The answers to this questionnaire have been provided on behalf of:

Country:	Czech Republic
Office:	
Person to be	contacted:
Name:	Mrs. Eva Schneiderová
Title:	Director of Patent Department
E-mail:	<u>*</u>
Telephone:	+ 420 222 383 458

Please note, that the following answers and information are based on the applicable legal provisions of the Act No.527/1990 Coll. on Inventions and Rationalization Proposals, as amended, (hereinafter "the Patent Act") and of the Act No.206/2000 Coll. on the Protection of Biotechnological Inventions.

#### Section I: General

Facsimile:

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term "applicable law" refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

- 1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.
- (1) Patents shall be granted for any inventions which are new, which involve an inventive step and which are susceptible of industrial application.
- (2) The following in particular shall not be regarded as inventions:
- a) discoveries, scientific theories and mathematical methods;
- b) aesthetic creations;
- c) schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers;
- d) presentations of information.
- (3) The patentability of the subject-matter or activities referred to in paragraph 2 is excluded only to the extent to which an application or a patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in these methods for treatment and these diagnostic methods.

### (see Section 3 (Patentability of inventions) of the Patent Act)

Biotechnological inventions are patentable, if they concern

- a) biological material, which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature,
- b) plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety, or
- c) microbiological or other technical process and a product, other than a plant or animal variety, obtained by this way.

(see Section 2 (Patentable biotechnological inventions) of the Act No.206/2000 Coll. on the Protection of Biotechnological Inventions)

 	• • • •

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.<sup>1</sup>

Patents shall not be granted in respect of:

a) inventions the exploitation of which would be contrary to public order or morality; this fact may not be concluded merely because the exploitation of invention is prohibited by law; b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes and the products thereof. (see Section 4 (Exclusions from patentability) of the Patent Act)

#### Patents shall be not granted to

- a) inventions, whose commercial exploitation would be contrary to public policy or to principles of morality, namely to processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, processes of using human embryos for industrial or commercial purposes or processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to man or animal, and also to animals resulting from such processes; however, the contradiction to public policy or to principles of morality shall not be deduced merely from the fact that the exploitation of the invention is prohibited by legal regulation,
- b) human body at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene; it does not apply to an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element, and

This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

c) plant and animal varieties or essential biological processes for the production of plants or animals.

(see Section 3 (Exclusions of patentability) of the Act No. 206/2000 Coll. on the Protection of Biotechnological Inventions)

- 1) Section 2 letter a) of the Act No. 132/1989 Coll., on the Protection of Rights to New Plant and Animal Varieties, as amended by Act No. 93/1996 Coll.
- <sup>2)</sup> Section 2 letter c) of the Act No.132/1989 Coll. 2 embryos for industrial or commercial purposes or processes for modifying the genetic identity

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

- (1) The proprietor of a patent (Section 34) shall have the exclusive right to use the invention, to authorise others to use the invention or to assign the patent to others.
- (2) The patent shall have effect as from the date of publication of the mention of its grant in the Official Bulletin of the Industrial Property Office (hereinafter referred to as "the Official Bulletin").
- (3) The applicant shall be entitled to appropriate remuneration from any person who uses the subject-matter of the invention application after the application has been published (Section31). The right to appropriate remuneration may be asserted as from the date on which the patent has effect.
- (4) An applicant filing an international application requesting grant of a patent in the Czech Republic and which has been published in compliance with the international treaty shall be entitled to appropriate remuneration in accordance with paragraph 3 only after the translation of the application into the Czech language has been published (Section 31).

## (see Section 11 (Effect of the patent) of the Patent Act)

Nobody shall be allowed without the consent of the proprietor of the patent,

- a) to make, offer, put on the market or use a product which is the subject-matter of the patent, or to import or stock the product for this purpose, or to dispose with it by another manner:
- b) to use a process which is the subject-matter of the patent or to offer the process for use;
- c) to offer, put on the market, use or import or stock for this purpose the product obtained directly by a process, which is the subject-matter of the patent; identical products shall be held to have been obtained by means of the process, which is the subject-matter of the patent, when it is highly probable that the product was obtained by means of the process, which is the subject-matter of the patent, and in spite of reasonable effort, the proprietor of the patent was not able to determinate the really used process; unless the contrary is proved. In proving the contrary, rights conferred by the trade secret protection shall be respected.

## (see Section 13 (Prohibition of direct use) of the Patent Act)

- (1) Nobody shall be allowed without the consent of the proprietor of the patent, to supply or offer to supply a person, other than the person authorised to use the patented invention, with the means relating to an essential element of the invention and serving in this sense to put in into effect, when it is obvious in the circumstances, that these means are suitable and intended for putting the patented invention into effect.
- (2) The paragraph 1 shall not apply when the means are products commonly existing on the market, unless the third person induces the purchaser to commit the act, prohibited by Section 13
- (3) Persons performing the activities referred to in Section 18, letters c) to e) shall not be considered as persons authorised to use the invention within the meaning of paragraph 1.

