

BMT/13/18 ORIGINAL: English DATE: November 8, 2011

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS GENEVA

## WORKING GROUP ON BIOCHEMICAL AND MOLECULAR TECHNIQUES, AND DNA-PROFILING IN PARTICULAR

Thirteenth Session Brasilia, November 22 to 24, 2011

THE USE OF MOLECULAR TECHNIQUES FOR PLANT VARIETY PROTECTION – APPROVED POSITION OF CIOPORA (AGM, ROME, 12TH APRIL, 2011)

Document prepared by the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA)

1. The CIOPORA GREEN PAPER on PLANT VARIETY PROTECTION (PVP, November 2002) has only in a limited way addressed the use of DNA and molecular technologies: "As to DNA charts, CIOPORA is in favor of a continued study of this method of description and identification of varieties so that it may be used by Plant Breeders' Rights Offices when it has been proven to be reliable and repeatable enough. For the time being, CIOPORA submits that one should abide by the traditional methods of description for DUS examination". In a footnote, a further study of these kinds of techniques at the international level coordinated by the Technical Committee of UPOV is encouraged.

2. In January 2008 CIOPORA published its Position Paper on ESSENTIALLY DERIVED VARIETIES (EDV) which is amongst others detailing the use of molecular markers for the assessment of genetic conformity in disputes on EDV.

3. In the current paper CIOPORA wants to update its position about the use of molecular techniques for Plant Variety Protection. In the current daily business molecular techniques have become common tools both in the breeding process and in disputes on variety identity and infringement (enforcement of Intellectual Property (IP) rights): there is no restriction for any party to use molecular or other techniques in support of its position. In this respect case law is continuously evolving. In the context of the grant of Plant Breeders' Rights however, a

regulatory framework for the use of molecular techniques needs to be put in place prior to their introduction and application.

4. Any improvement that enhances the reproducibility, efficiency and harmonization of the current DUS examination process, while maintaining the reliability of the testing and the scope of protection of the current PVP system, is in the benefit of the breeders. CIOPORA is aware that the existing examination system, due to increasing costs for evaluation by the increasing number of applications for Plant Breeders' Rights (PBR) (in terms of both species and applications per species), is more and more under pressure. Additionally, by the increase in the number of UPOV members, there is a growing concern about the sound application of the current PVP systems worldwide.

5. The effective enforcement of IP rights is of utmost importance for breeders. CIOPORA supports the elaboration of a standard *modus operandi* of DNA analysis as a tool to improve the enforcement of IP rights; molecular markers are then very useful for variety identification. Concerning the determination of Essentially Derived Varieties the assessment of genetic conformity is indispensable. Already in its cover letter to the EDV paper CIOPORA has opened the possibility to breeders to develop a list which could contain further details which would then have to be delivered by parties to EDV-disputes, e.g. details on the method of DNA preparation, the fingerprint technique used, the number and specificity of primers and the number and localization of marker bands included in the analysis, allowing an independent expert to judge whether the method, technique, primers etc. used is appropriate or not.

6. In the view of all above, a voluntary integration of the procedures for DUS and PBR granting with new tools, such as molecular markers, that could allow a stronger enforcement of plant variety rights is highly desirable.

7. In order to achieve such integration, CIOPORA recognizes that the use of molecular markers for the enforcement of IP rights, the determination of Essentially Derived Varieties and variety examination can be useful:

- As supportive tools for the enforcement of Plant Variety Rights. At the current stage molecular markers can be used to rule out that plant material is infringing a plant variety right (in case of a large genetic distance) or to furnish a *prima facie* proof that plant material belongs to a protected variety or to a mutation thereof.
- To determine the genetic conformity between initial varieties and their essentially derived varieties.
- In the development of integrative examination procedures for existing characteristics, provided this new procedure is fully corresponding and predictive to the traditional phenotypic characteristic (Option 1(a) "Use of molecular characteristics which are directly linked to traditional characteristics (gene specific markers)" in UPOV documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. ["Characteristic-specific molecular markers" in document BMT/DUS/1 Draft 6]). Appropriate and recurrent calibration to the standard procedure needs to be procured when adopting such an integrative testing method.

## BMT/13/18 page 3

- To generate a genetic conformity measure as additional information when planning DUS trials, to come to an optimized setting of variety comparisons in DUS trials and for management of reference collections (Option 2 "Calibration of threshold levels for molecular characteristics against the minimum distance in traditional characteristics" in UPOV documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. ["Calibrated molecular distances in the management of variety collections" in document BMT/DUS/1 Draft 6]). Care must be taken that no phenotypically similar varieties are omitted from the comparative trials. To avoid appeal in later examination years, which unnecessarily expand the examination period, applicants and owners of reference varieties must be fully informed and consulted on beforehand about the composition of the trials.
- As a reference DNA fingerprint that functions as part of a certified plant passport, additional to the variety description. Fingerprint data are generally confidential and owned by the holder of the respective variety and can only be disclosed with the owner's permission; a general permission could be granted to the independent examination offices for building databases for their internal use only. CIOPORA is not in favor of disclosing this information to external parties. However, the methodology for fingerprinting must be accessible to qualified labs, external of the examination offices. Methodologies should be in line with the guidelines provided by the UPOV-BMT working group (UPOV document TGP/17/1 BMT Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction). In the long term a new variety examination system for DUS that fully exploits the advantages of molecular marker techniques might be achieved (Option 3 "Use of molecular marker characteristics" in UPOV documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. ["Use of molecular marker characteristics" in document BMT/DUS/1 Draft 6]); for asexually reproduced ornamentals and fruit crops, such a new system can offer many benefits that need to be further evaluated. However, regarding the current state of the art and the limited knowledge about the effect on the scope of protection of titles granted under the current system, this is today not within reach.

8. CIOPORA is seriously concerned about a possible decreasing minimal distance between varieties for granting PBR or degrading the scope of protection. Any change to the Plant Variety Protection system holds a significant risk to this. Nevertheless, no PVP system is able to correspond fully to the value of innovative breeding products; all PVP systems are aimed at achieving a good level of IP protection and must be amenable for the enforcement of IP rights.

9. In this view, CIOPORA is in favor of any improvement to the essential basis for granting PBR, the current examination procedures or the management of a PVP system that creates more transparency, improves the reliability of examination, strengthens PVP or facilitates enforcement. CIOPORA is fully aware of the potential that molecular markers can offer and supports the further integration of their application in the current PVP system, at this stage on a voluntary basis. Nevertheless, molecular techniques are not most suited to replace Uniformity and Stability testing; currently also for Distinctness there are severe constraints. CIOPORA is convinced that a harmonized approach, coordinated at the international level and taking into account a necessary transitional period must be followed; the UPOV-Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) is

## BMT/13/18 page 4

best suited to guide the process of finding acceptable applications of molecular markers in these fields.

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