



Voluntary Report – Voluntary - Public Distribution **Date:** April 14, 2023

Report Number: CH2023-0065

Report Name: MARA Publishes Information to Improve Public Awareness of Essentially Derived Varieties

Country: China - People's Republic of

Post: Beijing

Report Category: Planting Seeds

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Report Highlights:

On April 10, 2023, the Development Center of Science and Technology of the Ministry of Agriculture and Rural Affairs (MARA) published information designed to improve public understanding of the Essentially Derived Variety (EDV) system. The information is designed as "question" and "answer" materials on the MARA website. Seed industry members report the EDV system will significantly improve the protection of breeders' rights and encourage initial variety breeding.

Summary:

On April 10, 2023, the Development Center of Science and Technology of MARA published Questions and Answers on EDVs (link in Chinese) on its website to promote public awareness of the EDV system. The People's Republic of China (PRC) amended Seed Law (see GAIN Report CH2021-0185 Final Seed Law Published), effective March 1, 2022, established the EDV system and encourages the breeding of initial varieties. Subsequently, on November 21, 2022, MARA released the revised draft for comments of the PRC Plant Variety Protection (PVP) Regulations (see GAIN Report CH2022-0127 China Releases Plant Variety Protection Regulations for Comments). One of the major revisions of the PVP regulations is to incorporate the implementation steps and methods of the EDV system. The final version of the PVP Regulation has not been published.

Although the PRC has not acceded to the UPOV 1991 Act, the establishment of the EDV system is expected to improve the protection of breeders' rights and encourage initial variety breeding. Meanwhile, industry members report additional work is necessary to fully implement the EDV system as there is no determined threshold of EDV for different crops. FAS China is aware of a rice industry EDV pilot project launched in December 2020. The agreed rice EDV judgment threshold is a genetic similarity coefficient of 92 percent. FAS China is not aware of any PRC official, or industry recognized EDV threshold for other crops.

BEGIN TRANSLATION

1. What are essentially derived varieties and initial varieties? How are these defined?

Essentially Derived Variety (EDV) refers to a variety that is substantially derived from the initial variety or derived from an essentially derived variety of the initial variety, which is obviously different from the initial variety, and except for the trait difference caused by derivation, it is the same as the initial variety in expressing the basic traits produced by the genotype or genotype combination of the initial variety. In layman's terms, it refers to a derivative variety selected after modification and improvement of a bred variety. The initial variety (IV) is relative to the EDV, and usually refers to the initial variety before modification and improvement.

The definition of a EDV and an IV depends on three factors: 1) whether there is a genetic dependence relationship between the varieties, and the EDV is bred from the IV; 2) whether there are obvious differences between the varieties; 3) Whether the basic traits of EDV and IV are the same.

2. What is the EDV system? Which countries in the world implement the EDV system?

In 1991, the International Union for the Protection of New Varieties of Plants (UPOV) created the EDV system in response to the use of biotechnology to transform other authorized varieties, stipulating that EDVs can apply for and obtain variety rights, but when commercialized, they need to get the consent of the owner of the IV rights. The purpose of creating this system is to establish a benefit distribution mechanism between IV rights holders and EDV rights holders. On one hand, it respects the innovations of others, and on the other hand, it encourages initial innovations in breeding and reduces modified breeding. As of the end of 2021, among the 78

members of UPOV (including national and regional organizations, involving 97 countries), 69 members including the United States, the European Union, and Japan (involving 88 countries) have implemented the EDV system. In 2021, China amended the Seed Law and establish a EDV system, becoming the 70th member and the 89th country to implement the EDV system in the world.

3. Why should China implement the EDV system?

The Central Party Committee and the State Council attaches great importance to the protection of intellectual property rights in the seed industry. China promulgated the "Regulations on the Protection of New Plant Varieties" in 1997, joined UPOV in 1999, and added a special chapter on new plant varieties protection in the Seed Law in 2015, effectively promoting the healthy development of the seed industry. Generally speaking, China's scientific and technological level of its seed industry is constantly improving, and the supply of seed resources is guaranteed. However, compared with the international advanced level, the level of initial innovation is not high, the phenomenon of imitation and modified breeding is common, and the problem of homogeneity of varieties is prominent. China has established a EDV system and made institutional arrangements for the protection of intellectual property rights in the seed industry to 1) encourage the initial innovation of varieties, promote the upgrading of varieties, and guarantee national food security; 2) respect the innovation achievements of others, which provides an effective means of protection for the establishment of a reasonable benefit sharing mechanism; and 3) stimulate the enthusiasm of enterprises for independent innovation and increase investment in research and development. This is an important institutional innovation to strengthen the protection of intellectual property rights based on the new stage of development, proceeding from China's reality and drawing on international experience, which is conducive to the establishment of a system and mechanism that lays the foundation for long-term benefits.

