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### **Commission Notice**

**on certain articles of Directive 98/44/EC of the European Parliament and of the Council  
of 6 July 1998 on the legal protection of biotechnological inventions**

## INTRODUCTION

Directive 98/44/EC on the legal protection of biotechnological inventions<sup>1</sup> (‘the Directive’) harmonises national law on the patentability of inventions relating to biological material. To this end, it sets out principles regarding the patentability of the human body and its parts, of animals and of plants.

The process leading to the adoption of the Directive lasted for more than 10 years, during which time the initial proposal<sup>2</sup>, dating from 1988, was rejected by the European Parliament in early 1995<sup>3</sup>. The Commission submitted a new proposal in December 1995<sup>4</sup>, allowing the EU co-legislators (‘the legislator’) to reach an agreement in early 1998, notably on patentable subject matter for such inventions and the scope of protection.

The Directive covers many different categories of biological materials, ranging from elements isolated from the human body, to plants<sup>5</sup> and animals, and to plant breeding (including the patentability of genetically modified organisms). Since the late 1990s, there has been significant technological progress in the plant sector, through the introduction of gene markers<sup>6</sup> in the crossing and selection of new plants/plant varieties. These markers allow for far more rapid — and improved — results than could be achieved with the classical techniques of selecting and crossing plants. As gene markers were only in the process of being developed when the Directive was adopted, it did not specifically address the issue of the patentability of the products emanating from the use of gene markers.

In March 2015, the Enlarged Board of Appeal (‘the Enlarged Board’) of the European Patent Office (‘the EPO’) decided that products derived from using essentially biological processes might be patentable, even if the process used to obtain the product (i.e. selecting and crossing the plants) is essentially biological and thus not patentable<sup>7</sup>. However, the patentability of such products runs into potential conflict with the legal protection provided to plant varieties under EU plant variety legislation as regards access to genetic resources<sup>8</sup>.

In December 2015, the European Parliament adopted a Resolution which asked the Commission to look into the patentability of products derived from essentially biological processes; the issue of cross-licensing between patents and plant variety rights; and access to deposited biological material, possibly by means of interpretative guidelines<sup>9</sup>. For its part, the

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<sup>1</sup> Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13.

<sup>2</sup> COM(88) 496, OJ C 10, 13.1.1989, p. 3.

<sup>3</sup> OJ C 68, 20.3.1995, p. 15.

<sup>4</sup> COM(1995) 661 of 13.12.1995, OJ C 296, 8.10.1996, p. 4.

<sup>5</sup> As regards plants, the main focus of the negotiations leading to the adoption of the Directive was the patentability of GMOs (where a specific gene is introduced in a plant, conferring to that plant the quality attached to the gene). While the Directive does not address regulatory aspects such as the commercialisation of these products within the EU, it laid down that such GMOs could be patented if patentability criteria were met, since they are *per se* biological material.

<sup>6</sup> A genetic marker is a gene or DNA sequence with a known location on a chromosome that can be used to identify individuals or species and their characteristics (specific traits). It can be described as a variation (which may arise due to mutation or alteration in the genomic loci) that can be observed.

<sup>7</sup> OJ EPO 2016, A27 (G 2/12) and A28 (G 2/13).

<sup>8</sup> Article 15 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, 1.9.1994, p. 1.

<sup>9</sup> P8\_TA-PROV(2015)0473: European Parliament Resolution of 17.12.2015 on patents and plant breeders’ rights, 2015/2981(RSP).

Council considered the matter at various meetings of the Agriculture and Fisheries<sup>10</sup> and Competitiveness<sup>11</sup> Councils. In addition, the Netherlands Presidency hosted, in cooperation with the Commission, a Symposium on 18 May 2016<sup>12</sup>. The consensus among stakeholders at that Symposium was for rapid and pragmatic solutions to address the identified legal uncertainty. Prior to the Symposium, the final report of the expert group on biotechnology and genetic engineering was published<sup>13</sup>.

In view of the above, this Notice sets out the Commission's views on the patentability of products emanating from essentially biological processes (addressed in Article 4 of the Directive). It also touches upon the issues of compulsory cross-licensing between plant variety rights and patents holders (addressed in Article 12) and access to biological material by a third party (addressed in Article 13). The Notice is intended to assist in the application of the Directive, and does not prejudice any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to interpret Union law.

