

Patentability of Plants

Committee on Biotechnological Inventions

A Comparison of National Laws

On 25 March 2015, the Enlarged Board of Appeal of the EPO rendered its decisions in the highly debated Broccoli II (G 2/13) and Tomatoes II (G2/12) cases. The proceedings for these cases had been consolidated.

The decisions concerned the interpretation of Article 53(b) EPC concerning exceptions to patentability, which states that "European patents shall not be granted in respect of 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."

The Enlarged Board of Appeal had previously interpreted the term "essentially biological processes for the production of plants" with regard to plant breeding methods in its decisions of 9 December 2010 in the Broccoli I (G 2/07) and Tomatoes I (G 1/08) cases.¹

The main question in the present disputes was whether the exception of essentially biological processes for the production of plants in Article 53 (b) EPC extends to product claims, including product-by-process claims²

The **epi** Committee on Biotechnological Inventions had argued in an elaborate amicus curiae brief on case G 2/13 that, for various reasons, the exclusion of essentially biological processes for the production of plants in Article 53 (b) EPC cannot have any negative effect on the allowability of a product claim directed to plants or plant material. The amicus curiae brief is available for consultation on the **epi** website.

The **epi**'s view was shared by the Enlarged Board of Appeal, which emphasised the distinction between a product claim, including a product-by-process claim, on the one hand, and a process claim, on the other hand.³ After applying the relevant methods of interpretation, the Enlarged Board came to the intermediate conclusion that the term "essentially biological processes for the production of plants" does not extend to products defined or obtained by such processes.⁴ Interestingly, the Enlarged Board did not stop there, but continued by asking whether secondary considerations necessitate a broader interpretation of the scope of the process exclusion.⁵ However, it concluded that a dynamic inter-

pretation is not required in this regard. Nor is a broadening of the process exclusion justified for reasons of threat of legal erosion of the process exclusion.⁶ The Enlarged Board made clear that the current issues concern patentability in terms of subject matter, which must be distinguished from the effect of the patent with regard to its scope of protection after grant.⁷ Though being aware of the numerous ethical, social and economic aspects at stake, the Enlarged Board stressed its role as a judicial body, which does not interfere in legislative decisions.⁸ To the referred questions in case G 2/13 (very similar to those in G 2/12), the Enlarged Board answered that:

"1. The exclusion of essentially biological processes for the production of plants in Article 53 (b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts.

2. (a) The fact that the process features of a product-by-process claim directed to plants or plant material other than a plant variety define an essentially biological process for the production of plants does not render the claim unallowable.

2. (b) The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.

3. In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53 (b) EPC."⁹

Already before the decisions of the Enlarged Board of Appeal, a few countries had adapted their legislation in order to exclude from patentability product claims where the claimed products have been generated by an essentially biological process for the production of plants. The **epi** Committee on Biotechnological Inventions has created the following overview of the national laws of the 38 EPC Contracting States in this regard.¹⁰

1 See Broccoli I (G 2/07, OJ EPO 2012, 230); and Tomatoes I (G 1/08, OJ EPO 2013, 206).

2 directed to plants or plant material.

3 See G 2/13, IV. Legal nature of the claimed invention, points 2–6.

4 See G 2/13, VII. Application of the rules of interpretation, 6. First intermediate conclusions, point 1.

5 See G 2/13, VIII. Need for secondary considerations, point 1.

6 See G 2/13, VIII. Need for secondary considerations, 3. Second intermediate conclusions.

7 See G 2/13, VIII. Need for secondary considerations, 2. Legal erosion of the exception to patentability, point 6 (b).

8 See G 2/13, VIII. Need for secondary considerations, 2. Legal erosion of the exception to patentability, point 6 (c).

9 See G 2/13, Order.

10 The contributions regarding the national laws have been made by **epi** members of the Committee on Biotechnological Inventions and by **epi** Board members.

National Laws on the Patentability of Plants

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?

