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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

First Session
Geneva, April 30 to May 3, 2001

INFORMATION PROVIDED BY WIPO MEMBER STATES CONCERNING PRACTICES RELATED TO THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Document prepared by the Secretariat

1. At its meeting of November 8 and 9, 1999, the Working Group on Biotechnology agreed to prepare a list of questions about practices related to the protection of biotechnological inventions under patent and plant variety protection systems or a combination thereof by WIPO Member States. The purpose of the questions is to obtain relevant information necessary for the identification of a number of issues concerning intellectual property protection of biotechnological inventions. The information obtained from the responses to the questions will be issued in a final report, based on a draft report written by the consultants who prepared the background document for the meeting of the Working Group (WIPO/BIOT/WG/99/1). The information contained in the Annex to this document draws upon the draft report prepared by the consultants.

2. Certain questions in the above-mentioned list address, *inter alia,* intellectual property issues which relate to genetic resources and arise in the context of the protection of biotechnological inventions. The Annex to this document reflects, in a synoptic manner, the information received from Member States through their answers to questions which may pertain, *inter alia*, to intellectual property and genetic resources (these are questions 1, 2, 3, 5, 6, 8, 9 and 10). The Annex consists of a table (Part 1) and an addendum (Part 2).

3. Fifty-seven Member States responded to at least one question posed in the list of questions. In cases where the answer to a question comprises more information than a mere "Yes" or "No" the full answers which the Member States submitted have been transcribed in the addendum to the table. In the table, an asterix (*) has been added to these responses. The answers of the Member States have been reflected in the addendum in the form in which they were received, including in cases where possible inconsistencies may exist with subsequent answers to other questions.

4. In some cases the answer did not include an explicit "Yes" or "No", but the answer was susceptible to being reflected as an affirmative or negative response. In such cases the response is reflected in the table within parenthesis as a constructed response and the full transcript of the answer is provided in the addendum. However, not all answers were susceptible to being reflected in the table as providing a clear affirmative or negative response to the relevant question. In such cases, the response to the question is reflected in the table as an asterix only (*) and the full transcript of the answer is provided in the addendum. The questions are identified in this document by the original numbers with which they were identified in the list of questions that was sent to the Member States.

4. The Committee is invited to take note of the information as contained in this document.

[Annex follows]

ANNEX

RESPONSES TO QUESTIONS ON PRACTICES RELATED TO THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS UNDER PATENT AND PLANT VARIETY PROTECTION SYSTEMS

PART 1

	Australia[1]	Austria	Bangladesh	Belarus	Belgium[ii]	Benin[iii]	Brazil	Bulgaria	Cameroon	Canada	China	Colombia	Cuba	Cyprus	Democratic People's Rep. of Korea	Denmark[iv]	Ecuador	El Salvador	Estonia	European Union[v]	Ethiopia	Finland	Germany[vi]	Guatemala	Hungary	Iceland	India	Ireland	Italy
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.	*	N*	N*	Y*	N*	Y*	Y	(Y)*	(Y)*	Y*	Y*	Y	*	Y	Y	Y*	*	N	N	(Y)*	Y*	N*	N*	Y*	--	N*	(Y)*	Y*	N
2. If the answer to question 1 is yes, please respond to the following questions:																													
a) Does your patent system consider that entire plants or animals are inventions?	(Y)*	N/A	N/A	N	N/A	N*	N	(Y)*	(N)*	Y*	Y	N*	N	Y	N*	Y	*	N/A	N/A	(Y)*	(N)*	N/A	N/A	N	--	N/A	(N)*	N*	--
b) If your answer to question 2(a) is yes, does your patent system exclude all such inventions from being patentable-subject matter, or does it only exclude certain types or animals? If it excludes only certain types, please identify the categories or characteristic of inventions that are excluded.	(N)*	N/A	N/A	N/A	N/A	Y*	N/A	(N)*	Y*	N/A	(Y)*	*	N/A	N*	N/A	(N)*	*	N/A	N/A	(N)*	(Y)*	N/A	N/A	N/A	--	N/A	(Y)*	N/A	--
c) Is there any 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 (for example, ethical or moral concerns)?	*	N/A	N/A	N	N/A	(N)*	N/A	(Y)*	--	N	Y*	(Y)*	Y*	(Y)*	Y*	Y*	Y	N/A	N/A	(Y)*	Y*	N/A	N/A	Y	--	N/A	(Y)*	Y*	--

Notations

( ) = Indicates a constructed response
* = Indicates additional information in the Part 2
-- = No response to an applicable question
N/A = Not applicable as reflected by Member States

	Japan	Kazakhstan	Lithuania[vii]	Madagascar	Malaysia[viii]	Mexico	Netherlands[ix]	New Zealand	Norway	Panama	Philippines	Poland	Portugal	Russian Federation	Saudi Arabia	Slovakia	Slovenia	Sri Lanka	Sweden	Switzerland[x]	Thailand	The Former Yugoslav Rep. of Macedonia	United Kingdom	United States[xi]	Uruguay	Uzbekistan	Venezuela	Zambia
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.	N*	N*	(Y)*	(Y)*	N/A*	Y	Y	N*	(Y)*	Y*	Y*	Y*	Y*	Y*	N	(Y)*	N	Y*	(Y)*	(Y)*	Y*	(Y)*	Y*	N*	(Y)*	*	Y*	N*
2. If the answer to question 1 is yes, please respond to the following questions:																												
a) Does your patent system consider that entire plants or animals are inventions?	N/A	Y*	(Y)*	--	N/A*	Y*	Y	Y	(Y)*	Y*	N	(Y)*	Y*	N	N	(Y)*	N/A*	*	(Y)*	(Y)*	(Y)*	--	Y*	N/A	*	--	Y*	--
b) If your answer to question 2(a) is yes, does your patent system exclude all such inventions from being patentable-subject matter, or does it only exclude certain types or animals? If it excludes only certain types, please identify the categories or characteristic of inventions that are excluded.	N/A	(N)*	(N)*	--	N/A*	(N)*	*	N*	(Y)*	*	N/A	(Y)*	*	N/A*	N	(N)*	N/A	N/A*	*	(N)*	(Y)*	--	(N)*	N/A	*	--	(N)*	--
c) Is there any 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 (for example, ethical or moral concerns)?	N/A	(Y)*	(Y)*	--	N/A*	*	Y	Y*	(Y)*	Y*	Y*	--	Y*	(Y)*	N	(Y)*	N/A	(Y)*	(Y)*	(Y)*	Y*	--	*	N/A	*	--	Y*	--

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	Australia[i]	Austria	Bangladesh	Belarus	Belgium[ii]	Benin[iii]	Brazil	Bulgaria	Cameroon	Canada	China	Colombia	Cuba	Cyprus	Democratic People's Rep. of Korea	Denmark[iv]	Ecuador	El Salvador	Estonia	European Union[vi]	Ethiopia	Finland	Germany[vi]	Guatemala	Hungary	Iceland	India	Ireland	Italy
3. Other than the exclusions above, is it possible to obtain patent protection in your country where:																													
a) the patent protection is directed to a plant or animal invention, *per se*, and it is not limited to a particular plant variety or animal variety;	(Y)*	Y	*	N*	Y*	(N)*	N	(Y)*	N	*	N	N	N*	Y	Y	Y*	*	--	Y	Y	(N)*	Y*	Y*	N	--	(Y)*	N	N	Y
b) the patent protection is limited exclusively to a plant or animal variety;	(Y)*	N	N/A	Y*	N*	(N)*	N	(N)*	N	(N)*	N	(N)*	*	Y	Y	N*	Y*	--	N	N	N*	N	N*	N	--	N	N	N	N
c) the patent encompasses a group of plant varieties or animal varieties that incorporate a common trait or characteristic incorporated into the class of organisms?	(Y)*	N	--	N*	N*	(N)*	N	(N)*	N	*	N	(N)*	(N)*	Y	Y	Y*	*	--	*	(Y)*	(N)*	Y*	N	N	--	N	N	N	N
5. Is it possible to obtain a patent in your territory on a microorganism that is new, involves an inventive step and is capable of industrial application?	(Y)*	Y	(N)*	Y*	Y	(N)*	N	(Y)*	(Y)*	(Y)*	Y	Y*	Y*	Y	Y	Y*	Y	Y	Y	Y	N*	Y*	Y	N	--	Y	(N)*	Y	Y
6. Is it possible to obtain a patent in your territory																													
a) on an essential biological process for the production of a plant or animal?	*	N	(N)*	Y	N*	N*	Y	(N)*	(N)*	(N)*	N	N*	N	Y	N	N*	*	N	N	N	N*	N*	N*	N	--	N	N/A	N	N
b) on subject-matter that is identical to that found in nature (e.g. plant or animal in its natural state)?	(N)*	*	*	Y	Y*	(N)*	N	(N)*	(N)*	N*	N*	N*	N	Y	N	Y*	N*	N	Y	Y*	N*	*	Y*	N	--	N	N/A	Y	N
c) on new uses of known biological material?	(Y)*	Y	(N)*	Y	Y*	(N)*	Y	(Y)*	(N)*	Y	Y	N*	N	Y	Y	Y*	N	Y	Y	(Y)*	N*	Y	Y	N	--	Y	N/A	Y	Y

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3. Other than the exclusions above, is it possible to obtain patent protection in your country where:																												
a) the patent protection is directed to a plant or animal invention, *per se*, and it is not limited to a particular plant variety or animal variety;	Y	Y	(Y)*	(Y)*	N/A*	Y	N	Y	(N)*	(Y)*	N	N	Y	*	N	(Y)*	Y	N	(Y)*	Y*	N*	--	Y	Y*	*	N	N	--
b) the patent protection is limited exclusively to a plant or animal variety;	Y	Y	(N)*	(Y)*	N/A*	N	N	Y	*	N*	N	N	N*	(N)*	N	(N)*	N	N	(N)*	N*	N	--	N	Y*	*	N	N	--
c) the patent encompasses a group of plant varieties or animal varieties that incorporate a common trait or characteristic incorporated into the class of organisms?	Y	Y	(N)*	(Y)*	N/A*	Y*	N	Y	*	Y*	N	N	N*	(N)*	N	(N)*	N	N	(Y)*	Y	N	--	Y*	Y*	*	N	N	--
5. Is it possible to obtain a patent in your territory on a microorganism that is new, involves an inventive step and is capable of industrial application?	Y	Y*	(Y)*	Y*	(Y)*	Y	Y	Y	(Y)*	Y	Y	Y*	Y*	Y*	Y	Y*	Y	(Y)*	(Y)*	Y	(Y)*	(Y)*	Y	Y	Y*	(Y)*	Y*	--
6. Is it possible to obtain a patent in your territory																												
a) on an essential biological process for the production of a plant or animal?	Y	N*	(N)*	N	(N)*	N*	N	Y	(N)*	Y	N*	N	N*	Y*	N	N*	Y	N	(N)*	N*	Y*	--	N	N*	N*	(Y)*	(N)*	--
b) on subject-matter that is identical to that found in nature (e.g. plant or animal in its natural state)?	*	N	(N)*	N	(Y)*	N*	N	Y*	(Y)*	N	N	*	N*	N	N	(N)*	Y*	N	*	*	N*	--	Y*	N	N*	(N)*	(N)*	--
c) on new uses of known biological material?	Y	Y	(Y)*	Y	(N)*	Y*	Y	Y*	(Y)*	(Y)*	Y	*	Y	Y*	Y	(Y)*	Y*	N	(Y)*	(Y)*	Y	--	(Y)*	Y	(N)*	(Y)*	Y*	--

