulations

The provisions of special regulations concerning dependency producing substances and preparations shall not be prejudiced.[11)]

Section 41a

Deleted

Section 42

Names of dependency producing substances according to the annexis of Government Regulation concerning a List of Dependency Producing Substances must be used in all official documents, commercial documents and forms. Massproduced medical preparations[11b)] shall be designated by their registered names.

Section 43

Collaboration of State Bodies

(1) Ministries and other central administrative authorities shall cooperate with the Ministry of Health, to the extent of their competences, in the drafting of background materials for

a) international organisations, with respect to the handling of dependency producing substances and preparations,

b) proposals for the inclusion of new substances among dependency producing substances in annexes of the Government Regulation Concerning a List of Dependency Producing Substances.

(2) Regional authorities shall provide the Ministry of Health, by the end of February, with information on dependency producing substances and preparations disposed of pursuant to Section 14 (3) during the previous calendar year.

(3) Customs Administration authorities of the Czech Republic shall be obliged to submit to the Police of the Czech Republic individual reports of persons cultivating opium poppy or cannabis pursuant to Section 29 as follows

a) a report pursuant to Section 29 (a) by June 10 of the relevant calendar year,

b) a report pursuant to Section 29 (b) forthwith.

(4) Customs Administration authorities of the Czech Republic shall be obliged to submit to the General Directorate of Customs individual reports of persons cultivating opium poppy or cannabis pursuant to Section 29 as follows

a) a report pursuant to Section 29 a) by June 10 of the relevant calendar year,

b) a report pursuant to Section 29 b) forthwith,

c) a report pursuant to Section 29 c) by March 31 for the previous calendar year.

(5) The General Directorate of Customs shall provide the Ministry of Agriculture with Information

a) pursuant to Section 29 a) by June 20 of the relevant calendar year,

b) pursuant to Section 29 b) by March 31 for the previous calendar year,

c) pursuant to Section 29 c) by April 30 for the previous calendar year on forms issued by the Ministry of Agriculture.

(6) The General Directorate of Customs shall provide the Ministry of Health with information

a) pursuant to Section 29 a) by June 20 of the relevant calendar year,

b) pursuant to Section 29 c) by April 30 for the previous calendar year on forms issued by the Ministry of Health.

(7) The State Institute for Drug Control and the Veterinary Institute shall

a) regularly inform the Ministry of Health of
1. accepted applications for registration of medicinal preparations containing dependency producing substances,
2. breach of duties following from this Act and decisions issued on its basis,

b) submit regularly to the Ministry of Health counterparts of legally valid decisions on registration of medicinal preparations containing dependency producing substances,

c) submit to the Ministry of Health annual reports pursuant to Section 26 (1) (a),

d) notify the competent regional authority regularly of breach of duties following from this Act and of decisions issued on this basis.

(8) The State Institute for Drug Control

a) shall act as the government agency with respect to cannabis for medical use,[2a)]

b) shall inform the Ministry of Health and the Police of the Czech Republic from time to time about
1. the measures taken to secure the growing and processing of cannabis for medical use,
2. licences granted for the growing of cannabis for medical use,
3. any breach of obligations arising from this Act and from decisions issued pursuant to it,

c) shall inform the Ministry of Health in line with Sec. 43a (4) f),

d) shall inform the Ministry of Health of inspections conducted in pharmacies and of any administrative proceedings commenced that are being conducted due to a breach of an obligation set by this Act, as at 30 April, 31 July, 30 October, and 31 January for the previous calendar quarter.

Section 43a
Competence of State Administrative Bodies

(1) In addition to activities stipulated in this Act, in the area of dependency producing substances and preparations the Ministry of Health shall also

a) make decisions on appeals against decisions of regional authorities and the State Drug Control Institute in cases set forth in Section 40 (5) and (6),

b) submit to the International Narcotics Control Board
1. quarterly information concerning import and export of narcotic drugs,[11c)] psychotropic substances[11d)] pursuant to Annex No. 5 of Government Regulation Concerning a List of Dependency Producing Substances and preparations containing these substances during the previous 3 months,
2. once annually, by June 30, information concerning the manufacture, production, growing, consumption, state of stocks and seized amounts of narcotic drugs and preparations containing these substances during the previous calendar year,[11e)]
3. once annually, by June 30, information concerning the manufacture, state of stocks, and import and export of psychotropic substances and preparations containing these substances during the previous calendar year,[11f)]
4. by June 30, an estimate of the needs for narcotic drugs,[11g)] psychotropic substances[11h)] and preparations containing these substances for the next calendar year, and supplements thereto[11i)] during the calendar year,

c) cooperate with the competent bodies of the country of the importer and exporter.