No	36
Yes	2

MS	National Law / EN translations	Remarks	Q
AL	<p>Law No. 9947 of 7 July 2008 Art. 6.2</p> <p>EN Translation <i>Exceptions to patentability</i> 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 obtained by means of such a process.</p>	<p>Art. 5.5 (c)</p> <p><i>Art. 5 Patentable Inventions</i> 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.</p>	No
AT	<p>Patentgesetz 1970 BGBl. 1970/259 idF BGBl. I 2013/126 (Patentgesetz) § 2(2) Patentgesetz § 2. Patente werden nicht erteilt für: (2) Patente werden nicht erteilt für Pflanzensorten oder Tierrassen sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren. (...)</p> <p>EN Translation <i>Patents shall not be granted for plants and animal varieties and for essentially biological processes for breeding plants and animals. [...]</i></p>	<p>Products derived from essentially biological processes can be patented.</p>	No
BE	<p>The Belgian Code of Economic law provides: 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. § 2. 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 1 er, 2°, n'affecte pas la brevetabilité d'inventions ayant pour objet un procédé microbiologique, ou d'autres procédés techniques, ou un produit obtenu par ces procédés.</p> <p>EN Translation Art. XI.5. § 1. <i>Shall be excluded from patentability:</i> (1) <i>plant and animal varieties;</i> (2) <i>essentially biological processes for the production of plants or animals.</i> § 2. <i>The inventions relating to plants and animals are patentable if the technical feasibility is not limited to a particular plant or animal variety.</i> § 3. <i>The paragraph 1, (2) shall not apply to microbiological processes or to the products obtained by such processes.</i></p>	<p>The patentability of plants is discussed in Art. XI.5. of the new Belgian Code of Economic law of which book XI entered into force on 1 January 2015.</p>	No

MS	National Law / EN translations	Remarks	Q
BG	<p>Bulgarian Patent Law Art. 7 (1)</p> <p>EN Translation <i>Exceptions to Patentability</i> (1) Patents shall not be granted for: (...) 3. plant varieties or animal varieties; 4. essentially biological processes for obtaining plants and animals.</p>	<p>Patentability of biotechnological inventions is set in Art. 7 a (3): <i>Inventions relating to plants or animals shall be considered patentable, if the technical realisation of the invention is not reduced to a certain plant or animal variety.</i></p>	No
CH	<p>Bundesgesetz über die Erfindungspatente (Patentgesetz, PatG) vom 25. Juni 1954 Art. 2(2)b Art. 2(2)b PatG Von der Patentierung sind ferner ausgeschlossen: [...] b. Pflanzensorten und Tierrassen und im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren; unter Vorbehalt von Absatz 1 patentierbar sind jedoch mikrobiologische oder sonstige technische Verfahren und die damit gewonnenen Erzeugnisse sowie Erfindungen, deren Gegenstand Pflanzen oder Tiere sind und deren Ausführung technisch nicht auf eine bestimmte Pflanzensorte oder Tierrasse beschränkt ist.</p> <p>EN Translation [Excluded from patentability are:] b. Plant and animal varieties and essentially biological processes for the production of plants and animals; however, subject to the provisions of paragraph 1 microbiological or other technical processes and the products obtained thereby are patentable and so are inventions relating to plants or animals provided that the working of said inventions is not technically confined to a specific plant or animal variety.</p>	<p>An essentially biological process that comprises at least one non-biological, technical step that is required for arriving at the desired solution (e.g. irradiation, temperature shock), will be patentable and so will be the products obtained by that process.</p> <p>Swiss patent law is clear as to the non-patentability of essentially biological processes but is somewhat silent as to the patentability of products obtained by essentially biological processes. From the wording of Art. 2 (2)b PatG, last half-sentence (emphasized in bold letters), it may be inferred, however, that it was not the legislator's intention to exclude novel and inventive products from protection solely because they have been obtained by essentially biological processes. This view seems to be confirmed by the federal court decision BGE 121 III 125 (1995), <i>Asta Medica vs Lendi</i>, which also emphasizes patentability of plant product inventions as long as they are not confined to specific plant varieties. This understanding is also mirrored by the examination guidelines wherein patentability of products obtained by essentially biological processes is not excluded although not explicitly stated either.</p> <p>In essence, the goal of the Swiss legislator is to avoid double protection of plant inventions by both the plant varieties protection act and the patent law.</p>	No
CY	<p>Patent Act of 1998 (Law 16(I)/98, as amended by Laws 21(I)/99, 153(I)/2000, 163(I)/2002 and 163(I)/2002). Article 5a</p> <p>EN Translation <i>Essentially biological processes for the production of 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 product that is a result of such methods.</i></p>	<p>The Biotech Directive (98/44) has been implemented in Cyprus law, as an amendment to the Patent Act of 1998.</p>	No
CZ	<p>Law No. 527/1990 Coll. on Inventions and Rationalisation Proposals (Patent Law) Section 4.b</p> <p>EN Translation <i>Exclusions from patentability</i> <i>Patents shall not be granted in respect of:</i> (...) <i>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.</i></p>	<p>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.</p> <p>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".</p>	No