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d) on chemical structures comprising nucleotide sequences corresponding in whole or in part to nucleotide sequences found in organisms (e.g. coding or non-coding)?	(Y)*	*	*	Y	Y*	--	N	(Y)*	N	Y*	Y*	N*	N*	Y	Y*	Y*	Y*	Y	N	(Y)*	(N)*	Y*	Y*	N	--	Y*	N/A	Y	Y*
e) on chemical structures comprising amino acid sequences corresponding to peptides or proteins produced by a naturally occurring organism, including plant, animals or a human being?	(Y)*	*	--	Y	Y*	--	N	(Y)*	N	Y*	Y	N*	N	Y	Y*	Y*	Y*	Y	Y	(Y)*	(N)*	Y*	Y*	N	--	Y*	N/A	Y	Y
8. Does your legislation include any special provisions to ensure the recording of contributions to inventions (such as the source of government funding, the source of genetic resources that originate or are employed in biotechnological inventions, the grant or prior informed consent to have access to those resources, etc.)? If the answer is yes, could you please provide a copy of the relevant legal provisions.	N	N	(N)*	N	N	--	N	(N)*	(N)*	N	Y*	Y*	N	N	N	Y*	Y*	N	N	(N)*	N*	N	N	N	(N)*	N	N/A	N	N
9. If your answer to question 8 is no, is your country planning to introduce legislation to ensure the recording of such contributions, as described above? If your answer is yes, could you please provide a copy of the relevant draft provisions and inform about the estimated timeframe for their enactment by the relevant authorities.	N	N	(Y)*	N	N	--	Y*	(N)*	*	(N)*	N/A	*	(N)*	N	(N)*	*	N/A	N	N	N/A*	*	N	N	N	(N)*	Y*	N/A	(N)*	N

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d) on chemical structures comprising nucleotide sequences corresponding in whole or in part to nucleotide sequences found in organisms (e.g. coding or non-coding)?	Y*	Y	(Y)*	Y	(Y)*	(Y)*	Y	Y*	(Y)*	Y	Y	Y*	Y*	Y*	N	(Y)*	Y	Y	(Y)*	(Y)*	Y	--	Y	Y	(N)*	(N)*	Y*	--
e) on chemical structures comprising amino acid sequences corresponding to peptides or proteins produced by a naturally occurring organism, including plant, animals or a human being?	Y*	Y	(Y)*	Y	(Y)*	(Y)*	Y	Y*	(Y)*	N	N*	Y*	Y*	Y*	N	(Y)*	Y	Y	(Y)*	(Y)*	Y	--	Y	Y	(N)*	(N)*	Y*	--
8. Does your legislation include any special provisions to ensure the recording of contributions to inventions (such as the source of government funding, the source of genetic resources that originate or are employed in biotechnological inventions, the grant or prior informed consent to have access to those resources, etc.)? If the answer is yes, could you please provide a copy of the relevant legal provisions.	N	N	(N) *	(N)*	(N)*	N	N	N	(N)*	N	N*	N	N	N*	N	(N)*	N	N	(N)*	N	N	--	N	N*	(N)*	N	(Y)*	--
9. If your answer to question 8 is no, is your country planning to introduce legislation to ensure the recording of such contributions, as described above? If your answer is yes, could you please provide a copy of the relevant draft provisions and inform about the estimated timeframe for their enactment by the relevant authorities.	N	N	(N)*	(N)*	(N)*	N	N	N	(N)*	N	N*	N	N	*	N	(N)*	N	N	(N)*	*	(N)*	--	N	N	*	N	*	--

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10. If your answer to question or 8 or 9 is yes, are those requirements a condition of patentability in the sense that the failure in disclosing such contributions will bar the patent from being granted and/or will constitute grounds for its invalidation or revocation? If they are not, what is the consequence of failing in meeting those requirements?	N/A	N/A	N/A*	N/A	N/A	--	N/A	N/A	N/A*	N/A	N*	Y*	N/A	N/A	N/A*	(N)*	Y	N/A*	N/A	(N)*	N/A	N/A	N/A	N/A	N/A*	--	N/A	N/A	N/A

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10. If your answer to question or 8 or 9 is yes, are those requirements a condition of patentability in the sense that the failure in disclosing such contributions will bar the patent from being granted and/or will constitute grounds for its invalidation or revocation? If they are not, what is the consequence of failing in meeting those requirements?	N/A	N/A	N/A	N/A	N/A*	N/A	N/A	N/A	N/A	N	N/A	N/A	N/A	N/A*	N	N/A*	(N)*	N/A*	(N)*	--	--	--	N/A	N/A	N/A*	N/A	*	--

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[i] In Australia, patents and plant variety protection are covered by the *Patents Act 1990* and the *Plant Breeder's Rights Act 1994* respectively. 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.

[ii] The Belgian response to the questionnaire should not be any different from the responses of the other European states. This is for two reasons. The first reason is that the Belgian legislation is phrased in almost identical terms as that of the other member countries of the European Patent Organization and Belgian courts have very little case materials or decisions that would be specifically Belgian; The second reason is that directive 98/44 of July 6, 1998 (JOCE L 213 of July 30, 1998) has been in force since July 30, 1998. It should be implemebted by July 30, 2000. In accordance with the ruling of the Court of Justice, national authorities must interpret legislation according to EU directives from the time of their entry into force ("principle of uniform interpretation affairs C-14/83, Von Colson, 10.4.84, C-106/89, Maarleasing, 13.11.90, C-185/97, Coote, 22.9.98).

[iii] It should be pointed out that Benin is a member of the African Intellectual Property Organization (OAPI) and the intellectual property legislation implemented in member nations is standard and defined in the different annexes to the Accord. Annex 1 deals with patents and Annex X deals with new plant variety development.

[iv] In Denmark patenting of inventions is regulated by The Consolidated Patents Act, hereafter referred to as The Act, and Order concerning patents and supplementary protection certificates, hereafter referred to as The Order. Denmark has ratified the European Parliament and Council directive (98/44) on the legal protection of biotechnological inventions. The Danish Parliament is for the moment debating the implementation into the Danish patent act. An implementation of the directive will lead to a change of The Act and The Order.

[v] The following elements of information are based on Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions (Directive 98/44/EC on the legal protection of biotechnological inventions entered into force on 30 July 1998. According to Article 15 of Directive 98/44/EC Member States shall be implement the provisions of the Directive not later than 30 July 2000. This directive has been notified by the European Communities under Act 63.2 of the TRIPS Agreement and is available as document IP/N/1/EEC/P/4.), as well as on Council Regulation 2100/94/EC of 27 July 1994 on Community plant variety rights. (Council Regulation 2100/94 on Community Plant Variety Rights entered into force on 1 September 1994. Articles 1, 2, 3, 5 to 29 and 49 to 106 were applicable from 27 April 1995. This Regulation has been notified by the European Communities under Article 63.2 of the TRIPS Agreement and is available as document IP/N/1/EEC/P/3.)

[vi] The English quotations of the regulations of the German Patent Law are cited from the WIPO web site Collection of Laws for Electronic Access. The EPC and EU regulations are cited form the original English version. The Plant Variety Protection Act is cited from an unofficial translation.

[vii] Matters on biotechnological inventions are regulated under patent system. This field is under responsibility of the State Patent Bureau of the Republic of Lithuania.

[viii] Malaysian Patent Act 1983 and Reg. 1986 (as at 20th, Jan 1996) does not have special provisions for protection of Biotechnology Invention. However, such inventions are still protected under Malaysia Law (please refer Sect. 13(1) of the Act). To date, Malaysian Patent Act does not give protection to plant and animal variety.

[ix] On the moment an amendment to the Dutch Patent Act is in discussions in Parliament, with which amendment the Directive 98/44/EC on the protection of biotechnological inventions will be implemented. The answers as given hereunder are given from the actual situation, so before the implementation of the EC-directive.

[x] Attention is called to the following points as far as the Swiss replies are concerned:

1. In the field of patent protection, Switzerland and Liechtenstein are bound by the Treaty of 22 December 1978 on the Protection Conferred for Inventions. (The text of this treaty can be found at <http//www.admin.ch/ch/f/rs/i2/0.232.149.514.fr.pdf> (in French). 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 (the Institute) and the Swiss patent legislation also apply to the territory of Liechtenstein. This bilateral treaty covers patents for inventions only.
2. 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 (Budapest Treaty).
3. 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.
4. The authorities responsible for the grant of titles of protection in the field of biotechnology are as follows:
   i. for patents (Switzerland and Liechtenstein): the Institute, Ministry of Justice and Police. 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.
   ii. for plant varieties (Switzerland only): the Bureau for Plant Varieties of 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.
5. In the field of biotechnological inventions, criteria for protection are the same as those applied in other technological fields. Court decisions relating to patentability are also applicable to such inventions.
6. Switzerland is party to the UPOV Convention (1978 Act). The Swiss Plant Variety Protection Law (LPV) is currently being revised in view of ratification of the 1991 Act of the UPOV Convention. The Swiss Patent Law is currently also being revised. It should be noted that the 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.

[xi] For reference purposes, the United States has included, as an appendix to this document, our responses submitted in the Review of Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

RESPONSES TO QUESTIONS ON PRACTICES RELATED TO THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS UNDER PATENT AND PLANT VARIETY PROTECTION SYSTEMS

♦

PART 2

♦

QUESTION 1

Australia—The only exclusion under Australian patent law is that applied to patents for human beings. Subsection 18(2) of the *Patents Act 1990* states that *"human beings and the biological processes for their generation"* are not patentable inventions.

Austria—No, only if protection is sought for a specific variety.

Bangladesh—No. Bangladesh has signed the final Act of the Uruguay Round on 15th April 1994. After signing of this agreement Bangladesh will have to implement the provision of 27.3(b) of TRIPS. Bangladesh is a least developed country, so it has time for formulation of "Plant Variety Protection Act" up to 31.12.2005. According to the need of the Country, Bangladesh is trying to formulate a legislation titled "Plant Variety Protection Act Bangladesh." It is now at advanced stage where the country appears to be selecting the *sui generis* option for protecting plant variety rights.

Belarus—Yes. It is defined in the Law of the Republic of Belarus "On Patents for Inventions and Utility Models" (Article 1).

Belgium—No, unless it pertains to an animal race or plant variety and if the technical feasibility of the invention is limited to one variety or one race (Law of 28.3.1984, art. 4, Directive 98/44 art. 4).

Benin—Yes. Under the OAPI system, plant varieties are protected by a plant variety certificate and not a patent.

Furthermore, Annex 1, Article 6, line c of the Bangui Accord defines non-patentable objects as follows: "The following cannot be patented: …. an invention, which has as it's subject matter plant varieties, animal races, essentially biological processes for the production of plants and animals and products obtained by these processes."

Bulgaria—Under the Bulgarian Patent Law (publ. State Gazette No. 27/1993), plant and animal inventions shall be regarded patentable, if they meet the novelty, inventive step, industrial applicability and sufficient disclosure requirements. The Law does not contain any specific provisions concerning the requirements for patentability and examination of plant and animal inventions.

