

Institut der beim Europäischen Patentamt zugelassenen Vertreter Institute of Professional Representatives before the European Patent Office Institut des mandataires agréés près l'Office européen des brevets

> Ausschuss für Biotechnologische Erfindungen Committee on Biotechnological Inventions Commission pour les Inventions en Biotechnologie

**National Laws on the Patentability of Plants (update 7 July 2019)** 

### **SUMMARY:**

Art 53(b) EPC excludes from patentability plants or animal varieties or essentially biological processes for the production of plants or animals. Some national laws contain a provision excluding from patentability, besides essentially biological processes, the products derived thereof.

# QUESTION (Q):

Is there a specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process?

The referral of the President of the EPO G3/19 document mentions that since the publication of the EU Notice in November 2016 allegedly all 38 contracting states (CS) have indicated and declared that under their national law and practice the products (plants and animals) of essentially biological processes are excluded from patentability (see § 103). It also mentions that the 28 EU member EPC Contracting States have declared their national law and practice to be in line with the interpretation of Article 4(1)(b) of the EU Biotechnology Directive set forth in the European Commission Notice. This results in the first place from the conclusions of the EU Council of the Ministers in which the Commission Notice was welcomed (see § 104). Further it mentions that the 10 non-EU member EPC Contracting States, too, have indicated that under their national law and practice plants and animals obtained by essentially biological breeding processes are not patentable. All these 10 Contracting States voted in favour of the introduction of Rule 28(2) EPC in June 2017. In view of the harmonising effect of the EPC and the high degree of alignment which has been *de facto* achieved91 this amounts to a clear indication that the national law and practice is the same as set forth in Rule 28(2) EPC (see § 105).

The members of the Biotech Committee have been asked to review the situation in their country and the replies can be seen below. **Only AT, BE, DE, FR, NL and PT can reply yes, IT replies no given the interpretation of our IT Biotech Committee member.** There is a discrepancy between sections 103-105 of the Referral G3/19 document and the actual position of some national offices insofar as they may have amended their national laws or have concrete intentions to do so. The Biotech Committee will follow this up and provide regular updates.

No	32
Yes	6

MS	National Law / EN translation	Remarks	Q
AL	Law No. 9947 of 7 July 2008  Art 6.2	Art 5.5 (c)	No
	EN Translation Exceptions to patentability Patents shall not be granted in respect of: 2. Plant or animal varieties or essentially biological processes for the production of plants or animals, without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product	Art 5 Patentable Inventions 5. Biotechnological inventions shall also be patentable if they concern: c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.  The referral document does not mention anything about AL. No changes reported for Albania.	
AT	obtained by means of such a process.  Patentgesetz 1970 BGBI. 1970/259 idF BGBI. I 37/2018 (Patentgesetz) § 2(2) Patentgesetz § 2. (2) Patente werden nicht erteilt für Pflanzensorten oder Tierrassen sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen oder Tiere. ()  EN Translation	§2(2) of the Austrian Patent Law in full reads: "(2) Patente werden nicht erteilt für Pflanzensorten oder Tierrassen sowie für im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen oder Tiere. Der Begriff der Pflanzensorte wird durch Artikel 5 der Verordnung (EG) Nr. 2100/94 über den gemeinschaftlichen Sortenschutz, ABI. Nr. L 227 vom 1. September 1994 S. 1, in der Fassung der Verordnung (EG) Nr. 2506/95, ABI. Nr. L 258 vom 28. Oktober 1995 S. 3, definiert. Ein Verfahren zur Züchtung von Pflanzen oder Tieren ist im wesentlichen biologisch, wenn es vollständig auf natürlichen Phänomenen wie	Yes

	Patents shall not be granted for plant and animal varieties and for essentially biological processes for producing plants and animals and plants or animals that are exclusively obtained by such processes. []	Kreuzung oder Selektion beruht. Erfindungen, deren Gegenstand Pflanzen oder Tiere sind, können patentiert werden, wenn die Ausführung der Erfindung technisch nicht auf eine bestimmte Pflanzensorte oder Tierrasse beschränkt ist. Satz 1 Teil 2, wonach Patente nicht für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren erteilt werden, berührt nicht die Patentierbarkeit von Erfindungen, die ein mikrobiologisches oder sonstiges technisches Verfahren oder ein durch diese Verfahren gewonnenes Erzeugnis zum Gegenstand haben, wobei ein mikrobiologisches Verfahren jedes Verfahren ist, bei dem mikrobiologisches Material verwendet, ein Eingriff in mikrobiologisches Material durchgeführt oder mikrobiologisches Material hervorgebracht wird."  The referral document mentions: In a similar manner, § 2 (2) S. 1 of the Austrian Patent Act sets forth since 2016: "No patents shall be granted for [] essentially biological processes for the production of plants and animals as well as plants or animals exclusively obtained by means of such processes; (emphasis added)."	
BE	The Belgian Code of Economic law was amended on 2/05/2019 (entered into force on 1/06/2019):  Art. XI.5.  § 1 Ne sont pas brevetables:  1° les variétés végétales et les races animales;  2° les procédés essentiellement biologiques pour l'obtention de végétaux ou d'animaux;  3° les végétaux ou animaux exclusivement obtenus par les procédés visés au 2°, y compris les parties de ces végétaux ou animaux constituant du matériel de reproduction.  § 2. Sans préjudice du paragraphe 1er, les inventions portant sur des végétaux ou des animaux sont brevetables si la faisabilité technique de l'invention n'est pas limitée à une variété végétale ou à une race animale déterminée.  § 3. Le paragraphe 1er, 2°, n'affecte pas la brevetabilité	Amendment in XI.5 applies to all pending applications and granted patents  "Not patentable are [] plants and animals exclusively obtained by processes according to paragraph 2 [i.e. essentially biological processes for the production of plants and animals], [] (emphasis added) and according to paragraph 3 plants or animals exclusively obtained from essentially biological processes and their propagating material".	Yes