In addition to this Notice, measures by the relevant actors could also be pursued to help bring greater certainty to this field. These comprise improved transparency (through the PINTO database<sup>14</sup>), access to genetic resources (through the International Licensing Platform<sup>15</sup>), and strengthened cooperation between the Community Plant Variety Office and the European Patent Office.

## **1. EXCLUSION FROM PATENTABILITY OF PRODUCTS OBTAINED BY ESSENTIALLY BIOLOGICAL PROCESSES**

### **1.1. ISSUES AT STAKE**

Article 4 of the Directive addresses the patentability of plants and animals, specifically excluding plant and animal varieties from the scope of patentable subject matter<sup>16</sup>. It also establishes that 'essentially biological processes for the production of plants and animals' are not patentable<sup>17</sup>. Article 2 of the Directive defines an essentially biological process as consisting entirely of natural phenomena such as crossing and selection<sup>18</sup>. However, the Directive does not state whether plants or plant material (fruits, seeds, etc.), or animals/animal material obtained through essentially biological processes, can be patented.

Even though the European Patent Organisation was not obliged *per se* to transpose the main provisions of the Directive into its legal corpus, nevertheless on 16 June 1999 its Administrative Council decided to amend the European Patent Convention's ('EPC') implementing rules in this sense<sup>19</sup>. While Article 53(b) of the EPC already excluded from patentability plant and animal varieties and essentially biological processes for the production

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<sup>10</sup> Councils of 13.7.2015 and 22.10.2015.

<sup>11</sup> Councils of 29.2.2016 and 29.9.2016.

<sup>12</sup> <http://english.eu2016.nl/events/2016/05/18/finding-the-balance---exploring-solutions-in-the-debate-surrounding-patents-and-plant-breeders%E2%80%99-rights>.

<sup>13</sup> The report is available at: <http://ec.europa.eu/growth/industry/intellectual-property/patents>. The group was created by Commission Decision C(2012) 7686 of 7.11.2012 setting up a Commission expert group on [the] development and implications of patent law in the field of biotechnology and genetic engineering.

<sup>14</sup> <http://pinto.euroseeds.eu>.

<sup>15</sup> <http://www.ilp-vegetable.org>.

<sup>16</sup> Article 4(1)(a) of the Directive.

<sup>17</sup> Article 4(1)(b) of the Directive.

<sup>18</sup> Article 2(2) of the Directive.

<sup>19</sup> OJ EPO 7/1999, p. 437.

of plants or animals, the Administrative Council decided to insert the other main relevant provisions of the Directive into the EPC's implementing regulations rather than in the text of the EPC. The consequence of that decision is that provisions of the two texts have to be taken into consideration when the EPO assesses the patentability of plant-related inventions<sup>20</sup>. However, if there is any conflict between these two sets of provisions, it is the EPC that prevails<sup>21</sup>.

On the basis of this legal framework, in December 2010, decisions taken by the Enlarged Board stated that essentially biological processes, making use of gene markers for selection, were not patentable subject matter, though these decisions did not pronounce on products obtained from these processes<sup>22</sup>. Through its subsequent decisions of March 2015, the Enlarged Board concluded<sup>23</sup> that a patent may be granted for plants/plant material obtained from essentially biological processes if the basic requirements of patentability are fulfilled<sup>24</sup>. The main rationale for the March 2015 decisions of the Enlarged Board is that exclusions from the general principle of patentability have to be narrowly interpreted in law. From its analysis of the official background documents for the negotiation leading to the EPC in 1973, the Enlarged Board determined that nothing could be interpreted in the sense that plants or plant materials obtained through essentially biological processes were to be excluded from patentability.

While these decisions of March 2015 are in line with the intentions of the drafters of the EPC, it is questionable whether the same result would have been reached in the EU context. Directive 98/44/EC does not distinguish between different layers of provisions, and its provisions should be interpreted together in their entirety. When trying to assess the intentions of the EU legislator when adopting the Directive, the relevant preparatory work to be taken into consideration is not the work which preceded the signature of the EPC in 1973, but that which relates to the adoption of the Directive.

## 1.2. NEGOTIATION OF THE DIRECTIVE

Following the rejection by the European Parliament in March 1995 of the joint text proposed by the Conciliation Committee (based on the original 1988 proposal), the Commission tabled a new proposal in December 1995. The patentability of plants and animals was covered by certain articles and recitals.

