
**Council for Trade-Related Aspects
of Intellectual Property Rights**

REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b)

ILLUSTRATIVE LIST OF QUESTIONS

Prepared by the Secretariat

Revision

1. At its meeting of 1-2 December 1998, the Council agreed to initiate the review due under Article 27.3(b) of the provisions of that subparagraph through an information-gathering exercise. In this connection, the Council invited Members that were already under an obligation to apply Article 27.3(b) to provide information on how the matters addressed in this provision were presently treated in their national law. Other Members were invited to provide such information on a best-efforts basis. In response to the Council's invitation, information had been received from Australia, Bulgaria, Canada, the Czech Republic, the European Communities and their member States, Hungary, Japan, Korea, Morocco, New Zealand, Norway, Poland, Romania, Slovenia, South Africa, Switzerland, the United States and Zambia (documents IP/C/W/125 and Addenda 1-17).
2. At its meeting of 2-5 April 2001, the Council agreed that the Secretariat re-issue the illustrative list of questions which it had prepared and circulated in December 1998 in response to a request from the Council (document IP/C/W/122). On 5 June 2001, the Secretariat compiled, in an informal note, the information provided by these Members in the form of a structured summary overview. The illustrative list of questions and the informal note were circulated as document IP/C/W/273. The note contained two synoptic tables in Annex II (Job No. 2689), one covering the information received regarding patent protection of plant and animal inventions and the other the information received regarding protection of plant varieties.
3. At its meeting of 5-7 March 2002, the Council invited Members, as reflected in paragraph 206 of document IP/C/M/35, to provide their responses to this illustrative list of questions, if they had not yet done so. The Council has received to date further responses from Estonia (IP/C/W/125/Add. 20); Hong Kong, China (IP/C/W/125/Add.21); Iceland (IP/C/W/125/Add.19); Lithuania (IP/C/W/125/Add.23); Slovak Republic (IP/C/W/125/Add.18); Thailand (IP/C/W/125/Add. 22); and a supplement from the Czech Republic (IP/C/W/125/Add.8/Suppl.1). The Council requested the Secretariat to update the synoptic tables annexed to IP/C/W/273 based on the further information submitted by Members (paragraph 195, IP/C/M/37/Add.1). The present document aims to respond to this request and replaces IP/C/W/273 and its annexes.
4. Annex I of the present document contains the illustrative list of questions first presented in IP/C/W/122; Annex II contains the updated version of the two synoptic tables attached to IP/C/W/273; Annex III contains the explanatory notes to the first synoptic table with respect to patent protection of plant and animal inventions and Annex IV has the explanatory notes to the second synoptic table regarding protection of plant varieties.

5. In providing their information, Members did not use the same format. A number of Members provided information by answering the questions listed in the illustrative list prepared by the Secretariat (document IP/C/W/122). Some other Members used the method suggested by Canada, the European Communities and their member States, Japan and the United States (document IP/C/W/126). Yet other Members answered both the questions in document IP/C/W/122 and those in document IP/C/W/126. Finally, there were Members who provided information without referring to either of these documents. Moreover, in some cases, especially in regard to the questions listed in document IP/C/W/122, questions were not posed in a way susceptible to a yes/no or other brief answer that could readily be reflected in synoptic form.

6. Accordingly, the Secretariat, in compiling the attached tables, has employed a combination of the questions posed in documents IP/C/W/122 and IP/C/W/126, with modifications where necessary to make the information suitable for presentation in synoptic form. Where a Member has provided additional information on a question posed, this is indicated by the use of an asterisk (*) in the table and that additional information has been reproduced in the annexes to this document. Of course, it has not been possible to reflect in this note all the information provided in the responses by Members circulated in documents IP/C/W/125 and Addenda; accordingly, this note should be read in conjunction with those documents. It might also be noted that, in the course of checking with delegations to ensure that the information made available by them was accurately reflected in the present note, some delegations provided additional information for the purposes of the present document.

7. In the tables, the following basic notation has been employed:

- "n.a." means not applicable;
- "*" refers the reader to the annexes for additional information on the point in question;
- a blank means that no information has been provided on the point in question; and
- "●" means that the reply is a combination of information provided in the original submission and supplementary information provided subsequently by the same Member.

ANNEX I

ILLUSTRATIVE LIST OF QUESTIONS ON ARTICLE 27.3(b)

A. PATENT PROTECTION OF PLANT AND ANIMAL INVENTIONS

1. To what extent are inventions concerning plants or animals, whether products or processes, patentable under your country's law, if they meet the conditions for patentability stipulated in Article 27.1 of the TRIPS Agreement?
 2. Where any such inventions are not patentable, even if they meet these conditions:
 - (i) To what extent is this due to *per se* exclusions from patentability?
 - (ii) To what extent is this based on other grounds (for example because conditions for patentability other than those stipulated in Article 27.1 are not met or in order to protect *ordre public* or morality (see Article 27.2 of the Agreement))?
 3. Please describe any specific provisions, guidelines, final judicial decisions and administrative rulings of general application concerning the application of the conditions for patentability stipulated in Article 27.1 to subject-matter addressed by Article 27.3(b).
 4. Where plant varieties are not as such patentable subject-matter under your country's law, please indicate the extent to which the scope of protection under patents for inventions concerning plants can nevertheless embrace plant varieties or a botanical taxon whose plants express a trait covered by the claims of a patent.
 5. Please provide any definitions used under your country's law with regard to subject-matter specifically excluded from patentability or specifically patentable (e.g. micro-organisms, microbiological processes, non-biological processes, plant varieties).
 6. To what extent is subject-matter that is identical to what occurs in nature patentable under your country's law?
 7. Explain the requirements under your country's law for ensuring adequate disclosure of the patentable inventions referred to above.
 8. What rights are conferred upon owners of the patents referred to above? Are product and process patents subject to the same rules as other patents? Do they benefit from the same protection as stipulated in Article 28 of the TRIPS Agreement?
 9. Are there any specific exceptions to these rights (affecting the scope or duration of the patents referred to above)? To what extent are exceptions, available in respect of plant variety rights (e.g. those referred to under question B.4(i) below), available in respect of rights conferred upon patent owners?
 10. Are there any specific provisions under your country's law for compulsory licensing in respect of the patents referred to above?
- N.B. Please ensure that your responses to the questions above cover each category of subject-matter specified in Article 27.3(b), namely micro-organisms, essentially biological processes for the production of plants or animals, microbiological processes, non-biological processes, plant varieties and other inventions concerning plants or animals.

B. PROTECTION OF PLANT VARIETIES

1. Does your country's law provide for the protection of plant varieties by plant breeder's rights, plant patents or any other *sui generis* system for the protection of plant varieties?

2. (a) If your country is a party to the International Convention for the Protection of New Varieties of Plants (UPOV), please indicate which Act or Acts of the UPOV Convention your country has signed; which it has ratified; to which it has acceded; and to the standards of which its law conforms but to which it has not (yet) adhered.
- (b) If your country is not a party to the UPOV Convention, does the protection offered to plant varieties under your country's law conform to the standards of any of the Acts of the UPOV Convention and, if so, which?

3. Please indicate whether concurrent protection under your country's plant variety protection law and its patent law is available (see also question A.4 above).

4. Please provide the following details of your country's *sui generis* system for the protection of plant varieties:

- (a) the relevant laws and regulations and, if they have been notified to the Council for TRIPS, a reference to the relevant WTO documents;
- (b) the definition of "plant variety";
- (c) the conditions required for protection;
- (d) the extent to which subject-matter that is already known to the public or identical to what occurs in nature is protectable under your country's *sui generis* system for the protection of plant varieties;
- (e) the extent to which protection can be based on characteristics of germplasm, as opposed to characteristics of plant varieties derived from such germplasm;
- (f) who is entitled to the rights;
- (g) the procedure for the acquisition of rights, including the authority in charge of administering the rights;
- (h) the rights conferred;
- (i) exceptions to the rights conferred, such as:
 - acts performed for research or experimental purposes;
 - acts performed to develop new varieties of plants;
 - acts performed to commercialize such newly developed varieties;
 - any "farmer's privilege" (e.g. acts performed by a farmer on his own land in respect of seed saved from the previous harvest);
 - acts done privately and for non-commercial purposes;
 - compulsory licensing.
- (j) the duration of protection;
- (k) transfer of rights;
- (l) enforcement of the rights.

ANNEX II

SYNOPTIC TABLE I: PATENT SYSTEM

	AUS	BGR	CAN	CHE	CZE●	EEC
1. <i>In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?</i>	No*	Yes	Yes*	Yes*	Yes*	Yes
2. <i>If the answer to question 1 is yes, please respond to the following questions:</i>						
(a) <i>Does your patent system exclude entire plants or animals as inventions?</i>	n.a.	No	Yes*	*	No*	No
(b) <i>If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded.</i>	n.a.	¹	n.a.	*, ¹	¹	¹
(c) <i>Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?</i>	n.a.*	Yes*	No	*	Yes*	Yes*
3. <i>Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?</i>						
(a) <i>A patent claim that is not limited to a specific plant or animal variety.</i>	Yes	*	No	Yes	*	Yes
(b) <i>A patent claim that is expressly limited to a plant or animal variety.</i>	Yes	No*	No	No	*	No
(c) <i>A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.</i>	Yes	*	No*	Yes	*	Yes
4. <i>Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?</i>	Yes	Yes	Yes*	Yes	Yes	Yes
5. <i>Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?</i>	Yes*	No*	No	No*	No*	No*
6. <i>Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?</i>	No*	No*	No	No*	No*	*
7. <i>Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?</i>	Yes*	Yes*	Yes	Yes*	Yes*	

* See Annex III for further information.

¹ Plant and animal varieties are excluded.

² Sexually reproduced plants are excluded.