The patentability of such inventions may be opposed, under Article 7(1) of the Patent Law, for reasons of public order or morality.

Cameroon—In Cameroon, a member state of the OAPI which has signed and ratified the revised Bangui Accord, it is not possible to patent an entire plant under Annex 1, Article 6 of the Bangui Accord.

Canada—Yes. To date, our 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 Appeal.

China—Yes. Under Article 25 of the Chinese patent law, no patent right shall be granted for animal and plant varieties.

Cuba—Current legislation recognizes plant varieties and animal races as inventions, not the entire plant or animal, however, the rights of the authors of these inventions are protected through an Author's Invention Certificate. It is therefore not possible to obtain a Patent Invention Certificate. We are contemplating introducing a *sui generis* form of protection for plant varieties that excludes protection for animal races.

Denmark—Yes. Plants and animals varieties are excluded from patentability. A patent on plant or animal as such can be denied for ethical reasons.

Ecuador—Yes for animals. No for plants.

European Union—Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Hereinafter referred to as the directive) provides that "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety".

Ethiopia—Yes, in our country there is a law that prohibits patenting of a plant or animal, whether it may be novel, capable of industrial application or involves an inventive step. The law, known as "Inventions, Minor Inventions and Industrial Designs, Proclamation, No. 123/1995", considers "plant or animal varieties or essentially biological processes for the production of plants or animals" as non-patentable inventions. (Article 4(1) (b)).

Finland—No. There are however exceptions that have to be taken into account.

a- Patents shall not be granted for inventions the exploitation of which would be contrary to morality or public policy.
b- Patents shall not be granted for plant or animal varieties.
(Patents Act, Chapter 1, Section 1)

So far no patents have been accepted on plants or animals.

Germany—No. There is no regulation in German or European Law prohibiting the grant of a patent regarding inventions which concern plants or animals.

But Section 2, item 2 German Patent Law (PatG), Art. 53 item b), European Patent Convention (EPC) and Article 4, paragraph 1 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Biotechnology Directive) provide that plant and animal varieties are not patentable.

(a) Section 2 PatG
Patents shall not be granted in respect of:
1. inventions the publication or exploitation of which would be contrary to public policy or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. The first sentence above shall not exclude the granting of a patent for an invention falling under Section 50(1);

2. plant or animal varieties or essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes or the products thereof.

(b) Art. 53 EPC exceptions to patentability
European patents shall not be granted in respect of:
(a) inventions the publication or exploitation of which would be contrary to "order public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

(c) Art. 4 Biotechnology Directive
1. The following shall not be patentable:
(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Guatemala—Yes. Our current patent law: Decree-Law 153-85, in Article 2, Exclusions from Patentability; paragraph b) considers plant varieties as exclusions from patentability.

Iceland—No, except for plant or animal varieties (art. 1.4.2 in the Icelandic Patent Act). However, according to Article 1.4.1, a patent shall not be granted for inventions which the use of would be contrary to morality or public order.

India—At present there is no legislation in India which provides patenting for any invention consisting of entire plants or animals or any parts thereof.

Ireland—Yes, as covered by Section 10(b) of the Patent Act, 1992, namely, "A patent shall not be granted in respect of a plant or animal variety or an essentially biological process for the production of plants or animals other than a microbiological process or the products thereof."

Japan—No. However, inventions liable to contravene public order, morality or public health shall not be patented according to Section 32 of the Patent Law, notwithstanding Section 29 [Patentability of inventions].

Kazakhstan—No. In August 1999 in the Republic of Kazakhstan the Law "On the Protection of the Selection Advancements" which specifies legal, economic and organizational bases in the field of the protection of new plant and animal varieties was adopted.

Lithuania—According to Article 2 of the Patent Law of the Republic of Lithuania the objects mentioned in the question are not eligible to be patented if they are deemed to be contrary to public interest, principles of humanity and morality or if they include varieties of plants or animals.

Madagascar—Article 8 of Ordinance 89-109 excludes from protection plant or animal varieties in cases of biological processes of plant or animal development. Before the new law goes into effect, the Office protects plant varieties in accordance with the terms of the TRIPS Agreement.

Malaysia—Questions 1, 2, 3, and 4 are not related as Malaysian Patent Act does not give protection of plant and animal variety.

New Zealand—No. However, "animals" does not include human beings. Human beings are not patentable under Section 2 of the Patents Act 1953, that is, a manner of new manufacture the subject of letters patent and grant of privilege within Section 6 of the Statue of Monopolies.

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—Yes, in Industrial Property Law 35, Article 15: the following inventions referring to living matter are exempt from patentability:

i) Essentially biological processes for the obtainment or reproduction of plants, animals, or their varieties, whenever DIGERPI considers them to be contrary to the morality, integrity, or dignity of the human being.

ii) Plant species and animal species and races.
iii) Biological material as it is found in nature.
iv) That referring to the living matter that makes up the human body.
v) Plant varieties.

Philippines—Yes. Sec. 22 of the IP Code provides for Non-Patentable Inventions which includes among others, plant varieties or animal breeds or essentially biological processes for the production of plants and animals.

Poland—Yes, in the effective law on inventive activity, as well as in the draft Industrial Property Law which will soon be adopted.

Portugal—Yes. (Art. 49° – 1 b) – PTL.)

Russian Federation—Yes, because at present the patent protection of entire plant or animal is not provided.

Slovakia—The Law no. 527/1990 Coll. on Inventions, Industrial Designs and Rationalization Proposals (hereinafter refer to as "Slovak Patent Law") provides the 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. Pursuant to Section 4, paragraph a) and c) of the Slovak Patent Law patents shall not be granted in respect of: (a) inventions contrary to public interest, particularly the principles of humanity and morality and (c) 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.

Sri Lanka—Yes. They are specifically excluded by our present laws and no changes are indicated in the proposed new legislation to be presented this year. The only reference to biological material in our Code of Intellectual Property Act of 1979 (the Act which is in operation today) is in Article 59.3 which excludes from patentability (only the relevant sections are given):

b. Plant or animal varieties or essentially biological processes for the production of plants or animals other than Microbiological processes and the products of such process.

d. Methods for the treatment by surgery or therapy or diagnostic methods practiced on the human or animal body.

Provided however that this paragraph shall not apply to the products used in any such methods.

Sweden—Under Section 1, fourth paragraph, item 2., of the Swedish Patents Act patents shall not be granted for plant or animal varieties or essentially biological processes for the production of plants or animals; patents may, however, be granted for microbiological processes and products resulting from such processes. The Court of Patent Appeals has in two cases (P87/129 and P 89/62) ruled that micro-organisms are patentable and, more importantly, that products of a microbiological process are patentable even if they constitute a plant variety or animal breed. Consequently, there is a legal basis for denying a patent on an invention consisting of an entire plant or animal under the conditions just mentioned.

Switzerland—According to Article 1.1 of the Swiss Federal Law on Patents for Inventions (LPI) "[p]atents for inventions shall be granted for new inventions applicable in industry." In other words, they must be new, involve and inventive step and be capable of industrial application. The three conditions must be met. Discoveries cannot be patented.

Article 1 *a* 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.

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) and have been adequately disclosed.

Thailand—Yes and it should be clearly stated here that the Patent Act of 1999 does not grant protection on plants or animals. According to Section 9, plants and animals are considered to be an unpatentable invention. However, they can be protected under the Plant Varieties Protection Law.

The former Yugoslav Republic of Macedonia—Concerning it's part A related to the Patent protection of plant and animal inventions I have to inform you that our national law "Act of industrial property" does not provide any protection for inventions dealing with animals in any way. In its Act 13, is defined what is the subject of patent protection and it says: "Invention representing new technical solution for certain problem new plant sort and hybrid resulting from creative work, which is technically viable and which could be applied in industrial or other type of activity, shall be protected by a patent."

United Kingdom—Yes. UK legislation informed by Article 4(2) of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions "Inventions which concern plants and animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."

United States—No. As noted in our responses in the TRIPS 27.3(b) review, the information herein is limited to issues relevant to plants and animals. In that regard, any information concerning animals is strictly confined to animal organisms other than human beings, as the latter has never been considered patentable subject matter.

Uruguay—Article 13 Section B of the new Patent and Industrial Design and Utility Models Law, No. 17.164, dated 2 September, 1999, that entered into effect on 18 January 2000, establishes that "The following will not be considered as inventions under the effects of this law: B) Plants and animals, except microorganisms, and essentially biological processes for the production of plants and animals, with the exception of non-biological or microbiological processes."

Uzbekistan—In accordance with Part 9, Article 5, of the Law of the Republic of Uzbekistan "On inventions, utility models and industrial designs" plant varieties and animal breeds are not recognized as inventions.

Venezuela—Yes, only in the case of species or animal races. (Art. 7, Paragraph c, Decision 344 of the Andean Community of Nations).

Zambia—No, but this answer would be incomplete without a descriptive comment. This is that, firstly, those prerequisites of a patentable art are contained in the definition of "Invention" under section 2(1) of our Patents Act (which is Chapter 400 of the 1995 Edition of the Laws of Zambia).

That definition states that an invention is "any new and useful art (whether producing a physical effect or not), process, machine, manufacture or composition of matter which is not obvious, or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention."

Secondly, Section 18 underscores these prerequisites by providing that a patent may be refused should the invention be considered to

(a) contradict well establish laws of nature
(b) foster immorality
(c) lack inventivity because it is just a substance capable of use as food or medicine and is a mere mixture of known ingredients possessing only the aggregates of the known properties of the ingredients.

Thirdly, Section 22 (1) provides, *inter alia*, all the five prerequisites (namely, novelty, industrial viability, inventive step, sufficient disclosure and agreement with moral and natural laws) as ground for contesting the grant of a patent. It means, in consequence, that the valid patentability of any art is subject to qualification of all those five prerequisites.

QUESTION 2 (a)

Australia—The Australian patent system regards entire plants and animals as inventions providing they are: novel, inventive, capable of industrial application, their generation or selection is repeatable, they are adequately described in the specifications, and they reflect some form of technical intervention, i.e. they do not reflect the plant or animal in its native state.

Benin—No. Under the OAPI system, entire plants and animals are not considered as inventions.

Bulgaria—Under the Bulgarian Patent Law (publ. State Gazette No. 27/1993), plant and animal inventions shall be regarded patentable, if they meet the novelty, inventive step, industrial applicability and sufficient disclosure requirements. The Law does not contain any specific provisions concerning the requirements for patentability and examination of plant and animal inventions.

The patentability of such inventions may be opposed, under Article 7(1) of the Patent Law, for reasons of public order or morality.

Cameroon—Under the OAPI system, entire plants and animals are not considered 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.

Colombia—No. Paragraph b) of Article 6 of Decision 344 of the Commission's Cartegena Agreement establishes that "the following will not be considered as inventions: Those that have as subject matter that which already exists' in nature or a replica thereof." Plant or animal inventions different from those exempt by paragraph b) are considered as inventions but they are not patentable owing to paragraph c) of Article 7 of Decision 344 that deals with the Common Regime for Industrial Property and Articles 2.1 and 37 of Law 243 of 1995, which approves the International Convention for the Protection of New Varieties of Plants, UPOV.

Democratic People's Republic of Korea—No, only asexually reproduced plants are patentable.