Article 4 of the 1995 proposal, the most relevant article for the patentability of products emanating from essentially biological processes, stated:

1. The subject of an invention shall not be considered unpatentable merely on the grounds that it is composed of, uses or is applied to biological material.

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<sup>20</sup> Article 53(b) of the EPC and rules 27 to 34 of the implementing regulations.

<sup>21</sup> As set out in Article 164(2) of the EPC.

<sup>22</sup> OJ EPO 2012, p. 130 (G 2/07) and OJ EPO 2012, p. 206 (G 1/08).

<sup>23</sup> Decisions of the Enlarged Board of Appeal of the EPO, G2/12 ('Tomatoes') and G2/13 ('Broccoli II') on 25.3.2015, OJ EPO 2016, p. 28, which stated: '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'.

<sup>24</sup> Article 52(1) of the EPC sets out these basic requirements: novelty (inventions should not be disclosed as such in the 'prior art', i.e. all the publications are available for the public); inventiveness (inventions should be easily deduced by a person skilled in the art, i.e. by a technician with average knowledge); and industrial application (inventions are susceptible to be used in industry, including agriculture).

2. Biological material, including plants and animals, as well as elements of plants and animals obtained by means of a process not essentially biological, except plant and animal varieties as such, shall be patentable.

This proposed article was accompanied by three other relevant articles and two recitals, which provided background regarding the patentability of biological material with a focus on plants and animals<sup>25</sup>. It can reasonably be understood from this proposed wording that the Commission's intention was that plants and animals obtained through an essentially biological process were not regarded as patentable subject matter. However, they could be patentable if the essentially biological process contained at least one non-biological step (such as a microbiological step<sup>26</sup>). In contrast to the Member States' subsequent detailed discussions in the first half of 1996 regarding the possibility to patent a plant variety through an invention which would cover plants, little or nothing was set out in the Commission proposal on essentially biological processes and the products of these processes.

However, most of these articles and recitals of the December 1995 proposal were proposed for amendment or deletion in June 1997 by the European Parliament in its first reading<sup>27</sup>. Parliament voted in favour of amending the article on definitions, including the term 'essentially biological processes'. It also proposed articles on the patentability of biological material and a specific provision on the patentability of plants and animals and its limits. All these articles were accompanied by recitals explaining Parliament's intentions in more detail.

With regard to this specific general provision dealing with the patentability of biological material, it is worth underlining that biological material which is isolated from its natural environment, or processed by means of a technical process, may be the subject of an invention. For this reason, the specific reference to the non-patentability of plants and animals obtained by an essentially biological process was removed from the text. However, these changes do not mean that Parliament intended to eliminate the exclusion of plants/animals obtained by essentially biological processes from patentability. In the explanatory statement accompanying Parliament's report, the Rapporteur stated that:

'Essentially biological procedures', i.e. crossing and selection of the whole genome [...] do not meet the general conditions for patentability, as they are neither inventive nor reproducible. Breeding is a reiterative process, in which a genetically stable end-product with the required characteristics is attained only after much crossing and selection. This process is so strongly marked by the individuality of the initial and intermediate material that an identical result will not be obtained upon its repetition. Patent protection is not appropriate for such procedures and *their products*<sup>28</sup>.

In its amended proposal, the Commission accepted the report and most of Parliament's amendments<sup>29</sup>, with the Commissioner responsible stating in the Parliament plenary that all amendments proposed by the Rapporteur could be approved unchanged or with minor modifications.

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<sup>25</sup> See the annex to this Notice for the full text of these provisions.

<sup>26</sup> See, in the Annex, recital 17 of the 1995 proposal.

<sup>27</sup> Opinion of the European Parliament of 16.7.1997, OJ C 286, 22.9.1997, p. 87.

<sup>28</sup> Italics added. Explanatory statement to the ROTHLEY report, 25.6.1997 (A4-0222/97), p. 38, footnote 5.

<sup>29</sup> COM(97) 446 of 29.8.1997, OJ C 311, 11.10.1997, p. 12. The Commission incorporated amendments related to biological material and plant-related issues voted in Parliament's 1<sup>st</sup> reading. In this context, Articles 4, 5, 6 and 7 of the initial proposal were deleted in line with Parliament's amendments 50, 51, 52 and 53. These articles were incorporated into Articles 2, 3 and 4 of the amended proposal. The Commission amended Article 2, using paragraphs 2, 3a, 3b and 3c as proposed by Parliament, and the Commission created a new Article 3, using paragraphs 1 and 3 of Parliament's amended Article 2. In addition, a new Article 2a, in line with Parliament's amendment 47, was introduced into the amended proposal in the form of a redrafted Article 4. Finally, the amended proposal incorporated Parliament's modifications for recitals 17 and 18 (amendments 18 and 22) and new recitals 17a, 17b and 17c.