MS	National Law / EN translations	Remarks	Q
DE	<p>Patentgesetz in der Fassung der Bekanntmachung vom 16. Dezember 1980 (BGBl. 1981 I S. 1), das zuletzt durch Artikel 1 des Gesetzes vom 19. Oktober 2013 (BGBl. I S. 3830) geändert worden ist</p> <p>§ 2 a (1)1 Patentgesetz <i>Patente werden nicht erteilt für</i> <i>1. Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren und <u>die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere;</u></i></p> <p>EN Translation <i>Patents shall not be granted for</i> <i>1. plant or animal varieties or for essentially biological processes for the production of plants or animals <u>and plants and animals exclusively obtained by such processes;</u></i></p> <p>(The underlined part has recently been added to the German provision. The amendment entered into force on 25 October 2013)</p>	<p><i>Bundestagsdrucksache 17/14222 regarding No. 1 (Amendment of Section 2a of the Patent Act – PatG):</i></p> <p><i>With this supplementation to Section 2a Subsection 1 Number 1 PatG, it will be clarified that, with regard to essentially biological processes for the production of plants and animals, <u>not only the processes but also plants and animals produced by such processes are not patentable, even if they are no plant or animal varieties which are anyhow excluded from patentability under Section 2a Subsection 1 Number 1 PatG.</u> The current version of this stipulation literally adopted Article 4 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ([...] – Biopatent Directive). In this respect, the Enlarged Board of Appeal of the European Patent Office determined in its decision concerning patent cases “broccoli” and “tomato” (G2/07 and G1/08) of December 9, 2010 that the mere use of technical process steps for performing or supporting essentially biological processes do not render the processes patentable. However, in its decision, the Enlarged Board of Appeal does not deal with the question of the patentability of products in the form of animal and plants produced by such animal- or plant related processes. The Federal Government is of the opinion that, according to the object and purpose of Article 4 of the Biopatent Directive, the patentability exclusion should mandatorily also apply to such animals and plants. The non-patentability of conventional breeding processes could otherwise be easily circumvented. In the interest of breeders and farmers, it shall therefore be clarified that plants and animals which immediately arise from their conventional breeding should not be covered by patents of third parties having generic product claims. The potential to obtain patent protection by the German industry – especially the chemical and pharmaceutical industry – should, however, not come restricted by anything going beyond the intention of this clarification. Products derived from biologically bred animals or plants, such as plant oils, should remain patentable provided they comply with the other patentability requirements. Only with a formulation which clearly relates the patentability exclusion of processes and products to the same matter, i.e. “plants and animals”, it will be possible to comply with the available scope for national regulations defined by the EU-Biopatent Directive which is particularly restricted to clarifications. In this context, the terms “plants and animals” do not only cover the produced animals and plants, but also material, such as seed, or in connection with animals, sperm, ovules and embryos, which is obtained by conventional biological processes and is useful for the production of plants and animals. The use of the term “exclusively” shall safeguard that undisputable patentable, especially genetically modified plants and animals will not be covered by the patentability prohibition because of the fact that they additionally underwent an essentially biological crossing and selection process.</i></p>	Yes
DK	<p>Patents Act, cf. Consolidate Act No. 91 of 28 January 2009 LBK nr 91 af 28/01/2009 Gældende (Patentloven)</p> <p>Section 1(4)-1(6)</p> <p>EN Translation <i>(4) Patents shall not be granted in respect of plant or 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.</i></p>	<p>The Danish patent law seems to be more “liberal” than the German law, and also slightly more than the Dutch law. This section was amended in the implementation of the Biotech Directive.</p>	No