В	d'inventions ayant pour objet un procédé microbiologique, ou d'autres procédés techniques, ou un produit obtenu par ces procédés.  EN Translation  Art. XI.5. § 1. Shall be excluded from patentability: (1) plant and animal varieties; (2) essentially biological processes for the production of plants or animals; (3) plants and animals exclusively obtained by processes according to paragraph 2, also comprising parts of these plants and animals which are propagating material § 2. The inventions relating to plants and animals are patentable if the technical feasibility is not limited to a particular plant or animal variety. § 3. The paragraph 1, (2) shall not apply to microbiological processes or to the products obtained by such processes.  Bulgarian Patent Law, last amended July 18, 2017, provides: Art 7 (1)	Patentability of biotechnological inventions is set in <b>Art. 7a(3):</b> Inventions relating to plants or animals shall be considered patentable, if the technical realisation of the invention is not limited to a certain plant	No
	EN Translation  Exceptions to Patentability (1) Patents shall not be granted for: () 3. plant varieties and animal breeds; 4. essentially biological processes for the production of plants or animals.	variety or animal breed.  Art. 7a(1) defines as patentable the products, referring to or containing biological material, or the method by which it is obtained, processed or used if they are new, have inventive step and industrial applicability, but is not specific with respect to the products obtained by essentially biological processes.	
С		The referral document does not mention anything about BG. No changes reported from MK.  An essentially biological process that comprises at least one non-	No

	PatG)	biological, technical step that is required for arriving at the desired	
	vom 25. Juni 1954 Art 2(2)b	solution (e.g. irradiation, temperature shock), will be patentable and so	
	Art 2(2)b PatG	will be the products obtained by that process.	
	Von der Patentierung sind ferner ausgeschlossen:	at any product of an any man product	
		Swiss patent law is clear as to the non-patentability of essentially	
	b. Pflanzensorten und Tierrassen und im Wesentlichen	biological processes but is somewhat silent as to the patentability of	
	biologische Verfahren zur Züchtung von Pflanzen und	products obtained by essentially biological processes. From the wording	
	Tieren; unter Vorbehalt von Absatz 1 patentierbar sind	of Art.2 (2)b PatG, last half-sentence (emphasized in bold letters), it may	
	jedoch mikrobiologische oder sonstige technische	be inferred, however, that it was not the legislator's intention to exclude	
	Verfahren und die damit gewonnenen Erzeugnisse sowie	novel and inventive products from protection solely because they have	
	Erfindungen, deren Gegenstand Pflanzen oder Tiere	been obtained by essentially biological processes. This view seems to be	
	sind und deren Ausführung technisch nicht auf eine	confirmed by the federal court decision BGE 121 III 125 (1995), Asta	
	bestimmte Pflanzensorte oder Tierrasse beschränkt	Medica vs Lendi, which also emphasizes patentability of plant product	
	ist.	inventions as long as they are not confined to specific plant varieties.	
		This understanding is also mirrored by the examination guidelines	
	EN Translation	wherein patentability of products obtained by essentially biological	
	[Excluded from patentability are:]	processes is not excluded although not explicitly stated either.	
		processes is not excluded although not explicitly stated either.	
	b. Plant varieties and animal varieties or essentially		
	biological processes for the production of plants and	In essence, the goal of the Swiss legislator is to avoid double protection	
	animals; however, subject to the reservation of paragraph	of plant inventions by both the plant varieties protection act and the	
	1, microbiological or other technical processes and the	patent law.	
	products obtained thereby as well as inventions that		
	concern plants or animals are patentable provided that	The referral document does not mention anything about CH. No changes	
	their application is not technically confined to a single	reported from CH.	
	plant or animal variety.		
CY	Patent Act of 1998 (Law 16(I)/98, as amended by Laws	The Biotech Directive (98/44) has been implemented in Cyprus law, as	No
	21(I)/99, 153(I)/2000, 163(I)/2002 and 163(I)/2002).	an amendment to the Patent Act of 1998.	
	Article 5a		
		The referral document does not mention anything about CY. No changes	
	EN Translation	reported from MK.	
	Essentially biological processes for the production of	Toportou from Mix.	
	plants or animals are not patentable. () It is understood		
	that the foregoing restriction shall not affect the		
	patentability of patents having as an object a		
	microbiological method or other technical methods or a	<u> </u>	