The Council largely endorsed the Commission's subsequent amended proposal (i.e. in which Parliament's position had been taken on board)<sup>30</sup>. This endorsement was reflected in the text of the Council common position of 26 February 1998<sup>31</sup>. Discussions in Council's instances essentially centred on the definition of essentially biological processes, and none of the Member States questioned Parliament's interpretation of products obtained by essentially biological processes.

### 1.3. PROVISIONS OF THE DIRECTIVE

The final wording of the Directive does not contain a provision on the patentability of products obtained through essentially biological processes.

On the one hand, it could be argued that if the legislator had intended to exclude this subject-matter from patentability, Article 4(1)(b) could have expressly referred to such an exclusion. In addition, Article 3(1) clearly states that inventions which are new, which involve an inventive step and which are susceptible of industrial application are patentable, even if they concern a product consisting of or containing biological material. For example, plants or fruit obtained by essentially biological processes obviously consist of biological material; it could therefore be argued that there is no reason to prohibit patents on such products.

On the other hand, having regard to the preparatory work related to the Directive, as summarised above, certain provisions of the Directive are only consistent if plants/animals obtained by essentially biological processes are understood as being excluded from its scope.

Firstly, Article 3(2), which was inserted by Parliament and accepted by the Commission and the Council, states:

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.

This Article could be interpreted in the sense that, to be the subject of an invention, biological material has to be isolated from its natural environment, which is definitely not the case for products obtained through essentially biological processes. Nor would the second option in this provision (i.e. production by means of a technical process) be applicable: products emanating from essentially biological processes cannot be regarded as biological material produced by means of technical processes. A biological process which consists of selection and crossing is by definition not a technical process. Therefore, it follows that plants or animals, which are covered by the generic term 'biological material', but which are obtained by a *non*-technical process (i.e. an essentially biological process), may not be the subject matter of an invention, and thus cannot give rise to a patent. It is reasonable to assume that the legislator considered it was not necessary to explicitly mention this exclusion.

Secondly, Article 4(1) of the Directive spells out the basic principle of exclusion from patentability of plant and animal varieties, and of essentially biological processes for the production of plants or animals. As an exception to this rule, Article 4(2) states that inventions which concern plants or animals are patentable if the technical feasibility of the invention is not confined to a particular plant variety (i.e. a plant grouping larger than a plant variety). This exception does not nullify the exclusion in paragraph one of this Article. An example of Article 4(2) is the case of a gene which is inserted into the genome of plants and leads to the creation of a new plant grouping characterised by this specific gene (i.e. genetic engineering).

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<sup>30</sup> Council document 10130/97, Codec 428, PI31.

<sup>31</sup> OJ C 110, 8.4.1998, p. 17. Parliament subsequently approved this common position on 12.5.1998, paving the way for the final adoption of the Directive on 6.7.1998.

By contrast, the crossing of the whole genome of plant varieties corresponding to an essential biological process would be excluded from patentability<sup>32</sup>.

Thirdly, recital 32 provides the legislator's explanation of Article 4. This recital states:

if an invention consists only of genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result *not of an essentially biological process* but of a biotechnological process<sup>33</sup>;

It can be understood from this recital that, if a new plant variety is bred through an essentially biological process, then this plant variety (i.e. the product obtained) is excluded from patentability. This recital clarifies the intention of the legislator. The trigger point for ensuring the patentability of either a plant or an animal is the technical process, such as for instance the insertion of a gene into a genome. Essentially biological processes are not of a technical nature and therefore, according to the position taken by the legislator, they cannot be covered by a patent.

Finally, Article 4(3) of the Directive specifies that patents are allowed for inventions which result from a microbiological process. This provision explicitly refers to Article 4(1)(b), i.e. the exclusion from patentability of essentially biological processes for the production of plants and animals. The legislator would only have considered it necessary to mention that a microbiological process was patentable subject matter if it had considered that the product obtained by such a process was patentable. The fact that Article 4(3) exists, on the one hand highlights the patentability of products obtained by microbiological processes, and on the other, is consistent with the view that the legislator's intention was to exclude from patentability products that are obtained by essentially biological processes.