(2) The Police of the Czech Republic shall

a) inform the Ministry of Health of any and all important facts required for its decision-making pursuant to this Act, in particular any theft of dependency producing substances and preparations and attempts at the theft thereof,

b) be entitled from time to time, through a designated contact workplace, in the event of the detection of a natural person in possession of cannabis or a preparation containing cannabis, make a remote query in the register of restricted medical preparations, kept pursuant to the Act on Pharmaceuticals,[6)] as to whether the natural person is registered as one to whom an individually prepared medical preparation with cannabis content has been given for medical use; the register shall immediately comply with the query and provide that information free of charge; in the event that the person is registered as one to whom an individually prepared medical preparation with cannabis content has been given for medical use, the register shall also provide, free of charge, the date of the issuance and the aggregate amount of an individually prepared medical preparation with cannabis content for medical use that has been provided.

(3) Customs Administration authorities of the Czech Republic

a)inform the Ministry of Health through the General Directorate of Customs of all important facts required for its decision-making pursuant to this Act,[11j)] particularly of any cases of seizure[11o)] of dependency producing substances and preparations,

b)provide through the General Directorate of Customs information on import or export of dependency producing substances and preparations to the Ministry of Health.

(4) State Institute for Drug Control

a)grant licences for the growing of cannabis for medical use; such a licence shall specify the area, parcel number, name of the cadastral district, name of the registered variety used, and the identification number of the block of soil, or section of a block of soil in line with the record in the soil utilisation registry,

b) check on the compliance of cannabis grown for medical use with the conditions set pursuant to Sec. 24a (2) and on the compliance of the processing and storage of cannabis for medical use with the correct production practice rules, and check whether it is secured against theft and abuse in order to protect public health,

c) purchase the entire crop of cannabis for medical use that has been grown and harvested and whose quality has been documented by a certificate specified in Sec. 24b (1), and shall do so within 4 months of its harvest,

d) export cannabis for medical use subject to the conditions set out by this Act,

e) ensure the safe storage, carriage, and distribution of cannabis for medical use, including through other persons on the basis of an agreement,

f) inform the Ministry of Health in writing or in electronic form signed with a guaranteed electronic signature pursuant to another legal regulation,[10a)]
1. by the end of February with respect to the previous calendar year, giving it a report of the amount of cannabis for medical purposes grown, processed, destroyed, accepted, and released, including any export, trade, inventory count and inventory movement,
2. by the end of April, about the estimated production of cannabis for medical use for the following calendar year; the said estimate may be modified[10b)] by the International Narcotics Control Board,[2a)]
3. by the fifteenth day of the following calendar month, by giving it a monthly report on the export of cannabis for medical use in the previous calendar month.

Section 44
Joint Provisions

An appeal lodged against a decision to withdraw a handling permit, an export permit, an import permit, a permit for the export of poppy straw, or a permit for the import of poppy straw, shall not have a dilatory effect.

Section 44a

The competence of regional authorities or district authorities of a municipality with extended competence pursuant to this Act shall constitute performance of delegated competence.

Section 44b

Forms set out in Sec. 5 (7), 8 (6) and (11), 9 (10), 22 (2), 25 (2), 26 (1), 27 (1), 30, 31 (1) a 43 (6) including Annexes, which are an integral part of them, set out Ministry of Health by degree and publish by way enabling remote access.

Section 44c

Empowering Provisions

(1) The Government shall set out in a regulation

a) a list of
1. narcotic substances included on List I, pursuant to the Single Convention on Narcotic Substances and
2. other narcotic substances that require, due to the scope of their abuse or because they pose a direct or indirect threat to health, that their handling only be permitted on the basis of a handling permit, or with respect to which it is, due to those reasons, necessary to ensure that medical preparations containing these substances were only issued at pharmacies on the basis of a prescription or application labelled with a blue stripe running from the bottom left-hand corner to the top right-hand corner,