The human body and its elements in their natural state are not to be considered patentable.

Ecuador—No, it does not consider animals as inventions. Yes, it considers plants as inventions.

European Union—See answer to question 1 above.

Ethiopia—Since the exclusionary clause or Article (Article 4) is entitled, "Non-patentable Inventions", one may argue that the law implicitly considers that plants or animals are inventions. However, such an interpretation is not warranted as the real intent to exclude plants or animals in the Ethiopian context stems from a belief that new plant or animal varieties are mere discoveries, not inventions.

By the way, we have found it difficult to understand what the term "entire" in your question really means.

India—Under present patenting system, inventions on living organisms including plants or animals are not considered.

Ireland—No, only plants or animals arising from a microbiological process may be considered as in Section 10(b).

Kazakhstan—Yes, new plant, animal varieties are specified in the Law "On the Protection of the Selection Advancements" as selection advancements.

Lithuania—The Patent Law does not exclude entire plants or animals from patentability. However, the human beings shall not be patented due to principles of morality.

Malaysia—Questions 1,2, 3, and 4 are not related as Malaysian Patent Act does not give protection to plant and animal variety.

Mexico—Yes, as long as it does not treat an invention dealing with a plant variety or animal race, which are excluded from patentability by Article 16 of the Industrial Property Law, in effect in Mexico from October 1st, 1994.

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—Yes, they are inventions, but our legislation exempt them from patentability.

Poland—The law fails to state what is eligible for being recognized as invention. It only specifies what is and what is not patentable subject matter. Consequently, entire plants or animals can be considered as inventions.

Portugal—Yes. (Art. 3° – 2 CE Dir.)

Slovakia—The Slovak Patent Law does consider entire plants or animals to be inventions.

Slovenia—See the 1. answer above.

Sri Lanka— Not defined in our patent system, but living organisms are specifically excluded from being patentable.

Sweden—As a matter of principle, biotechnological inventions whether they consist of or contain animal material or plant material can constitute inventions on the same conditions as other inventions. They may, however, be excluded from patentability as mentioned under 1. above.

Switzerland—See replies to question 1 above.

Thailand—Please see answer to question 1.

United Kingdom—Yes. It is possible to obtain patents for claims directed towards plant and animals.

Uruguay—As laid down in the previous answer, it is not necessary to respond to this question.

Venezuela—Yes, only for the case of plants.

Question 2 (B)

Australia—The Australian patent system only excludes human beings from patentability. All other plants and animals are patentable provided that they meet all of the normal standards for patentability.

Benin—Yes. Our patent system excludes from patentability all inventions of this kind.

Bulgaria—Under the Bulgarian Patent Law (publ. State Gazette No. 27/1993), plant and animal inventions shall be regarded patentable, if they meet the novelty, inventive step, industrial applicability and sufficient disclosure requirements. The Law does not contain any specific provisions concerning the requirements for patentability and examination of plant and animal inventions.

The patentability of such inventions may be opposed, under Article 7(1) of the Patent Law, for reasons of public order or morality.

Cameroon—Yes. Under the OAPI system, Annex 1, Article 6 of the revised Bangui Accord excludes from patentability "any invention of plant varieties, animal species, biological processes regarding plants and animals other than microbiological processes and the products resulting from these procedures."

China—Our patent system excludes all plants and animals inventions from being patentable subject matter.

Colombia—The answer to question 2 a) was negative.

Cyprus—No, it does not exclude any invention.

Denmark—As regard to plants, plants *per se* are patentable subject matter. Only plant varieties are excluded from being patentable. Concerning animals, both animals *per se* as well as animal varieties, have been considered as unpatentable in Denmark. When the Directive on legal protection of biotechnological inventions is implemented in The Act there will be a restricted possibility to obtain patents on animals. Animal varieties will still be excluded from patentability.

Ecuador—Plants: "Inventions that may evidently be contrary to the health or life of persons or animals; to the preservation of plants; or to the preservation of the environment." (Article 7 b) of Decision 344, Common Regime for Industrial Property, from the Commission's Cartagena Agreement, current Andean Community of Nations).

European Union—Article 4(1) of the Directive 98/44/EC states that plant and animal varieties shall not be patentable.

Ethiopia—As you can read from the relevant Article I quoted before, our patent law excludes all such inventions from being patentable subject matter.

India—All plants and animals are excluded from patenting.

Kazakhstan—Plant and animal variety exclusion is not permitted.

Lithuania—The Patent Law does not provide any exclusion, but the provisions of Article 2 mentioned in par. 1 shall be fulfilled.

Malaysia—Questions 1, 2, 3, and 4 are not related as Malaysian Patent Act does not give protection to plant and animal variety.

Mexico—The Industrial Property law only excludes the taxonomic level of the plant variety or animal race. Taxonomic levels differing from these categories would in principle be patentable inasmuch as they comply with the patentability requisites.

Netherlands—All plants and animals.

New Zealand—No, all types of animals are patentable however "animals" does not include human beings.

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—

1. Plant species, animal species and races
2. Biological material as it is found in nature
3. That referring to the living material that makes up the human body.
4. Plant varieties

Poland—Any inventions of this kind are excluded from being patentable subject matter, including plant or animal varieties or essentially biological processes for the production of plants or animals, except for microbiological processes or the products thereof.

Portugal—Plant and animal varieties are excluded. (Art. 49° – 1 b) – PTL.)

Russian Federation—The answer to question 2a is "no".

Slovakia—See the answer to the question no. 1

Sri Lanka—Does not arise.

Sweden—As mentioned in the reply to question 1., microbiological processes are patentable under the conditions mentioned there.

Switzerland—See replies to question 1 above.

Thailand—All plants and animals except microorganism which is not naturally existing are excluded from being patentable subject matter.

United Kingdom—UK Patents Act (1977) excludes patents for any variety of plants or animals.

Uruguay—As laid down in the previous answer, it is not necessary to respond to this question.

Venezuela—There are no exclusions for the patentability of plants.

QUESTION 2 (c)

Australia—As stated in the answers to questions 1 and 2(b), subsection 18(2) of the Patents Act expressly excludes human beings from patentability.

Benin—Under our legislation, denial of a patent to protect plant or animal inventions is not motivated by ethical or moral considerations. This is simply because of the fact that plant protection is regulated by the provisions of Annex X of the Bangui Accord, which deal with protection of new plant varieties.

Bulgaria—Patentability of such inventions may be opposed under Article 7(1) of the Patent Law, for reasons of public order or morality.

China—Yes. Under Article 5 of the Chinese patent law, no patent right shall be granted for any invention-creation that is contrary to laws of the state or social morality or that is detrimental to public interest.

Colombia—Yes. Article 7 of Decision 344, dealing with Industrial Property, establishes non-patentable inventions. Amongst these exceptions are found: inventions contrary to public or moral order, or to good practices; inventions that are evidently contrary to the health or life of persons or animals, to the preservation of plants or the environment; species and animals races and essentially biological processes for this production, and inventions dealing with the material that make up the human body and deal with its genetic identity.

Cuba—Yes. Patents are not issued to plant varieties and animal races only Author's Invention Certificates. Likewise, solutions that run contrary to social interests, the principles of humanity, or the principles of morality, are not recognized as patentable, in accordance with that established by the legislation.

Cyprus—The grant of a patent on any categories of plant or animal inventions is precluded on grounds of public order and moral grounds.

Democratic Peoples's Republic of Korea—Yes, refer to Patent Law, Article 32:

Article 32, Unpatentable Inventions:

> Inventions liable to contravene public order or morality or to injure public health shall not be patentable, notwithstanding the provisions of Article 29(1) and (2).

Denmark—Yes. If the invention would be contrary to law and order or morality.

European Union—Article 6(1) of Directive 98/44/EC states that "Inventions should be considered unpatentable where their commercial exploitation would be contrary to the order public or morality…". Article 6(2)(d) provides that on the basis of Article 6(1) "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.

Ethiopia—Although not explicitly attached with any categories of plant or animal inventions, yes, there is also a provision that excluded "inventions contrary to public order or morality"

(Article 4(1) (a)). This could also be invoked, as appropriate, to exclude certain categories of plant or animal inventions from patentability.

India—On ethical, moral and other grounds, patenting is not allowed on any category of inventions on plant or animals.

Ireland—Yes, as defined in Section 10(a), namely, "A patent shall not be granted in respect of an invention the publication or exploitation of which would be contrary to the public order or morality, provided that the exploitation shall not be deemed to be so contrary only because it is prohibited by law."

Kazakhstan—The legal protection of a selection advancement the name of which contradicts the moral and humanity principles is not granted.

Lithuania—Article 2 of the Patent Law of the Republic of Lithuania provides patents shall not be granted for the inventions which are deemed to be contrary to public interest, principles of humanity and morality.

Malaysia—Questions 1, 2, 3, and 4 are not related as Malaysian Patent Act does not give protection to plant and animal variety.

Mexico—In the Industrial Property Law, a prohibition does not explicitly exist directed at plant varieties or animal races for moral or ethical reasons. However, in Article 4 of the Industrial Property Law, inventions that are contrary to the public order, morals, or good customs, are regulated, stating to the letter:

"*A patent, registration, or authorization, will not be granted, nor will publicity be given in the Gazette to any of the juridical figures or institutions that regulate this Law, when its contents or form are contrary to the public order, morals, or good customs, or contravene any legal provision.*"

New Zealand—Yes. The Patents Act 1953 excludes inventions from patentability which are contrary to morality.

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—Yes. In Article 15 of Intellectual Property Law 35, Numeral I, establishes that: essentially biological cases for the obtainment or reproduction of plants, animals, or their varieties, whenever DIGERPI considers them to be contrary to the morality, integrity or dignity of the human being.

Philippines—Yes, Sec. 22, IP Code (refer answer to question no. 1).

Portugal—Yes. (Art. 49° – 1 a) – PTL.)

Russian Federation—The Patent Law excludes plant varieties and animal breeds from subject matters recognized as patentable inventions.

Slovakia— According to the Section 4, paragraph a) of the Slovak Patent Law, patents shall not be granted in respect of inventions contrary to public interest, particularly the principles of humanity and morality.

Sri Lanka— Although the basis is not defined in the Legislation, perceived problems include i. the ability of plants and animals to reproduce themselves unlike other inventions, ii. ethical considerations and iii. inability of the patent system to compensate generations of farmers and rural populations who have contributed through human selection for the development of desired characteristics in varieties which have been used to develop the new variety.

Sweden—In addition to the considerations mentioned above relating to plant or animal inventions, Section 1, fourth paragraph, item 1. of the Patents Act prescribes that patents may not be granted for inventions the exploitation of which would be contrary to morality or public order.

Switzerland—See replies to question 1 above.

Thailand—Yes and it involves both ethical and moral concerns.

United Kingdom—No explicit exclusion of plant or animal inventions from patentability on moral grounds in the UK law but the UK Act allows examiners to object to an invention "*the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behavior*." Such decisions would be informed by the EC Directive on the legal protection of biotechnological inventions (98/44/EC). This Directive is currently in the process of being implemented into the UK Patents Act.

Uruguay—As laid down in the previous answer, it is not necessary to respond to this question.

Venezuela—Yes, only in the case of species or animal races. (Art. 7, Paragraph c, Decision 344 of the Andean Community of Nations).

