



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Deputy Director General for the Food Chain

Brussels,
SANCO.E2/ICN/lav (2014) 1247015

Dear Mr Button,

Subject: EU suggestions on Essentially Derived Varieties (EDV)

According to the procedure introduced on the occasion of the 26th ordinary session of the UPOV Council, please find, in the Annex I, the suggestions of the European Union for matters concerning essentially derived varieties (EDV) for consideration of the advisory group to the Administrative and Legal Committee (CAJ-AG) at its next session in October 2014.

The suggestions correspond to the text in italics highlighted.

Yours sincerely,

Ladislav Miko

Mr Bernard Van Goethem
Director
DG Health and Consumers
for the DDG absent

Enclosure: Annex I

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Annex I

Comments of the European Union (in italics) on agenda point 4 (a) of CAJ meeting 10 April 2014 on matters concerning essentially derived varieties (EDV):

<p>(i) Use of information of the initial variety to obtain essentially derived varieties</p>	<p>The CAJ-AG recalled that it had agreed that consideration should be given to the following text as a <u>starting point</u> of a possible example on the use of information of the initial variety to obtain essentially derived varieties (see doc CAJ-AG/13/8/2, para. 6-7): The <u>use of molecular data</u> from an initial variety, for the purpose of selection of genotypes from a population that is <u>mostly related</u> to the initial variety, to produce a variety with a similar genotype may provide evidence of predominant derivation.</p> <p><i>Firstly, the use of Marker assisted selection (MAS), as a process whereby a marker (morphological, biochemical or DNA/RNA variation) is used for indirect selection of a genetic determinant or determinants of a trait of interest (e.g. productivity, disease resistance, abiotic stress tolerance, and/or quality) cannot be seen as an evidence of predominant derivation although it may, under certain circumstances, be seen as an indication of predominant derivation. Secondly the term 'mostly related' is too vague in order to give evidence of derivation, even indirect one.</i></p> <p><i>Therefore, the EU and its Member States cannot agree with the current text as it is, but can agree to further work on it as a starting point taking into account our previous comments.</i></p> <p>The CAJ-AG noted that the concept of <u>indirect derivation</u> was already introduced in document UPOV/EXN/EDV/1:</p> <p>“5. EDVs are obtained, either directly or indirectly, from a variety which is called the “initial variety”. In the example in Figure 1, variety B is an essentially derived variety from variety A and is predominantly derived from variety A. EDVs can also be indirectly obtained from an initial variety. In the example in Figure 2, Variety C is essentially derived from Initial Variety ‘A’, but is predominantly derived from variety B.</p> <p>“6. Irrespective of whether variety C has been obtained directly from the initial variety A or not, it is an essentially derived variety from variety A if it fulfills the definition stated in Article 14 (5) (b).</p> <p>“7. Another example of an indirect way in which it might be possible to obtain an EDV from an initial variety could be the use of a hybrid variety to obtain a variety which is essentially derived from one of the parent lines of the hybrid.”</p> <p><i>The EU and its Member States can agree that the concept of <u>indirect derivation</u> was already introduced in document UPOV/EXN/EDV/1:</i></p> <p><i>Nevertheless concerning the paragraph 7, we consider that the text has to be clarified and to be completed with a reference to the definition stated in Article 14 (5) (b)..”</i></p>
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(ii) Relationship between Article 14(5)(b)(i) &(iii) of the 1991 Act of UPOV Convention

The CAJ-AG noted that the text (a-h) would be circulated with the Draft Report (document CAJ-AG/13/8/10 Prov.), with three months to be provided for comments (see document CAJ/AG/13/8/10 Prov., paragraph 44(h));

The CAJ-AG requested the Office of the Union to prepare a text for inclusion in a new draft of document UPOV/EXN/EDV/2 on the following basis:

(a) to include a Preamble with a reference to the mandate of the 1991 Diplomatic Conference (see document DC/91/140): ‘Resolution on Article 14(5)

‘The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to 19, 1991, requests the Secretary-General of UPOV to start work immediately after the Conference on the establishment of draft standard guidelines, for adoption by the Council of UPOV, on essentially derived varieties.’”

The EU and its Member states can agree to include a Preamble with a reference to the mandate of the 1991 Diplomatic Conference (see document DC/91/140):

(b) to clarify in the Preamble the purpose of the guidance in relation to members of the Union and stakeholders;

The EU and its Member states can agree to clarify in the Preamble the purpose of the guidance in relation to members of the Union and stakeholders.