	EST	HKC	HUN	ISL	JPN	KOR
1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?	Yes *	Yes *	Yes *	Yes *	No *	Yes
2. If the answer to question 1 is yes, please respond to the following questions: (a) Does your patent system exclude entire plants or animals as inventions? (b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded. (c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?	No * 1	No * 1	No No	No 1*	n.a. n.a.	No * 2
3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways? (a) A patent claim that is not limited to a specific plant or animal variety. (b) A patent claim that is expressly limited to a plant or animal variety. (c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.	Yes No Yes	Yes * No * *	Yes Yes Yes	Yes No Yes	Yes Yes Yes	Yes Yes Yes
4. Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?	Yes *	Yes *	Yes	Yes *	Yes	Yes *
5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?	No *	No *	No *	No *	Yes	No *
6. Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?	*	*	No	*	No *	No
7. Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?		Yes *	Yes *			No

[illegible]

	SVK	SVN	THA	USA	ZAF	ZMB
1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?	Yes*	No	Yes*	No	Yes	Yes
2. If the answer to question 1 is yes, please respond to the following questions: (a) Does your patent system exclude entire plants or animals as inventions? (b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded. (c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?	No* *,1 Yes*		Yes* n.a.	n.a. n.a.	No *, 1 Yes*	No n.a. Yes*
3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways? (a) A patent claim that is not limited to a specific plant or animal variety. (b) A patent claim that is expressly limited to a plant or animal variety. (c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.	* No* *	Yes Yes Yes		Yes Yes Yes	No No 	Yes Yes Yes
4. Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?	Yes	Yes	Yes*	Yes	Yes	Yes
5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)?	No*	Yes	No*	No*	No	
6. Is it possible to obtain a patent in your territory for subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?	No*	Yes*	No*	No*	No*	
7. Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?			No*	Yes*	n.a.	No

SYNOPTIC TABLE II: PLANT VARIETY PROTECTION SYSTEMS

	AUS	BGR	CAN	CHE	CZE•	EEC
1. Do the laws applicable to your territory provide for a <i>sui generis</i> form of protection for a new plant variety?	Yes	Yes	Yes	Yes	Yes	Yes
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes	Yes	Yes	Yes	Yes	Yes
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991	1991	1978	1978*	1991*	1991
4. If <i>sui generis</i> protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder: (a) acts performed for research or experimental purposes, or to develop new varieties of plants? (b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics? (c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land? If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	No Yes* No* No*	No No* No*	No No No	No* No* No* No	No Yes No* Yes*	No Yes No* Yes*
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?	No	No*	No	No*	*	
6. Does your legislation provide for other exceptions to the rights conferred?	Yes*	Yes	Yes		*	
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for <i>sui generis</i> protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	*	Yes*	Yes*	Yes*	Yes* (1/4/6)	Yes*
8. To be entitled to rights under <i>sui generis</i> plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?	Yes	Yes	Yes		*	
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	No	No*	No	No	No	No
10. What are the conditions that your law require for protection? ¹	d,u, s,n ¹	d,u,s,n,pd ¹	d,u,s,n,pd ¹		d,u,s,n,pd ¹	
11. What is the duration of protection?	25/20*	30/25*	18*		25/30*	

* See Annex IV for further information.

¹ d=distinctness; u=uniformity; s=stability; n=novelty; pd=proper denomination

	EST	HKC	HUN	ISL	JPN	KOR
1. Do the laws applicable to your territory provide for a <u>sui generis</u> form of protection for a new plant variety?	Yes	Yes	No	Yes*	Yes	Yes
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes	Yes*	Yes	Yes	Yes	Yes
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991	1991*	1978	1991	1991	1991
4. If <u>sui generis</u> protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder: (a) acts performed for research or experimental purposes, or to develop new varieties of plants? (b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics? (c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land? If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	No* Yes* No* Yes*	No* Yes* Yes* No*	n.a. n.a. n.a. n.a.	No* Yes* No* Yes*	No Yes* No* No	No Yes No No
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?	No*	No*	n.a.	No*		No
6. Does your legislation provide for other exceptions to the rights conferred?		Yes*	Yes			Yes
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	Yes* (1/4/6)	Yes* (1/4/6)	Yes*	Yes* (1/4/6)	Yes*	Yes*
8. To be entitled to rights under sui generis plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?		Yes*	Yes			Yes
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	*	*	No	No	No	No
10. What are the conditions that your law require for protection? ¹		d,u,s,n*, ¹	d,u,s,n,pd ¹			d,u,s,n,pd ¹
11. What is the duration of protection?		20/25*	15/18*			25/20*

	LTU	MAR	NOR	NZL	POL	ROM
1. Do the laws applicable to your territory provide for a <i>sui generis</i> form of protection for a new plant variety?	Yes	Yes	Yes	Yes	Yes	Yes
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes*	Yes	Yes	Yes	Yes	Yes*
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991	1991*	1978*	1978	1991	1991
4. If <i>sui generis</i> protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder: (a) acts performed for research or experimental purposes, or to develop new varieties of plants? (b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics? (c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land? If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	No* No* No* Yes*	No* Yes* No* No*	No* No* No	No No No	No No	No Yes No No*
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?	No*	No*		No	No	No
6. Does your legislation provide for other exceptions to the rights conferred?	Yes*	Yes*		Yes*	Yes	Yes*
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for <i>sui generis</i> protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	Yes* (1/4/6)	Yes*	Yes*	Yes*	Yes*	Yes*
8. To be entitled to rights under <i>sui generis</i> plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?	Yes*	Yes*		Yes*	Yes	Yes*
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	*		No	No*	*	No
10. What are the conditions that your law require for protection? ¹	d,u,s,n ^{*,1}	d,u,s,n,pd ¹		d,u,s,n ¹	d,u,s,n,pd ¹	d,u,s,n,pd ¹
11. What is the duration of protection?	25/30*	20/25/30*		23/20*	30/25*	30/25*

	SVK	SVN	THA	USA	ZAF	ZMB
1. Do the laws applicable to your territory provide for a <i>sui generis</i> form of protection for a new plant variety?	Yes	Yes	Yes	Yes*	Yes	No*
2. If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?	Yes	Yes	*	Yes	Yes	n.a.
3. If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).	1991*	1991	*	1991	1991*	n.a.
4. If <i>sui generis</i> protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder: (a) acts performed for research or experimental purposes, or to develop new varieties of plants? (b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics? (c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land? If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?	No Yes No No	No Yes No Yes*	No* No* No* Yes	No* Yes No* No	No No No	n.a. n.a. n.a. n.a.
5. Would acts done privately and for non-commercial purposes require the authorization from the right holder?			No*	No	No	n.a.
6. Does your legislation provide for other exceptions to the rights conferred?			Yes*		Yes	n.a.
7. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for <i>sui generis</i> protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?	Yes* (1/4/6)	Yes*	*	Yes*	No*	n.a.
8. To be entitled to rights under <i>sui generis</i> plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?				Yes	Yes*	n.a.
9. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?	No	No*	*	No*	*	n.a.
10. What are the conditions that your law require for protection? ¹			d,u,s,n ^{*1}		d,u,s,n ¹	*
11. What is the duration of protection?			12/17/27*	25/20*	25/20*	n.a.

ANNEX III

Explanatory Notes to Synoptic Table I

Patent System

Question 1: *In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel, capable of industrial application, involves an inventive step and has been adequately disclosed?*

Australia

No.

The main legislative provisions relevant to Article 27.3(b) are the *Patents Act 1990*¹ and the *Plant Breeders Rights Act 1994*², which respectively provide the legislative basis for the patent system and the system for plant variety protection. Both laws have been notified to the WTO. The two systems operate independently in practice, and the grant of a right under one system does not in itself affect any entitlement under the other system, provided all conditions for eligibility are met.

Under the Patents Act patenting of biotechnology inventions is allowed. The issue of whether genes and life forms should be excluded from the patents system was considered during parliamentary debate to the legislation in 1989. The result of the debate was a single exclusion – human beings and biological processes for their generation. Therefore, in Australia, provided the patent application meets all the usual requirements for patentability (i.e. is novel, inventive, fully described etc.), a biotechnology patent will be treated no differently from any other patent application, in line with the general TRIPS principle (Article 27) that patent rights should be available regardless of the field of technology concerned.

The Plant Breeder's Rights Act provides for certain exclusive commercial rights to a registered plant variety. Only new or recently exploited varieties can be registered. A new variety is one which has not been sold with the breeder's consent. A recently exploited variety is one which has been sold with the breeder's consent for up to 12 months in Australia and for overseas varieties this limit is up to four years (with the exception of trees and vines for which a six year overseas prior sale limit is permitted). To be eligible for protection the applicant must show that the new variety is distinct, uniform and stable. To obtain acceptance of an application and provisional protection it must be established that there is a prima facie case that the variety is distinct from all other varieties of common knowledge. To obtain a grant of PBR the applicants must verify these claims normally by conducting a comparative test growing which includes the new variety and the most similar varieties of common knowledge.

The Australian Patents Act has no specific exclusions from patentability (except section 18(2) — human beings and the biological processes for their generation are not patentable subject matter), based on ethical or moral grounds, of inventions being either products or processes and concerning plants and animals. However the grant of a patent for an invention may be refused on the ground that the use of the invention would be contrary to law (section 51(1)).

¹ Document IP/N/1/AUS/P/1

² Document IP/N/1/AUS/P/2

Canada

Yes.

To date, Canadian courts have held that higher life forms (e.g. multi-cellular differentiated organisms) are not patentable subject-matter. This matter is still under appeal before the Federal Court of Appeals.

Switzerland³

Yes.

According to Article 1.1 of the Swiss Federal Law on Patents for Inventions (LPI; text notified according to Art. 63.2 of the TRIPS Agreement on January 31, 1996 (see document IP/N/1/CHE/1 at p. 10)), "[p]atents for inventions shall be granted for new inventions applicable in industry." In other words, they must be new, involve an inventive step and be capable of industrial application. The three conditions must be met. Discoveries cannot be patented.

Article 1a specifies that "[p]atents shall not be granted for new varieties of plants or animal breeds...". Article 2 of the LPI, which enumerates inventions that are excluded from patentability, does not mention plants or animals. Thus, all inventions concerning entire plants and animals, and parts thereof, are patentable under Swiss law, provided they meet the legal requirements.

³ Attention is called to the following points as far as the Swiss replies are concerned:

- a. In the field of patent protection, Switzerland and Liechtenstein are bound by the Treaty of 22 December 1978 on the Protection Conferred by Patents for Inventions (treaty notified under Article 4(d) TRIPS in 1996 (see document IP/C/4/CHE/1)). This treaty was concluded within the framework of their Customs Union Treaty of 1923. Under this treaty, both countries form a unitary territory of protection. In other words, patents granted by the Swiss Federal Institute of Intellectual Property and the Swiss patent legislation also apply to the territory of Liechtenstein. This bilateral treaty only covers patents for inventions.
- b. Both Switzerland and Liechtenstein are parties to the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973. Further, both countries are parties to the Patent Cooperation Treaty of 1970 and to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 1977 (conventions administered by WIPO).
- c. In the field of biotechnology, most of the patent applications (with effect for Switzerland and Liechtenstein) are made via the "EPO's route". Statistically speaking, the number of applications via the "national route" alone is decreasing.
- d. The authority responsible for the grant of patents in the field of biotechnology (for Switzerland and Liechtenstein) is the Swiss Federal Institute of Intellectual Property (hereinafter "Institute"), Ministry of Justice and Police, in Berne. When it receives national patent applications, the Institute does not examine whether they are new and have an inventive step. It only examines if the inventions are capable of industrial application. Novelty and inventive step are left to the court, in case of litigation. In the field of biotechnological inventions, criteria for protection are the same as those applied in other technological fields. Thus, court decisions relating to patentability are also applicable to biotechnological inventions.
- e. Switzerland is party to the UPOV Convention (1978 Act). The Swiss Plant Variety Protection Law is currently being revised in view of ratification of the 1991 Act of the UPOV Convention.
- f. Revision of the Swiss Patent Law is under consideration as well.
- g. It should be noted that revision of both laws is also aimed at obtaining a higher degree of convergence with the European Community law (Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the Legal Protection of Biotechnological Inventions. Council Regulation 2100/94 of July 1994 on Community Plant Variety Rights).