	product that is a result of such methods.		
CZ	Law No. 527/1990 Coll. on Inventions and Rationalisation Proposals (Patent Law)  Section 4.b  EN Translation  Exclusions from patentability  Patents shall not be granted in respect of: () b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes and the products thereof.	In two relevant Czech Laws (Nos. 527/1990 and 206/2000), there is no provision that explicitly excludes patentability of plants (or animals) obtained by essentially biological process. Consequently, the patentability of plant, wherein the plant is produced by essentially biological processes, would be an issue of official/judicial interpretation of the existing legal provisions. Unfortunately, up to now there is no relevant case law in the Czech Republic.  Plant or animal varieties or essentially biological processes for the production of plants or animals are excluded from patentability by the Patent Law (Law No. 527/1990), nevertheless, the Law No. 206/2000, on the Protection of Biotechnological Inventions (which is an implementation of Biotech Directive 98/44/EC) in Section 2.b classifies plants and animals among the patentable inventions, "if the technical feasibility of the invention is not confined to a particular plant or animal variety".  The referral document does not mention anything about CZ. No changes	No
DE	Patentgesetz in der Fassung der Bekanntmachung vom 16. Dezember 1980 (BGBI. 1981 I S. 1), das zuletzt durch Artikel 1 des Gesetzes vom 19. Oktober 2013 (BGBI. I S. 3830) geändert worden ist § 2a (1)1 Patentgesetz  Patente werden nicht erteilt für  1. Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere;  EN Translation  Patents shall not be granted for  1. plant or animal varieties or for essentially biological processes	reported for CZ.  Bundestagsdrucksache 17/14222 regarding No. 1 (Amendment of Section 2a of the Patent Act – PatG):  The referral document mentions: "  With effect from 2013 § 2a (1) Nr. 1 of the German Patent Act was amended to provide as follows: "No patents shall be granted for [] essentially biological processes for the production of plants and animals as well as plants or animals exclusively obtained by means of such processes; (emphasis added).""	Yes

	for the production of plants or animals and plants and		
	animals exclusively obtained by such processes;		
	(The underlined part has recently been added to the		
	German provision. The amendment entered into force on		
	25 October 2013)		
DK	Patents Act, cf. Consolidate Act No. 91 of 28 January 2009	The Danish patent law seems to be more "liberal" than the German law,	No
	LBK nr 91 af 28/01/2009 Gældende (Patentloven)	and also slightly more than the Dutch law. This section was amended in	
	Section 1(4)-1(6)	the implementation of the Biotech Directive.	
	EN Translation	The referral document does not mention anything about DK. No changes	
	(4) Patents shall not be granted in respect of plant or	reported from DK.	
	animal varieties. Patents may, however, be granted for		
	inventions, the subject-matter of which is plants or animals		
	if the technical feasibility of the invention is not confined to		
	a particular plant or animal variety. In this Act a "plant		
	variety" means a plant variety as defined in Article 5 of		
	Council Regulation (EC) No. 2100/94 on Community plant variety rights.		
	vanety rights.		
	(5) Patents shall not be granted in respect of essentially		
	biological processes for the production of plants or		
	animals. In this Act an "essentially biological process"		
	means a process consisting entirely of natural phenomena		
	such as crossing or selection. Patents may, however, be		
	granted for microbiological processes or other technical processes or products obtained by such processes. In this		
	Act a "microbiological process" means any process		
	involving microbiological material, performed on		
	microbiological material or resulting in microbiological		
	material.		
	(6) Inventions may be patentable even if they relate to a		
	product consisting of or containing biological material or to		
	a process by means of which biological material is		

	produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject-matter of an invention even if it previously occurred in nature. In this Act "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.		
EE	Estonian Patent Act of March 16, 1994 EN Translation Art 6 § 6. Subject of invention () (2) The following, inter alia, are not regarded as the subject of inventions: () 8) plant and animal varieties; Art 7	The Estonian Patent Act excludes from patentability plant and animal varieties and essentially biological processes for the production of biological materials, plants or animals. There is no legal provision excluding the products derived from essentially biological processes from patentability.  The referral document does not mention anything about EE. No changes reported from EE.	No
	EN Translation  Non patentable inventions () (2) The following biotechnological inventions shall not be protected by a patent: () 5) essentially biological processes for the derivation of biological materials, plants or animals, except microbiological processes for the derivation of microorganisms; 6) inventions the application of which is confined to a single plant or animal variety. (3) For the purposes of this Act, "essentially biological process for the derivation of a biological material, plant or animal" means a process which consists entirely of natural phenomena such as crossing and selection.	Art 5 2 of the Cooriele Detect Law evaluates accountable higherical	Na
ES	Law No. 24/2015 of 24 July on Patents	Art 5.3 of the Spanish Patent Law excludes essentially biological	No

