Article 15 Access to genetic resources

216. What is the relative priority afforded to implementation of this Article and the associated decisions by your country?					
a) High		b) Medium	X	c) Low	

217. To what extent are the resources available adequate for meeting the obligations and recommendations made?							
a) Good		b) Adequate	Micro-org.	c) Limiting	X	d) Severely limiting	

Further comments on relative priority and on availability of resources

(217) Resources are adequate for meeting the obligations and recommendations in relation to micro-organisms (see BCCM). In general however, available resources for this article and the related decisions are limiting (same distinction is made for questions 221 and 222).

(general) The draft Bill transposing the Directive 98/44/EC on the legal protection of biotechnological inventions into Belgian law is breaking new grounds compared with the Directive as regards the following issues:

- Patentability of the elements of the human body, including the genes
Unlike the Directive, the transposition text does not stipulate that a gene may constitute a patentable invention but states that a gene may provide *a basis* for a patentable invention. This is a terminological correction induced by the wording of the Article 52 of the European Patent Convention and of the Article 2 of the Belgian Patent Act. This will not give rise to a difference in interpretation according to the principle of similar interpretation. The transposition Bill provides explicitly that the human body is not an asset, that patentability conditions must be met and that the monopoly resulting from the patent is limited to what constitutes the invention and in particular, that is does not impede the free disposal of preexisting elements, as implicitly referred to in the Directive, notably in Article 5 thereof.

- Non-patentability if the invention is contrary to public order and morality
New examples of non-patentability for the aforementioned reason are added to the Belgian Patent Act. As the European Directive (Article 6, §2) does not give an exhaustive list of examples, the national legislator is empowered to take other cases into account. The transposition text provides an additional specification insofar as it does not cover the cases where the exploitation of the invention is contrary to law and order but those where the *conditions of development of the invention* are contrary to public order and morality. The Belgian legislator may legitimately consider that the exploitation of the invention and the conditions of its development are entangled. The examples to be added concern the inventions developed in violation of human rights, of the Convention on Biological Diversity or without the consent of the donor when it comes to human body samples.

- Definition of invention
The transposition text may include a definition of the invention in the Belgian Act of 28 March 1984 with the aim to put into force the consensus which is generally accepted and according to which inventions are patentable whereas discoveries are not. The very idea of a definition of the invention gives rise to criticism because it is feared that this definition will freeze the evolution of law. Nevertheless, the definition proposed only includes non-controversial elements that are found in the constant legal practice and theory.

- Mention of the geographical origin of the living matter from which the invention is derived
It is proposed, as provided for in the 27th preamble, that the states require the applicant to mention the geographical origin of the living material from which he developed his invention. This provision reinforces the sovereign rights of the states concerning their biological resources, which are guaranteed in the Convention on Biological Diversity. In accordance with the 27th preamble, this requirement is only to be fulfilled when the biological origin is known.

- Limitations of the monopoly resulting from the patent
It is specified that the monopoly is limited to what constitutes the invention and that it will not impede the free disposal of preexisting elements. These elements are only the repetition of a traditional rule in patent law, aiming at reassuring the public opinion, especially as regards human genes.

(*This text is provided for information only and does not bind the Belgian state as to the final content of the legislation transposing the Directive 98/44/EC into Belgian law*.)

Moreover, regardless of the transposition of the Directive 98/44/EC, it can prove useful to say that the Act of 28 January 1997 adapting the Patent Act of 28 March 1984 to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), annexed to the Agreement instituting the World Trade Organisation, has amended the Article 4, §2, of the Patent Act in order to complement the notion of public order by referring to the protection of the health and life of people and animals, to the preservation of plants and to the protection against serious damages to the environment. So Belgium has literally included the notions of the Article 27.2 of the TRIPS Agreement into its patent law.

(general) For what concerns policy on access to genetic resources, the 'Belgian Co-ordinated Collections of Micro-organisms' are public *ex situ* collections. Technically, the biological resources conserved in their facilities are publicly available through printed and on-line catalogues, at cost-covering prices. BCCM has developed a policy summarised in the MOSAICC code of conduct (see www.belspo.be/bccm/mosaicc).