b) a list of
1. narcotic substances included on List II, pursuant to the Single Convention on Narcotic Substances and
2. other narcotic substances with respect to which it must be ensured, due to the scope of their abuse or because they pose a direct or indirect threat to health, that medical preparations containing these substances were only issued at a pharmacy on the basis of a prescription or an application not labelled with a blue stripe,

c) a list of
1. narcotic substances included on List IV, pursuant to the Single Convention on Narcotic Substances and
2. other narcotic substances with respect to which it must be ensured, due to the scope of their abuse or because they pose a direct or indirect threat to health, that substances and preparations containing these other narcotic substances were only used for limited research and scientific purposes and very limited therapeutic purposes, specified in the handling permit,

d) a list of
1. psychotropic substances included on List I, pursuant to the Convention on Psychotropic Substances and
2. other psychotropic substances with respect to which it must be ensured, due to the scope of their abuse or because they pose a direct or indirect threat to health, that substances and preparations containing these other psychotropic substances were only used for limited research and scientific purposes and very limited therapeutic purposes, specified in the handling permit,

e) a list of
1. psychotropic substances included on List II, pursuant to the Convention on Psychotropic Substances and
2. other psychotropic substances which require, due to the scope of their abuse or because they pose a direct or indirect threat to health, that their handling only be permitted on the basis of a handling permit, or with respect to which it is, due to those reasons, necessary to ensure that medical preparations containing these substances were only issued at pharmacies on the basis of a prescription or application labelled with a blue stripe running from the bottom left-hand corner to the top right-hand corner,

(f) a list of psychotropic substances included on List III, pursuant to the Convention on Psychotropic Substances,

(g) a list of
1. psychotropic substances included on List IV, pursuant to the Convention on Psychotropic Substances and
2. other psychotropic substances with respect to which it must be ensured, due to the scope of their abuse or because they pose a direct or indirect threat to health, that medical preparations containing these substances were only issued at a pharmacy on the basis of a prescription or an application not labelled with a blue strip and

h) a list of preparations included on List III, pursuant to the Single Convention on Narcotic Substances.

(2) The Government shall set out the lists pursuant to

(a) paragraph (1) a) in Annex 1 to the Regulation, pursuant to Paragraph (1),

(b) paragraph (1) b) in Annex 2 to the Regulation, pursuant to Paragraph (1),

(c) paragraph (1) c) in Annex 3 to the Regulation, pursuant to Paragraph (1),

(d) paragraph (1) d) in Annex 4 to the Regulation, pursuant to Paragraph (1),

(e) paragraph (1) e) in Annex 5 to the Regulation, pursuant to Paragraph (1),

(f) paragraph (1) f) in Annex 6 to the Regulation, pursuant to Paragraph (1),

(g) paragraph (1) g) in Annex 7 to the Regulation, pursuant to Paragraph (1), and

(h) paragraph (1) h) in Annex 8 to the Regulation, pursuant to Paragraph (1).

(3) To implement Section 24, the Ministry of Agriculture shall set out, in a regulation, a list of poppy varieties that comply with the condition of having a maximum morphine content of 0.8% in dry pod matter, and the method of liquidation of poppy straw.

Section 45
Transitory Provisions

(1) Permits for handling of narcotic drugs and psychotropic substances or preparations and special permits for export or import of narcotic drugs and psychotropic substances or preparations issued pursuant to the former regulations shall be considered to be handling permits, export permits, import permits, permits for export of poppy straw or permits for import of poppy straw, as appropriate, pursuant to this Act for a period of 6 months from the date of effect hereof.

(2) Proceedings on issuing a permit for handling of narcotic drugs and psychotropic substances or preparations and on issuing a special permit for export or import of narcotic drugs and psychotropic substances or preparations issued pursuant to the former regulations,[13)] that have not been validly completed by the date of effect hereof, shall be discontinued.

(3) Manufacturers of auxiliary substances shall be obliged to register with the Ministry of Health (Section 16) within 3 months of the legal force of this Act.

PART SEVEN

Section 51

Legal Force

This Act enters into effect on January 1, 1999.

[1)] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, as Amended.

[2a)] Decree No. 47/1965 Coll., on the Single Convention on Narcotic Drugs, as amended by Communication No. 458/1991 Coll., the Protocol on amendments to the Single Convention on Narcotic Drugs of 1961.

[2c)] Convention on Psychotropic Substances promulgated under No. 62/1989 Coll.

[2e)] Section 16 (5) of Act No. 79/1997 Coll.