QUESTION 3 (a)

Australia—Australia offers patent protection for individual plant and animal varieties, plants and animals *per se* and groups of plant or animal varieties. Australian practice regards plant and animal inventions no differently to any other inventions. Any plant or animal variety is patentable provided the invention meets the normal standards for patentability.

Bangladesh—Formulation of Plant Variety Protection Act is not completed.

Belarus—No, it is not possible.

Belgium—Yes, see question 1.

Benin—This is not possible. In effect, Annex X regarding protection of new plant varieties grants protection to plant varieties noticeably distinguishable from other varieties (Article 6).

Bulgaria—The patent law does not provide for any restrictions in cases where the invention relates to animals or plants as such and suits the patentability requirements under Article 6(1) of the Patent Law.

Canada—Plant and animal varieties are not patentable subject matter.

Cuba—No. Protection by an Author's Invention Certificate and not by a patent is issued to the invention consisting of a concrete plant variety or concrete race of animal, not to that consisting of a plant or animal.

Denmark—Yes, see above.

Ecuador—Yes for plants. No for animals.

Ethiopia—Taking Ethopia's strong view as expressed in various fora, including at the Organization of African United (OAU) and the Convention of Biological Diversity (CBD) in support of a "no patent on life forms" policy, we do not see any possibility for any one to obtain patent protection even where such a protection is directed to a plant or animal invention, and not limited to a particular plant or animal variety.

Finland—Yes. Exception (a) above must be considered. [*Note by the Secretariat:* this response refers to Exception (a) as stated in the response by Finland to question 1]

Germany—Yes. Article 4, paragraph 2, Biotechnology Directive (see above) provides that inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Iceland—There is no provision in the Icelandic Patent legislation that prohibits patents on plant or animal invention, *per se*, except for varieties of these.

Lithuania—The patent shall be granted for plant or animal provided the invention is not limited to a particular plant or animal variety.

Madagascar—If the conditions of patentability are fulfilled a patent can be issued after review of WIPO examination reports (under the auspices of ICSE).

Malaysia—Question 1, 2, 3, and 4 are not related as Malaysian Patent Act does not give protection to plant and animal variety.

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—Essentially biological cases for the obtainment or reproduction of plants, animals, or their varieties, whenever DIGERPI considers them to be contrary to the morality, integrity or dignity of the human being.

Russian Federation—The patent protection is granted to plant varieties and animal breeds under a special law which doesn't consider these subject matters as inventions.

Slovakia—The present Slovak Patent Law does not exclude the possibility to obtain patent protection where the patent protection is directed to a plant or animal invention, *per se*, and where it is not limited to a particular plant variety or animal variety.

Sweden—As follows from what is said above, biotechnological inventions are patentable under the same conditions as other inventions, but patents can not be granted for human beings, etc. or plant or animal varieties or biological processes for the production of those. From this follows that a plant or animal invention, not limited to a particular plant or animal variety, would in principle be patentable under the usual conditions.

Switzerland—Yes. See replies to question 1 above.

Thailand—No, as previously mentioned, the protection of a plant or animal invention (*per se*) falls within the scope of the plant varieties protection law.

United States—Responses to items a) through c) - Yes.

Uruguay—Derives from previous answers.

QUESTION 3 (b)

Australia—Australia offers patent protection for individual plant and animal varieties, plants and animals *per se* and groups of plant or animal varieties. Australian practice regards plant and animal inventions no differently to any other inventions. Any plant or animal variety is patentable provided the invention meets the normal standards for patentability.

Belarus—Yes. Cultures of plant and animal cells can be patentable subject matters.

Belgium—No, see question 1.

Benin—It is not possible to obtain patent protection because the title of patent relates exclusively to inventions and not to new plant varieties.

Bulgaria—Plant varieties and animal breeds are excluded from patent protection under Article 7 (3) of the Patent Law.

Canada—Plant and animal varieties are not patentable subject matter.

Colombia—In Colombia, neither plants nor animals in general are protected by patents, and as a consequence there is no protection for varieties of plants or animals.

Cuba—Protection is exclusively limited to the plant variety or animal race and by an Author's Invention Certificate.

Denmark—No, see above.

Ecuador—Yes to a plant variety.

Ethiopia—Obviously no, it is not possible.

Germany—No. Section 2, item 2, German Patent Law (PatG); Article 53, item b), European Patent Convention (EPC); and Article 4, paragraph 1 of the Biotechnology Directive (see above) provide that plant and animal varieties are not patentable.

Lithuania—The patent shall not be granted.

Madagascar—If the conditions of patentability are fulfilled a patent can be issued after review of WIPO examination reports (under the auspices of ICSE).

Malaysia—Questions 1, 2, 3, and 4 are not related as Malaysian Patent Act does not give protection to plant and animal variety.

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—No, but there exists in our Law 23, Title V, Norms that protect plant varieties, where plant varieties are protected by one of these *sui generis* laws.

Portugal—No. (Art. 49° – 1 b) – PTL.)

Russian Federation—The mentioned special law doesn't limit patentability exclusively to certain plant varieties or animal breeds.

Slovakia—According to Section 4, paragraph c) of the Slovak Patent Law, the 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 the exception of industrial micro-organisms serving for production and biotechnological processes and the products thereof, which are patentable.

Sweden—In this case patents can not be granted (unless the plant or animal variety is a product of a microbiological process).

Switzerland—No. See replies to question 1 above.

United States—Responses to items a) through c) - Yes.

Uruguay—Derives from previous answers.

QUESTION 3 (c)

Australia—Australia offers patent protection for individual plant and animal varieties, plants and animals *per se* and groups of plant or animal varieties. Australian practice regards plant and animal inventions no differently to any other inventions. Any plant or animal variety is patentable provided the invention meets the normal standards for patentability.
In relation to part (c), although a group of plant or animal varieties is patentable the specification must provide sufficient information to enable the generation of all varieties claimed. In addition a common inventive feature must link all members of the group such that the patent claims are limited to a single invention.

Belarus—No, it is not possible.

Belgium—No, see question 1.

Benin—Idem [*Note by the Secretariat:* this response refers to the response by Benin to question 3(b).]

Bulgaria—Where the patent application concerns a group of plant varieties or animal breeds, possessing common characteristics incorporated into the class of organisms, there are no legal grounds for the patent protection thereof.

Canada—The particular trait or characteristic may be patentable, but not the group of plants or animals.

Colombia—In Colombia, neither plants nor animals in general are protected by patents, and as a consequence there is no protection for varieties of plants or animals that incorporate a characteristic common in the class of organism.

Cuba—The patent is not applied.

Denmark—Yes, it is possible to obtain a patent e.g. on a group of plants that incorporate common characteristics even though it encompasses plant varieties, provided that it is not restricted to one specific plant variety.

Ecuador—We do not have legislation to this respect.

Estonia—There is no practice in this field in Estonia, question is still theoretically debatable.

European Union—Recital 31 states that a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants.

Ethiopia—No such distinction is made under the law.

Finland—Yes. Exception (a) above must be considered. [*Note by the Secretariat:* this response refers to Exception (a) as stated in the response by Finland to question 1]

Lithuania—The patent shall not be granted.

Madagascar—If the conditions of patentability are fulfilled a patent can be issued after review of WIPO examination reports (under the auspices of ICSE).

Malaysia—Questions 1, 2, 3, and 4 are not related as Malaysian Patent Act does not give protection to plant and animal variety.

Mexico—Yes, but it will be restricted exclusively to the group of varieties of plants or animals supported by the description (examples).

Norway—According to Norwegian law, patents shall not be granted for plant varieties or animal species which is interpreted to extend to (i) plants and animals in general, including varieties and species, (ii) parts of plants or animals or cell-lines, including germ-lines, which can differentiate to entire plants or animals, and (iii) processes for producing plants and animals. Our patent system exclude plants and animals from being patentable-subject matter even if the subject matter is an invention which is novel, involves an inventive step, is capable of industrial application and has been adequately disclosed.

Panama—Yes, when it is framed within a procedure for a new class of microorganisms.

Portugal—No. (Art. 49° – 1 b) – PTL.)

Russian Federation—The mentioned special law doesn't provide for an inclusion into a patent of a group of plant varieties or animal breeds.

Slovakia—The exclusion from patentability, according to the Section 4, paragraph c) of the Slovak Patent Law, is also applicable to the patent encompasses a group of plant varieties or animal varieties that incorporate a common trait or characteristic incorporated into the class of organisms.

Sweden—The question seems to concern the issue of common traits or characteristics and not towards the plant or animal varieties as such; under those conditions patent protection would seem to be possible under the same conditions as indicated under 3.a). (This would correspond to practice in the European Patent Office, for instance in decision G1/98).

United Kingdom—Yes, especially in light of the recent decisions of the EPO Enlarged Board of Appeal *in Re.* Novartis AG (G01/98 and Directive Art. 4(2)).

United States—Responses to items a) through c) - Yes.

Uruguay—Derives from previous answers.

QUESTION 5

Australia—In Australia patent protection is available for microorganisms provided that the invention meets all the usual criteria for patentability. In particular the invention must reflect technical intervention by man, for example the claims define an isolated or cultured microorganism and the claimed invention is adequately disclosed in the specification.

Bangladesh—We have developed biosafety rules, obtaining of patent on microorganisms may be possible in the near future.

Belarus—Yes, stems of microorganisms can be patentable subject matters.

Benin—This intellectual property subject matter is not dealt with by the applicable legislation in Benin, i.e. the Annexes to the Bangui Accord.

Bulgaria—Microorganisms *per se*, which suit the novelty, inventive step and industrial applicability requirements, are patentable.

Cameroon—In OAPI territory it is possible to obtain a patent for microorganisms which fulfills the conditions of patentability. Annex 1, Article 6 of the revised Bangui Accord.

Canada—Microorganisms, including cell lines and hybridomas, are patentable.

Colombia—Yes. As long as it is not already existing in nature or is a replica thereof.

Cuba—Yes, it is possible to protect the strains of microorganisms that comply with the requisites of patentability only through an Author's Invention Certificate. Patent protection is envisaged.

Denmark—Yes, it is possible to obtain a patent on a microorganism, isolated from its natural environment.

Ethiopia—No, it is not possible. Microorganisms are not, in fact, identified as separate from plants or animals.

Finland—Yes, (Patents Act, Chapter 1, Section 1).

India—Not under the present patenting system.

Kazakhstan—Yes, in accordance with Article 6.2 of the Patent Law of the Republic of Kazakhstan.

Lithuania—The patent shall be granted.

Madagascar—Yes, it is possible to obtain a patent for a microorganism.

Malaysia—Man made living microorganisms is patented in Malaysia if it fulfill the general criteria, i.e., new, involved an inventive step and industrially applicable. (Please refer Sect. 13(1)(b)).

Norway—In Norway, it is possible to obtain a patent on a microorganism that is new, involves an inventive step and is susceptible of industrial application.

Poland—Yes, provided that it has been adequately disclosed and it is not found in nature.

Portugal—Yes. (Art. 49° – 1 b) – PTL)

Russian Federation—Yes. Under the Patent Law a microorganism strain and cultures of plant or animal cells may be subject matters of an invention.

Slovakia—Yes, it is possible to obtain a patent in the Slovak Republic on a micro-organism that is new, involves an inventive step and is capable of industrial application.