MS	National Law / EN translations	Remarks	Q
	<p>(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.</p> <p>(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.</p>		
EE	<p>Estonian Patent Act of March 16, 1994 Art. 7</p> <p>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 micro-organisms; 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.</p>		No
ES	<p>Law No. 11/1986 of March 20, 1986 on Patents <i>Ley 11/1986, de 20 de marzo de 1986, por la que se aprueba la Ley Patentes y Modelos de Utilidad</i> Art. 5.3</p> <p>EN Translation Non-patentable subject matter are: 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.</p> <p>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.</p>	<p>Art. 5.3 of the Spanish Patent Law excludes essentially biological processes but <u>not</u> the products.</p> <p>There is a proposal for changing the Spanish patent law in the near future, but this provision will not be amended.</p>	No
FI	<p>Finnish Patents Act, No. 550 of December 15, 1967 Chapter 1, Section 1 as amended 30.6.2000/650 and 18.11.2005/896</p> <p>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). (...) 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 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.</p>	<p>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.</p> <p>The Biotech Directive was implemented to Finnish Patents Act by amendment which entered into force on 30th 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.</p>	No

MS	National Law / EN translations	Remarks	Q
	<p><i>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.</i></p> <p><i>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.</i></p>		
FR	<p>French Intellectual Property Code (CPI) Art L611-19</p> <p>EN Translation <i>The following shall not be patentable:</i> 1° animal varieties; 2° plant varieties as defined in Article 5 of Regulation (EC) No. 873/2004 introducing new rules governing intellectual property ownership of Community plant variety rights; 3° 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.</p>	<p>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)).</p> <p>The new provisions recognize that biological material (i.e., any material containing genetic information and capable of reproducing itself or being 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).</p> <p>On July 7, 2015, the French IPO published a Communication stating that pursuant to the provisions of article L-611-19, the exclusion of essentially biological processes from patentability extends to the results of such processes, i.e. extend to plants obtained by performing such processes, even when said plants are not varieties. As a consequence and according to this Communication, the French IPO will refuse national French patent applications that would be directed to crossing and selection processes to obtain plants or directed to plants obtained by crossing and selection.</p> <p>Up to date there is no case law in France with respect to the patentability of plants or plant material product claims, wherein the plants or plant materials are produced by an essentially biological non-patentable process.</p>	No
GB	<p>UK Patents Act 1977 Section 76A and Schedule A2</p> <p><i>76A Biotechnological inventions</i> <i>(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.</i> <i>(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.</i> SCHEDULE A2 BIOTECHNOLOGICAL INVENTIONS <i>(...)</i></p>	<p>Section 76A and Schedule A2 of the UK Patent Act excludes from 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.</p>	No

MS	National Law / EN translations	Remarks	Q
	<p>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.</p> <p>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.</p> <p>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; (...)</p>		
GR	<p>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</p> <p>EN Translation Patents shall not be granted in the following cases: b. plant or animal varieties or biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.</p>	<p>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 there from. 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. 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).</p>	No
HR	<p>Croatian Patent Act Art. 6.1</p> <p>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.</p>	<p>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.</p>	No
HU	<p>Hungarian Patent Act (Act XXXIII of 1995 on the protection of inventions by patents) Art. 6.4.b</p> <p>EN Translation</p> <p>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.</p> <p>5. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety or animal breed. (...)</p>	<p>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.</p>	No
IE	<p>Irish Patents Act 1992 Section 10b</p> <p>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.</p>	<p>The Irish Patents Act 1992 at present does not contain provisions which exclude plants and animals exclusively obtained by such processes.</p>	No

MS	National Law / EN translations	Remarks	Q
IS	<p>Icelandic Patents Act No 17/1991 Art. 1</p> <p>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 [...]"</p>	<p>The relevant provisions are almost identical to the Danish Patent Act.</p>	No
IT	<p>Italian Industrial Property Code (IIPC) <i>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</i> Art. 45.4.b</p> <p>EN Translation <i>Patentable subject matter</i> (...) 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. 5. The provision of paragraph 4 shall not apply to micro-biological processes and products obtained by these processes.</p> <p>As to plants or group of plants, Art. 81 IIPC recites:</p> <p><i>Art. 81-quater Patentability</i> 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, (...)</p>	<p>Plant varieties are clearly excluded from patent protection.</p> <p>Then exclusion of patentability of plants is limited to plants univocally used for the production of plant varieties <u>and</u> obtained solely through essentially biological processes.</p>	No
LI	See under "CH"		No
LT	<p>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)</p> <p>EN Translation <i>Patents should not be granted for</i> (...) 2) plant or animal varieties or essentially biological methods for obtaining thereof. <i>This provision does not apply to microbiological production methods of plants or animals and to the products obtained by such methods, in case the technical implementation of the invention is not limited to a particular plant or animal variety.</i></p>	<p>What is emphasized in bold appeared as from 30/06/2005.</p>	No