It should be noted that inventions the implementation of which would be contrary to public order and morality cannot be patented (Article 2.a LPI), although they fulfill all other requirements for protection (novelty, inventive step and industrial applicability, disclosure, etc.) Those requirements are not limited to inventions relating to living material; they apply to all fields of technology.

Czech Republic

Yes.

According to Section 4, paragraph (b) of the Czech Patent Law No. 527/1990 Coll. as amended by the Law Amending Some Laws on the Protection of the Industrial Property No. 116/2000 Coll., patents are not granted on plant and animal varieties and essentially biological processes for the production and improvement of plants and animals. This provision is based on the Article 53(b) of the European Patent Convention. The inventions concerning plants and animals as such provided that they meet basic requirements of patentability do not fall under the exclusion mentioned above. The application of patent practice in the Czech Republic does not dispose of any precedent of a patent claim which would explicitly cover a plant or an animal.

Estonia

Section 7(2)6 of the Patents Act stipulates that "biotechnological inventions that can be used solely for one particular plant or animal variety" shall not be protected with patents.

Hong Kong, China

Yes.

Section 93(6) of the Patents Ordinance ("PO") provides that a plant or animal variety shall not be patentable. See also the answer to question 2(c).

Hungary

Yes.

See Articles 1(1) and 6(2) of the Patent Act.⁴

Iceland

It is not directly prohibited in the Patents Act to grant a patent for plants and animals, *per se*. However, according to Article 1(4)(2) of the Icelandic Patents Act No. 17/1991, a patent shall not be granted for plant or animal varieties.

Japan

No.

In principle, *there is no such basis*. However, if inventions are liable to contravene public order, morality or public health, they shall not be patented (Article 32 of Japanese Patent Law).

⁴ See document IP/C/W/125/Add.1.

Lithuania

Under Article 2 of the Lithuania Patent Law, inventions concerning plants or animals (products or biological processes) are not patentable. Article 2 of the Patent Law provides that the patent shall not be granted for plant or animal varieties or essentially biological processes for the production of plants or animals.

Norway

Yes.

According to the Norwegian Patents Act, Section 1, fourth indent, number 2, as it is interpreted, patents cannot be granted for plants, animals and processes for their production.

New Zealand

No.

However, "animals" does not include human beings. Human beings are not patentable under section 2 of the New Zealand Patents Act 1953, that is, a manner of new manufacture the subject of letters patent and grant of privilege with section 6 of the Statute of Monopolies. The Patents Act 1953 excludes inventions from patentability which are contrary to morality.

Slovak Republic

Yes.

Pursuant to Section 4, paragraph (c) of the Slovak Patent Law No. 527/1990 Coll., "patents shall not be granted in respect of plant or animal varieties and biological processes for the production and improvement of plants or animals, with exception of industrial micro-organisms serving for production and biotechnological processes and the products thereof, which are patentable." The patent practice in the Slovak Republic does not dispose of any precedent of patent claim, which would explicitly cover a plant or an animal.

Thailand

According to the Patent Act, B.E. 2522 as amended by the Patent Act (N0.2) B.E. 2535 and the Patent Act (No.3), B:E:2542 (hereinafter "the Patent Act"), a patent may be granted for any invention, whether product or process, which is new, involves an inventive step and is capable of industrial application (Section 5).

Under Section 9 of the Patent Act, plants and animals *per se*, however, are not patentable, regardless of the fact that such inventions meet the conditions for patentability (i.e. new, involves an inventive step and is capable of industrial application). Nonetheless, there is no provision in the Patent Act precluding methods or processes for the production of plants and animals from patentability. In other words, although plants and animals are not patentable, methods or processes for the production of plants and animals may be patentable under the Patent Act.

Question 2: *If the answer to question 1 is yes, please respond to the following questions:*

(a) *Does your patent system exclude entire plants or animals as inventions?*

Canada

Yes.

To date, our courts have held that entire plants *per se* and animals *per se* are not patentable subject-matter. This matter is still under appeal before the Federal Court of Appeal.

Switzerland⁵

See reply to question 1 above.

Czech Republic

No.

According to Section 4, paragraph (b) of the Czech Patent Law No. 527/1990 Coll. as amended by the Law Amending Some Laws on the Protection of the Industrial Property No. 116/2000 Coll., patents are not granted on plant and animal varieties and essentially biological processes for the production and improvement of plants and animals. This provision is based on the Article 53(b) of the European Patent Convention. The inventions concerning plants and animals as such provided that they meet basic requirements of patentability do not fall under exclusion mentioned above. The application of patent practice in the Czech Republic does not dispose of any precedent of patent claim which would cover a plant or an animal.

Estonia

Section 6(2)8 of the Patents Act indicates that plant and animal varieties are not regarded as the subject of an invention.

Hong Kong, China

No.

Whether such inventions are patentable depends on whether they comply with Section 93(1) of the Patent Ordinance (see the answer to question 3(a)).

Korea

No.

Regarding plants, only asexually reproduced plants are patentable under Article 31 of the Patent Act. However, there is no provision in the Patent Act that explicitly denies the patentability of animal *per se*.

Lithuania

See answer 1. Patents are granted for microbiological processes for the production of plants or animals or the products thereof (under Article 2.3 of Patent Law).

⁵ See footnote to question 1.

Slovak Republic

See the answer to question 1.

Thailand

See answer to question 1.

(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded.

Switzerland⁶

See reply to question 1 above.

Iceland

See the answer to question 1.

Lithuania

See the answer to question 2(a).

Slovak Republic

See the answer to question 1.

Thailand

See answer to question 1. Additionally, according to Section 9, not only plants and animals are excluded from patent protection, extracts therefrom (both from plants and animals) are also not patentable.

South Africa

The Patents Act, No. 57 of 1978 (as amended) "the Act" states that a patent shall not be granted for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step, are capable of industrial application and have been adequately disclosed?

Australia

See answer to Question 1.

⁶ See footnote to question 1.

Bulgaria

Yes.

Article 7.1 of the Patent Law provides for exclusion from patentability of plant or animal inventions, the prevention of publication and exploitation of which is necessary to protect *ordre public* or morality.

According to Article 7.3 of the Patent Law, plant varieties and animal breeds, as well as essentially biological processes for their production, are specifically excluded from patentability.

Switzerland⁷

As indicated above (question 1), inventions the implementation of which would be contrary to public order and morality cannot be patented (Article 2.a LPI). "Morality" is construed as including human and animal dignity.

Czech Republic

Yes.

According to Section 4, paragraph (a) of the Czech Patent Law, patents are not granted in respect of inventions the exploitation of which would be contrary to "*ordre public*" or morality.

European Communities

Yes.

Following Article 6(1) and (2)(d) of Directive 98/44/EC "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality..." and, in particular, "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 animals resulting from such processes" shall be considered unpatentable.

Estonia

According to Sections 7(1)1 and 7(2)4 of the Patents Act, patent protection shall not apply to:

- inventions contrary to *ordre public* and morality; and
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to the health care of human beings or animals, and also animals resulting from the use of such processes.

Hong Kong, China

Section 93(5) of the Patent Ordinance provides that "an invention the publication or working of which would be contrary to public order ("*ordre public*") or morality shall not be a patentable invention". This exclusion has not yet been tested in the Hong Kong courts. No patent has so far been found contrary to public order or morality in Hong Kong, China.

⁷ See footnote to question 1.

Korea

Yes.

Even though not specifically mentioned in the related Act, it is generally understood, and stipulated in the "Examination Guideline for Inventions in Specific Fields," that the following are not patentable: inventions concerning humans or human organs; inventions in which humans are a constituent of the invention; and methods of diagnosis, therapy, or surgical treatment for humans. Under Article 32 of the Patent Act, inventions that would contravene public order or morality, or be harmful to public health, shall not be patentable. Inventions lacking the description requirement are also not patentable under Article 42.3 of the Patent Act.

Lithuania

According to Article 2 of Patent Law, patents shall not be granted for inventions the commercial exploitation of which would be in contrary to public interests, principles of morality and humanity.

Slovak Republic

According to Section 4, paragraph (a) of the Slovak Patent Law No. 527/1990 Coll., "patents shall not be granted in respect of inventions contrary to public interest, particularly the principles of humanity and morality."

Thailand

Any inventions contrary to public order, morality, health or welfare are not protected under the Patent Act (Section 9(5)).

South Africa

It is provided in the Act that a patent shall not be granted for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour.

Zambia

Yes.

The Patents Act Cap. 400 does not exclude any field of technology from protection. However, the Registrar has the discretion to deny protection to inventions deemed to be contrary to public morality or law.

The Act does not exclude any field of technology from protection. However, the Registrar has the discretion to deny protection to inventions deemed to be contrary to public morality or law. Further, substances used as food or medicine which are mere mixtures of known ingredients, or a process for obtaining such mixture are excluded from patentability. Section 38 herein refers.

Question 3: *Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?*

(a) *A patent claim that is not limited to a specific plant or animal variety.*

Bulgaria

See answer to question 2 (c), above.

Czech Republic

There has not been such a case in implementing practice up to now.

Hong Kong, China

Yes.

Such an invention must satisfy the provision of Section 93(1) of the PO (i.e. must be susceptible of industrial application, is new and involve an inventive step) and must not be in breach of Section 93(5). See the answer to question 2(c).

Poland

The answer is "no" in general, however with reservation that it does not concern non-biological processes.

Questions 3(a) and 3(b) would be easier to understand if they were accompanied with practical examples. It may be so that our "No" reply to question 3(a) results from our different comprehension of this question. If the Secretariat had in mind any undefined plant variety the reply to this question would be "Yes". One has to bear in mind though that each case is considered on an individual basis, in the context of the entire application with a description, drawings and reservations attached to it. As a result, giving a clear-cut "Yes" or "No" reply is not completely credible.

Slovak Republic

We have not had such a case in our practice yet.

(b) *A patent claim that is expressly limited to a plant or animal variety.*

Bulgaria

No.

See answer to question 2 (c), above.

Czech Republic

There has not been such a case in implementing practice up to now.

Hong Kong, China

No.

See the answer to question 1

Poland

The answer is "no" in general, however with reservation that it does not concern non-biological processes.

Questions 3(a) and 3(b) would be easier to understand if they were accompanied with practical examples. It may be so that our "No" reply to question 3(a) results from our different comprehension of this question. If the Secretariat had in mind any undefined plant variety the reply to this question would be "Yes". One has to bear in mind though that each case is considered on an individual basis, in the context of the entire application with a description, drawings and reservations attached to it. As a result, giving a clear-cut "Yes" or "No" reply is not completely credible.

Romania

Yes, for animal varieties.

Slovak Republic

See the answer to question 3(a).