Beside BCCM, other institutions involved in *ex situ* and *in situ* management of biological resources have developed, sometimes in co-ordination with similar bodies at international level, appropriate administrative and policy measures to operate according to the terms of Article 15.

218. Has your country endeavoured to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties (15(2))?	
a) no	
b) yes – limited extent	X
c) yes – significant extent	
219. Is there any mutual understanding or agreement in place between different interest groups and the State on access to genetic resources (15(4))?	
a) no	
b) yes – limited extent	X
c) yes – significant extent	

220. Has your country an open participation planning process, or any other process in place, to ensure that access to resources is subject to prior informed consent (15(5))?	
a) no	
b) early stages of development	
c) advanced stages of development	X
d) processes in place	
221. Has your country taken measures to ensure that any scientific research based on genetic resources provided by other Contracting Parties is developed and carried out with the full participation of such Contracting Parties (15(6))?	
a) no measures	
b) some measures in place	Micro-org.
c) potential measures under review	X
d) comprehensive measures in place	
222. Has your country taken measures to ensure the fair and equitable sharing of the results of research and development and the benefits arising from the commercial and other use of genetic resources with any Contracting Party providing such resources (15(7))?	
a) no measures	
b) some measures in place	Micro-org.
c) potential measures under review	X
?d) comprehensive measures in place	
If so, are these measures	
a) Legislation	
b) Statutory policy or subsidiary legislation	
c) Policy and administrative measures	X

Decision II/11 and Decision III/15. Access to genetic resources

223. Has your country provided the secretariat with information on relevant legislation, administrative and policy measures, participatory processes and research programmes?	
a) no	
b) yes, within the previous national report	X
c) yes, through case-studies	
d) yes, through other means (please give details below)	X
224. Has your country implemented capacity-building programmes to promote successful development and implementation of legislative, administrative and policy measures and guidelines on access, including scientific, technical, business, legal and management skills and capacities?	
a) no	
b) some programmes covering some needs	X
c) many programmes covering some needs	
d) programmes cover all perceived needs	
e) no perceived need	

225. Has your country analysed experiences of legislative, administrative and policy measures and guidelines on access, including regional efforts and initiatives, for use in further development and implementation of measures and guidelines?	
a) no	
b) analysis in progress	X
c) analysis completed	
226. Is your country collaborating with all relevant stakeholders to explore, develop and implement guidelines and practices that ensure mutual benefits to providers and users of access measures?	
a) no	
b) yes – limited extent	X
c) yes – significant extent	
227. Has your country identified national authorities responsible for granting access to genetic resources?	
a) no	
b) yes	X
228. Is your country taking an active role in negotiations associated with the adaptation of the International Undertaking on Plant Genetic Resources for Food and Agriculture?	
a) no	
b) yes	X

Decision V/26. Access to genetic resources

229. Has your country designated a national focal point and one or more competent national authorities to be responsible for access and benefit-sharing arrangements or to provide information on such arrangements?	
a) no	X
b) yes	
c) yes, and Executive Secretary notified	
230. Do your country's national biodiversity strategy, and legislative, administrative or policy measures on access and benefit-sharing, contribute to conservation and sustainable use objectives?	
a) no	
b) to a limited extent	
c) to a significant extent	X
Parties that are recipients of genetic resources 231. Has your country adopted administrative or policy measures that are supportive of efforts made by provider countries to ensure that access to their genetic resources is subject to Articles 15, 16 and 19 of the Convention?	
a) no	
b) other arrangements made	X
c) yes	

232. Does your country co-operate with other Parties in order to find practical and equitable solutions supportive of efforts made by provider countries to ensure that access to their genetic resources is subject to Articles 15, 16 and 19 of the Convention, recognizing the complexity of the issue, with particular consideration of the multiplicity of prior informed consent considerations?	
a) no	
b) yes (please provide details)	X
233. In developing its legislation on access, has your country taken into account and allowed for the development of a multilateral system to facilitate access and benefit-sharing in the context of the International Undertaking on Plant Genetic Resources?	
a) no	X
b) legislation under development	
c) yes	
234. Is your country co-ordinating its positions in both the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources?	
a) no	
b) taking steps to do so	
c) yes	X
235. Has your country provided information to the Executive Secretary on user institutions, the market for genetic resources, non-monetary benefits, new and emerging mechanisms for benefit sharing, incentive measures, clarification of definitions, *sui generis* systems and “intermediaries”?	
a) no	X
b) some information provided	
c) substantial information provided	
236. Has your country submitted information on specific issues related to the role of intellectual property rights in the implementation of access and benefit-sharing arrangements to the Executive Secretary?	
a) no	
b) yes	X
237. Has your country provided capacity-building and technology development and transfer for the maintenance and utilisation of ex situ collections?	
a) no	
b) yes to a limited extent	X
c) yes to a significant extent	