MS	National Law / EN translations	Remarks	Q
LU	<p>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</p> <p>Art. 5 bis</p> <p>EN Translation</p> <p>1. Not patentable are:</p> <p>a) Plant and animal varieties</p> <p>b) Essentially biological methods for obtaining plants or animals.</p> <p>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.</p> <p>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.</p>		No
LV	<p>Patent Law of the Republic of Latvia (in force since 01.03.2007)</p> <p>Art. 10 (Biotechnological Inventions)</p> <p>EN Translation</p> <p>1. A patent shall be granted to biotechnological inventions:</p> <p>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;</p> <p>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</p> <p>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.</p> <p>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.</p>		No
MC	<p>Patent law in Monaco N°606 of June 20, 1955</p>	<p>There is no specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process.</p>	No
MK	<p>Macedonian Law on Industrial Property</p> <p>Art. 26.1</p> <p>EN Translation</p> <p>A patent may not protect an invention:</p> <p>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;</p> <p>(...)</p>		No
MT	<p>Maltese Patents and Designs Act (Cap. 417 Laws of Malta)</p> <p>Art. 4.5</p> <p>A patent shall not be granted in respect of: (...)</p> <p>e) plant and animal varieties:</p> <p>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:</p> <p>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;</p> <p>(f) essentially biological process of the production of plants or animals:</p> <p>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;</p> <p>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.</p> <p>(...)</p>		No

MS	National Law / EN translations	Remarks	Q
NL	<p>Dutch Patent Act 2010 (Rijksoctrooiwet 2010) Art. 3.1.d</p> <p>EN Translation <i>No patents shall be issued for:</i> (...) (c) <i>plant or animal varieties,</i> (d) <i>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 there by (...)</i></p>	<p>Unlike the EPC and in conflict with 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</p>	Yes
NO	<p>The Norwegian Patents Act, no 9 of December 15, 1967 (last amending Act on July 1, 2013) Section 1</p> <p>EN Translation <i>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.</i> <i>Subject matters not regarded as inventions include anything which merely consists of:</i> 1. <i>discoveries, scientific theories and mathematical methods;</i> 2. <i>aesthetic creations;</i> 3. <i>schemes, rules or methods for performing mental acts, playing games or doing business, or programs for computers;</i> 4. <i>presentations of information.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><u><i>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.</i></u></p> <p><i>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.</i></p>	<p>Products obtained by microbiological or other technical processes are patentable, but the law does not say anything of products obtained by essentially biological processes.</p> <p>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 tax on of the lowest rank, which</p> <ol style="list-style-type: none"> 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. <p>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.</p>	No