(c) *A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.*

Bulgaria

The scope of protection under patents for inventions concerning plants could be restricted to the cell ancestor of a new plant, proceeding from a new patentable plant genetic material and passing over to the tissue plant culture obtained from that cell. The latter may further become the ancestor of a new plant variety or even of a higher taxon unit, but such as they are, they are subject to protection only under the Law on the Protection of New Plant Varieties and Animal Breeds. See also answer to question 2.c above.

Canada

No.

The particular gene may be patentable, but not the group of plants and animals.

Czech Republic

See the replies above.

Hong Kong, China

There has been no case on this topic in Hong Kong, China.

Whether such an invention is patentable must depend on whether it complies with Section 93(1) of the Patent Ordinance (PO). Commentators elsewhere have taken the view that plants and animals altered by genetic manipulation are not varieties within the meaning of the European

Patent Convention, but rather are representatives of a large family characterized by some novel gene, such as one imparting resistance to a herbicide. (See paragraph 1.20 of the C.I.P.A. Guide to Patents Act (4th Edition).) In such a case, the prohibition against patentability as regards plant or animal varieties contained in Section 93(6) of the PO may not be applicable.

Lithuania

A patent claim is expressly limited, i.e. patents are not granted for plant or animal varieties, however, the separate genes may be patentable.

Poland

Yes, regarding plants.

No, regarding animals.

Slovak Republic

See the answer to the question 3(a).

Question 4: *Is it possible to obtain a patent in your territory on a micro-organism that is novel, involves an inventive step and is capable of industrial application?*

Canada

Yes.

Microorganisms, including cell lines and hybridomas, are patentable.

Estonia

Yes.

As far as biological material can be the subject of an invention (Section 6(1) of the Patents Act).

Hong Kong, China

Yes.

In relation to microorganisms and short-term patents, the PO contains detailed provisions relating to the deposit of such microorganisms. (See Section 128 of the PO and Section 73 of the Patents (General) Rules.).

Iceland

According to Article 1(4)(2) of the Icelandic Patents Act No. 17/1991, it is possible to obtain a patent for microbiological processes and products resulting from such processes. It is not directly prohibited in the Patents Act to grant a patent for a micro-organism.

Korea

Yes.

See answer to question 1.

Lithuania

Patents, as it was mentioned in answer 1, are granted for microbiological processes for the production of plants or animals or the products thereof (under Article 2.3 of Patent Law).

Poland

Yes.

According to Article 12(1) of the present Law on Inventive Activity of 1972 (consolidated act of 1993), patents are not granted for new plant varieties and animal breeds as well as for biological processes for the cultivation of plants or breeding of animals. Although no explicit patentability of micro-organisms is provided for, in practice patents are granted also for microbiological inventions.

Under the new Industrial Property Law, which is likely to be adopted in the first half of 1999, patents will not be granted for plant varieties or animal breeds as well as essentially biological processes for the cultivation of plants or breeding of animals. It will also be explicitly stipulated that patents will be granted for microbiological processes and the products thereof.

Thailand

Modified micro-organisms and modification of their components are patentable (Section 9).

Question 5: *Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)? If not, please identify the legal basis under which these inventions are deemed ineligible to be patented.*

Australia

See answer to question 1, above. Section 18(2) of the Patent Act provides that "human beings and biological processes for their generation are not patentable inventions."

Bulgaria

No.

Article 7.3 of the Patent Law. See answer to question 2 (c) above.

Switzerland⁸

The denial of a patent on such a process is based on Article 1a of the LPI.

⁸ See footnote to question 1.

Czech Republic

No.

According to Section 4, paragraph (b) of the Czech Patent Law No. 527/1990 Coll. as amended by the Law Amending some Laws on the Protection of the Industrial Property No. 116/2000 Coll., patents are not granted on plant and animal varieties and essentially biological processes for the production and improvement of plants and animals.

European Communities

No.

Article 4(1)(b) of Directive 98/44/EC reads: "essentially biological processes for the production of plants or animals" are not patentable.

Article 2(2) of Directive 98/44/EC reads: "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

Estonia

It is not possible to obtain a patent on an essentially biological process for the production of plant or animal. Under Section 7 (2)5 of the Patents Act, processes are unpatentable which are biological in essence and are used for deriving biological materials, producing plant or animal varieties, except microbiological processes for deriving micro-organisms. An essentially biological process for the derivation of a biological material or production of plant or animal varieties is defined in Section 7(3) as a process which consists entirely of natural phenomena, including crossing and selection.

Hong Kong, China

No.

Section 93(6) of the Patent Ordinance provides that an "essentially biological process for the production of plants or animals" shall not be patentable.

Hungary

No.

Essentially biological processes are considered to be the same category as discoveries and therefore they fall under the provisions of Article 1 of the Patent Act.

Iceland

No.

According to Article 1(4)(2) of the Icelandic Patents Act, patents shall not be granted for "essentially biological processes for the production of plants or animals".

Korea

No, because that is not an "invention" under the principal sentence of Article 29 of the Patent Act.

Lithuania

Article 2 of the Patent Law provides that patent shall not be granted for plant or animal varieties or essentially biological processes for the production of plants or animals. However, this provision shall not apply to microbiological processes for the production of plants or animals or the products thereof.

Poland

No.

Article 12(1) of the present Law on Inventive Activity of 1972 (Consolidated Act of 1993) as well as under the new Industrial Property Law, which is likely to be adopted in the first half of 1999.

Slovak Republic

No.

See section 4(c) of the Slovak Patent Law.

Thailand

Plant varieties *per se* are not patentable subject-matter under the Patent Act, but any process for obtaining new plant varieties may be patentable, provided that it is new, involves an inventive step and is capable of industrial application. (Plant varieties are however, protected under the Plant Variety protection Act (B.E. 2542 (1999)).

United States

No, if the claim is limited to naturally occurring essentially biological processes comprising the steps for sexual or asexual reproduction of a plant or sexual reproduction of an animal. Such a claim would fail to meet one or more of the patentability requirements of utility, novelty and non-obviousness under Sections 101, 102 and 103 of title 35, United States Code.

Question 6: *Is it possible to obtain a patent in your territory covering subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?*

Australia

No.

If a claim defines a product or composition *per se* which already exists in nature it is neither a "manner of manufacture" nor novel and therefore is considered non-patentable under the Patents Act. If there has been any technical intervention of man to change the form of the product from that in which it existed in nature, the product would be patentable, provided it meets the requirements of patentability such as inventiveness and novelty. Thus a claim to protein x, which existed in nature, is unpatentable whereas a claim to an isolated and purified protein x would be patentable. Specific DNA sequences are generally considered fragments of chromosomes. As they do not occur in isolation in nature, they are patentable. Methods or processes of making products that occur in nature are patentable.

Bulgaria

No. According to the established practice, processes and products that are identical with what exists in nature are not patentable, for they do not meet the inventive step requirement. In such cases, processes for the isolation of products existing in nature, or methods for the use of processes or products existing in nature as they are, are considered patentable.

Switzerland⁹

Subject-matter that is identical to that found in nature is patentable, if 1) such subject matter is not known at the moment of patent application, and 2) the process used for its isolation or identification is new. All subject matter that is identical to that found in nature not meeting these two conditions is considered to be a discovery, and is therefore not patentable under Swiss law.

Czech Republic

Yes.

According to the Czech Patent Law No. 527/1990 Coll., patents are granted to inventions which are new, which involve an inventive step and are susceptible of industrial application. Discoveries are not patentable. (See Section (3), paragraphs 1 and 2 of the Czech Patent Law.)

Section 2(a) of the Law on the Protection of Biotechnological Inventions No. 206/2000 Coll. reads: "Biotechnological inventions are patentable, if they concern biological material, which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature".

Following Section 1(a) of the Law on the Protection of Biotechnological Inventions No. 206/2000 Coll., "biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system".

European Communities

Article 3(2) of Directive 98/44/EC reads. "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

Following Article 2(1) of Directive 98/44/EC, "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system."

Estonia

Yes, (artificial re-creation and clones are permitted).

Hong Kong, China

There has been no case in Hong Kong, China on this topic.

Section 93(1) of the PO provides that an invention is patentable if it is susceptible of industrial application, is new and involves an inventive step. Section 93(2) of the PO provides a list of what shall not be regarded as inventions. This list includes: a discovery, scientific theory or mathematical method.

⁹ See footnote to question 1.

The fundamental point to note is that "a discovery" is not patentable. Products or compositions are not excluded from patentability under Hong Kong law on the grounds that they are nature-identical. The question is whether there is a discovery. It is probably the case that the finding of a new substance or micro-organism occurring freely in nature is a discovery. However, if it is necessary to develop a process to extract the substance or micro-organism, such a process, and the material obtained from this process, may well be patentable. Much depends on the facts of a particular case, and the state of the art.

Iceland

Yes, if the invention is novel, involves an inventive step and is susceptible to industrial application.

Japan

No.

An invention is required to be *creation* under the Japanese Patent Law. In this connection, mere discoveries, including materials existing in nature or natural phenomena, where no creation of technical ideas is made purposefully, do not fall under inventions. Therefore, *it is impossible to obtain a patent which claims materials existing in nature or natural phenomena*.

However, chemical substances, microorganisms and the like are to be regarded as creations when they are humanly extracted from materials existing in nature. Therefore, those claims are patentable.

Lithuania

If a claim defines a product or composition which already exists in nature, it is considered non-patentable under the Patent Law. According to the Patent law, this subject-matter is considered to be a discovery.

Norway

No.

It is not possible to obtain a patent in Norway covering plants and animals in their natural state. However, microorganisms identical to those found in nature are eligible to be patented if they are isolated and meet the conditions for patentability.

New Zealand

No.

Subject-matter which is found in nature is patentable provided it is not claimed either in the natural state, or does not encompass the plant or animal found in its natural state or as it is normally found in nature.

Poland

The answer is "no" in general, but when the subject is obtained by synthetic processes, namely by microbiological processes, the answer is "yes".

Romania

No.

Only inventions that involve a creative effort are patentable subject-matter. Example: under Rule 11(2)(b) of Government Decision No. 152/1992, chemical and biological substances existing in nature are patentable provided that a creative effort is involved.

Slovak Republic

No.

According to Section 3, paragraph (1) of the Slovak Patent Law patents shall be granted for any inventions which are new, which involve an inventive step and which are susceptible of industrial application. Because mere discoveries, including materials existing in nature, do not meet all mentioned criteria, they are not patentable.

Slovenia

Yes, provided that usual patentability requirements are met.

Thailand

The definition of the term "invention" stipulated in section 3 of the Patent Act, which reads: "invention means any innovation or invention which creates a new product or process, or any improvement of a known product or process", may, to some extent, reflect the underlying principle of the patent system that patents shall not be granted for things occurring in nature. Along that line is the provision of Section 9(1), which excludes micro-organisms and their components already existing in nature as well as extracts of plants and animals from patentability.

With regard to the subject-matter identical to what occurs in nature, according to the Patent Act, neither modified nor naturally existing plants and animals can be patented.

United States

No.