## (see Section 13a (Prohibition of indirect use) of the Paten Act)

- (1) The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
- (2) The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through this process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
- (3) The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, in which the product is incorporated or in which the genetic information is contained and performs its function, except the human body at the various stages of its formation or development.

(see Section 6 (Scope of Protection) of the Act No. 206/2000 Coll. on the Protection of Biotechnological Inventions)

Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

X Private and/or non-commercial use:

- X Experimental use and/or scientific research;
- X Preparation of medicines;<sup>2</sup> (as far as individual preparation is concerned)
- X Prior use;

3.

- X Use of articles on foreign vessels, aircrafts and land vehicles;
- X Acts for obtaining regulatory approval from authorities;
- X Exhaustion of patent rights;
- X Compulsory licensing;
- X Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.<sup>3</sup>

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

For example, extemporaneous preparation of prescribed medicines in pharmacies.

For example, in some countries where patent rights extend to propagated or multiplicated material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

# Section II: Private and/or non-commercial use

4.	If the exception is contained in statutory law, please provide the relevant provision(s):
,	ghts of the proprietor of the patent shall not be infringed by use of the ted invention:
*	cts done for non-commercial purposes; section 18 d) of the Patent Act)

5.	If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:			
6.	(a) What are the public policy objectives for providing the exception?			
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:			
7.	If the applicable law defines the concepts "non-commercial", "commercial" and/or "private", please provide those definitions by citing legal provision(s) and/or decision(s):			
8.	If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):			
9.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:			
	Yes			
	105			
10.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:			

# Section III: Experimental use and/or scientific research 4

11. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights of the proprietor of the patent shall not be infringed by use of the protected invention: e) in acts relating to the subject-matter of the invention done for experimental purposes including experiments and tests required under a special regulation before the drug is put on the market. (see Section 18 e) of the Paten Act) 12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary: 13. (a) What are the public policy objectives for providing the exception? (b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions: Does the applicable law make a distinction concerning the nature of the 14. organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

15.	If the applicable law defines the concepts "experimental use" and/or "scientific research", please provide those definitions by citing legal provision(s) and/or decision(s):
16.	If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:
	Experimentation and/or research should aim to:
	determine how the patented invention works determine the scope of the patented invention determine the validity of the claims seek an improvement to the patented invention invent around the patented invention other, please specify:
17.	If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:
	Research and/or experimentation must be conducted on or relating to the patented invention ("research on") Research and/or experimentation must be conducted with or using the patented invention ("research with") Both of the above
	Please explain by citing legal provision(s) and/or decision(s):
18.	If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:
	A non-commercial purpose A commercial purpose Both of the above The commercial intention of the experimentation and/or research is not relevant
19.	If the applicable law makes a distinction between "commercial" and "non-commercial" purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

20.	scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
21.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
	Yes

22.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:				
Section	on IV: Preparation of medicines				
23.	If the exception is contained in statutory law, please provide the relevant provision(s):				
prote	ights of the proprietor of the patent shall not be infringed by use of the cted invention:				
medic	the individual preparation of a medicament in a pharmacy based on a cal prescription including acts concerning the medicament so prepared;  Section 18 c) of the Patent Act)				
(200 2					
24.	If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:				
25.	(a) What are the public policy objectives for providing the exception? Please explain:				
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:				
26.	Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:				
27.	Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?				
	Vee				

Yes X No

	If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):
28.	If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
29.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
	Yes
30.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:
Section	on V: Prior use
31.	If the exception is contained in statutory law, please provide the relevant provision(s):
"the prinven he can (2) In reque	patent shall not have effect vis-à-vis a person (hereinafter referred to as prior user") who has already exploited the invention independently of the tor or proprietor of the patent or who has made preparation therefore, that in prove, before the priority right began (Section 27).  I case of failure to reach agreement, the prior user shall be entitled to st a court that his right to be recognized by the proprietor of the patent.  Section 17 (Limitation of effects of patent) of the Patent Act).
32.	If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
33.	(a) What are the public policy objectives for providing the exception? Please

explain:

(Ł	b) Where possible, please explain with references to the legislative history,
p	arliamentary debates and judicial decisions:

34.	How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):
	Exploitation of the invention independently of the inventor of proprietor of the patent or who has made preparation therefore before the priority right began
35.	Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:
	No
36.	According to the applicable law, can a prior user license or assign his prior user's right to a third party?
	Yes X No
37.	In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?
	Yes No
	If yes, please explain what those conditions are:
38.	Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?
	Yes X No
	If yes, please explain the conditions under which such use can continue to apply:
39.	If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your

answer by citing legal provision(s) and/or decision(s):

parliamentary debates and judicial decisions:

Questionnaire on Exceptions	and	Limitations	to	Patent	Rights
				pa	age 16

.....