Art 5.3	processes but <u>not</u> the products.	
EN Translation Non-patentable subject matter are: 2. Plant and animal varieties. However, inventions having as an object plants or animals are patentable if the technical feasibility of the invention is not limited to a particular plant or animal variety.	The Guidelines for examination (July 2016) mention the exclusion of the essentially biological processes but are silent about the products (plant and animals) obtained by an essentially biological process.  The referral document does not mention anything about ES. No changes reported from ES.	
3. Essentially biological processes for the production of plants or animals. For these purposes essentially biological processes means processes which consist entirely of natural phenomena such as crossing and selection.		
The previous paragraph will not affect the patentability of inventions related to a microbiological method, or to any other technical method, or to a product obtained by such methods.		
Finnish Patents Act, No. 550 of December 15, 1967  Chapter 1, Section 1 as amended 30.6.2000/650 and 18.11.2005/896	Finnish Patents Act excludes from patentability plant or animal varieties and essentially biological processes for the production of plants or animals. There is no legal provision excluding the products derived from essentially biological processes from patentability.	No
EN Translation Anyone who has, in any field of technology, made an invention which is susceptible of industrial application, or his or her successor in title, is entitled, on application, to a patent and thereby to the exclusive right to exploit the invention commercially, in accordance with this Act (18.11.2005/896).	The Biotech Directive was implemented to Finnish Patents Act by amendment which entered into force on 30 <sup>th</sup> June 2000. The implementation was done in cooperation with other Nordic countries. Therefore the legislation regulating the patenting of biotechnological inventions is very similar in different Nordic countries.	
() Patents shall not be granted for plant or animal varieties. Inventions which concern plants or animals shall nevertheless be patentable if the technical feasibility of the invention is not confined to a particular plant or animal	The referral document does not mention anything about FI. No changes reported from FI.	

variety. The concept of plant variety within the meaning of this Act is defined by Article 5 of Council Regulation (EC) No 2100/94 on Community plant variety rights. Patents shall not be granted for essentially biological processes for the production of plants or animals. For the purposes of this Act a process for the production of plants or animals shall be considered essentially biological if it consists entirely of natural phenomena such as crossing or selection. What is said above 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. For the purposes of this Act 'microbiological process' means any process involving or performed upon or resulting in microbiological material.

Inventions shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. 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. For the purposes of this Act 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

FR French Intellectual Property Code (CPI)

Art L611-19

#### **EN Translation**

The following shall not be patentable:
1º animal varieties;
2º plant varieties as defined in Article 5 of Regulation (EC)
No. 873/2004 introducing new rules governing
intellectual property ownership of Community plant variety

Following the EU Directive N°98/44 of July 6, 1998 on biotech inventions, the French Parliament enacted a law on bioethics on August 6, 2004 (J.O n° 182 of August 7, 2004, which deals with the human body (Article L.611-18 of the French Intellectual Property Code)) and another law on the protection of biotechnological inventions on December 8, 2004 (J.O n° 286 of December 9, 2004, which deals with plants and animals (Article L.611-19 of the French Intellectual Property Code)).

The new provisions recognize that biological material (i.e., any material containing genetic information and capable of reproducing itself or being

rights;

3º essentially biological processes for the production of plants and animals. A process that consists entirely of natural phenomena such as crossing or selection shall be regarded as biological process.

- 3° bis Products exclusively obtained by the essentially biological processes defined in 3°, including the elements constituting these products and the genetic information they contain;
- 4° Processes for modifying the genetic identity of animals which are likely to cause them suffering without substantial medical benefit to man or animal, as well as animals resulting from such processes.
- II Notwithstanding the provisions of (I), 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.
- III The provisions of I (3°) shall be without prejudice to the patentability of inventions which concern a technical process, in particular a microbiological one, or a product obtained by means of such a process; any process involving or resulting in or performed upon a microbiological material shall be regarded as a microbiological process.

reproduced in a biological system) may be involved in a patentable invention, provided that it can be isolated from its natural environment or produced by means of a technical process and that it complies with the traditional patentability requirements (the invention must be new, involve an inventive step, and be susceptible of industrial applications).

The Biodiversity Law of August 2016 (Law for the recovery of biodiversity, nature and landscape dated August 8, 2016, which entered into force on August 9, 2016) has introduced two amendments into the Code de la propriété intellectuelle (CPI) by excluding from patentability products exclusively obtained by essentially biological processes (Article L611-19 3°bis).

UK Patents Act 1977

Section 76A and Schedule A2 of the UK Patent Act excludes from

No

	76A Biotechnological inventions (1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2. (2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.  SCHEDULE A2 BIOTECHNOLOGICAL INVENTIONS () 3 The following are not patentable inventions— () (f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process. 4 Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. 11 In this Schedule: "essentially biological process" means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection; ()	patentability any essential biological process for the production of animals or plants. The UK has no legal provision excluding the products derived from essentially biological processes from patentability.  The referral document does not mention anything about GB. The GB position has not changed.	
GR	Law No. 1733/87 (FEK 171 A' of 22.09.1987) "Technology transfer, inventions, and technological innovation" as amended by Art 18, of Law No. 1739/1987 (FEK 201, A' of 20.11.1987) Article 5.8.b  EN Translation Patents shall not be granted in the following cases: b. plant or animal varieties or biological processes for the	The Greek national law "Technology transfer, inventions, technological innovation and establishment of the Commission of Atomic Energy" (number 1733/1987 as in force) contains a provision excluding the varieties of plants and animals from patentability, besides essentially biological and microbiological processes and the products derived therefrom. The products derived from essentially biological processes for the production of plants or animals are not excluded from patentability. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.	No

