Draft working paper of the Commission services Nr 11, does not necessarily reflect the position of the Commission, for consultation of experts of Working Party on legislation on Seeds and Plant Propagating Material only

Review of legislation on marketing seed and plant propagating material, 11 April 2011

Issue: Registration of varieties and other material

General comment: In the legal drafting the present requirements were kept (status quo) as regards the issues subject to the impact assessment.

1. Scope of chapter: This chapter covers only species listed in Annex I (currently regulated species). In order to ensure a consistent and comprehensive approach, it should be discussed whether registration should be compulsory for varieties only, or also for other material (with officially recognised description, including denomination). For instance, the current provisions on forestry productive material have their own logic for the identification of material on the basis of e.g. region of harvesting, locality, altitude, which is used for the official description.

2. Article 2: The new draft maintains provisionally a system of national registration of varieties, which could later on lead to registration at EU level. A decision whether such a system should be maintained, amended or replaced by a more centralised system will depend on the outcome of the <u>ongoing impact assessment</u>.

3. Article 2: The new draft introduces the term "register" instead of "catalogue" and "registration" instead of "acceptance" of varieties. This is done in order to ensure clarity and consistency with all terms. It should be discussed whether such a change of terminology is reasonable and desirable.

4. Article 2(7): See Annex II for the possible options on structuring the variety register. In option 2 (see also legal text of this Article) the variety register is subdivided in four parts (A: varieties with officially described identity (DUS); B: varieties with officially recognised description (no DUS); C: material with officially recognised description (no DUS); and D: forest material. It should be discussed whether such a categorisation is reasonable and would lead to more clarity and transparency with regards to production and marketing of reproductive material.

5. Article 2(7): VCU testing is an obligatory requirement for any variety of agricultural plant species as the current legislation requires. So when it is carried out it should be indicated in the register. However, any selection of an option on VCU depends on the final outcome of the <u>ongoing impact assessment</u>. It should be discussed whether such an option is desirable and consistent with the objectives of the new legislation.

6. Article 7 2(7) (b): It still remains to be seen where the appropriate legal base for the 'preservations seed mixtures' can be laid down. There is a national authorisation system for the mixtures on the basis of their origin (including some quality requirements).

7. Article **3**: It should be discussed whether other or more detailed requirements should be laid down for the registration of varieties.

8. Article 4: It should be discussed whether a reference to the CPVO database on denominations would be useful.

9. Article 5(2): The new draft adopts the DUS definition of Regulation 2100/1994, and not the definition of Directive 2002/53/EC. To discuss whether this would be appropriate.

10. Article **5(2)(a)**: To discuss whether a comparison should made with any other variety of common knowledge in the EU. The Plant Variety Rights legislation provides for a comparison so that a variety should be distinguishable from any other variety whose existence if a matter of common knowledge on the date of application.

Annex I - Provisions of the new draft Regulation on registers and registration requirements for varieties and other material

CHAPTER X REGISTRATION OF VARIETIES AND OTHER MATERIAL

Article 1 General provision

Varieties and other material of plant species listed in Annex I shall be registered in accordance with the provisions of Articles x-y, in order to ensure a transparent procedure for the placing on the market of reproductive material within the Union.

Section 1 National variety register

Article 2 National variety register

[system open to the outcome of the impact assessment]

1. Each Member State shall establish, update and publish at least in electronic format a single national register of varieties and other material of plant reproductive material (hereinafter: "varieties register") belonging to the species listed in Annex I.

In the case of varieties (inbred lines, hybrids) which are intended solely as components for final varieties, the provisions of paragraph 1 shall apply only to the extent that the reproductive material which belongs to them are to be placed on the market under their names.

Component varieties shall be indicated as such.

The conditions under which the provisions of this paragraph shall also apply to other component varieties may be determined in accordance with the procedure referred to in Article x [comitology].

2. The variety register shall include, at least:

- a) the name of the species;
- b) the variety denomination and synonyms; and
- c) the date of the registration.

Where maintenance breeding of a variety is required, the name of the person or persons responsible for this in their countries shall be indicated. When several persons are responsible for the maintenance of a variety, the names need not be published. If the names are not published, the variety registers shall indicate the authority holding the list of names of persons responsible for maintenance of the variety.

3. Member States shall, as far as possible, ensure at the time of registration that the variety is known by the same name in all Member States. If it is known that reproductive material of a given variety is placed on the market in another Member State under a different name, that name shall also be indicated in the variety register.