(general) Various States made a first attempt to affirm the rights of indigenous peoples and to give effect to the equitable sharing objective laid down in Article 15 of the Convention on Biological Diversity.

In *Europe*, a first effort in that direction was established within the framework of the recently approved EU Biotechnology Directive (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Invention, 213 *Official Journal of the European Communities - Legislation*, July 30 1998, 13). In an attempt to implement the fair and equitable sharing principle of the Convention on Biological Diversity, Recital 27 was introduced in the EU Biotechnology Directive. Recital 27 requires that "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". Recital 27 contains a praiseworthy principle, but the wording of Recital 27 is so noncommittal, that one can wonder if the introduction of the Recital will sort any effect.

Belgium is the only EU member State that has so far taken Recital 27 seriously. An attempt to enforce Recital 27 was made in the Draft Proposal of August 8 2000 holding various modifications of the Patent Act of March 28 1984 (French: *Avant-projet de loi modifiant la loi du 28 mars 1984 sur les brevets d'invention, en ce qui concerne la brevetabilité des inventions biotechnologiques*). The origin requirement, laid down in recital 27 of the Directive, has undergone two major changes. First, the recital has been given a stronger legal basis by inserting it in the Draft Proposal as full provision, more in particular as § 4 of Article 4. Second, the recital has been given a new wording.

The proposed new article stipulates that the exploitation of an invention is contrary to public order and morality, especially when the invention can be shown to have been developed in circumstances which run counter to public order and morality, which is the case when an invention is developed on the basis of plant or animal material which was imported in violation of the law of the country of origin of these materials: *"§ 4. L'exploitation d'une invention est contraire à l'ordre public et aux bonnes moeurs notamment lorsqu'il est établi que l'invention a été développée dans des conditions contraires à l'ordre public et aux bonnes moeurs. Tel est le cas par exemple: - lorsqu'une invention est développée à partir de matière biologique prélevée ou exportée en violation des dispositions des Articles 3, 8 j), 15 et 16 de la Convention de Rio sur la diversité biologique du 5 juin 1992."*

As a consequence, an invention which uses plant or animal material which was imported in violation of the law of the country of origin, would run counter to Belgian public order and morality, and could be revoked on the basis of Article 49 §1 (1) of the Belgian Patent Act of 1984 (Art. 49 §1 (1) 1984 BPA Act stipulates that a patent may be revoked by court if the subject matter of the patent falls within Articles 3 or 4, or does not meet the requirements of Articles 2, 5, 6 and 7. Cf. Art. 138 (1) (a) EPC which stipulates that a European patent may be revoked if the subject matter of the European patent is not patentable within the terms of Articles 52 to 57).

The Draft Proposal implementing Recital 27 in the Belgian Patent Act has, however, met considerable opposition in legal doctrine, as well as in societal circles.

First, objections from a logistic nature were launched. Which body is going to check whether or not the informed consent was asked properly? Which body is going to effectuate the control of the origin of the plant and animal material? The current Belgian Patent Office? Is this institution equipped to

perform such an activity? When is such control going to take place? Always, or only on demand of a third party?

Second, questions from a more legal or opportunist nature were put forward. Is the introduction of such a weighty sanction – viz. the nullification of a patent – in proportion to the shortcoming? Is it justified and/or opportune that the Belgian patent legislator enforces sanctions against non-compliance with foreign legislation? Is the nullification of a patent an appropriate way to express the concern for equitable legal relationships? Is the annulment of a potentially profitable patent beneficial for the country of origin? Should one not think of other mechanisms – outside the scope of patent law – to bring about equitable sharing between countries hosting plant and animal material and countries using those materials?

