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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. prev. doc.:	5590/17
Subject:	Council conclusions on the Commission Notice on certain Articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions - Adoption

1. In response to calls from both the European Parliament and the Council, the Commission published in the Official Journal of the European Union a Notice on certain Articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions¹. This Notice sets out the Commission's views on the patentability of products emanating from essentially biological processes. It also touches upon the issues of compulsory cross-licensing between plant variety rights and patents holders and access to biological material by a third party.

¹ OJ C 411, 8.11.2016, p. 3.

2. On 30 January 2017, the Working Party on Intellectual Property agreed on a set of draft Council conclusions regarding the above mentioned Commission Notice.

 3. The Council is therefore invited to :
 - a) adopt, under the A items of one of its future meetings, the conclusions set out in the Annex to this Note, and
 - b) decide to publish these conclusions in the Official Journal of the European Union.
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Council conclusions
on the Commission Notice on certain Articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions

THE COUNCIL OF THE EUROPEAN UNION:

1. RECALLING:

- that Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions² sets out principles regarding the patentability of biological material, such as animals or plants;
- the decisions of the Enlarged Board of Appeal of the European Patent Office (EPO) of 25 March 2015 in Cases G2/12 (on Tomatoes II) and G2/13 (on Broccoli II), which decided that products derived from essentially biological process might be patentable, even if the process used to obtain the product is essentially biological and thus not patentable;
- the International Convention for the Protection of New Varieties of Plants of 2°December°1961 (the UPOV Convention) and its subsequent amendments;
- its discussions of 13 July and 22 October 2015 and of 29 February, 29 September, 28 November and 12 December 2016;

² OJ L 213, 30.7.1998, p. 13.

- the resolution of the European Parliament of 17 December 2015 'on patents and plant breeders' rights'³;
 - the final report of 17 May 2016 of the expert group on the development and implications of patent law in the field of biotechnology and genetic engineering⁴;
 - the Presidency symposium of 18 May 2016 on 'Finding the balance: exploring solutions in the debate surrounding patents and plant breeders' rights'.
2. RECOGNISING that the decisions of the Enlarged Board of Appeal of the EPO of 25 March 2015 on Tomatoes II and Broccoli II are in conflict with the provisions of certain Member States, and that clarity on this matter is necessary.
 3. WELCOMES the Commission Notice of 3 November 2016 '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'⁵, without prejudice to potential future rulings of the Court of Justice of the European Union. The Notice increases clarity in this field within the EU and contributes to restoring an appropriate balance between patent-related rights and plant variety rights.
 4. RECALLS that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products obtained through essentially biological processes.
 5. TAKES NOTE of the other issues addressed in the Notice, namely compulsory cross-licensing and access to and deposit of biological material.

³ <http://www.europarl.europa.eu>

⁴ <http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/>

⁵ OJ C 411, 8.11.2016, p. 3.

6. CALLS ON the Commission to:

- a) further analyse, as regards conditions for compulsory cross-licensing, issues related to significant technical progress of considerable economic value for the plant variety or invention and also further analyse issues related to the scope of protection of patents, as such analyses could be helpful in the development of new varieties based on existing patented genes;
- b) present in 2017, on the basis of Article 16(c) of Directive 98/44/EC, a report on the development and implications of patent law in the field of biotechnology and genetic engineering, so as to address remaining issues identified by the expert group and that may need to be clarified in order to increase certainty in this field.

7. URGES Member States, in their capacity as members of the European Patent Organisation, to advocate that the practice of the European Patent Organisation is aligned with these conclusions.