[3)] Act No. 125/1997 Coll., on wastes, as amended.

[4)] Section 25 (1) (a) of Act No. 87/1987 Coll., on veterinary care.

[5)] Section 33 et seq. of Act No. 79/1997 Coll.

[5a)] Section 39 of Act No. 79/1997 Coll.

[5d)] Sections 187, 187a, 188 and 188a of Act No. 140/1961 Coll., the Criminal Code.

[5f)] Council Regulation (EC) No. 1485/96 of 26 July 1996, laying down detailed rules for the application of Council Directive 92/109/EEC, as regards customer declarations of specific use relating to certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances, as amended by Commission Regulation (EC) No. 1533/2000.

[6)] Section 2 (1) of Act No. 79/1997 Coll.

[6a)] Section 39 of Act No. 378/2007 Coll.

[6b)] Decree No. 54/2008 Coll

[6c)] Section 50 of Act No. 79/1997 Coll.

[7)] Sections 162, 162a and 220 of Act No. 13/1993 Coll., as amended by Act No. 113/1997 Coll.

[8a)] Decree No. 47/1965 Coll., as amended by Communication No. 458/1991 Coll. Convention on Psychotropic Substances promulgated under No. 62/1989 Coll.

[9)] Sections 309 to 311 of Act No. 13/1993 Coll., as amended by Act No. 113/1997 Coll.

[10)] Act No. 283/1991 Coll., on the Police of the Czech Republic, as amended.

[10a)] Act No. 227/2000 Coll., on electronic signature and amendment to some other laws (Act on electronic signature), as amended. Government Regulation No. 304/2001 Coll. implementing Act No. 227/2000 Coll., on electronic signature and amendment to some other laws (Act on electronic signature).

[10b)] Art. 19 and 21 of) Decree No. 47/1965 Coll.

[10c)] Act No. 160/1992 Coll., on health care in non-state health-care facilities, as amended.

[10d)] Section 4 (3) of Act No. 79/1997 Coll.

[10e)] Section 1 of Decree No. 304/1998 Coll., stipulating cases where an export permit for export of auxiliary substances is not required, details of keeping records of dependency producing substances, preparations and precursors, and on documentation of dependency producing substances, as amended by Decree No. 143/2000 Coll.

[10f)] Article 3 of Council Regulation (EEC) No. 3677/90, as amended by Council Regulation (EEC) No. 900/92

[10h)] Act No. 344/1992 Coll., on the land registry of the Czech Republic (the Cadastral Act), as amended.

[10i)] Section 3a of the Act No. 152/1997 Coll., as amended.

[10j)] Decree No. 123/2006 Coll., as amended by Decree No. 72/2014 Coll.

[10g)] Act No. 219/2003 Coll., on the placement of plant seeds and seedlings into circulation and on amending certain acts (Act on Seed and Seedling Circulation), as amended.

[10p)] Section 2 of the Act No. 513/1991Coll., Commercial Code.

[11)] E.g. Act No. 79/1997 Coll., Act No. 40/1995 Coll., on regulation of advertising and amending and supplementing Act No. 468/1991 Coll., on operation of radio and television broadcasting, as amended, Act No. 13/1993 Coll., as amended, Act No. 563/1991 Coll., on accounting, as amended.

[11a)] Art. 18 of the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances promulgated under No. 462/1991 Coll.

[11b)] Act No. 79/1997 Coll.

[11c)] Art. 1,2,13,20 and 25 of) Decree No. 47/1965 Coll.

[11d)] Art. 1 and 2 of Convention on Psychotropic Substances promulgated under No. 62/1989 Coll.

[11e)] Art. 1,2,13,20 and 27 of Decree No. 47/1965 Coll.

[11f)] Art. 1,2,3,12 and 16 of Convention on Psychotropic Substances promulgated under No. 62/1989 Coll.

[11g)] Art. 1,12 a 19 of Decree No. 47/1965 Coll.
[11 i)] Art. 12 and 19 of Decree No. 47/1965 Coll.
[11l)] Sec. 79 of Criminal Code
[11o)] Sec. 309 to 312 of Act. No. 13/1993 Coll
[14)] Act No. 137/2006 Coll., on public procurement, as amended.
[15)] Act No. 552/1991 Coll., on state control, as amended.
[16)] Act No. 526/1990 Coll., on prices, as amended.