	production of plants or animals; this provision does not apply to microbiological processes or the products thereof.	Inventions relating to plant (or animal) varieties have patentability, only if the technical feasibility of the invention is not confined to a particular plant (or animal) variety. See presidential Decree 321/2001, the implementation of the EU Directive 98/44 on the legal protection of biotechnological inventions (relevant Art 2 -3).  The referral document does not mention anything about G. No changes reported from GR.	
HR	Croatian Patent Act Art 6.1  EN Translation  Excluded from patent protection shall be:  1. inventions which concern animal breeds, plant varieties and essentially biological processes for the production of plants or animals, with the exception of inventions which concern non-biological and microbiological processes and products resulting from such processes, as provided for in Article 5, paragraph (4) of this Act; a microbiological process shall imply, under this Act, any process involving or performed upon or resulting in microbiological material.	Art 5.4) () An invention which concerns plants or animals shall be considered patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety and if the process for carrying out the invention is not essentially biological.  No confirmation could be obtained that similar legislative initiatives (as in PL) are under way in HR	No
HU	Hungarian Patent Act (Act XXXIII of 1995 on the protection of inventions by patents)  Art 6.4.b  EN Translation  4. The following shall not be patentable: (a) plant varieties [Article 105(a)] and animal breeds; (b) essentially biological processes for the production of plants or animals.  5. Inventions which concern plants or animals shall be	Art 6 of the Hungarian Patent Act excludes from patentability only essentially biological processes for the production of plants and animals. Hungary has no legal provision excluding the products derived from essentially biological processes from patentability.  The referral document does not mention anything about HU.  No further update available at this moment, law may change but not sure.	No

	patentable if the technical feasibility of the invention is not confined to a particular plant variety or animal breed.  ()		
E	Irish Patents Act 1992 Section 10b  A patent shall not be granted in respect of () b) a plant or animal variety or an essentially biological process for the production of plants or animals other than a micro-biological process or the products thereof.	The Irish Patents Act 1992 at present does not contain provisions which exclude plants and animals exclusively obtained by such processes.  The referral document does not mention anything about IE. No changes reported from IE.	No
IS	Icelandic Patents Act No 17/1991  Art 1  EN Translation  () A patent shall not be granted for plant or animal varieties. It is however possible to grant patents for inventions pertaining to plants and animals if the implementation of the patent is not confined for technical reasons to a particular plant or animal variety. In this Act, plant variety refers to a plant variety as it is defined in the Act on Plant Variety Rights, No. 58/2000.  A patent shall not be granted on an essentially biological process for producing plants or animals. By an essentially biological process, this Act refers to a method that on the whole is based on natural phenomena such as crossing and selection []"	The relevant provisions are almost identical to the Danish Patent Act.  The referral document does not mention anything about IS. No changes reported from IS.	No
IT	Italian Industrial Property Code (IIPC) Decreto Legislativo 10 febbraio 2005, n. 30 Codice della proprieta' industriale, a norma dell'articolo 15 della legge 12 dicembre 2002, n. 273 and further amendments Art 45.4.b  EN Translation Patentable subject matter ()	Plant varieties are clearly excluded from patent protection. The exclusion of patentability of plants is limited to plants univocally used for the production of plant varieties <u>and</u> obtained solely through essentially biologically processes.  The referral document mentions: "Article 81 quater (e) of the Italian Industrial Property Code provides since 2010: "The following may be patented provided that they meet the requirements of novelty and inventive activity and are susceptible to industrial	No

	<ul> <li>4. It cannot be a patentable subject-matter () b) plant varieties and animal breeds and essentially biological processes for production of animals or plants, including new plant varieties with respect to which the invention consists only of the genetic modification of another plant variety, even if such modification results from a process of genetic engineering.</li> <li>5. The provision of paragraph 4 shall not apply to microbiological processes and products obtained by these processes.</li> <li>As to plants or group of plants, Art 81 IIPC recites:</li> <li>Art 81-quater Patentability 1. It can be patentable, subject to fulfilment of novelty, inventive step and industrial applicability requirements: () e) an invention relating to plants or animals or a plant grouping characterized by the expression of a specific gene and not by its whole genome, provided that their application is not limited, from a technical standpoint, to the obtainment of a particular plant variety or animal species and that they are not obtained by means of essentially biological processes only, ()</li> </ul>	<ul> <li>application: e) an invention regarding plants or animals [], if their application is not limited [] to the obtainment of a specific plant variety or animal species, and they are not exclusively obtained by essentially biological processes, [] (emphasis added)." "</li> <li>This was as in NL at that time unlike the EPC in 2010 and in conflict with the interpretation of the Biotech Directive (98/44 EC)</li> <li>Position of our IT member in 2019: I confirm that based on our interpretation of Art. 81 quarter of Italian Industrial property code (IIPC), the answer is NO.</li> <li>In fact, the exclusion of patentability of plants refers to two conditions:</li> <li>1. The invention should relate to plants univocally used for the production of plant varieties and</li> <li>2. The plants are obtained solely through essentially biologically processes.</li> <li>Given that the legislator used the coordination term "and", we are of the opinion that BOTH conditions need to be fulfilled to exclude the plants from patentability.</li> </ul>	
LT	See under "CH"  Lithuanian Patent Law (Law on Patents of 18 January 1994, No. I-372 as changed on: 08 November 1994; 09 and 23 December 1997; 15 June 2000; 21 December 2000; 30 October 2001; 30 June 2005; 08 June 2006; 10 May 2007; 23 December 2010)  Art 5.1 paragraph 2)  EN Translation (available (from Consolidated version)	The referral document does not mention anything about LT. No official comments/suggestions from the officers of Lithuanian Patent Office	No No