It is worth underlining that the same reasoning applies to animals. Even if, strictly speaking, there is no intellectual property right covering animal varieties at EU level, the same exception applies to animal varieties, namely that neither animal varieties nor essentially biological processes for the production of animals can be patented. The same approach — i.e. exclusion from patentability — should thus apply to animals that are directly obtained from essentially biological processes.

*The Commission takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.*

## 2. COMPULSORY CROSS-LICENSING

The 1995 proposal introduced the system of compulsory cross-licensing for cases when a breeder would not be able to acquire or exploit a variety right without infringing a prior patent and vice versa<sup>34</sup>. The proposed Article 14(3) stated:

Applicants for the licences referred to in paragraph 1 and 2 must demonstrate that:

- (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
- (b) exploitation of the plant variety or the invention for which the licence is requested is dictated by the public interest and the plant variety or the invention constitutes significant technical progress.

<sup>32</sup> This approach has been followed in France, Germany and the Netherlands in their respective national patent legislation.

<sup>33</sup> Italics added.

<sup>34</sup> COM(95) 661, Article 14(3).

These basic principles for the exploitation of a plant variety or an invention were explained in the proposed recitals 32 and 33, as follows:

(32) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in a Member State in a form of a compulsory licence where, in relation to the genus or species concerned, public interest demands the exploitation of the plant variety for which the licence is requested and the plant variety represents significant technical progress;

(33) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access against a fee must be granted in a form of a compulsory licence where public interest demands the exploitation of the invention for which the licence is requested and the invention represents significant technical progress;

Two conditions were set for triggering access to compulsory licensing in Article 12(3) of the Directive<sup>35</sup>. The first obligation provided for applicants to demonstrate that they had applied unsuccessfully to the holder of the patent or plant variety right to obtain a contractual licence. The second condition means that exploitation of the plant variety right must constitute demonstrable significant technical progress of considerable economic interest.

The criterion of the obligation on the applicant to demonstrate ‘significant’ technical progress of a plant variety (compared with the ‘technical teaching of a patent’) is however a stronger requirement than the criterion of ‘distinctness’ that is required under plant variety protection law<sup>36</sup>.

The demonstration of significant technical progress could be more difficult in the case of plant varieties than in the case of patents. Pursuant to Article 12(3), compulsory cross-licences would only have to be granted in cases where the new variety represents a genuine agricultural achievement. Incremental improvements to varieties which have been initially developed from a patented plant would be subject to compulsory cross-licensing. Likewise, breeders who have developed an essentially derived variety also have to obtain the assent of the holder of the first variety for the purpose of commercialising the new plant variety.

It is worth underlining that the condition relating to considerable economic interest was introduced during the discussions within Council. This was done against the backdrop of the TRIPs Agreement<sup>37</sup>, which at that time had itself only recently entered into force.

Further to the adoption of the Directive, Regulation (EC) No 2100/94 on Community plant variety rights was amended by Council Regulation (EC) No 873/2004, so as to align to the Directive the provisions of the 1994 Regulation dedicated to the compulsory licences<sup>38</sup>.

The double condition relating to technical progress and economic value might be cumbersome for a plant variety right holder to demonstrate. This wording was inspired by Article 31(1) of TRIPs, which deals with the situation in which a patent cannot be exploited without infringing another patent. However, the way plant varieties are assessed by plant variety offices differs significantly from the approach taken by patent offices: while plant variety offices make sure that the new variety is distinct (from other varieties of common knowledge), uniform, stable and new in comparison with existing varieties, patent offices merely focus on technical teaching arising from the invention from a theoretical point of view. In addition, it is difficult to predict before the placing on the market of a new plant variety whether it will be an economic success.

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<sup>35</sup> The draft Article 14(3) in the 1995 proposal.

<sup>36</sup> See Articles 6 and 7 of Regulation 2100/94.

<sup>37</sup> See Article 31(1)(i) of the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

<sup>38</sup> OJ L 162, 30.4.2004, p. 38.