(c) to include the text of document UPOV/EXN/EDV/1 “Explanatory Notes on EDV under the 1991 Act of the UPOV Convention”, which was adopted by the Council, at its 43rd ordinary session, held in October 22, 2009 (see doc. C/43/17“Report”,para.23);

The EU and its Member states can agree to include the text of document UPOV/EXN/EDV/1 “Explanatory Notes on EDV under the 1991 Act of the UPOV Convention”, which was adopted by the Council, at its 43rd ordinary session, held in October 22, 2009.

(d) to include the text of draft UPOV/EXN/EDV/2 “Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention” (revision) that had already been agreed by the CAJ-AG;

The EU and its Member States can agree to include for further consideration the text of draft UPOV/EXN/EDV/2 “Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention” (revision).

(e) to consider the inclusion of relevant part of the draft guidance presented in document IOM/6/2 “EDV” at the 6th Meeting with International Organizations (IOM/6), taking into consideration the discussions at the IOM/6 on the above proposals contained in document IOM/6/5 “Report” (copies of documents IOM/6/2 “EDV” and IOM/6/5 “Report” in the four languages of the Office of the Union are posted, as reference documents, on the CAJ-AG/13/8 section of the UPOV website);

The EU and its Member States can agree to include relevant part of the draft guidance presented in document IOM/6/2 “EDV” taking into consideration the discussions at the IOM/6 on the above proposals contained in document IOM/6/5 “Report”.

(f) to include the following elements from the EDV Seminar:

(i) the need to consider the situation in different crops/species and methods of breeding, e.g. mutants;

(ii) to explain the need to consider both predominant derivation (genetic conformity) and essential characteristics (phenotype) and for both those aspects to be considered as possible starting points, noting that the result would be the same;

The EU and its Member States can agree to include to include the following elements from the EDV Seminar: the need to consider the situation in different crops/species and methods of breeding, and to explain the necessity to consider both predominant derivation (genetic conformity) and essential characteristics (phenotype) and for both those aspects to be considered as a possible starting point.

(g) to include, as a possible starting point, the text of the explanatory note 6(ii) on Article 5 “Effects of the Right Granted to the Breeder” presented in document IOM/IV/2 (see document IOM/6/2 “Essentially Derived Varieties”, paragraph 12, and document CAJ-AG/12/7/3, paragraph 11, reproduced below):

“(ii) the derived variety must retain almost the totality of the genotype of the mother variety and be distinguishable from that variety by a very limited number of characteristics (typically by one).

The EU and its Member States can agree to include, as a possible starting point to be further developed, the text of the explanatory note 6(ii) on Article 5 “Effects of the Right Granted to the Breeder” presented in document IOM/IV/2 (see document IOM/6/2 “Essentially Derived Varieties”, paragraph 12, and document CAJ-AG/12/7/3, paragraph 11, reproduced below) with a slight modification for clarity:

	<p><i>“(ii) the derived variety must retain almost the totality of the genotype of the mother initial variety and be distinguishable from that variety by a very limited number of characteristics (typically by one).</i></p> <p>(h) the Office of the Union to provide possible EDV examples based on: the examples provided in document IOM/6/2 “EDV”; the examples provided by Australia and Japan in the EDV Seminar; the example provided on the use of information of the initial variety to obtain EDVs; and the explanatory note 6(ii) on Article 5 “Effects of the Right Granted to the Breeder” presented in document IOM/IV/2 (see paragraphs 41 and 44(g) of document CAJ/AG/13/8/10 Prov.); the CAJ-AG would have 3 months to provide comments on the EDV examples. The Delegation of Australia offered to provide additional information on the context of the examples provided by Australia at the 9th session of CAJ-AG.</p> <p><i>The EU and its Member States can agree that the Office of the Union shall provide for consideration possible EDV/non EDV examples based on the elements provided in document IOM/6/2 “EDV”, the examples provided by Australia of what is not declared as an EDV during the Seminar, and the explanatory note 6(ii) on Article 5 “Effects of the Right Granted to the Breeder” presented in document IOM/IV/2 (see paragraphs 41 and 44(g) of document CAJ/AG/13/8/10 Prov.). The Japanese delegation can be requested to provide more concrete elements in order to better understand their approach with regard to the examples (e.g. enhancement of disease resistance, earliness in ripening) quoted in their guidance document on PVP and Seed Act.</i></p> <p><i>In the EU, at CPVO level, there is a working group which reflects notably on what is an EDV and what cannot be considered as an EDV. The work is not finalised yet. The EU and its Member can agree to continue the discussions during the next CAJ-AG in Autumn.</i></p>
<p>Approach to advance on relevant matters</p>	<p>(see document CAJ-AG/13/8/10 “Report”, para. 81):</p> <ul style="list-style-type: none"> • Circulation of the “Draft Report” (document CAJ-AG/13/8/10 Prov.) by November 15, 2013, with EDV examples • Comments on the “Draft Report” (document CAJ-AG/13/8/10 Prov.) by December 13, 2013 • Comments on EDV examples by 21/2/2014 • Circulation of new drafts of relevant explanatory notes by 9/5/2014; • Comments on new drafts of relevant explanatory notes by 21/6/2014; • Revised new drafts of relevant explanatory notes to be posted by August 29, 2014.