	of May 01, 2018) of Paragraph 2 part 1 Art. 5 of Lithuanian Patent Law, to be read:  "1. The following shall be considered unpatentable: <> 2) plant or animal varietes or essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes for the production of plants or animals or the products thereof, as well as to plants or animals, if technical implementation of the invention is not restricted to a concrete plant or animal variety"		
LU	Loi du 20 juillet 1992 portant modification du régime de brevets d'invention telle que modifiée par la loi du 24 mai 1998 et par la loi du 11 août 2001 et par la loi du 7 avril 2006 et la loi du 25 avril 2008  Art 5bis  EN Translation  1. Not patentable are:  a) Plant and animal varieties  b) Essentially biological methods for obtaining plants or animals.  2. Inventions concerning plants or animals are patentable if the technical implementation of the invention is not limited to a particular plant or animal variety.  3. Paragraph 1, item b), does not affect the patentability of inventions related to a microbiological method, or to other technical methods, or to a product obtained by such methods.	The referral document does not mention anything about LU, our LU member reports no change for LU envisaged	No
LV	Patent Law of the Republic of Latvia (in force since 01.03.2007) Art. 10 (Biotechnological Inventions) EN Translation	The referral document does not mention anything about LV. No changes reported from LV.	No

	<ol> <li>A patent shall be granted to biotechnological inventions:</li> <li>1.1. containing biological material isolated from its natural environment or acquired with the help of a technical method, even if it has been previously met in nature;</li> <li>1.2 pertaining to plants or animals if the technical nature of the invention does not confine itself to some specific plant or animal variety; and</li> <li>1.3. pertaining to microbiological or other technical method or a product acquired with such a method if it is not a plant or animal variety.</li> <li>2. A patent shall not be granted to plant or animal varieties or to the basically biological methods for the acquisition of plant or animal varieties.</li> </ol>		
MC	Patent law in Monaco N°606 of June 20, 1955	There is no specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process.  The referral document does not mention anything about MC. No changes reported from MC.	No
MK	Macedonian Law on Industrial Property Art 26.1  EN Translation  A patent may not protect an invention:  1) which relates to new animal and plant varieties and essentially biological processes for the production of animals or plants, with the exception of biotechnological inventions, for which the technical feasibility is not restricted to a certain type, and microbiological processes and products generated from such processes;  ()	The referral document does not mention anything about MK. No changes reported from MK.	No
MT	Maltese Patents and Designs Act (Cap. 417 Laws of Malta) Art 4.5	The referral document does not mention anything about MT. No changes reported from MK.	No

	A patent shall not be granted in respect of: () e) plant and animal varieties: Provided that patents shall not be granted for plant varieties only after a new form of plant variety protection is introduced in such form as may be prescribed: Provided further that a patent may still be granted for a plant variety in respect of which a patent application is still pending on the date that a new form of plant variety protection is prescribed; (f) essentially biological process of the production of plants or animals: Provided that this is 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; 6. 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. ()		
NL	Dutch Patent Act 2010 (Rijksoctrooiwet 2010)  Art 3.1.d  EN Translation  No patents shall be issued for:  ()	Unlike the EPC in 2010 and in conflict with the interpretation of the Biotech Directive (98/44 EC), the Dutch Patent Act 2010 excludes from patentability plants or animals produced by essentially biological processes, even if the technical feasibility of the invention is not confined to a particular plant or animal variety.	Yes
	(c) plant or animal varieties, (d) essentially biological processes, entirely consisting of natural phenomena such as crossings and selections, for the production of plants or animals as well as the products obtained as a result thereby ()	The referral document mentions: "Already since the implementation of the EU Biotechnology Directive, Article 3(1)(d) of the Dutch Patent Act provides: "No patents shall be issued for [] essentially biological processes consisting entirely of natural phenomena such as crossing or selection in order to produce plants or animals and the products obtained thereby (emphasis added).""	
NO	The Norwegian Patents Act, no 9 of December 15, 1967 (last amending Act on July 1, 2013)  Section 1	Products obtained by microbiological or other technical processes are patentable, but the law does not say anything of products obtained by essentially biological processes.	No

### **EN Translation**

Within any technical field, any person who has made an invention which is susceptible of industrial application, or his successor in title, shall, in accordance with this Act, have the right on application to be granted a patent for the invention and thereby obtain the exclusive right to exploit the invention commercially or operationally.

Subject matters not regarded as inventions include anything which merely consists of:

- 1. discoveries, scientific theories and mathematical methods:
- 2. aesthetic creations:
- 3. schemes, rules or methods for performing mental acts, playing games or doing business, or programs for computers;
- 4. presentations of information.

Inventions may also constitute patentable inventions when they concern a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used. 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 already occurs in nature. Biological material means, for the purpose of this legal text, material that contains genetic information, and can reproduce itself or be reproduced in a biological system.