- 45. The exception applies in relation to:
  - X Vessels
  - X Aircrafts
  - X Land Vehicles Spacecraft

46.	In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):
47.	Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):
48.	If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
49.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
	Yes
50.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

## Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

The rights of the proprietor of the patent shall not be infringed by use of the protected invention:

e) in acts relating to the subject-matter of the invention done for experimental purposes including experiments and tests required under a special regulation before the drug is put on the market.

See Section 18 e) of the Patent Act (as amended by the Act No.378/2007  Coll, on Pharmaceuticals , see Article 125)

If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
(a) What are the public policy objectives for providing the exception? Please explain:
(b) Where possible, please explain with references to the legislative history,
parliamentary debates and judicial decisions:
So called "Bolar provison" in Section 18(e) of the Patent Act implements Art.10(6) of Directive 2004/27/EC of the EP and of the Council of 31
March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use
Who is entitled to use the exception? Please explain:
The exception covers the regulatory approval of:
any products certain products. Please describe which products:
Please indicate which acts are allowed in relation to the patented invention under the exception?
Making
Using
Selling Offering for colo
Offering for sale Import
Export
Other. Please
specify:
If the applicable law provides for other criteria to be applied in determining the
scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

58.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
	Yes
59.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:
Secti	on VIII: Exhaustion of patent rights
60.	Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:
	□ National X Regional International Uncertain, please explain
	If the exception is contained in statutory law, please provide the relevant provision(s):
	If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
61.	(a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:
	The exhausting regime reflects that Czech Republic is member state of the European Union.
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

<b>0</b> Ζ.	importation or other distribution of the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?
	Yes No Uncertain
	Please explain your answer by citing legal provision(s) and/or decision(s):
63.	Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:
	Yes
64.	Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:
Section	on IX: Compulsory licenses and/or government use
Comp	pulsory licenses
65.	If the exception is contained in statutory law, please provide the relevant provision(s):
all or	the proprietor of the patent unreasonably does not exploit the invention at exploits it insufficiently and he did not accept a due offer for a licence ment in a reasonable term, the Office, upon the justified request, may

- grant a non-exclusive right to use the invention (compulsory licence); the compulsory licence may not be granted before the expiry of the period of 4 years as from the filing date of the invention application or 3 years as from the grant of the patent; whichever period expires last (2) The compulsory licence may be also granted, where an important public
- interest is endangered.
- (3) The Office shall establish conditions, the scope and duration of the compulsory licence in its decision concerning the granting of the compulsory licence, taking into account circumstances of the case. The compulsory licence may be granted mainly for the supply of the home market.

- (4) The compulsory licence may only be assigned within the transfer of the enterprise or its part, where the entrepreneur uses the invention based on the compulsory licence (thereinafter "compulsory licence holder").
- (5) The compulsory licence holder may waive the right to use the invention during the term of duration of the compulsory licence by notification made to the Office; on the day of delivery of the notification, the effect of decision on the grant of compulsory licence lapses.
- (6) The Office shall revoke a compulsory licence or change conditions, scope or duration of the compulsory licence on the request of the proprietor of the patent in which he shall prove that conditions for the grant of compulsory licence have been changed and are unlikely to recur or the holder does not exploit the compulsory licence during one year or does not implement conditions established by the grant of the compulsory licence.
- (7) The grant of a compulsory licence shall not affect the right of the proprietor of the patent for the compensation of the value of the licence. If the value of the licence is not agreed by concerned parties it shall be determined, upon request, by the court, taking into account the importance of the invention and the value of the licence contracts in the relevant technical field.
- (8) The compulsory licence shall be recorded in the Patent Register (Section 69)..

(see Section 20 (Compulsory licence) of the Patent Act)

Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2007 on compulsory licensing of patents relating to the manufacture of

pharmaceutical products for export to countries with public health problems is also applicable in the Czech Republic.

- (1) If a breeder cannot obtain or exploit a plant or animal variety right without infringing a prior patent, he may apply for a compulsory licence for nonexclusive use of the invention protected by the patent. The Office will grant the compulsory licence, if the breeding certificate holder applied unsuccessfully to the holder of the patent to obtain a contractual licence and if the plant or animal variety constitutes significant technical progress of considerable economic interest compared with the invention, protected by the patent. In this case, the holder of the patent will be entitled to a cross-licence to commercial use of protected variety on the same conditions, as applied for a compulsory licence according to a special legal regulation.
- (2) If a compulsory licence to commercial use of protected plant or animal variety has been granted to the holder of the patent according to a special legal regulation, the breeding certificate holder will be entitled to a cross-licence to use the patent of invention.