Notwithstanding these challenges, it is expected that compulsory cross-licensing will not pose a major issue in the case of protected varieties because of the compulsory breeder's exemption that is provided for, on the one hand in Article 27(c) of the Unified Patent Court Agreement, and on the other in Article 15(c) of the Regulation on plant variety rights. Article 15(c) states that 'acts done for the purpose of breeding, or discovering and developing other varieties' are excluded from the scope of the right. In this way, free access to the widest possible source of genetic material is ensured, thus stimulating innovation.

Some uncertainty could however arise when a patent claim targets native traits, because breeders could then be prevented from developing new varieties. This particular issue goes beyond the scope of the present Notice, and would benefit from further reflection, including, if appropriate, the publication of another report on the development and implications of patent law in the field of biotechnology and genetic engineering<sup>39</sup>.

*Concerning the conditions for compulsory cross-licensing set out in Article 12(3)(b) of Directive 98/44/EC, the Commission may further analyse issues related to 'significant technical progress of considerable economic value' for the plant variety or invention.*

### **3. ACCESS TO AND DEPOSIT OF BIOLOGICAL MATERIAL**

The 1995 proposal regulated the deposit, access and re-deposit of biological material for the purpose of patent procedures. These rules were based on the principles governed by the 1977 WIPO Budapest Treaty of on the international recognition of the deposit of microorganisms for the purposes of patent procedure<sup>40</sup>.

To meet the fundamental requirement to provide an enabling disclosure in a patent application which allows for a person skilled in the art to carry out the invention, patent law requires the deposit of the biological material for which patent protection is being sought. In the case of biotechnological inventions, the written description of the invention must be supplemented by a physical component, accessible at least to the international depositary authorities who acquired this status by virtue of Article 7 of the Budapest Treaty.

Since not all Member States were contracting parties to the Budapest Treaty when the Directive was negotiated and adopted, the intention of the EU legislator was to harmonise patent procedures of biotechnological patent applications in the Member States. This was achieved by requiring the deposit of biological material, as an additional requirement to that of an adequate description of the invention.

Pursuant to the requirement of deposit, the 1995 proposal also set out the rules for access to biological material, where an invention concerns or involves the use of biological material which is not available to the public and which cannot be sufficiently described in a patent application.

Access to the deposited biological material is provided by supplying a sample:

- a) to those authorised under the national patent law up to the first publication of the patent application;
- b) to anyone requesting it or, on the applicant's request, only to an independent expert between the first publication of the application and the granting of the patent; and

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<sup>39</sup> As provided for in Article 16(c) of the Directive.

<sup>40</sup> See <http://www.wipo.int/budapest/en>.

- c) to anyone requesting it after the patent has been granted, provided the patent has not been revoked or cancelled.<sup>41</sup>

Article 15(3) of the 1995 proposal set out the duties of those requesting a sample of the deposited material and the rights of the patent applicant or proprietor to expressly waive the use of it or any material derived from it only for experimental purposes, as follows:

The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

- (a) not to make it or any matter derived from it available to third parties; and
- (b) not to use it or any biological material matter derived from it except for experimental purposes unless the patent holder or applicant, as applicable, expressly waived such an undertaking.

The Council wished to add a new recital in respect of Articles 15 and 16 explaining that the deposit of biological material with a recognised depositary institution was intended as a means of making information available to the public concerning the material for which a patent protection was being sought. However, in the end this idea was not retained.

Article 15 of the proposal, re-numbered as Article 13(3) in the Commission's amended proposal, was subject to minor textual amendments during subsequent discussions in the Council and Parliament. Notably, the 'unless' clause, which previously applied to points (a) and (b), now only applies to point (b):

The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

- (a) not to make it or any material derived from it available to third parties; and
- (b) not to use it or any biological material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waived such an undertaking.

The Council common position indicated that Article 13 (Article 15 of the 1995 proposal) remained unchanged. Since the wording is quite self-explanatory, it should not give rise to multiple interpretations.

*The Commission takes the view that the wording of Article 13(3) of Directive 98/44/EC provides for balanced and sufficient accessibility to a sample of patented biological material deposited with a recognised depositary institution under the WIPO Budapest Treaty.*

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<sup>41</sup> Article 15(2) of the 1995 proposal.