Sri Lanka—Microbiological processes and the products of such processes are patentable (See Art. 59.3.b. of the present Act quoted in answer to Question 1). In the proposed Act it should be possible to obtain a patent on microorganisms.

Sweden—As mentioned above under 1. it is possible to obtain a patent on a micro-organism under the conditions mentioned.

Thailand—It is possible to obtain a patent on a microorganism unless it is a naturally occurring microorganism.

The former Yugoslav Republic of Macedonia—The answer to question 5 that refers to a patent protection on a microorganism is that they can be granted only if they alone are not the subject-matter of the invention. Deposits may also be made for the purposes of patent procedure before the IPPO with any international depository institution recognized by the office (a list published in the official journal of the office).

Uruguay—Yes. (see norm cited in question 1.)

Uzbekistan—In accordance with r.1.2 of "Regulations concerning drafting and filing of applications for granting provisional patent of the Republic of Uzbekistan" are recognized, as patentable subject matter, microorganism strains, cultures of plant or animal cells as well as consortium of microorganisms, cultures of plant or animal cells and the use of microorganisms for a new purpose.

Venezuela—Yes, it is possible to patent microorganisms.

QUESTION 6 (a)

Australia—The only processes excluded from patent protection are essentially biological processes for the generation of human beings. Subsection 18(2) of the *Patents Act* states that biological processes for the generation of human beings are not patentable inventions.

Bangladesh—Relevant rules and regulations for biotechnology products are under process. Obtaining a patent on an essentially biological process for the production of a plant or animal may be possible in the near future.

Belgium—No, except for microbiological processes (law of March 28, 1984, art. 4, Directive 98/44, art. 4).

Benin—No. Annex 1, Article 5 of the Bangui Accord clearly states that essentially biological processes for plant or animal production cannot be patented. We have no specific provisions concerning essentially biological process for the protection of plants or animals as such.

Bulgaria—Under Article 7(3) of the Patent Law, essentially biological processes for the production of plants or animals are excluded from patent protection.

Cameroon—An essentially biological process for plant or animal production is not patentable under the OAPI system.

Canada—Essentially biological processes, such as natural cross breeding processes, are not eligible to be patented.

Colombia—No. (Paragraph c) of Article 7 of Decision 344, Common Regime of Industrial Property.

Denmark—No, it is not possible to obtain a patent on essentially biological processes, such as natural cross breeding processes.

Ecuador—Yes for a plant variety. No for an animal race.

Ethiopia—No, essentially biological processes for the production of a plant or animal are non-patentable in our country. (Article 4 (1) (b) of Proc. No. 123/1995).

Finland—No. (Patents Act, Chapter 1, Section 1).

Germany—By way of supplementation of the remarks that follow it has to be noted that in any case the general requirements for the grant of a patent have to be fulfilled, i.e. the invention is susceptible of industrial application, is new and involves an inventive step.

No. Article 2, item 2, German Patent Law (PatG); Article 53, item b), European Patent Convention (EPC); and Article 4, paragraph 1 b), Biotechnology Directive (see above) exclude patent protection for essentially biological processes for the production of plants or animals.

Kazakhstan—No, since a patent is only issued for a plant or animal variety.

Lithuania—The patent shall not be granted according to Article 2 of the Patent Law.

Malaysia—Essentially biological process is not patented in Malaysia.

Mexico—No, this is excluded from patentability in Article 16, paragraph 1 of the Industrial Property Law.

Norway—Patents are not granted for essential biological processes for the production of plants and animals.

Philippines—No. (Sec. 22, IP Code, refer answer to question no. 1)

Portugal—No. (Art. 49° – 1 b) – PTL)

Russian Federation—Yes. The Patent Law recognizes “a process” as a subject matter and processes of variety indicated in the question are not excluded from patentable subject matters.

Slovakia—No, it is not possible to obtain a patent in the Slovak Republic on an essentially biological process for the production of a plant or animal. Pursuant to the Section 4, paragraph c) of the Slovak Patent law, the 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 the exception of industrial micro-organisms serving for production and biotechnological processes and the products thereof, which are patentable.

Sweden—It is not possible to obtain a patent on an essentially biological process for the production of a plant or an animal (only microbiological processes are patentable).

Switzerland—No. The denial of a patent on such a process is based on Article 1 *a* of the LPI, which is in accordance with Article 27.3(b) of the TRIPS Agreement.

Thailand—Yes, if it meets the requirements (i.e. novelty, inventive step and industrial applicability) prescribed in the Patent Act of 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 novelty, nonobviousness and utility under Sections 101, 102 and 103 of title 35, United States Code.

Uruguay—No. (Art. 13, Section B, cited.)

Uzbekistan—Under Part 8 of the Law of the Republic of Uzbekistan "On inventions, utility models and industrial designs" are recognized as patentable inventions – processes of production of microorganism strains, cultures of plant or animal cells and consortium of microorganisms and cultures of plant or animal cells.

Venezuela—It is not possible to patent essentially biological processes.

QUESTION 6 (b)

Australia—The Australian Patents Act requires an invention to be a "manner of manufacture." This means a patentable invention must reflect some technical intervention by man, and a claim cannot define a product in such a way that it encompasses the product as it exists in nature. For example, if a claim defines protein X, bacteria X or gene X, where protein X, bacteria X or gene X are naturally occuring, then the claim would be considered to define unpatentable subject matter. However, if there has been some technical intervention to change the form of the product from that which exists in nature; for example the claim defines a purified or isolated bacteria X, protein X or gene X, the claim would be acceptable – provided it met all standard criteria for patentability.

Austria—Only if a sufficient technical step or a special industrial applicability is disclosed.

Bangladesh—May be difficult.

Belgium—Yes, if it is isolated or otherwise produced and on the condition that is has an industrial application. (law of March 28, 1984, art. 2, directive 98/44, art. 5).

Benin—Likewise, a plant or animal identical to one found in nature cannot be patented.

Bulgaria—No patent protection is provided for subject matter that is identical to that found in nature.

Cameroon—Idem for an object or animal in its natural state. [*Note by the Secretariat:* This response refers to the response by Benin to question 6(a).]

Canada—No. Subject matter identical to that found in nature (e.g., a plant or animal in its natural state) is not patentable.

China—No. Since our patent system excludes all plants and animals inventions from being patentable subject matter, subject matter that is identical to plant or animal in its natural state is also excluded from being patentable subject matter.

Colombia—No. (Paragraph b) of Article 6 of Decision 344, Common Regime of Industrial Property.

Denmark—Yes. It is possible to obtain a patent on subject matter, isolated from its natural state. (See also point 5 and 6 (d)).

Ecuador—No, in no case.

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

"Biological material" is defined in Article 2(1) of the directive as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

Ethiopia—Obviously no.

Finland—In general, to find a substance freely occurring in nature is mere a discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process may be patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters, and it is new in the absolute sense of having no previously recognized existence, then the substance *per se* may be patentable. In addition, the substance must be capable of industrial application, involve an inventive step and be adequately disclosed.

Plants or animals in their natural state would probably rather be considered as discoveries or plant or animal varieties.

Germany—By way of supplementation of the remarks that follow it has to be noted that in any case the general requirements for the grant of a patent have to be fulfilled, i.e. the invention is susceptible of industrial application, is new and involves an inventive step.

Yes. Article 3, paragraph 2, Biotechnology Directive provides as follows: 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.

Japan—A merely discovered thing existing in nature does not constitute an invention under Section 2 of the Patent Law and cannot be patented. However, an invention of a thing which is artificially isolated from nature does constitute an invention under Section 2 of the Patent Law and is patentable provided that the invention meets other relevant criteria.

Lithuania—The patent shall not be granted unless there has been a technical intervention to change the object's characteristics.

Malaysia—It is possible to get a patent in Malaysia for subject-matter that is identical to that found in nature, chemical structures comprising amino acid sequences and nucleotide sequences whole part or in part found in organism including plants, animal or human being. However, the protection of the above mentioned only given if human intervention is introduced in producing such material, not merely from a known lab analysis. The plant and animal itself do not fall in this category.

Mexico—No, this is excluded from patentability in Article 16, paragraph II of the Industrial Property Law.

New Zealand—Yes, provided the scope of the claims does not encompass the sequences in their natural state or as they are normally found in nature.

Norway—Biological material which is isolated from its natural environment, may be patentable subject matter, even if the matter is identical to that found in nature, e.g. microorganisms and genes and proteins. Plants and animals are, however, excluded from being patentable subject matter, see our answers to questions 1-4.

Poland—Only to the extent to which it has been obtained by means of a chemical or micro-biological process.

Portugal—No. (Art. 49° – 1 b) – PTL)

Slovakia—According to the Slovak Patent Law, a subject-matter that is identical to that found in nature (e.g. plant or animal in its natural state) is a subject of a discovery. Because mere discoveries, including materials existing in nature do not meet all criteria for patentability, they are not patentable.

Slovenia—Yes, provided that usual patentability requirements are met.

Sweden—Generally speaking, a patent can be granted only for what constitutes an invention and not for what is merely a discovery of, for instance, a formerly unknown substance/plant/animal. Such a discovery may, however, be further developed into an industrially applicable invention. Furthermore, 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.

In this context it should be mentioned that Section 2, fourth paragraph, of the Patents Act contains a provision to the effect the requirement of novelty does not prevent the granting of a patent for a known substance or a known composition of substances for use in a method as mentioned in Section 1, third paragraph, provided that the substance or composition is not known in methods of this type.

Switzerland—Subject matter that is identical to that found in nature is generally considered to be a discovery and therefore not patentable under Swiss patent law. 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.

Thailand—No, it is more likely that the said subject matter would not pass the novelty test.

United Kingdom—Yes. Products or compositions are not excluded from patentability on the grounds that they are identical to those found in nature, providing that the requirements of novelty are met. However, it should be noted that plant and animal varieties are excluded from patentability by the UK Patents Act. It should be noted that discoveries are not patentable under UK law. The finding of a new substance or micro-organism in nature is a discovery and not an invention, but if (as is generally the case) it were necessary to isolate and extract the new substance or micro-organism and a process was developed for this purpose, then this process and the material when obtained by this process are eligible to be patented. Each case is assessed on its own merits in the light of the state of the art.

Uruguay—No, Art. 13, Section G) also establishes that "Biological and genetic material, as found in nature," are not considered to be inventions. And Section A) of the same article excludes from patentable inventions "The discoveries…".

Uzbekistan—Under Part 9, Article 5, of the Law of the Republic of Uzbekistan "On inventions, utility models and industrial designs" subject matter that is identical to that found in nature (e.g. plant or animal in its natural state) is not recognized as patentable inventions.

Venezuela—They are not patentable as they are not considered inventions (Art. 6, Paragraph b, ejusdem).

QUESTION 6 (c)

Australia—Patent protection is available for new uses of known material. If an applicant has discovered a new and previously unsuspected property of a known compound which involves an inventive step, the applicant is entited to claim use of the compound provided the claims are limited to this new use.

Bangladesh—May be possible in the future.

Belgium—Yes, traditionally the notion of a new invention applies equally to a new application of a known element.

Benin—Nor on new applications of a known biological material.

Bulgaria—It is possible to obtain a patent on new uses of known biological materials.