(see Section 9 (Compulsory licence and compulsory cross-licence) of the Act No. 206/2000 Coll. on the Protection of Biotechnological Inventions)

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:


- 67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):
  - X Non-working or insufficient working of the patented inention
  - X Refusal to grant licenses on reasonable terms
    Anti-competitive practices and/or unfair competition
  - X Public health, in the framework of public interest

	X National security X National emergency and/or extreme urgency Dependent patents Other, please specify:
68.	(a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:
69.	If the applicable law provides for the grant of compulsory licenses on the ground of "non-working" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):
70.	Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):  Yes.
	(see Section 13 of the Patent Act)
71.	In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?
	X Yes
	No
	If yes, what is the time period? 4 years as from the filing date of the patent application or 3 years as from the grant of the patent
	Four years have expired since filing of an application or three years have expired from granting a patent, where the time limit, which expires later, shall apply (see Section 20(1) of the Patent Act).

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

X Yes

No

If yes, what are "legitimate reasons"?

The Office shall revoke a compulsory license or change conditions, scope or duration of the compulsory license on the request of the proprietor of the patent in which he shall prove that conditions for the grant of compulsory license have been changed and are unlikely to recur or the holder does not exploit the compulsory license during one year or does not implement conditions established by the grant of the compulsory license. (see Section 20(6) of the Patent Act)

73.	If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):
	There are no such legal definitions.
74.	If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):
75.	If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:
76.	Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:
	The grant of a compulsory licence shall not affect the right of the proprietor of the patent for the compensation of the value of the licence. If the value of the licence is not agreed by concerned parties it shall be determined, upon request, by the court, taking into account the importance of the invention and the value of the licence contracts in the relevant technical field.  (see Section 20(7) of the Patent Act).
77.	If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:
	The compulsory licence may be also granted, where an important public interest is endangered.  (see Section 20(2) of the Patent Act.)
78.	Please indicate how many times and in which technological areas compulsory
	in the state of th

licenses have been issued in your country:

No compulsory licence has been granted in the Czech Republic up to
now

79.	Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
	Yes
80.	Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:
	see reply ad 78
Gove	rnment use
81.	If the exception is contained in statutory law, please provide the relevant provision(s):
	No such exception is provided for in the Czech patent law
82.	If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
83.	What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):
	Non-working or insufficient working of the patented invention Refusal to grant licenses on reasonable terms Anti-competitive practices and/or unfair competition Public health National security National emergency and/or extreme urgency Dependent patents Other, please specify:
84.	(a) What are the public policy objectives for providing government use in your country?
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

85.	If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:
86.	Please indicate how many times and in which technological areas government use has been issued in your country:
87.	Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
88.	Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

# Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

- 89. If the exception is contained in statutory law, please provide the relevant provision(s):
- (1) The person, who has obtained the plant propagating material being subject of the patent from its holder or with his consent, is authorised to use for reproduction during his agricultural activity except commercial exploitation, also the product of his harvest.
- (2) The person, who has obtained the animal reproductive material being subject of the patent from its holder or with his consent, is authorised to use this material during his agricultural activity except commercial exploitation; this includes making the animal or other animal reproductive material available.

(see Section 8 (Limitation of rights of patent holder) of the Act No. 206/2000 Coll., on the Protection of Biotechnological Inventions)

90.	If the exception is provided through case law, please cite the relevant
	decision(s) and provide a brief summary of such decision(s):

91.	(a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:		
	(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:		
	Section 8 (1) and (2) of the Act No. 206/2000 Coll., on the Protection of Biotechnological Inventions implements Article 11(1) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions .		
92.	Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):		
93.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:		
94.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:		
Breede	ers' use of patented inventions		
95.	If the exception is contained in statutory law, please provide the relevant provision(s):		
	see reply ad 89		

96.		If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

97.	breeders' use of patented inventions? Please explain:
	(b) Where possible, please explain with references to the legislative history,
	parliamentary debates and judicial decisions:
	see reply ad 91
98.	Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):
99.	Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
100.	Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:
Sectio	on XI: Other Exceptions and Limitations
101. provide	Please list any other exceptions and limitations that your applicable patent law es:
	No other exceptions and limitations are applicable in the Czech patent law.

102.	In r	In relation to each exception and limitation, please indicate:				
	(i)	the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):				
	(ii)	the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:				
	(iii)	the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):				
	In a	addition, in relation to each exception and limitation, please explain:				
	(i)	whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):				
	(ii)	if there have been any challenges encountered in the practical implementation of the exception in your country:				
103.	syste	er mechanisms for the limitation of patent rights external to the patent em exist in your country (for example, competition law), please list and ain such mechanisms:				

[End of Questionnaire]