<p>(iii) Matters concerning EDVs that are not granted protection in their own right</p>	<p>The CAJ-AG agreed to consider the development of guidance on the matters raised in paragraphs 15 to 18 of document CAJ-AG/13/8/2, concerning the status of essentially derived varieties that were not granted protection in their own right, after the adoption of the revised document UPOV/EXN/EDV/2.</p> <p>The CAJ-AG noted that the matters raised in paragraphs 15 to 18 of document CAJ-AG/13/8/2 would not arise if breeders protected EDVs in their own right.</p> <p><i>The EU and its Member States can agreed to consider the development of guidance on the matters raised in paragraphs 15 to 18 of document CAJ-AG/13/8/2, concerning the status of essentially derived varieties that were not granted protection in their own right, after the adoption of the revised document UPOV/EXN/EDV/2.</i></p> <p><i>The EU and its Member states can agree that the matters raised in paragraphs 15 to 18 of document CAJ-AG/13/8/2 would not arise if breeders protected EDVs in their own right.</i></p>
<p>(v) Soft law, dispute settlement mechanisms</p>	<p>The CAJ-AG noted the closing remarks of the President of the Council in Session III of the EDV Seminar “Possible role of future UPOV guidance on essentially derived varieties” in relation to the following topics:</p> <ul style="list-style-type: none"> (i) experiences on the role of “soft law”/guidance in different jurisdictions and in relation to other subject matters; and (ii) the potential of alternative dispute settlement mechanisms as a tool for building guidance resulting from award/expert determination EDV cases. <p>The CAJ-AG agreed to consider the inclusion of information on alternative dispute settlement mechanisms for EDV matters in document UPOV/EXN/EDV/2, including a reference to document UPOV/INF/21 “Alternative Dispute Settlement Mechanisms”. As a first step, the CAJ-AG agreed that the Office of the Union should prepare an information document for the CAJ-AG on developments on alternative dispute settlement mechanisms at CIOPORA, the International Seed Federation (ISF) and the World Intellectual Property Organization (WIPO). In that regard, the CAJ-AG noted that one aspect for consideration would be the possible role of UPOV in the provision of experts on EDV matters.</p> <p><i>The EU and its Member States can take note of the closing remarks of the President of the Council in Session III of the EDV Seminar “Possible role of future UPOV guidance on EDVs” in relation to the following topics: (i) experiences on the role of “soft law”/guidance in different jurisdictions and in relation to other subject matters; and (ii) the potential of alternative dispute settlement mechanisms as a tool for building guidance resulting from</i></p>

award/expert determination EDV cases.

The EU and its Member states can agree to consider the inclusion of information on alternative dispute settlement mechanisms for EDV matters in document UPOV/EXN/EDV/2, including a reference to document UPOV/INF/21 “Alternative Dispute Settlement Mechanisms”. As a first step, the Office of the Union should prepare an information document for the CAJ-AG on developments on alternative dispute settlement mechanisms at CIOPORA, the International Seed Federation (ISF) and the World Intellectual Property Organization (WIPO). In that regard, it was noted that one aspect for consideration would be the possible role of UPOV in the provision of experts on EDV matters for such alternative dispute settlement mechanisms.