Third, the objection was raised by some that the introduction of the recitals as full provisions, runs counter to the pursuit of harmonisation in the Directive. Others, however, argued that the Belgian viewpoint might serve as an example for other member states (expert analysis).

(general) Vegetative and generative material is distributed, free of charge, to public institutions working in the areas of research, breeding, conservation and education. No material is provided to individuals or commercial firms.

For the time being the Belgian Botanic Garden is addressing the exchange of genetic resources and benefit sharing to develop a policy which is in line with most of the other European botanic gardens. The same is going on in other European countries. It is aimed that the European countries develop a common strategy for exchange of material between botanic gardens.

(219) Some collaborations exist between formal research programmes and the private sector (nurseries, seed producers, processing industry, etc.).

(223) BCCM has co-ordinated the MOSAICC project. This project involved 12 partners including the ‘World Federation for Culture Collection (WFCC)’. WFCC has sent information concerning MOSAICC to the secretariat.

(223 d) Information was/is provided to the CBD-Secretariat through the Belgian Clearing-House Mechanism and the Belgian Biosafety Clearing-House.

(225) Research project from the Flemish Research Council on 'Intellectual Property Rights and Biodiversity' (2000-2003); Centre Intellectual Property Rights, KU Leuven.

(226) MOSAICC included representatives of public and private, for-profit and non-profit institutions, from developed as well as developing countries.

(227) Authorities granting access to genetic resources have been identified but not necessarily in the framework of the CBD. Some authorities have been in place even before the Convention. These include local, regional and national authorities competent in environmental matters.

(230 & 231) See above-mentioned information on the content of the draft Bill transposing the Directive 98/44/EC into Belgian law: as previously mentioned, the Belgian legislator is thinking about inserting into the Belgian Patent Act (though it would be better to find a solution on multilateral level) a disposition based on the 27th preamble of the Directive on the Legal Protection of Biotechnological Inventions, i.e. the applicant should include information on the geographical origin of the biological resources used to develop his invention, if known. This is the logical application of the rule

according to which the invention must be described precisely enough in the patent application. If the applicant does not know the origin, he has to mention it as well. Every applicant making a false statement or providing wrong information intentionally shall be prosecuted in accordance with the penal provisions of common law applicable to the making of false statements to the public authority. This possible new obligation is self-standing inasmuch as it is not a new patentability criteria (novelty, inventive step and industrial application) and is not, as such, a fundamental provision inherent in patent law.

In so far the principles that have been translated in the provisions and recommendations of the CBD were not yet taken into consideration, OSTC integrates progressively the provisions and recommendations of the CBD into its research contracts, also contracts involving institutions from other countries. It also follows the recommendations of other competent authorities such as DGIC (see also general comment on Article 16 Access to and transfer of technology).

(232) In view of finding practical and equitable solutions, BCCM follows COP-5 conclusions V/26 A.6. stating: "[The COP] notes that voluntary measures, including guidelines, may help ensure realisation of the objectives of the Convention, and to that end invites the parties to consider promotion of their use". Such guidelines should include recommendations for an efficient implementation of the prior informed consent concept.

See also the comment above in relation to question 226, more specifically through MOSAICC coherent approach of CBD and TRIPS Agreement plus Budapest Treaty with regard to micro-organisms. MOSAICC has been initiated by a public funded consortium. Although MOSAICC do not express the position of the administration, this project reflects the importance given to the implementation of Article 15 by the administration in charge of the BCCM program.

(234) Until now, two IU-CBD co-ordination meetings have been organised. WIPO and TRIPS discussions and activities are taken into account in this context. A contact group composed of officers from competent administrations exists.

(236) The European Communities and their Member States, with the Swedish Presidency, sent a letter dated 2 February 2001 containing several contributions to the Secretary of the Convention on Biological Diversity (notably a general note written within the task force 'Biodiversity' of the Council of the European Union between September and February 2001).

Belgium have sent a significant delegation to the first meeting of the WIPO intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore. Outputs of this forum will certainly be relevant in this matter.

(237) See questionnaire on Article 9 and the initiatives taken by other *ex situ* conservation facilities such as the National Botanic Garden of Belgium.