Under US law and practice, a patent may not be granted on a claim that is limited to subject matter indistinguishable from the form in which it is found in nature. For example, a claim drawn to a naturally occurring bacterium, per se, would fail to satisfy the requirements for novelty and utility (Section 101 of title 35, United States Code). However, these requirements, as well as the requirement of non-obviousness, are considered to be met, when a claim is directed to an isolated and/or purified composition containing naturally occurring subject matter that exhibits new or unexpected properties.

South Africa

No.

Although this aspect is not covered specifically, the Act states that anything which consists of a discovery shall not be an invention for the purposes of this Act.

Question 7: *Does your patent system include any special provisions to ensure adequate disclosure regarding inventions covered by Article 27.3(b) (for example, micro-organisms)?*

Australia

Yes.

Section 41 of the Patents Act sets out the additional requirements for specifications relating to micro-organisms.

In summary, a deposit is strictly necessary if:

- (1) an invention involves the modification or cultivation of a micro-organism (other than where the micro-organism itself is an invention); and
- (2) a person skilled in the relevant art in the patent area could not be reasonably expected to perform the invention without having a sample of the micro-organism ; and
- (3) the micro-organism is not reasonably available to a person skilled in the relevant art in the patent area.

The Patent Office would also require a deposit if the claimed micro-organism could not be reasonably expected to be obtained by reproduction or generated based on the information supplied in the specification, for example where the invention resides in an organism produced by a random mutation process or is a specific hybridoma secreting a particular monoclonal antibody.

Otherwise deposits are not required but applicants can choose to deposit if they wish. The Patent Office accepts that a written description can in some circumstances provide the skilled worker with enough detail to reproduce the inventive micro-organism and that this information would be a sufficient disclosure.

The Patent Office does not accept deposits made with institutions other than those recognised under the Budapest treaty. However if the invention and claims relate to a use, cultivation or modification of a micro-organism, the office accepts that deposits other than those made by the applicant could be readily available as required by point (3) above. In that circumstance, the applicant would not require a Budapest Treaty deposit.

The Patent Office accepts any form of deposit that is reproducible and which is accepted by international depository authorities (including plant cell cultures, plasmids and seeds) but notes that international depository authorities have limitations on the nature of materials they will accept and the Patent Office is bound by any such limits.

Bulgaria

Yes.

Article 37.1 of the Patent Law contains general provisions for ensuring adequate disclosure of the subject matter of an invention. In cases where the patent application refers to a biological object which cannot be disclosed in such a way as to enable a person skilled in the art to carry out the invention, and the said object is not generally available, the description required upon filing of the application shall contain indication of the fact of deposition with a specifically authorized international institution. The deposition shall be made no later than the priority date (Article 37.2 of the Patent Law).

Switzerland¹⁰

Yes.

Both Switzerland and Liechtenstein are parties to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 1977.

Czech Republic

Yes.

The Czech Republic is a member of the Budapest Treaty on the Deposit of Microorganisms of 1977. Special provisions are included in the Law on the Protection of Biotechnological Inventions No. 206/2000 Coll.

Hong Kong, China

Yes.

See the answer to question 4 above.

Hungary

Yes.

Hungary is member of the Budapest Treaty on the Deposit of Microorganisms (1977).

Lithuania

Patent Law provides that a specification must disclose the invention in such full and clear terms as to enable any persons skilled in the art to which it pertains to sue the invention. Where a patent application refers to a biologically reproducible material which cannot be disclosed in the application in such as was as to enable any person skilled in the art to use it, and such material is not available to the public, it shall be deposited for safe-keeping with a depository institution. The patent application filed with the State Patent Bureau shall be accompanied by a document about the deposition of such biological material.

Norway

Yes.

Adequate disclosure of the patentable invention is secured through Section 8, second indent, and Section 8a of the Patents Act. The provisions comply with the Budapest Treaty 1977 (as modified in 1980).

New Zealand

No.

Section 10(3) of the Patents Act 1953 requires that every complete specification shall particularly describe the invention and the method by which it is to be performed, and shall disclose the best method of performing the invention which is known to the applicant and for which he [or she] is entitled to claim protection.

¹⁰ See footnote to question 1.

Poland

Yes.

There are no special requirements in this respect regarding this type of inventions. As in case of other inventions, a patent application should include a description of the invention disclosing its nature in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. If the presentation of a micro-organism, which is not available to the public or can not be described in a complete manner, is required for carrying out the invention, the said presentation to this extent can be made by reference to the deposit of the micro-organism made in a collection of micro-organisms. For the purpose of recognising the deposit as meeting the conditions of invention's disclosure, a depositary institution is obliged to make the deposit accessible for any third parties throughout patent granting procedure and at least throughout the entire duration of the patent.

Thailand

There is no special requirement for ensuring adequate disclosure in the case of inventions referred to under question A.6. However, the general provisions for ensuring adequate disclosure as set forth in section 17 of the Patent Act shall also apply to this type of invention as follows:

- the patent application shall contain a detailed description of the invention;
- such a description shall be, as such, full, concise and clear and exact terms as to enable any person ordinarily skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention; and
- the description shall set forth the best mode contemplated by the inventor (the applicant) to carry out his invention.

United States

Yes.

If the Patent and Trademark Office (PTO) concludes that it is not possible to practice an invention involving a micro-organism on the basis of the application alone, the PTO will require the applicant to deposit a sample of the micro-organism. In such situations, the applicant must make a deposit of the micro-organism in a form consistent with the micro-organism deposit rules (i.e., section 1.801 *et seq.*, of title 37 of the Code of Federal Regulations).

ANNEX IV

Explanatory notes to Synoptic Table II

Plant Variety Protection System

Question 1: *Do the laws applicable to your territory provide for a sui generis form of protection for a new plant variety?*

Iceland

On 19 May 2000, a bill on plant variety protection was passed in the parliament. The Icelandic Plant Variety Protection Act No. 58/2000 provides a *sui generis* form of protection for a new plant variety.

United States

Yes.

US laws provide for a *sui generis* form of protection for sexually reproduced and tuber propagated plant varieties, under the Plant Variety Protection Act (Section 2321 *et seq.* of title 7, United States Code).

Under US law, anyone who develops a new *plant variety* may obtain one of three forms of protection, two of which depend on the manner of reproduction of the plant variety:

- If the variety was developed through *sexual reproduction* or *tuber propagation*, the breeder may obtain a plant variety protection certificate under the Plant Variety Protection Act (Section 2321 *et seq.* of title 7, United States Code) administered by the Plant Variety Protection Office of the Department of Agriculture.
- If the variety, other than tuber propagated plants, was developed through *asexual reproduction*, the breeder may obtain a plant patent under the Plant Patent Act (Section 161 *et seq.* of title 35, United States Code) from the United States Patent and Trademark Office.
- Regardless of its method of propagation, the developer of a new plant *invention*, i.e., a plant variety or an invention concerning plants of a higher taxonomic classification, may obtain a utility patent under the general Patent Law (i.e., an invention patent under Section 101 of title 35, United States Code) from the United States Patent and Trademark Office.

Zambia

No.

Currently, Zambia has in place a draft Plant Breeders Rights Act. It would appear that the same is based on the principles of the 1991 Act of the UPOV Convention. Under UPOV 1991, parties are free to protect plant varieties by plant breeders rights. The Act works basically in the interest of the farmer at local community level. It would be advisable, therefore, if the Plant Breeders Rights Act was to be used in Zambia as an alternative to patenting of plant varieties in Zambia.

Question 2: *If the answer to question 1 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?*

Hong Kong, China

Hong Kong China is not a member of UPOV, and is therefore unable to say categorically that Cap.490 conforms to the standards defined in one of the Acts of UPOV. However, Hong Kong, China had in mind the 1991 UPOV Act when drafting Cap. 490.

Lithuania

Lithuania is not yet a party to the UPOV. However, the law on the protection of plant varieties conforms to the standards of the UPOV Convention, particularly the 1991 Act.

Romania

Yes.

Romania is not yet a party to the International Convention for the Protection of New Varieties of Plants (UPOV). Preparations are being made to accede to the Convention – 1991 Act – and it is considered that the legislation in force conforms with that Act.

Thailand

Thailand is not a party to the UPOV Convention. However, the Plant Varieties Protection Act has some subject-matters which conform to the 1978 Act of the UPOV Convention.

Question 3. *If the answer to question 2 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).*

Switzerland¹

The present Federal Law on New Plant Varieties of 20 March 1975 (LPV; text notified according to Art. 63.2 of the TRIPS Agreement on January 31, 1996 (see document IP/N/1/CHE/1 at p. 11)) is based upon the 1978 Act. It is currently being revised in view of ratification of the 1991 Act.

Czech Republic

Law No. 408/2000 Coll., on the protection of plant variety rights is based upon the 1991 Act of the UPOV, but the accession procedure has not yet finished.

Hong Kong, China

Hong Kong, China is not a member of UPOV, and is therefore unable to say categorically that Cap.490 conforms to the standards defined in one of the Acts of UPOV. However, Hong Kong, China had in mind the 1991 UPOV Act when drafting Cap. 490.

¹ The authority responsible for the grant of plant variety certificates is the Swiss Bureau for Plant Varieties, from the Federal Office of Agriculture, Ministry of Economy. The Bureau does not proceed to an examination as to substance. It is empowered to refer to examinations and field tests made by the authorities of States that are Contracting Parties of the UPOV Convention.

Morocco

The Council of the International Convention for the Protection of New Varieties of Plants (UPOV) has examined and recognized that the Moroccan law on the protection of new plant varieties is consistent with the Acts of the UPOV Convention of 1978 and 1991.

Norway

Norway has acceded to the International Convention of 2 December 1961 for the Protection of New Varieties of Plants (UPOV Convention), as revised on 23 October 1978. The Norwegian Plant Variety Act and supplementary regulations are in conformity with this convention and partly also conform to UPOV 1991.

Slovak Republic

Law No. 132/1989 Coll. on the Protection of Rights of New Varieties and Animal Breeds was in conformity with standards defined in the 1978 Act, but the amendment introduced by Law No. 22/1996 Coll. brought the protection system in conformity with standards defined in the 1991 Act of the International Convention for the Protection of New Varieties of Plants.

Thailand

Thailand is not a party to the UPOV Convention. However, the Plant Varieties Protection Act has some subject-matters which conform to the 1978 Act of the UPOV Convention.

South Africa

South Africa is a member of UPOV and has ratified the 1978 Convention. We have acceded to the 1991 Convention, and our Plant Breeders' Rights Act, No. 15 of 1976 (as amended) "the Act", was further amended by the Plant Breeders' Rights Amendment Act, No 673 of 1996 to bring South Africa's legislation into conformity with the 1991 Convention. The last mentioned Act was approved by Parliament and entered into force on 19 April 1996. The 1991 Convention has, however, not been ratified by South Africa.

Question 4. *If sui generis protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:*

- (a) *acts performed for research or experimental purposes, or to develop new varieties of plants;*

Switzerland

No.

According to Article 12(3) of the LPV, the authorization of the right holder is not necessary when using the propagating material of protected varieties to breed or market new varieties ("breeder's exemption"). The authorization of the right holder, however, is necessary if the protected varieties have to be used repeatedly to produce the new varieties.