Cameroon—Idem as above. [*Note by Secretariat:* This response refers to the responses of Cameroon to questions 6(a) and 6(b).]

Colombia—No. Articles 1 and 16 of Decision 344, Common Regime of Industrial Property.

Denmark—Yes, it is possible to obtain a patent on new use of know biological material.

European Union—Under Articles 52(4) and 54(5) of the European Patent Convention, the fact that a substance or compound forms part of the state of the art shall not exclude from patentability its use in a method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human or animal body provided that its use for any such method is not comprised in the state of the art.

Ethiopia—Again, it is not possible.

Lithuania—The patent shall be granted.

Malaysia—No protection is given for a new use for a known biological material.

Mexico—Yes, as long as the uses comply with the requisites for patentability, especially inventive activity.

New Zealand—Yes, except medical treatment of humans.

Norway—Patents are granted for new uses of known biological material, except when the biological material are plants or animals.

Panama—Article 11 of our legislation establishes that the special use of a product or the non-obvious use of the product are considered inventions.

Poland—Under the present law - no; under the Industrial Property Law to be adopted soon - yes.

Russian Federation—Yes, but only on those uses of biological material that are themselves recognized as patentable inventions.

Slovakia—If the basic conditions of patentability (novelty, inventiveness, industrial application) are met, it is possible to obtain a patent.

Slovenia—Yes, only as a second medical use.

Sweden—The exclusion from patentability of plant and animal varieties and to biological material (other than certain microbiological material) applies to those as objects.

Theoretically new uses of such material could be patentable under the general conditions applicable to patentability, in particular, a) that it is a new, involves an inventive step and is capable of industrial application, b) that it does not imply a method for, for instance, therapeutic treatment or a diagnostic method to be practiced on humans or animals (which would be contrary to the provisions of Section 1, third paragraph, of the Act), and c) the use of that invention would not be contrary to morality or public order.

Switzerland—It is possible to obtain a patent for known substances or compounds which are, as such, included in the state-of-the-art or are subject to a prior right, but do not comply with those conditions (therefore, which are not known) as far as their use for implementing a surgical or therapeutic treatment or a diagnosis method. To the extent that these substances or compounds are not meant for such a use, they are considered novel.

United Kingdom—As a general rule, claims to a known substance or composition for a particular purpose are understood as a claim to the material *per se*. Therefore, if the invention lies in a new method of using a known material only the new method can be claimed. However, the UK Patents Act does provide an exception to this rule in the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body. The fact that the substance or composition is known does not prevent the invention from being taken as new as long as the use of the substance or composition in such a method is not known. It follows then that it is possible to obtain a patent on known biological material.

Uruguay—It should be clarified that in accordance with prior legislation, chemical products were not patented in Uruguay, and in accordance with Art. 126 of the new Law, pharmaceutical and chemical products will be patentable starting on 1 November 2001.

The response is in principle negative because, besides the previously mentioned exclusionary norms, the object would lack novelty and/or inventive step; and should also be considered if the protection of the use does not constitute an indirect form of protecting the product.

Uzbekistan—In accordance with Part 8, Article 5, of the Law of the Republic of Uzbekistan "On inventions, utility models and industrial designs" the use of a known biological material for a new purpose is recognized as a patentable invention.

Venezuela—Yes, they are patentable.

QUESTION 6 (d)

Australia—Patent protection is available for nucleotide sequences provided the sequences meet all the normal standards of patentability. In particular, the invention must be a "manner of manufacture" (see question 6(b) above) and the invention must have an industrial application.

Austria—Only if sufficient technical steps or a special industrial applicability is disclosed.

Bangladesh—The issue is still being debated.

Belgium—Yes, see question 6 b).

Bulgaria—Chemical structures comprising nucleotide sequences corresponding in whole or in part to nucleotide sequences found in an organism are protected, where they meet the patentability criteria for products of the invention category.

Canada—Yes, chemical structures composed of a sequence of nucleic acids and corresponding to genetic information found in a living organism are patentable.

China—Yes, they are protected as chemical products.

Colombia—No. Protection is granted solely to the sequences of nucleotides that do not occur in nature or are a replica of those occurring in nature. (Paragraph B) of Article 6 of Decision 344, Common Regime of Industrial Property.

Cuba—No, it is not possible to patent chemical structures comprising of nucleotide sequences corresponding in whole or in part to that found in an organism.

Democratic People's Republic of Korea—Yes, provided that nucleotide sequences are capable of industrial application.

Denmark—Yes, it is possible to obtain a patent on chemical structures comprising nucleotide sequences. Human and animal genes in their natural state in the body are not patentable. However, isolated genes in the shape of a well-defined nucleotide sequence as well as a synthetic nucleotide sequence are eligible to be patented. Examples of allowable types of claims are nucleotide sequences, DNA or RNA sequence, vector, plasmid or recombinant DNA. Distinctions are not made as to the source of the genetic information.

Ecuador—Yes, with the exception of material composing the human body and its genetic identity.

European Union—Article 5(b) of the directive provides that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Ethiopia—There is no explicit provision to that effect. But, it is a matter of whether such chemical structures do constitute essentially biological processes or not.

Finland—Yes, the industrial application of the sequence must be disclosed in the patent application.

Germany—By way of supplementation of the remarks that follow it has to be noted that in any case the general requirements for the grant of a patent have to be fulfilled, i.e. the invention is susceptible of industrial application, is new and involves an inventive step.

Yes, under the conditions in Article 3, paragraph 2, Biotechnology Directive (see above).

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

Italy—Yes. Under certain conditions (See Article 5, 2-3 of Directive 98/44).

Japan—Yes, however, a mere DNA without indication of a function or specific asserted utility is not a patentable invention.

Lithuania—The patent shall be granted if chemical structures claimed has been obtained from organism by isolation, purification or other technical intervention.

Malaysia—It is possible to get a patent in Malaysia for subject-matter that is identical to that found in nature, chemical structures comprising amino acid sequences and nucleotide sequences whole part or in part found in organism including plants, animal or human being. However, the protection of the above mentioned only given if human intervention is introduced in producing such material, not merely from a known lab analysis. The plant and animal itself do not fall in this category.

Mexico—Genetic material, inasmuch as it is found in nature, is excluded from patentability by Article 16, paragraph II; however, when it has been isolated and characterized, it is susceptible to patenting, since it is then different from that found in nature (example: contained in any vector).

Nucleotide sequences are patentable under the Industrial Property Law as long as the sequence in question is attributed to a function or activity, and is sufficiently demonstrated as such in the description (in examples).

We consider open reading frameworks, where the protein they codify is unknown, do not comply with the industrial application nor the sufficiency in description requisites.

New Zealand—Yes, provided the scope of the claims does not encompass the sequences in their natural state or as they are normally found in nature.

Norway—Patents are granted for nucleotide sequences corresponding in whole, or in parts, to nucleotide sequences found in an organism.

Poland—Yes. In a description a protein with a defined biological function should be determined.

Portugal—Yes, in a general way, if there is any related technical application (if the nucleotide sequences are not EST) and if these chemical structures have to be obtained by a technical process (e.g. purification and/or isolation).

Russian Federation—Yes (when in conformity with the established conditions of patentability).

Slovakia—If the basic conditions of patentability (novelty, inventiveness, industrial application) are met, it is possible to obtain a patent. The importance is put on existence of technical step, isolation from natural source and characteristics that are applicable in industry.

Sweden—It would be possible to obtain, under the usual conditions, a patent on chemical structures as mentioned in the question; however, the novelty requirement may sometimes be problematic in this context.

Switzerland—Chemical structures comprising “nucleotide” sequences which correspond in whole or in part to those found in an organism can be patented only if the general patenting conditions are met: that it is an invention (not a discovery), that it is novel, that it is the result of inventive activity and is industrially applicable.

A simple DNA sequence with no function indication does not contain any technical teaching and therefore, would not constitute a patentable invention. In order to comply with the criteria of industrial applicability, it is necessary, if a sequence or a partial sequence of a gene is used to produce a protein or a partial protein, to specify which protein or partial protein is being produced and what is its function.

Uruguay—The new Law does not set defined criteria regarding these structures, but the case could fall within the patentability exclusionary norms previously mentioned. Additionally, questions could exist about the novelty and inventive step of the product.

Uzbekistan—According to the standard documentation for chemical structures comprising nucleotide sequences corresponding in whole or in part to nucleotide sequences found in an organism (e.g. coding or non-coding) a patent or a provisional patent is not granted.

Venezuela—Yes, they are patentable as long as the nucleotide sequence is codified.

QUESTION 6 (e)

Australia—Patent protection is available for peptides and proteins that meet all the standard criteria for patentability. As discussed above in response to 6(b) and (c) the invention must reflect technical intervention and show some discernable industrial application.

Austria—See 6 b)

Belgium—Yes, see question 6 b).

Bulgaria—It is possible to obtain a patent on chemical structures comprising amino acid sequences corresponding to peptides or proteins produced by a naturally occurring organism, including plants, animals or a human being.

Canada—Yes, chemical structures composed of a sequence of amino acids and corresponding to an amino acid sequence found in a living organism are patentable.

Colombia—No. Protection is granted solely to the sequences of amino acids that do not occur in nature or are a replica of those occurring in nature. (Paragraph b) of Article 6 of Decision 344, Common Regime of Industrial Property.

Democratic People's Republic of Korea—Yes, provided that amino acid sequences are capable of industrial application.

Denmark—Yes, it is possible to obtain a patent on chemical structures comprising amino acid sequences, even if it exists in nature provided that it has been isolated from its natural source. No distinctions are made to the source of the amino acid sequence.

Ecuador—Yes, except that noted in 6 (d).

European Union—See answer to question 6(d) above.

Ethiopia—Basically, there is no patent system for biotechnology in general, and modern biotechnology (genetic engineering) in particular in our country.

Finland—Yes, the industrial application of the amino acid sequence must be disclosed in the patent application.

Germany—By way of supplementation of the remarks that follow it has to be noted that in any case the general requirements for the grant of a patent have to be fulfilled, i.e. the invention is susceptible of industrial application, is new and involves an inventive step.

Yes, under the conditions in Article 3, paragraph 2, Biotechnology Directive (see above).

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

Japan—Yes, however, a mere peptide or a mere protein without indication of a function or specific asserted utility is not a patentable invention.

Lithuania—The patent shall be granted if amino acid sequences claimed have been obtained from naturally occurring organism by means of technical intervention.

Malaysia—It is possible to get a patent in Malaysia for subject-matter that is identical to that found in nature, chemical structures comprising amino acid sequences and nucleotide sequences whole part or in part found in organism including plants, animal or human being. However, the protection of the above mentioned only given if human intervention is introduced in producing such material, not merely from a known lab analysis. The plant and animal itself do not fall in this category.

Mexico—Peptides or proteins are patentable in the moment that they have been isolated and characterized from their natural state, and once a function has been sufficiently ascribed to them in the patent request.

New Zealand—Yes, provided the scope of the claims does not encompass the sequences in their natural state or as they are normally found in nature.

Norway—Patents are granted for amino acid sequences corresponding to peptides or proteins produced by naturally occurring organism, including plants, animals and human beings.

Philippines—No. (Note: If no alterations done on the amino acid sequence to produce significant difference to differentiate it from the naturally occurring.)

Poland—Yes, but only if they have been obtained by means of a chemical or biological process.