A patent cannot be granted in respect of plant or animal varieties. Inventions that concern plants or animals may, however, be patentable if usage of the patent is not technically limited to one particular plant or animal variety. The King may, by regulation, determine what should be considered a plant or an animal variety.

Also relevant is the patent regulation's definition of "plant variety"; **Section 88 Definition of plant variety** 

Under the patent act and regulation a plant variety is understood to be a stock of plant within a single botanical taxon of the lowest rank, which

- 1. Can be defined on the basis of the characteristics resulting from a given genotype or combination of genotypes,
- 2. can be distinguished from any other population of plants on the basis of the occurrence of at least one of the said characteristics, and
- 3. can be considered as a unit with regard to the ability to reproduce unchanged.

The existence of characteristics as mentioned in first paragraph no. 1, can be invariable or variable between variety constituent parts of the same kind, provided that the variation level is due to the genotype or combination of genotypes.

The referral document mentions "In NO the examination guidelines of the Norwegian Intellectual Property Office were amended in August 2017 in order to clarify that the practice is in conformity with amended Rule 28(2) EPC. The relevant part of section C - chapter IV - 2a.3.2 reads in translation: "Plants and animals that are the result of such essentially biological process are also exempted from patenting."

No changes reported from NO.

A patent cannot be granted for what are essentially biological processes to produce plants or animals. An essentially biological process means, for the purpose of this legal text, a process, which consists entirely of natural phenomena such as crossing or selection. A patent may, on the other hand, be granted for microbiological or other technical processes or for a product produced by such processes. A microbiological process means, for the purpose of this legal text, any process involving, performed upon or resulting in the production of microbiological material.

A patent shall not be granted for methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals. This provision shall not prevent the grant of patents for products, including substances and compositions of substances, for use in such methods.

Industrial Property Law (IPL), Act of 30 June 2000 (as amended)

# **EN Translation** Art. 29

- **1.** Patents shall not be granted for:
- (ii) plant varieties or animal breeds and purely biological processes for the production of plants or animals; this provision does not apply to microbiological production processes or the products obtained by the processes.
  - **2.** The process for the production of plants or animals, referred to in Art. 29.1, item ii) is purely biological if it consists entirely of natural phenomena such as

While essentially (in Polish purely) biological processes for the production No of plants varieties or animal breeds are excluded from patentability, there is no explicit exclusion of patentability of products derived from such biological processes.

Furtheremore, it is not possible to obtain a patent for a new plant variety or animal breed, irrespective of their production process, i.e. even produced by a microbiological process.

According to Article 93<sup>1</sup> of the IPL "microbiological process" means any process involving or performed upon or resulting in microbiological material.

As plant varieties or animal breeds are excluded from the patent protection, the processes for production of plant varieties or animal breeds do not protect indirectly products obtained directly by the

	crossing or selection.	processes according to Art. 64 of the IPL:	
		Article 64 A patent granted for a process of manufacture shall also cover products directly obtained by means of that process.	
		However, in accordance with Art. 93 <sup>2</sup> of the IPL biotechnological inventions directed to plants or animals not restricted to a single plant variety or animal breed are patentable: <b>Art. 93<sup>2</sup>. 1</b> The following, in particular, shall be considered as biotechnological inventions eligible for granting a patent protection:  ()  3) inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety.  However, the law does not exclude a possibility of obtaining a patent for processes for the production of new plant varieties or animal breeds (not purely biological), despite the fact that they lead to production of new	
		purely biological), despite the fact that they lead to production of new varieties or breeds.	
		The referral document mentions that: "In PL the legislator is discussing an amendment of Article 29(1) item 2 of the Polish Industrial Property Act to read: "Patents shall not be granted for: [] essentially biological methods of breeding plants or animals, as well as products obtained by these methods (emphasis added)."".	
		No changes available yet for PL.	
PT	[From 01.07.2019] Portuguese Industrial Property Code (IPC) - Decree-Law 110/2018 of 10 December 2018)	The referral document mentions: "In PT Article 52(3)(B) of the Código da Propriedade Industrial has been amended with effect from 1 July	Yes

The new Portuguese IP code entering in force on 01.07.2019 will explicitly prohibit the protection for plants or animals exclusively obtained by means of an essentially biological process.

Art 52 Limitations regarding patents (...)

3. The following shall also not be the subject matter of a patent:

(...)

c) Plant and animal varieties and essentially biological processes for obtaining plants or animals, and plants or animals exclusively obtained by such processes.

(...)

Art 53 Special cases of patentability

1. The following shall be patentable:

(...)

(...)

