INTRODUCTION

1. DNA molecular techniques are possibly used in the following three areas: DUS testing, variety identification and the judgment of essential derivation. At present in Japan, DNA variety identification techniques are used for measures against the infringement of plant breeders’ rights (PBRs). Recently, matters to be considered in the use of DNA variety identification techniques for the measures have been identified. The outline of such measures taken by National Center for Seeds and Seedlings (NCSS) was reported at the twelfth session of the BMT, held in Ottawa, Canada, from May 11 to 13, 2010 (see document BMT/12/6 “Project of Preserving Specimens and DNA of Protected Varieties in Japan”). The following part of this paper briefly explains the current situation of the measures taken by NCSS and the points to keep in mind when using DNA variety identification technique in anti-infringement measures.

SIMILARITY TEST BY DNA ANALYSIS

2. NCSS has provided variety similarity tests which compare suspicious plant material with a protected variety for the purpose of supporting the holders of PBRs to prove the infringement of their rights. The similarity tests consist of three kinds of tests; characteristic comparison tests with visual checks and measurements on varieties; growing tests in the same way as the DUS test; and variety identification tests by DNA analysis. These tests are conducted at the request of the holders of PBRs. The DNA analysis test is available for the crops that meet the following conditions:

   1. DNA variety identification technique is developed and validated; and
   2. DNA profiles of varieties put on the market in Japan have been examined, and a variety is clearly distinguishable from any other varieties by using the DNA profiles.

VALIDATION OF DNA VARIETY IDENTIFICATION TECHNIQUES

3. If an official method of DNA variety identification technique for a species has already been established, NCSS uses the method for variety identification test. Otherwise, NCSS conducts a validation test of DNA variety identification method which has been developed by a research institute. Specifically, each DNA marker of the method has to be validated according to the ISO13495: Principles of selection and criteria of validation for varietal identification methods using specific nucleic acid.
PRESERVATION OF SPECIMENS OF PROTECTED VARIETIES

4. When DNA variety identification techniques are used to examine the infringement of PBRs, the most important point is that the origins of the samples of plant varieties used for DNA analysis are clear. Even if the DNA type of samples of a protected variety submitted by a client (a right holder) who requests a DNA analysis test matches the DNA profile of suspicious material, it does not prove infringement of the plant breeder’s right. Because there is no evidence to confirm that the samples of the protected variety and the suspicious material provided by the client are their true samples. Therefore an alleged infringer can deny not the test results but the validity of the samples to disprove the right holder’s claims.

5. In order to settle this problem, NCSS takes measures such as witnessing the sampling of a suspicious material by the client and preserving the specimens of protected varieties. Especially, NCSS has been implementing a project for preserving specimens of protected varieties which is entrusted by the Ministry of Agriculture, Forestry and Fisheries. In the project, the plant material (e.g. leaves) of protected varieties at the time of DUS testing are collected and freeze-dried as specimens for long term storage. Owing to these measures, if the DNA profile of the preserved specimen of the protected variety corresponds to the DNA profile of the sample of the suspicious material, it proves that the suspicious material and the protected variety are identical and the infringement of the plant breeder’s right is established.

CONCLUSION

6. NCSS started the similarity tests service in 2004 and has carried out a total of 170 cases of the tests since then. Out of the 170 cases, 110 cases involved a similarity test using DNA variety identification technique. NCSS also started the preservation of specimens of protected varieties since 2008 and has preserved about 3,000 specimens by now.

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