MS	National Law / EN translations	Remarks	Q
PL	<p>Industrial Property Law (Law of June 30, 2000 on Industrial Property (as last amended by Law of 23 January 2004, and Law of June 29, 2007))</p> <p>Art. 29</p> <p>EN Translation <i>Patents shall not be granted for: (...)</i> 2) <i>plant varieties or animal breeds as well as purely biological processes of or animals breeding; this provision does not apply to microbiological processes for breeding or products obtained by these processes.</i> 2. <i>A process for plants or animals breeding referred to in Art. 29.1. is purely biological if it consists entirely of crossing, selection or other natural phenomena.</i></p>	<p>While essentially biological processes of plants or animals production are excluded from patentability, there is no explicit exclusion of patentability of products derived from essentially biological processes.</p> <p>Furthermore, biotechnological inventions directed to plants or animals other than strictly plant variety or animal breed are patentable. I.e.:</p> <p><i>Art. 93.1. Patentable biotechnological inventions are in particular: (...)</i> 3) <i>inventions relating to plants or animals if technical feasibility of the invention is not confined to a particular plant variety or animal breed.</i></p>	No
PT	<p>Portuguese Industrial Property Code (IPC) – (approved by Decree-Law 36/2003 of 5 March and amended by Decree-Law 318/2007 of 26 September, Decree-Law 360/2007 of 2 November, Decree-Law 143/2008 of 25 July and Law 16/2008 of 1 April)</p> <p>Art. 53.3.b</p> <p>EN Translation <i>Limitations regarding patents</i> 3. <i>The following shall also not be the subject matter of a patent: (...)</i> b) <i>Plant or animal varieties, as well as essentially biological processes for the production of plants or animals; (...)</i></p> <p><i>Art. 54 Special cases of patentability</i> 1. <i>The following shall be patentable: (...)</i> d) <i>An invention concerning plants or animals, if its technical feasibility is not confined to a particular plant or animal variety;</i> e) <i>A biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature;</i> f) <i>An invention concerning a microbiological process or other technical processes, or products obtained by means of such processes.</i> 2. <i>An essentially biological process for the production of plants or animals means any process consisting entirely of natural phenomena such as crossing or selection. (...)</i></p>	<p>These matters are set forth in greater detail in the “<i>Guide to Procedures concerning Technological Rights</i>”, published by INPI, which states as follows:</p> <p><i>5.2.1. Plant varieties</i> <i>The term “plant variety” is defined in Rule 26(4) EPC. A patent will not be granted if the material claimed is directed to a specific plant variety or to specific plant varieties. However, if the invention relates to plants and animals and if the technical feasibility of the invention is not confined to a particular plant or animal variety, the invention is patentable (see IV, 3.2) [Rule 26(4), Rule 27(b) EPC].</i> <i>When a claim to a process for the production of a plant variety is examined, Article 97(2) IPC (Article 64(2) EPC) shall not be taken into consideration (see G1/98, OJ 3/2000, 111). Therefore, a claim to a process for the production of a plant variety (or plant varieties) is not a priori excluded from patentability simply because the resulting product constitutes or may constitute a plant variety.</i></p> <p><i>5.2.2. Processes for the production of plants or animals</i> <i>A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. To give some examples, a method of crossing, interbreeding or selectively breeding, say, horses, involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth, e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also IV, 4.8.1) [Rule 26(5) EPC].</i></p>	No
RO	<p>Romanian Patent Law 64/1991</p> <p>Art. 9.b</p> <p>EN Translation <i>Patents shall not be granted under this Law in respect of: (...)</i> b) <i>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; (...)</i></p>	<p>Art. 7.b-c</p> <p><i>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.</i> <i>Inventions in the field of biotechnology shall be patentable if they relate to: (...)</i> b) <i>plants or animals, if the technical feasibility of the invention is not limited to a particular plant variety or animal breed;</i> c) <i>a microbiological process or other technical process or a product, other than a plant variety or animal breed, obtained by means of said process.</i></p>	No

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RS	<p>Serbian Patent Law (Issued in "Official Gazette of the Republic of Serbia", no. 99/11, dated December 27th 2011); in force since January 4th, 2012</p> <p>Art. 9.3</p> <p>N Translation <i>Exceptions to Patentability</i> 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 consisting entirely of natural phenomena such as crossing or selection.</p>		No
SE	<p>The Patents Act (Swedish Statute Book, SFS, 1967:837, in the version in force from July 1, 2014)</p> <p>Article 1 a</p> <p>EN Translation <i>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.</i> (...) <i>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.</i> (...) <i>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.</i> (...) (Act 2004:159).</p>	Under Swedish law, there is no provision excluding products derived from essentially biological processes.	No
SI	<p>Intellectual Property Act</p> <p>Art. 16</p> <p>EN Translation <i>Subject-matter of short-term patent protection</i> (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.</p>		No
SK	<p>Slovak Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (The Patent Act)</p> <p>Art. 6.1</p> <p>EN Translation <i>Exceptions to patentability</i> 1. Patents shall not be granted to a) plant and animal varieties, b) essentially biological processes for creation plants or animals, (...)</p>	<p><i>Art. 3 Definition of terms</i> For purposes of this Act (...) c) essentially biological process for creation plants or animals shall mean a process based exclusively on natural phenomena such as breeding or selection, (...)</p>	No

MS	National Law / EN translations	Remarks	Q
		<p><i>Article 5</i> <i>Patentability of inventions</i> 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), (...)</p>	
SM	<p>Industrial Property Consolidation Act of the Republic of San Marino, Law n. 79 of 25 May 2005 Art. 2.4</p> <p>EN Translation <i>(Subject-matter of the patent and exclusions from patentability)</i> 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.</p>	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
TR	<p>Turkish Decree Law 551 Art. 6</p> <p>EN Translation <i>(Non-Patentable subject matter and Inventions)</i> (...) Patent shall not be granted for inventions in respect of following subject matter. b) Plant or animal varieties/species or processes for breeding/ plant or animal varieties/species, based mainly on biological grounds.</p>		No

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