- d) Without prejudice to paragraph b) of paragraph 3 of the preceding article, an invention having as its object vegetable or animal, if its technical feasibility is not confined to a particular plant or animal variety;
- e) A biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature;
- f) An invention having as its object a microbiological process or other technical processes, or products obtained by such processes.
- 2. It is understood by essentially biological process of obtaining plants or animals, any process which consists entirely of natural phenomena, such as crossing or

2019: "No patents shall also be granted for [...] essentially biological processes for the production of plants or animals and the plants or animals obtained exclusively by means of such processes (emphasis added).""

	selection.		
RO	Romanian Patent Law 64/1991  Art 9.b  EN Translation  Patents shall not be granted under this Law in respect of: () b) plant varieties and animal breeds, as well as the essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes or products obtained thereby; ()	Art 7 - A patent shall be granted for any invention having as a subject- matter a product or a process, in all technological fields, provided that it is new, involves an inventive step and is susceptible of industrial application. Inventions in the field of biotechnology shall be patentable if they relate to: () b) plants or animals, if the technical feasibility of the invention is not limited to a particular plant variety or animal breed; c) a microbiological process or other technical process or a product, other than a plant variety or animal breed, obtained by means of said process.	No
RS	Serbian Patent Law (Issued in "Official Gazette of the Republic of Serbia", no. 99/11, dated December 27 <sup>th</sup> 2011); in force since January 4 <sup>th</sup> , 2012  Art 9.3  EN Translation  Exceptions to Patentability  A patent shall not be granted in respect of: ()  3. a plant or animal variety or an essentially biological process for the production of a plant or animal, provided that this provision shall not apply to microbiological processes or the products obtained by means of such process. ()  Essentially biological process referred to in item 3) of this Article for the production of plants or animals is a process	No change envisaged in Romania according to our member  No change envisaged in Serbia according to our member	No

	consisting entirely of natural phenomena such as crossing or selection.		
SE	The Patents Act (Swedish Statute Book, SFS, 1967:837, in the version in force from July 1, 2014)  Article 1 a	Under Swedish law, there is no provision excluding products derived from essentially biological processes.	No
	EN Translation	The referral document does not mention anything about SE. No changes envisaged in SE.	
	Patents are not granted in respect of plant varieties or		
	animal breeds. A patent may, however, be granted in		
	respect of an invention that relates to plants or animals if		
	the technical feasibility of the invention is not confined to a		
	particular plant variety or animal breed. The concept of a		
	plant variety is defined in Chapter 1, Article 3, of the Act on		
	the Protection of Plant Varieties Rights (Act 1997:306).		
	Patents shall not be granted in respect of essentially		
	biological processes for the production of plants or		
	animals.		
	()		
	A patent may, however, be granted for an invention that		
	concerns a microbiological process or another technical		
	process or a product obtained by means of such a		
	process.		
	()		
	An invention may be patentable even if it concerns a		
	product consisting of or containing biological material or a		
	process through which biological material is being produced, processed or used. A 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 occurs in nature.		
	()		
	(Act 2004:159).		
SI	Intellectual Property Act	The referral document mentions: "	No
	Art 16		' '

SK	EN Translation Subject-matter of short-term patent protection (1) With the exception of processes, plant varieties and animal breeds, a short-term patent may be granted for inventions which are new, susceptible of industrial application and are the result of a creative effort.  Slovak Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts	No confirmation could be obtained that similar legislative initiatives (as in PL) are under way in SI.  Art 3 Definition of terms For purposes of this Act	No
	as Amended (The Patent Act) Art 6.1  EN Translation Exceptions to patentability 1. Patents shall not be granted to a) plant and animal varieties, b) essentially biological processes for creation plants or animals, ()	() c) essentially biological process for creation plants or animals shall mean a process based exclusively on natural phenomena such as breeding or selection, ()  Article 5 Patentability of inventions 1. Patents shall be granted for inventions from all fields of technology, which are new, involve inventive activity and are industrially applicable. 2. Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilised, including cases when invention relates to () b) a plant or an animal, if a technical feasibility of an invention is not reduced to a particular plant or animal variety (Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety), ()  The referral document does not mention anything about SK. No changes reported for SK.	
SM	Industrial Property Consolidation Act of the Republic of San Marino, Law n. 79 of 25 May 2005  Art 2.4	The wording excluding plants and animals exclusively obtained by such processes present in DE and NL law is not present in San Marino Act	No

	EN Translation (Subject-matter of the patent and exclusions from patentability) 4. The following inventions are not patentable: () c) inventions concerning animal varieties or essentially biological processes for the production of animals varieties; this provision shall not apply to microbiological processes and the products thereof; () 5. An essentially biological process means a process, which consists entirely of natural phenomena such as crossing or selection.	The referral document does not mention anything about SM. No changes reported for SM.	
TR	Industrial Property Law 6769 (Enactment Date:22.12.2016; in force since 10.01.2017)  Patentable inventions and exceptions to patentability  Article 82- () (3) Patent shall not be granted for the following inventions:  a) Inventions against public order or morality. b) Plant or animal varieties or essentially biological processes for the production of plants or animals, excluding microbiological processes or the products thereof; () (5) Microbiological process mentioned in subparagraph (b) of paragraph three means any process involving or performed upon or resulting in microbiological material; essentially biological process means the	Articles 82(3)(b-d) and (5) of the new IP Code includes non-patentable biotechnological inventions to bring the law in line with the provisions of the EPC. Concerning the plant varieties, previous law was also excluding the patentability of plant varieties therefore nothing has changed in that matter.  Currently there is no National Court decision regarding the patentability of plant varieties.  The referral document does not mention anything about TR. No further changes reported in TR.	No

production of plants or animals consisting entirely of natural phenomena such as crossing or selection.

(...)