Furthermore, Article 12(1) of the LPV only prohibits acts performed on a professional (commercial) level; therefore, all acts performed for research or experimental purposes or to develop new varieties of plants, on a non-professional level, are not prohibited by this provision.

Estonia

No.

Section 40 of the Plant Variety Rights Act stipulates: "A protected variety may be used without a licence issued by the holder of the plant variety right:

- 1) in scientific research and in official trials conducted for the purposes of comparison;
- 2) as parental material for the purpose of breeding new varieties;
- 3) privately, and for non-profit purposes."

Hong Kong, China

No.

See Sections 26(b)(ii) and (iii) of Cap. 490.

Iceland

No.

An authorization is not required. According to Article 18(2) of the Plant Variety Protection Act, the breeder's right shall not extend to utilization for experimental purposes

Lithuania

Exceptions to the rights conferred: acts performed for research or experimental purposes. A variety may be used without the breeders authorization if the acts are done for scientific purposes.

Morocco

No.

Article 17 of the Law states that the breeder's right does not cover:

- Acts performed privately for non-commercial purposes;
- acts done for experimental purposes;
- acts carried out to create new varieties as well as the acts contemplated in the second and third paragraphs of Article 16 above, performed with such varieties, provided that:
 - the protected variety is not used repeatedly in order to produce the new variety;
 - the new variety is not derived essentially from the protected variety if the latter is not itself essentially a derived variety;
 - the new variety is clearly distinguishable from the protected variety; and
 - acts performed by farmers for the purposes of reproduction or propagation on their own farms using the products of the harvest obtained by planting the

protected variety, with the exception of tree crops and ornamental and floral plants (farmer's privilege).

Norway

No.

However, consent is necessary if producing the new variety for commercial purposes involves continuous use of the protected variety.

Thailand

There are exceptions under the Act to the rights for research or experimental purposes in Section 33, paragraph 2.

United States

No, with respect to plant variety protection certificates issued under the Plant Variety Protection Act.

(With respect to utility patents issued under the general Patent Law, or plant patents issued under the Plant Patent Act, such acts would not require prior authorization from the holder of the patent if the acts were done for purely non-commercial purposes. Acts with a commercial motivation or purpose however, would provide a basis for a finding of infringement of the patent, if done without prior authorization from the right holder.)

(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics;

Australia

Yes, provided that:

- (i) the distinct variety has been declared an essentially derived variety from the protected variety; or
- (ii) the production of the distinct variety required the repeated use of protected variety (i.e. the distinct variety is a dependant variety).

Switzerland

No.

The present LPV does not address the issue of essentially derived plant varieties. Thus, acts performed to commercially exploit varieties that are distinct from protected varieties but share their essential characteristics do not require the prior authorization of the right holder.

The current revision of the LPV will take into account the "essentially derived and certain other varieties", as well as other situations prescribed by the 1991 Act of the UPOV Convention.

Estonia

Yes.

If the exploited variety is essentially derived from the protected initial variety or from a variety that is itself predominantly derived from that initial variety.

Hong Kong, China

Yes.

If essentially derived from the protected initial variety. See Section 31(1) of Cap. 490. A variety is treated as an essentially derived variety of another variety if:

- (a) it is predominantly derived from that other variety;
- (b) it retains the relevant characteristics that result from the genotype or combination of genotypes of that other variety;
- (c) it is clearly distinguishable from that other variety; and
- (d) except for the differences which result from the act of derivation, it confirms to the initial variety in the expression of the relevant characteristics that result from the genotype or combination of genotypes of that other variety.
(Section 31(3) of Cap. 490.).

Iceland

Yes.

An authorization is required. According to Article 16 of the Plant Variety Protection Act, the protection shall include a variety which is essentially derived from the registered variety. A plant variety is considered essentially derived from a variety if it is predominantly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Japan

Yes.

Acts performed to commercially exploit a variety which falls under the following conditions *require* the prior authorization of the right holder:

- (i) The variety was bred from an initial variety, while retaining the essential characteristics of the initial variety, by selection of variation, backcrossing, transformation by genetic engineering, etc.
- (ii) The variety is clearly distinguishable from the initial variety in terms of characteristics.
- (iii) The initial variety is a protected variety and is not a variety which falls under the conditions (i) and (ii).

Lithuania

A variety may be used without the breeders authorization if the acts are done for the purposes of breeding other varieties.

Morocco

Yes.

See answer to question 4.a above.

Norway

No, provided that the new variety is distinct from the protected variety in the characteristics that define the latter. This will be determined on a case-by-case basis.

Thailand

Yes.

There are exceptions under the Act to the rights for developing new varieties of plants and to the right to commercialize such newly developed varieties in Section 33, paragraphs 1 and 2.

(c) *acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land.*

Australia

No, unless the taxa is one declared by regulation to be one to which the farm saved seed exemption does not apply (currently no taxa have been subject to such a declaration).

Bulgaria

No.

In order to stimulate agricultural production, farmers are entitled to use for their own needs, for the purpose of reproduction in their own farms, products of a harvest they have obtained through planting in their own farms, propagating material of a variety other than the hybrid or the artificially obtained variety, protected by a certificate. This provision is applied only to plant species included in a list endorsed by the Ministry of Agriculture.

Switzerland

No.

Under the present law, farmers have the right to use the harvesting of (protected) seed in view of another use for further replantings in their own holdings (farmer's privilege).

It is expected that the revised LPV will provide the possibility to grant the farmer's privilege through an ordinance. The farmer's privilege is likely to be restricted to certain agricultural crops enumerated in a list.

Czech Republic

No.

The answer applies to certain agricultural crop plants.

European Communities

No.

The answer applies to certain agricultural crops.

Estonia

No.

At the request of the right holder or his representative the farmer must provide information about the quantities of the seed harvested.

A licence fee has to be paid if the protected variety is grown for personal purposes on a territory bigger than 10 ha.

Hong Kong, China

Yes.

Prior authorization is required unless the particular types of plant within which the protected variety is classified have been prescribed for exemption under Section 26(c) of Cap. 490.

Iceland

No.

An authorization is not required. According to Article 18(1) of the Plant Variety Protection Act, protection does not extend to private utilization for non-commercial purposes.

Japan

No.

Where farmers legitimately obtain the seeds and seedlings of the protected variety, produce the product of the harvest by using the said seeds and seedlings, except for which belong to a plant genus or species which is propagated vegetatively and is stipulated by the Ordinance of the Ministry of Agriculture, Forestry and Fisheries, and further use the said product of harvest as the seeds and seedlings on their own holdings, *the effects of the breeder's right shall not extend to the seeds and seedlings and the harvested materials obtained from them*, except as otherwise prescribed by a contract.

Lithuania

Farmers and other land users may use the protected variety without the breeder's authorization when

- they use the propagating material from the harvest of a protected variety, raised on their farm or on holdings used by them for their farm needs

Morocco

No.

See answer to question 4.a above.

Thailand

Yes, there are exceptions under the Act to the rights for "farmer's privilege" in Section 33, paragraph 4.

United States

No, with respect to plant variety protection certificates issued under the Plant Variety Protection Act.

(With respect to plant patents issued under the Plant Patent Act, their protection extends only to specific acts of asexual reproduction of the protected variety, or sale or use of the *plant* that is the subject of the grant. Harvesting and reuse of *seeds* from such a plant involve *sexual* propagation of the plant, and as such would not be covered by the plant patent rights.)

(With respect to utility patents issued under the general patent law, such acts would require the prior authorization of the patent owner.)

If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?

Australia

No.

The exercise of PBR rights is at the discretion of the rights holder and legislation does not stipulate remuneration except in respect of the issue of a compulsory license or acquisition. However, in circumstances where the harvested material or product from harvested material has been produced without a reasonable opportunity for the grantee to exercise their right on the propagative material (e.g. through the operation of farm saved seed), and the use of that harvested material or product does not qualify as an exemption (see answer to question (i) above), the grantee may choose to exercise their rights on the harvested material or product as if it was the propagative material.

Czech Republic

Yes.

In the case of question 4(c) above, the answer applies to farmers other than "small farmers".

European Communities

Yes.

In the case of question 4 (c) above, the answer applies to farmers other than "small farmers".

Estonia

See the response to question 3(c).

Hong Kong, China

There is no particular right for remuneration. The rights of a grantee under Cap. 490 are a proprietary right. It is the responsibility of a grantee to bring legal action against any person infringing his/her rights through civil proceedings in the courts.

Iceland

According to Article 17(3) the Minister can set rules to oblige parties propagating varieties of specifically prescribed species, exclusively for use in their own operations, to pay licence fees.

Lithuania

The farmers and other land uses may be exempt from the payment of the remuneration when the area of their own holdings or plot of the land used is not larger than the area prescribed by the Minister of Agriculture.

Morocco

No.

See answer to question 4 (a) above.

Romania

No.

But the party performing the act provided in the answer to 4.b above without the right holder's authorization may be obliged to pay for damages.

Slovenia

Yes, only in case under c); the farmer must pay the holder a suitable remuneration. The remuneration is suitable if it is sensibly lower than the amount charged for the licensed production of propagating material of this variety in the same area; small farmers shall not be required to pay any remuneration to the breeder.

Question 5. *Would acts done privately and for non-commercial purposes require the authorization from the right holder?*

Bulgaria

No.

Article 20 of the Law on the Protection of New Plant Varieties and Animal Breeds provides for the following exceptions to the plant breeder's rights:

"acts performed by farmers privately and for non-commercial purposes; [...]."

Switzerland

No.

See answer to question 4 (a) above.

Czech Republic

According to Section 19, paragraph (9)(c) of the Law No. 408/2000 Coll., the exploitation of the propagation material performed for own use of a natural person shall not constitute a breach to the protective rights.

Estonia

No.

Section 40 of the Plant Variety Rights Act stipulates: "A protected variety may be used without a licence issued by the holder of the plant variety right:

- 1) in scientific research and in official trials conducted for the purposes of comparison;
- 2) as parental material for the purpose of breeding new varieties;
- 3) privately, and for non-profit purposes."

Hong Kong, China

No.

Section 26 of Cap. 490 permits use for non-commercial purposes.

Iceland

According to Article 18(1) of the Plant Variety Protection Act, protection does not extend to private utilization for non-commercial purposes.

Lithuania

A variety may be use without the breeders authorization if the acts are done privately and for non-commercial purposes.

Morocco

No.

See answer to question 4 (a) above.

Thailand

No.

There are exceptions under the Act to the rights for private and non-commercial acts in Section 33, para 5.

Question 6. *Does your legislation provide for other exceptions to the rights conferred?*

Australia

Yes.

Certain compulsory licensing provisions may apply if the grantee of PBR in a plant variety does not take all reasonable steps to ensure reasonable public access to that plant variety. Reasonable

public access to a plant variety covered by PBR is taken to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand. This entails the granting of a license to sell and to produce propagating material of plants of that variety for sale on such terms and conditions (including the provision of reasonable remuneration to the grantee) as is considered would be granted by the grantee in the normal course of business.