4. A variety which is not clearly distinguishable:

a) from a variety previously accepted in the Member State in question or in another Member State, or

b) from another variety which has been assessed with regard to distinctness, stability and uniformity in accordance with rules corresponding to those of this Regulation, without, however, being a variety known in the Union within the meaning of Article y (DUS),

shall bear the name of that variety. This provision shall not apply if this name is likely to mislead or cause confusion concerning the variety in question, or if, pursuant to all the provisions of the Member State concerned governing the names of varieties, other facts prevent its utilisation, or if the rights of third parties impede the free use of that name in connection with the variety in question.

5. Member States shall compile a file on each variety registered, containing a description of the variety and a clear summary of all the facts on which this registration was based.

6. The genetically modified varieties which have been registered shall be clearly indicated as such in the variety registers.

7. The national registers shall be subdivided in two parts [option 2 of Annex II]:

- a) Part A: varieties with <u>official description of identity</u>; and
- b) Part B: varieties with <u>officially recognised description</u>, including in particular varieties:
 - i. which have been traditionally grown in particular localities and regions and are threatened by genetic erosion;
 - ii. with no intrinsic value for commercial crop production, but developed for growing under particular conditions;
 - iii. serving the interest of conserving plant genetic resources;
- c) Part C: other material with officially recognised description;
- d) Part D: forest material with official description of identity.

In Part A, varieties with satisfactory value for cultivation and use shall be indicated as such.

8. Detailed rules about the format and content of the variety registers may be adopted in accordance with the procedure referred to in Article x [(comitology].

Requirements for registration of varieties and other material

Article 3 Basic requirements

1. In order to register a variety or other material in a variety register, following requirements shall apply:

- (a) availability of official description of identity pursuant to the specific rules of Article x (official description of identity), and suitable denomination for varieties
- (b) availability of officially recognised description
- (c) availability of officially recognised description and suitable denomination, for other material
- (d) the requirements laid down in Annex x, for forest material

2. In the case of a genetically modified variety, the variety shall be registered only if the GMO it consists of has been authorised for cultivation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003, the variety shall be accepted only if it has been approved in accordance with that Regulation.

3. A variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (1) shall be registered only if it has been authorised under the relevant legislation.

4. It shall be decided by Article x [comitology] to which tier referred to in paragraph 1 (a) to (c) plant genera or species and/or varieties shall belong.

Specific conditions may be established in accordance with Article x [comitology] for the registration of specific varieties in Part B of the national registers.

Article 4 **Denomination of varieties**

For the purpose of the registration of a variety in Part A of a variety register, the criteria set out in Article 63 of Council Regulation (EC) No 2100/94 shall apply concerning the suitability of the denominations of that variety.

Detailed rules as to the suitability of denominations of varieties may be adopted in accordance with the procedure referred to in Article x [comitology].

Official identification of varieties

1. For the purposes of registration of a variety in Part A of a national register, the identity of a variety shall be confirmed if a variety is proven distinct, uniform and stable.

2. A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application determined pursuant to Article x (date of application).

The existence of another variety shall in particular be deemed to be a matter of common knowledge if on the date of application determined pursuant to Article x (date of application):

(a) it was the object of a plant variety right or entered in an official register of plant varieties, in the Union or any Member State, or in any intergovernmental organization with relevant competence;

(b) an application for the granting of a plant variety right in its respect or for its entering in such an official register was filed, provided the application has led to the granting or entering in the meantime.

Rules adopted in accordance with Article x (comitology) may specify further cases as examples which shall be deemed to be a matter of common knowledge.

3. A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description.

4. A variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

Article 6

Value for cultivation and use of a variety

For the purpose of the indication of a variety in Part A of a variety register as having a satisfactory value for cultivation and use, a variety of agricultural crops shall be regarded as such if, compared to other varieties registered in the variety register of the Member State in question, its qualities, taken as a whole, offer, at least as far as production in any region is concerned, a clear improvement either for cultivation or, as regards the uses which can be made of the crops or the products derived there from. Where other, superior characteristics are present, individual inferior characteristics may be disregarded.

Detailed rules concerning the requirements for the value for cultivation and use of varieties belonging to particular species or groups of species shall be adopted in accordance with the procedure referred to in Article x [comitology].

Annex II - Option for structure of the Register on varieties

Option 1:

For Agricultural crops, Vegetables, Vine, Fruit and Forest Reproductive Material the following subdivision is made, as appropriate:

a) Part A: varieties with official description of identity

b) Part B: varieties with officially recognised description

c) Part C: other material with officially recognised description

d) Part D: Forest material with official description of identity

Option 2:

For all regulated plant species:

a) Part A: varieties with official description of identity

b) Part B: varieties with officially recognised description

c) Part C: other material with officially recognised description

d) Part D: forest material with official description of identity

Option 3:

It would be indicated by a footnote for each registered variety/material on basis of what information/testing [see a) to c)] it has been registered.