**Annex: Evolution of the inter-institutional discussions within the framework of the co-decision procedure**

(Bold denotes changes)

Commission proposal (13.12.1995) <sup>42</sup>	European Parliament amendments (16.7.1997) <sup>43</sup>	Commission amended proposal (29.8.1997) <sup>44</sup>	Council common position (26.2.1998) <sup>45</sup>
<p>Recital 17</p> <p>Whereas, in order to determine the extent to which plant and animal varieties are to be excluded from patentability, it should be specified that the exclusion concerns those varieties as such and that, consequently, it does not prejudice the patentability of plants or animals obtained by means of a process at least one stage of which is essentially microbiological, irrespective of the basis of the basic biological material to which that process is applied.</p>	<p>Recital 17 (Amendment 18)</p> <p><b>Whereas this directive shall be without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are in general patentable provided that the practicability of the invention is not technically confined to a single plant or animal variety.</b></p>	<p>Recital 17</p> <p>Whereas this directive shall be without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are in general patentable provided that the application of the invention is not technically confined to a single plant or animal variety.</p>	<p><b>Recital 29</b></p> <p>Whereas this directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety.</p>

<sup>42</sup> Commission proposal, COM(1995) 661 of 13.12.1995, OJ C 296, 8.10.1996, p. 4.

<sup>43</sup> Opinion of the European Parliament of 16.7.1997, OJ C 286, 22.9.1997, p. 87.

<sup>44</sup> Commission amended proposal, COM(97) 446 of 29.8.1997, OJ C 311, 11.10.1997, p. 12.

<sup>45</sup> Council common position of 26.2.1998, OJ C 110, 8.4.1998, p. 17.

Commission proposal	European Parliament amendments	Commission amended proposal	Council common position
	<p>New recital 17a (Amendment 19)</p> <p><b>Whereas the concept ‘plant variety’ is defined by the law protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore processes individuality; whereas it is clearly distinguishable from other varieties.</b></p>	<p>Recital 17a</p> <p>Whereas the concept ‘plant variety’ is defined by the law protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore processes individuality; whereas it is clearly distinguishable from other varieties.</p>	<p><b>Recital 30</b></p> <p>Whereas the concept ‘plant variety’ is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore processes individuality and is clearly distinguishable from other varieties.</p>
	<p>New recital 17b (Amendment 20)</p> <p><b>Whereas a plant totality which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises plant varieties.</b></p>	<p>Recital 17b</p> <p>Whereas a plant totality which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises plant varieties.</p>	<p><b>Recital 31</b></p> <p>Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants.</p>
	<p>New recital 17c (Amendment 21)</p> <p><b>Whereas, however, if an invention consists only of genetically modifying a particular plant variety and producing a new variety from it, the new variety shall be excluded from patentability even if the genetic modification</b></p>	<p>Recital 17c</p> <p>Whereas, however, if an invention consists only in genetically modifying a particular plant variety, it shall be excluded from patentability even if the genetic modification is the result not of breeding but of a genetic engineering procedure.</p>	<p><b>Recital 32</b></p> <p>Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and <b>if a new plant variety is bred, it will</b> still be excluded from patentability even if the genetic modification is the result not of <b>an essentially</b></p>

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	<b>is the result not of breeding but of a genetic engineering procedure.</b>		<b>biological process but of a biotechnological process.</b>
<p>Recital 18</p> <p>Whereas, for the purposes of determining whether or not it is possible to patent essentially biological processes for obtaining plants or animals, human intervention and the effects of that intervention on the result obtained must be taken into account.</p>	<p>Recital 18 (Amendment 22)</p> <p><b>Whereas a procedure for the breeding of plants and animals is essentially biological if it is based on crossing whole genomes (with subsequent selection and perhaps further crossing of whole genomes).</b></p>	<p>Recital 18</p> <p>Whereas a procedure for the breeding of plants and animals is essentially biological if it is based on crossing the whole genomes (with subsequent selection and perhaps further crossing of whole genomes).</p>	<p><b>Recital 33</b></p> <p><b>Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological.</b></p>
<p>Article 2:</p> <p>For the purposes of this directive:</p> <p>1. 'biological material' means any material containing genetic information and capable of self-reproduction or of being reproduced in a biological system;</p> <p>2. 'microbiological process' means any process involving or performed upon or resulting in microbiological material; a process consisting of a succession of steps shall be treated as a microbiological process if at least one essential step of the process is microbiological;</p>	<p>Article 2 (Amendment 48)</p> <p><b>1. Inventions which are novel, based on inventive activity and capable of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a procedure by means of which biological material is produced, processed or used.</b></p> <p><b>2. 'Biological material' means any material containing genetic information and is capable of reproducing itself or being reproduced in a biological system.</b></p>	<p><b>Article 2</b></p> <p><b>1. For the purposes of this Directive,</b></p> <p>(a) <i>Biological material</i> means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;</p> <p>(b) <i>Microbiological process</i> means any process involving or performed upon or resulting in</p>	<p>Article 2</p> <p>1. For the purposes of this Directive,</p> <p>(a) 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;</p> <p>(b) 'microbiological process' means any process involving or performed upon or resulting in</p>