Portugal—Yes, in a general way, if there is any related technical application (if the sequences are not EST). However genetic code of a natural living being *per se* is not eligible.

Russian Federation—Yes (when in conformity with the established conditions of patentability).

Slovakia—If the basic conditions of patentability (novelty, inventiveness, industrial application) are met, it is possible to obtain a patent. The importance is put on the existence of technical step, isolation from natural source and characteristics that are applicable in industry.

Sweden—Also in this case, it would be possible to obtain a patent; what is said under d) would apply also here.

Switzerland—See answer above. [*Note by Secretariat:* This response refers to the response of Switzerland to question 6(d).]

Uruguay—Idem, with greater reservations. [*Note by Secretariat:* This response refers to the response of Uruguay to question 6(d).]

Uzbekistan—According to the standard documentation for chemical structures comprising amino acid sequences corresponding to peptides or proteins produced by a naturally occurring organism, including plants, animals or a human being a patent or a provisional patent is not granted.

Venezuela—Yes, it is possible to protect them; excluding those coming from human beings (Article 7, Paragraph d, ejusdem), and as long as the inventor intervenes in order to obtain the result or technical solution. That is to say that a substance found in nature that must first be isolated from its medium and characterized by the development of a process may be patented if it has not been previously identified.

QUESTION 8

Bangladesh—Bangladesh has no legal provision on this matter, but it is under process.

Bulgaria—The patent law contains no provisions of this kind and we do not plan to include any.

Cameroon—Such provisions do not exist as yet, however, it is not to be excluded that they be developed in, more or less, the near future.

China—Yes. In June 10, 1998, Interim Measures for the Administration of Human Genetic Resources issued by the state council of China came into force. The Measures are enacted for the purpose of efficiently protecting and rationally utilizing human genetic resources in the People's Republic of China, strengthening the research and development of human genes and promoting international cooperation and exchange on the basis of equality and mutual benefits. According to Article 4 of the Measures, the State adopt a reporting and registration system on important pedigrees and genetic resources in specified regions. No institution or individual may sample, collect, trade, export human genetic resources or take them outside the territory of the People's Republic of China, or provide them to other countries in any form without permission.

Colombia—Yes. We attach a copy of Decision 391 of the Commission's Cartagena Agreement, which treats Access to Genetic Resources.

Denmark—Yes. The applicant must have a written assignment from the inventor, when he applies for a patent. The Order will be supplemented with a provision according to which the applicant should provide information's about the geographic origin of the biological material, if he is in possession of the information. The Convention on Biodiversity must be respected.

Ecuador—Yes. Enclosed is Decision 391, Common Regime for Industrial Property, from the Commission's Cartagena Agreement, current Andean Community of Nations.

European Union—Recital 27 of the directive reads as follows "Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;"

Ethiopia—No. We are now in the process of developing a legislation on access to genetic resources which addresses all the issues raised—such as origin, prior informed consent, etc.

Hungary—The legislation of our country does not include any special provisions to ensure recording of contributions to inventions.

Lithuania—Lithuanian legislation includes no special provisions.

Madagascar—Such provisions do not exist in the National legislation.

Malaysia—Malaysian Patent Office does not have provision regarding the contributions to inventions.

Norway—Our legislation does not include any provisions that ensure the recording of ownership interests to natural resources in inventions concerning biological material.

Philippines— No. Our present law on patent does not provide for special provisions, i.e. source of government funding, the grant of prior informed consent.

Russian Federation—No, it doesn't include.

Slovakia—Present patent legislation does not include any special provisions to ensure the recording of contributions to inventions.

Sweden—There are no such provisions as mentioned in the question and there are presently no plans in this respect.

United States—No. The parenthetical examples appears to have no relationship to the question that has been posed. None of the examples contributes to the process of arriving at a given invention. At most, the examples may be collaterally related to a given invention; the invention, itself, is unaffected.

Uruguay—Not currently, without prejudice to the provisions of the Convention on Biological Diversity. Nevertheless, norms relating to this issue can be found in various agreements existing in research and development organizations.

Venezuela—The Constitution of the Bolivarian Republic of Venezuela recognized the public interest of science, technology, knowledge, innovation and their applications and necessary information systems, supposing for the last existence of information registries that involve the aspects mentioned in the questionnaire. In that sense, article 110 of the present Constitution, part of the recognition of the interest of the public in these aspects, imposes on the Venezuelan State the obligation to assign sufficient resources and to create a national science and technology system. For purposes of clarification, we will cite the complete text of the referenced Constitutional provision:

> "Article 110. The State recognizes the public interest of science, technology, knowledge, innovation, and their applications and necessary information systems, since they are fundamental instruments for economic, social and political development in the country, as well as national security and sovereignty. In order to promote and develop those activities, that State shall assign sufficient resources and create a national science and technology system in accordance with the law. The private sector shall lend resources for these reasons. The state shall guarantee compliance with the ethical and legal principles that must regulate scientific, humanistic and technological research activities. The law shall determine the modes and media necessary for compliance with this guarantee.

The Venezuela juridical order does not contain any provision that expressly set forth the registry of sources of government financing; nevertheless, there are different public, private and mixed institutions that take as their primary and fundamental priorities, for the purpose of creating new technologies, the financing of technological research and studies. Amongst others, we can mention the recently created Ministry of Science and Technology, that brings together in one organization various institutions that were originally created to promote and finance scientific research (Such as CONCIT). Additionally, INTEVEP, a brother organization of Petroleos de Venezuela, S.A., complies with this important mission.

In respect to the registry of sources of genetic resources that give rise to biotechnology inventions or are utilized in them, there exists Decision 391 of the Commission's Cartagena Agreement on the Common Regime for Access to Genetic Resources, which is the Law of the Bolivarian Republic of Venezuela, as well as for other countries that make up the Andean Community of Nations. The aforementioned legal instrument encourages research projects that promote the identification, registry, characterization, conservation, and sustainable use of biodiversity and products derived from genetic resources (Article 8). Likewise, the member countries have agreed to assure and facilitate access to technologies that utilize genetic resources and derived products through the corresponding access contracts (Article 9). Special reference should be made to the content of the last paragraph of Article 10 of Decision 391, which states:

> "(…) Likewise, (the Member Countries) shall establish sub-regional programs for technical and scientific training in the subject of information, follow-up, control, and evaluation of the activities dealing with genetic resources and their derived products and for the development of collaborative investigations." (Parenthesis ours.)

In general, Decision 391 of the Commission's Cartagena Agreement establishes obligations for member countries of general and specific scope for the promotion of biotechnical research, the mechanisms and forms for accessing the genetic material, as well as the registry of information related to it all. These comments satisfy questions 9 and 10 of the

questionnaire. It is possible to view Decision 391 through the following URL: http://www.comunidadandina.org.

QUESTION 9

Bangladesh—Our country is planning to introduce a legislation entitled "Biodiversity and Community Knowledge Protection Act."

Brazil—Yes, there is a law pending of approval, not accessible by moment.

Bulgaria—The patent law contains no provisions of this kind and we do not plan to include any.

Cameroon—These provisions have not been developed as yet.

Canada—At this time no legislative changes are contemplated. A consultation process on the patenting of higher life forms has recently been launched.

Colombia—The answer to question 8 was affirmative.

Cuba—Up until now, it is not envisaged that legislation will be introduced that guarantees the recording of such contributions.

Democratic People's Republic of Korea—No policy at this time.

Denmark—See point 8 above.

European Union—See answer to question 8.

Ethiopia—We have a zero draft now on access to genetic resources, the copy of which may be available from the Biodiversity Conservation and Research Institute. Enactment may be possible in 2002.

Hungary—It is not planned in our country to introduce legislation to ensure the recording of contributions described under question (8).

Iceland—Yes, it is planned to introduce such a legislation but information about the time frame is not available.

Ireland—No proposals at present.

Lithuania—Not yet.

Madagascar—Such provisions do not exist in the National legislation.

Malaysia—Malaysian Patent Office does not have provision regarding the contributions to inventions.

Norway—There are no planning in our country to introduce legislation that will ensure the recording of proprietary as mentioned in question 8.

Philippines—No. Inclusion of such special provisions in the patent law is no longer necessary because they are considered in our pending legislation for the Plant Variety Protection. (Note: the lead agency in-charge in the implementation of PVP is the Dept. of Agriculture.)

Russian Federation—This problem is now under study.

Slovakia—There are no plans to introduce legislation to ensure the recording of such contributions, as described above, under consideration at present.

Sweden—There are no such provisions as mentioned in the question and there are presently no plans in this respect.

Switzerland—Switzerland supports the efforts made at international level to find a satisfactory solution to the above-mentioned problematic. Once such a solution is identified and accepted by consensus at a multilateral level, Switzerland will envisage introducing the adequate provisions in its national law.

Thailand—We have no plan to introduce the said legislation at this moment.

Uruguay—A national norm is currently being studied whereby it's elaboration will especially take into account Art. 15 of the aforementioned Convention on Biodiversity, amongst other sources.

Venezuela—These comments satisfy questions 9 and 10 of the questionnaire. [*Note by the Secretariat*: This statement was included in the answer of Venezuela to question 8]

QUESTION 10

Bangladesh—Does not arise.

Cameroon—We replied in the negative to 8 and 9.

China—No. Under patent law, those requirements are not a condition of patentability. But failure in meeting the requirements concerned will be punished according to related administrative laws or regulations.

Colombia—Yes. Decision 391 of the Commission's Cartagena Agreement, which treats Access to Genetic Resources, in the second additional provisions, states that: "The Member Countries shall not recognize rights, including the intellectual property rights, over genetic resources, derived or synthesized products, and intangible components associated, obtained, or developed during an access activity that does not comply with the provisions of this Decision. Additionally, the affected Member Country may request the nullification and interpose actions that were a part of the case in the countries that had conferred rights or granted protection titles." The third additional provision of the Decision dictates that "The competent national offices for Intellectual Property matters shall require that the solicitor state

the registration number of the access contract, and provide a copy of it, as a prior requisite for the concession of the respective right, when the solicitor is certain or has reason to believe that the products or processes whose protection is requested have been obtained or developed from genetic resources or from products derived from the genetic resources of any of the Member Countries." In agreement with that contract and a copy of the contract is a condition of patentability, in the sense that not presenting the requirement constitutes an obstacle to the concession of the patent or would justify its invalidation or revocation when the invention to be protected by patent is obtained or developed from genetic resources or from the genetic resource of any of the Member Countries.

Democratic People's Republic of Korea—No policy at this time.

Denmark—It is not a condition of patentability.

European Union—See answer to question 8.

Hungary—In view of our answers to 1. and 2. The question under this point is not applicable.

Malaysia—Malaysian Patent Office does not have provision regarding the contributions to inventions.

Russian Federation—The answers to questions 8 and 9 are "no".

Slovakia—Considering answers to question 8 and 9 – not applicable.

Slovenia—See the answer under 8. 9 above.

Sri Lanka—Does not arise.

Sweden—There are no such provisions as mentioned in the question and there are presently no plans in this respect.

Uruguay—Nothing to the effect has been established thus far.

Venezuela— These comments satisfy questions 9 and 10 of the questionnaire. [*Note by the Secretariat*: This statement was included in the answer of Venezuela to question 8]

[End of Annex and of document]