Czech Republic

Section 21 of the Law No. 408/2000 Coll. provides for a compulsory licence.

Hong Kong, China

Section 29 of Cap. 490 enables a third party to obtain an order from the Registrar of Plant Varieties Rights in relation to the sale of reproductive material relating to a particular plant variety if such is not available for purchase at a reasonable price.

Lithuania

A compulsory licence may be concluded where there is a lack in the state of the protected variety of significance for the national economy or if the breeder has not been propagating the variety for a 3 year period after the entry thereof in the List of Protected Varieties.

Morocco

Yes.

Article 21 of the Law prescribes that upon expiry of a period of three years following the delivery of the certificate or four years from the filing date of their application, any legal person governed by public or private law may obtain a compulsory licence for this certificate if at the time of the application, barring any valid excuses, the holder of the certificate or his successor:

- has not yet started to exploit or to make effective and serious preparations to exploit the new variety covered by the certificate on Moroccan territory; or
- has not sold the product covered by the certificate in quantities large enough to satisfy the needs of the national market; or
- if the exploitation or sale of the variety has been abandoned for more than three years in Morocco.

Articles 22, 23 and 24 define the conditions for the grant and the withdrawal of compulsory licences.

New Zealand

Yes.

The Plant Variety Rights Act 1987 provides that any person may at any time after the expiration of three years from the making of a grant, on payment of the prescribed fee, request the Commissioner [of Plant Variety Rights] to consider whether or not reasonable quantities of reproductive material of a reasonable quality of the variety concerned are available for purchase by members of the public at a reasonable price. Where such a request is made, the Commissioner shall give the grantee concerned notice of it and a reasonable time to be heard in relation to it.

If after considering any submissions made by that grantee, the Commissioner is satisfied that, reasonable quantities of reproductive material of reasonable quality of the variety concerned are not available for purchase by members of the public at a reasonable price, the Commissioner shall issue to the person who made the request one or both of the following:

- a compulsory licence for the reproduction and sale of reproductive material of that variety;
- an order requiring the grantee to sell to that person reproductive material of that variety.

In considering whether or not reasonable quantities of reproductive material of reasonable quality are available to members of the public at a reasonable price, the Commissioner shall not take into account any reproductive material that is available only subject to the condition that all or any of the produce from that material must be sold or offered to a specified person, or to one of a specified group of persons, or to a member of a specified class or description of person.

Romania

Yes.

The granting of a compulsory licence does not prevent the variety patent owner from exploiting the variety or granting licences to third parties (Article 37(4) of Law No. 255/1998).

Thailand

Yes.

There is compulsory licensing under the Act in Sections 36 and 37. The Minister of the Ministry of Agriculture and Cooperatives with the approval of the Commission, has the power to issue a Notification prohibiting the production, sale, distribution in any matter, importation or exportation of new plant varieties for the period of time. The Director- General of the Department of Agriculture, with the approval of the Commission, has the power to authorise the use of the right holder of a new plant variety in case of no sale or insufficient of the propagating material of that new plant variety.

Question 7. *Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for sui generis protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?*

Australia

Only new or recently exploited varieties can be registered. A new variety is one which has not been sold with the breeder's consent. A recently exploited variety is one which has been sold with the breeder's consent for up to 12 months in Australia and for overseas varieties this limit is up to four years (with the exception of trees and vines for which a six year overseas prior sale limit is permitted).

Bulgaria

Yes.

Plant variety is deemed to be new if, at the date of filing the application for a certificate, the variety or propagating material of the variety or harvest thereof has not been offered for sale, sold, or otherwise used commercially, or has been offered with the consent of the breeder in the territory of the Republic of Bulgaria for not more than one year, or in the territory of any other country for not more than 6 years concerning trees and vines or 4 years concerning any other plant species (Article 8.1 of the Law on the Protection of New Plant Varieties and Animal Breeds).

Canada

Yes.

Protection cannot be obtained for a variety that has been sold in Canada prior to application, or sold outside of Canada for four (4) years, or six (6) years for woody plants prior to application. The exception to this is for "recently prescribed categories". There is a transitional period, of one year from the date Regulations came into effect, that permits the sale of varieties prior to application. In this case, varieties may have been sold in Canada after 1 August 1990, and sold outside of Canada after 1 August 1984 for woody plants and after 1 August 1986 for all other plants.

Switzerland

Yes.

According to Article 5(3) of the LPV, "[t]he fact that a variety is itself generally known shall in no way detract from its character of novelty unless, at the time the application was filed, the variety had already been offered for sale or marketed in Switzerland or – for more than four years – abroad, with the consent of the breeder or his successor in title."

The current revision of the LPV will take into account the features of the 1991 Act of the UPOV Convention.

Czech Republic

Yes.

According to Section 4, paragraph (1)(a) and (b) of the Law No. 408/2000 Coll., "the variety shall be deemed to satisfy the condition of novelty if, at the day of filing of the application for grant of protective rights the propagating material or material from the variety harvest has not been sold or otherwise disposed of to others by or with the consent of the breeder, for purposes of exploitation of the variety:

(a) in the territory of the Czech Republic earlier than one year before the application has been filed, or

(b) outside the Czech territory earlier than four years before the application has been filed or, in the case of trees or of vines, earlier than six years before the application has been filed".

European Communities

Yes.

In the case of availability within the Community: 1 year; in the case of availability outside the Community: 4 years or, for trees or vines, 6 years.

Estonia

Yes.

Protection can be obtained for a plant variety that was known to the public or was publicly available prior to the application for *sui generis* protection for that plant variety.

In the case of availability of a plant variety in Estonia, the time-limit is one year. In the case of availability in the territory of another state, the time-limit is four years and in the case of trees and grapevines, the time-period is not longer than six years.

Hong Kong, China

Yes.

Section 18(4)(a) provides that a variety is new if there has been no sale of that variety in Hong Kong for more than 12 months before an application was made, or no sale outside Hong Kong in respect of trees or vines for a period of six years, or a period of four years in every other case.

Hungary

Yes.

The variety shall be deemed to be new if it has not been offered for sale or marketed with the consent of the breeder or his successor in title:

- (a) in the country earlier than one year before the date of priority;
- (b) abroad earlier than four years or, in the case of trees and vines, earlier than six years before the date of priority.

Iceland

According to Article 2(1)(4) of the Plant Variety Protection Act, a protection can be granted if the variety is new, i.e. propagating or harvested material of the variety has not been sold or offered for public sale or otherwise disposed of, by or with the consent of the breeder, for purposes of commercial utilization of the variety:

- in Iceland, earlier than one year before the above-mentioned date; or
- in another country, earlier than four years or, in the case of trees or of vines, earlier than six years before the above-mentioned date.

According to Article 2(2), a variety is considered to be known if it has been sold or offered for public sale, is registered in an official variety list or is generally known through other means.

Japan

Yes.

A plant variety may not be protected when it is not clearly distinguishable in terms of characteristics from any other varieties which have been publicly known in Japan or foreign countries before the filing of the application for variety registration.

A plant variety may not be protected when the seeds and seedlings or harvested materials of the applied variety have been transferred in the course of business, in Japan earlier than one year before the filing date of such an application for protection, or in foreign countries earlier than four years before the filing date of such an application for protection (or earlier than six years in the case of a variety belonging to perennial plants such as trees). However, this shall not apply where such transfer was made for the purpose of experiment or research, or where such transfer was made against the will of the breeder.

Korea

Yes.

Article 13.2 of the Act provides that, among the varieties which have already been known at the time when species or genus of the plants entitled to variety protection under the Act are determined in accordance with the Ordinance of the Ministry of Agriculture and Forestry, a variety falling under any of the following category shall be entitled to protection, provided that an application for variety protection thereof is made within one year from the date of the determination:

- (i) a variety registered or specified under the past relevant laws.
- (ii) a variety whose protection rights are registered in foreign countries.
- (iii) a variety whose breeder and initial circulation date are verified.

Lithuania

Under the plant variety protection system in Lithuania to be protectable, a variety shall be new. The variety shall be deemed to be new if, at the date of filing of the application, the propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by the initiative or with the consent of the breeder:

- (1) in the Republic of Lithuania earlier than 1 year before the above-mentioned date,
- (2) in the territory of another state earlier than 4 years or, in the case of trees, vines or of berry shrubs earlier than 6 years before the said date.

Morocco

Yes.

Article 6 of Law No. 9-94 prescribes that a variety is deemed to be new if, at the date of filing the application for the breeder's right, the reproductive material or propagating material or the harvested or processed material of the variety has not been sold or otherwise transferred to third parties by or with the consent of the breeder with a view to the commercial exploitation of the variety, for at least one year in Morocco or at least four years, or in the case of trees or vines, at least ten years abroad.

Besides, Article 76 provides that for a transition period of one year from the effective date of the Moroccan Law, an application may be filed for the protection of varieties that have been offered for sale, otherwise used commercially or disseminated in Morocco or abroad prior to the effective date of the present law. If that protection is granted, its duration is reduced by the number of full years that have elapsed between the date when the variety was first offered for sale, otherwise commercially used or disseminated and the filing date of the application.

The same rule applies, *mutatis mutandis*, to varieties of species added to the list of protected species after the entry into force of the present law (Article 76).

Norway

Yes.

Protection cannot be obtained for a variety that has been offered for sale in Norway with the right holder's consent prior to the filing of an application for a plant breeder's right. Offering for sale abroad that has taken place less than four years prior to the filing date does not preclude protection. For varieties of trees and vine stock the period is six years. In other cases, public knowledge of the variety prior to the filing date does not preclude protection.

New Zealand

Yes.

Protection can be obtained for a plant variety known to the public or publicly available prior to the application for *sui generis* protection for that plant variety provided there has been no sale of that variety with the agreement of any relevant owner of that variety:

- (i) in New Zealand, for more than 12 months before the date on which that application was made; and
- (ii) overseas, for more than six years before that date, in the case of a woody plant, or for more than four years before that date in every other case.

Poland

Yes.

The duration of a variety's being known to the public is not taken into account. However, it must satisfy the novelty criterion. All varieties, including a variety which was not created by discovery must satisfy the criterion of distinctness according to Article 7 of the UPOV Convention (Act 1991).

Romania

Yes.

The variety is deemed new if, on the filing date of the application for the grant of protection, or on the priority date, propagating material or harvested material of the variety has not been sold or otherwise disposed of to others, either by or with the consent of the breeder, for the purpose of commercial exploitation of the new variety: (a) on the territory of Romania, earlier than one year before the filing date of the application for a variety patent.

Slovak Republic

Law No. 132/1989 Coll. on the Protection of Rights of New Varieties and Animal Breeds as amended by No. 22/1996 Coll. in Part II, Article 4, paragraph 5 determines the conditions for granting breeder's certificates in respect of a variety. The variety is "new" if its propagating or harvesting material has not been sold or otherwise disposed to others:

- (a) within the territory of the Slovak Republic previous to one year before the date of filing the application;
- (b) within the territory of any country:
 - (1) in the case of varieties of fruit trees, forest or garden woods, or wines, previous to six years before the date of filing the application;
 - (2) in the case of varieties of any other species, previous to four years before the date of filing of the application.