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<p>3. 'essentially biological process for the production of plants or animals' means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal-breeding process.</p>	<p><b>3. Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature.</b></p> <p><b>3a.</b> 'Microbiological process' means any process involving or performed upon or resulting in microbiological material.</p> <p><b>3b. A procedure for the breeding of plants or animals shall be defined as essentially biological if it is based on crossing and selection.</b></p> <p><b>3c. The concept 'plant variety' shall be defined by the law protecting new varieties.</b></p>	<p>microbiological material.</p> <p>2. A procedure for the breeding of plants or animals shall be defined as essentially biological if it is based on crossing and selection.</p> <p>3. The concept of <i>plant variety</i> is <b>defined by Article 5 of Regulation (EC) No 2100/94.</b></p>	<p>microbiological material.</p> <p><b>2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.</b></p> <p>3. The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.</p>
		<p><b>Article 3</b></p> <p><b>1. For the purposes of this Directive,</b> inventions which are novel, imply inventive activity and are capable of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a procedure by means of which biological</p>	<p>Article 3</p> <p>1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which</p>

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		<p>material is produced, processed or used.</p> <p><b>2.</b> Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if already occurred in nature.</p>	<p>biological material is produced, processed or used.</p> <p><b>2.</b> Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it previously occurred in nature.</p>
	<p>new Article 2a (Amendment 47)</p> <p><b>1. The following shall not be patentable:</b></p> <p><b>(a) plants and animal varieties,</b></p> <p><b>(b) essentially biological procedures for the breeding of plants and animals.</b></p> <p><b>2. Inventions which concern plants or animals may be patented if the practicability of the invention is not technically confined to a particular plant or animal variety.</b></p> <p><b>3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical procedure or a product obtained by means of</b></p>	<p><b>Article 4</b></p> <p>1. The following shall not be patentable:</p> <p>(a) plants and animal varieties;</p> <p>(b) essentially biological procedures for the breeding of plants and animals.</p> <p>2. Inventions which concern plants or animals may be patented if the application of the invention is not technically confined to a particular plant or animal variety.</p> <p>3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical procedure or a product obtained by means of such a procedure.</p>	<p>Article 4</p> <p>The following shall not be patentable:</p> <p>(a) plants and animal varieties;</p> <p>(b) essentially biological <b>processes for the production</b> of plants and animals.</p> <p>2. Inventions which concern plants or animals <b>shall</b> be patented if <b>the technical feasibility</b> of the invention is not confined to a particular plant or animal variety.</p> <p>3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical <b>process</b> or a product obtained by means of such a <b>process</b>.</p>

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	<b>such a procedure.</b>		
<p>Article 4</p> <p>1. The subject of an invention shall not be considered unpatentable merely on the grounds that it is composed of, uses or is applied to biological material.</p> <p>2. Biological material, including plants and animals, as well as elements of plants and animals obtained by means of a process not essentially biological, except plant and animal varieties as such, shall be patentable.</p>	<p>Article 4 (Amendment 50)</p> <p>Deleted</p>	<p>Deleted</p>	<p>Deleted</p>
<p>Article 5</p> <p>Microbiological processes and products obtained by means of such processes shall be patentable.</p>	<p>Article 5 (Amendment 51)</p> <p>Deleted</p>	<p>Deleted</p>	<p>Deleted</p>
<p>Article 6</p> <p>Essentially biological processes for the production of plants or animals shall not be patentable.</p>	<p>Article 6 (Amendment 52)</p> <p>Deleted</p>	<p>Deleted</p>	<p>Deleted</p>
<p>Article 7</p> <p>Uses of plants or animal varieties and processes for their production,</p>	<p>Article 7 (Amendment 53)</p> <p>Deleted</p>	<p>Deleted</p>	<p>Deleted</p>

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other than essentially biological processes for the production of plants or animals, shall be patentable.			