Slovenia

Yes, provided that a plant variety for which an application was filed in the Republic of Slovenia has not been sold or commercially exploited in the territory of the Republic of Slovenia more than one year before the filing of the application, and outside the Republic of Slovenia not more than four years before the filing date (in case of trees and vine, not more than six years).

Thailand

According to Sections 52 and 53 of the Act, subject-matters are: a person who collects, procures or gathers general domestic plant varieties, wild plant varieties or any part of such plant varieties for the purposes of variety development, education, experiment or research for commercial or non-commercial purposes shall make a profit-sharing agreement and comply with the Regulation prescribed by the Commission.

United States

Yes, with respect to plant variety protection certificates issued under the Plant Variety Protection Act. The applicable periods of time are (a) for disclosures within the United States, one year, and (b) for disclosures outside the United States, (i) six years for new tree or vine varieties, and (ii) four years for all other types of varieties.

(With respect to plant patents and utility patents, protection can be obtained, notwithstanding a disclosure of the plant variety or plant invention up to one year prior to the date of application for protection.)

South Africa

No.

Varieties which are generally known to the public or which are identical to what occurs in nature are not protectable under our sui generis system for the protection of plant varieties.

Question 8: *To be entitled to rights under sui generis plant variety protection does one have to be the person who bred, or discovered and developed the variety, or his successor in title?*

Czech Republic

According to Section 2(b) of the Law No. 408/2000 Coll., "holder means the breeder who has been granted protective rights to the variety, or his successor in title".

According to Section 2(c) of the Law No. 408/2000 Coll., "breeder means the natural or legal person, who bred, or discovered and improved a variety or the person for whom someone else created a variety as part of fulfilment of tasks in relation to an employment contract or another similar relationship, unless a written agreement stipulates otherwise; legal successor of the breeder shall also be considered as breeder".

Hong Kong, China

Under Section 18(2)(b) of Cap. 490, one of the requirements for an application to be treated as being eligible for the making of a grant is that the Registrar is satisfied that the applicant is an owner of that variety. Section 2 of Cap. 490 defines an owner, in relation to any variety, as: "a person who bred or discovered and developed that variety; an agent of that person; a successor to that person".

Lithuania

To be entitled to rights under Lithuania's legislation to plant protection, one has to be the person who bred, or discovered and developed the variety or his successor in title.

Morocco

Yes.

The entitlement to rights is reserved for the breeder, who is defined as follows:

- The person who has created, discovered or developed a variety;
- the person who employs the aforementioned person or who commissioned his work, subject to any contractual provisions to the contrary;
- the successor in title of the first or the second above-mentioned person, as appropriate.

New Zealand

Yes.

The 'owner' is entitled to rights in relation to any variety. Section 2 of the New Zealand Plant Variety Rights Act 1987 defines 'owner' as a person "who bred or discovered that variety, and includes a successor of that person".

Romania

Yes.

The breeder is entitled to the rights in a variety patent.

South Africa

Yes.

An application for the grant of a plant breeder's right may be made by:

- (1) the breeder of a new variety of a kind of plant; or
- (2) if the breeder is an employee (irrespective of whether or not he is paid a salary) whose duties are such that they involve plant breeders' activities relating to the kind of plant in question, and the new variety in question was bred in the performance of such duties, the employer of such breeder; or
- (3) the successor in title of the breeder or employer referred to in paragraph (a) and (b) respectively.

The aforesaid application may only be made by a person who: -

- is a citizen of, or is domiciled in, the Republic or a convention country or an agreement country; or
- in the case of a juristic person, has a registered office in the Republic or a convention country or an agreement country.

Question 9. *Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?*

Bulgaria

No.

Germplasm characteristics can be protected by a patent for invention, where the patentability requirements are met. Characteristics of a plant variety derived from such germplasm are protected by a plant breeder's rights certificate.

Estonia

The issue is currently under consultation with the UPOV.

Hong Kong, China

Protection is only granted if criteria like distinctiveness, uniformity, and stability (which are based upon the characteristics of the plant varieties) can be fulfilled.

Lithuania

Plant variety protection is predicated on identification of expressed characteristics of plant varieties.

New Zealand

No.

Protection is only granted based upon characteristics of plant varieties derived from germplasm.

Poland

Basically, for the purpose of examination as to distinctness, uniformity and stability, botanical characteristics are used. In case of the botanical characteristics not being sufficient enough to ascertain that a variety meets the distinctness criterion, methods with the use of genotype characteristics are used. The latter are taken as complementary characteristics.

Slovenia

No, protection is predicated on identification of expressed characteristics of plant varieties.

Thailand

The plant Variety Protection Act, B.E. 2542 has granted protection only for the new plant varieties derived from any germplasm.

United States

No, with respect to plant variety protection certificates. The determination of novelty for a variety is presently made through reference to the phenotype or expressed characteristics of the plant variety.

No, with respect to plant patents, for the same reason (i.e., the evaluation of novelty and non-obviousness of the plant variety is based on phenotypical or expressed characteristics of the plant variety).

No, with respect to utility patents. If a gene is present in the plant in its natural state, its identification alone cannot be a basis for protection, regardless whether it is expressed or unexpressed. To rely on genes for patentability of a plant, they would have to be introduced into the plant by human intervention. Introduction of a gene that does not express a difference in the characteristics of the plant may render it novel and arguably nonobvious under the general Patent Law. However, the criterion of utility would not be met, as the unexpressed gene did not change the original utility of the plant, as occurring in nature.

South Africa

Protection for a variety can only be obtained if it is morphologically distinguishable from any other known variety of the same kind of plant. Protection cannot be obtained on differences which are based on characteristics of the germplasm.

Question 10: *What are the conditions that your law require for protection?*

Australia

A variety is registerable if: it has a breeder; and is distinct, uniform and stable. It must also be new or only recently exploited.

A new variety is one which has not been sold with the breeder's consent. A variety is taken to be recently exploited if propagating or harvested material of the variety has been sold, with the breeder's consent, for up to 12 months in Australia. For sales made in the territory of another contracting party (UPOV Member State) the limit is up to four years for all taxa (with the exception of trees and vines for which a six-year time limit on sales is permitted).

To obtain acceptance of an application and provisional protection it must be established that there is a *prima facie* case that the variety is distinct from all other varieties of common knowledge. To obtain a grant of PBR the applicants must verify these claims normally by conducting a comparative test growing which includes the new variety and the most similar varieties of common knowledge.

Hong Kong, China

Novelty: protection can only be considered for a variety that has not been sold in Hong Kong for more than 12 months and elsewhere in the world for six years, in the case of trees and vines, or for more than four years, in every other case.

Distinctiveness: To be considered for protection, the Registrar must be satisfied that the variety is clearly distinguishable in one or more important characteristics from existing varieties whose existence is a matter of common knowledge at the time of application. Distinguishing characteristics must be capable of precise description.

Uniformity: the Registrar must be satisfied that the variety is sufficiently uniform or homogeneous in its relevant characteristics, subject to any variation that may be expected having regard to any particular features of its sexual reproduction or vegetative propagation, before the variety can be considered for protection.

Stability: the Registrar must be satisfied that the variety retains its relevant characteristics over a number of generations of reproduction or propagation or, where a particular cycle of reproduction or multiplication is specified by the application, at the end of each cycle.

Lithuania

Under the Law on the Protection of Plant Varieties, the exclusive rights have to be granted to the registered variety upon establishing that variety satisfies the criteria of novelty, distinctness, uniformity, and stability and has been designated by a denomination. It must be different from every denomination which designates, in the territory of the Republic of Lithuania or any other state, an existing variety of the same plant species or of a closely related species.

Thailand

According to Section 11 and 12 of the Act, the conditions required for the protection of new plant varieties are novelty, distinctness, uniformity, stability, not exploited in or outside the kingdom for more than one year and distinct from other plant varieties existing on the date of filing the application.

Zambia

As earlier indicated, Section 18 allows the Registrar on a discretionary basis to refuse certain classes of applications for a patent. However, plant varieties do not fall within any of the classes. Therefore by interpretation, it is possible for the Registrar to grant a patent for a plant variety, but only if it can meet the criteria of an invention and if the complete specification "fully described the invention and the manner in which it is to be performed". (Section 14(3) of the Act). What would

need to be resolved, however, in such a situation would be the question of obviousness and reproducibility.

Question 11: *What is the duration of protection?*

Australia

In tree and vine varieties, PBR continues for 25 years from the date of granting, and in all other varieties, for 20 years from the date of granting.

Bulgaria

The term of validity of a plant variety certificate as from its date of grant is as follows:

- 30 years for tree or vine varieties;
- 25 years for other varieties.

Canada

18 years for all species.

Czech Republic

According to Section 23, paragraph (1) of the Law No. 408/2000 Coll., generally the duration of protection is 25 years; 30 years for protected varieties of trees, hops, vines and potatoes.

Hong Kong, China

Plant variety rights are granted for a term of 25 years in the case of trees and vines, and 20 years in every other case.

Hungary

Under Article 106(4) patent protection shall have a duration of 15 years from the date of the grant of a plant variety patent or, in the case of trees and vines, of 18 years from such date.

Korea

Under Article 56 of the Act, the variety protection right shall expire at the end of the 20th calendar year following the date of the registration of its establishment. For ornamental trees and fruit trees, the right shall expire at the end of the 25th calendar year following the date of the registration of its establishment.

Lithuania

The legal protection to a plant variety shall be granted for a period of 25 years, whereas for potatoes, trees, berry shrubs and vines that said period shall be 30 years from the date of entry thereof in the List of Protected Varieties.

Morocco

The duration of protection is 20 years for varieties used as field crops, 25 years for tree and vine varieties and 30 years for date palm.

New Zealand

Protection in New Zealand is available for:

- 23 years for woody plants including root stock; and
- 20 years for all other plant types.

Poland

Plant Breeder's Rights protection starts from the date of grant and its term is:

- 30 years with respect to grape-wine varieties as well as trees and their rootstocks,
- 25 years with respect of other varieties.

Romania

The duration of protection is 25 years from the date of granting of the variety patent. For new fruit tree, vine and ornamental tree varieties the duration of protection is 30 years from the date of granting of the variety patent.

Thailand

According to Section 31 of the Act, the variety protection right shall expire at:

- The end of the 12th calendar year following the date of the registration of its establishment for biennials.
- The end of the 17th calendar year following the date of the registration of its establishment for trees.
- The end of the 27th calendar year following the date of the registration of its establishment for tree-based utilizations.

United States

25 years from date of issue for vines and trees, and 20 years from issue for all other varieties under a plant variety protection certificate. In addition, 20 years from filing date for patents.

South Africa

For trees and vines - 25 years; and in all other cases - 20 years.