4. What is the difference for an EDV to apply for a plant variety right?

An EDV can apply for a new plant variety right, and the application procedure is the same as the current application procedure for plant varieties. If eligible, the new plant variety right will be granted by the competent department of agriculture, rural areas, forestry and grasslands of the State Council.

5. Under what circumstances does an EDV need to be identified? How is it identified?

EDVs do not need to be identified when applying for plant variety rights. Only when there is a dispute with the owner of the IV right does the EDV need to be identified. Identification mainly adopts molecular identification, field identification and other methods. Molecular identification is mainly used to identify the genetic similarity of varieties at the molecular level, and those that meet or exceed the threshold are usually EDVs. Molecular identification has the advantages of simplicity, speed, accuracy, and strong operability, and is the main method for identification of EDVs. Field identification mainly compares the phenotypic traits of varieties to determine whether there is a derivation relationship. When neither molecular identification nor field identification can be accurately determined, it is necessary to combine breeding records, breeding process, etc. for comprehensive determination.

6. How are benefits shared between the owner of the EDV and the owner of the IV?

When an EDV is used commercially, the consent of the owner of the IV right shall be obtained, and commercial returns shall be given in accordance with the contract. How specific benefits are shared shall be determined through consultation or prior agreement between the variety rights holders of both parties. What needs to be explained is that if the IV has not obtained the variety right, there is no legal basis for rights, and the share of benefits cannot be obtained in accordance with the law. In practice, industry associations can organize to formulate and publish profit sharing principles and contract models generally recognized in the industry for reference by stakeholders.

7. During the implementation of the EDV system, what are the acts that infringe the owner of the IV rights?

According to Article 28 of the new Seed Law, the consent of the owner of the IV right should be obtained when implementing relevant behaviors of EDVs. Relevant behaviors include:

- 1) Production and reproduction;
- 2) processing for reproduction;
- 3) Sales and promises to sell;
- 4) Import and export;
- 5) Reuse the propagation material of the authorized variety to produce the propagation material of another variety for commercial purposes;
- 6) To store the propagation material of the EDV for the purpose of carrying out the abovementioned acts.

If the act of implementing the above provisions involves the harvested material obtained from the unauthorized use of the propagating material of the substantially derived variety, the permission of the IV right holder shall also be obtained; however, except where the IV right owner has had a reasonable opportunity to exercise its rights on the propagating materials.

- 8. What should be done if there is a dispute over an EDV? When an EDV dispute occurs, the parties may entrust an identification agency to carry out the identification. Based on the identification results, the following four methods may be adopted:
- 1) Self-negotiation. The parties reach a settlement agreement through voluntary and equal negotiation. In practice, the parties are encouraged to settle on their own.
- 2) Administrative mediation. If the negotiation fails, the parties may request the competent department of agriculture, rural areas, forestry and grasslands of the people's government at or

above the county level where the infringement occurred or where the accused infringer is domiciled to conduct mediation. If an agreement is reached through mediation, the parties shall perform it; if the party fails to perform the agreement or the mediation fails to reach an agreement, it may bring a lawsuit to the people's court according to law.

- 3) Arbitration. The parties may sign a written agreement, specifying that they voluntarily submit the dispute to an arbitration institution agreed by both parties for arbitration to resolve the dispute. If the parties have reached an arbitration agreement and one party files a lawsuit to the people's court, the people's court shall not accept the case, unless the arbitration agreement is invalid; After the award is made, if the parties apply for arbitration or bring a lawsuit to the people's court for the same dispute, the arbitration commission or the people's court shall not accept it; If the award is revoked or not enforced by the people's court according to law, the parties may apply for arbitration in accordance with the arbitration agreement reached between the two parties, or bring a lawsuit to the people's court.
- 4) Legal dispute in the people's court. According to the "Interpretation of the Supreme People's Court on Several Issues Concerning the Trial of Dispute Cases of New Varieties of Plants," if a dispute over an EDV belongs to the type of case accepted by the people's court, the parties may also directly bring a lawsuit to the people's court. For infringement cases involving EDVs, the intellectual property court, and the intermediate court designated by the Supreme People's Court shall be tried as the court of first instance, and the Supreme People's Court shall hear the appeal against the first-instance judgment.

9. Which breeding methods are likely to produce EDVs?

From the perspective of breeding practice, it is possible to produce EDVs through systematic breeding, backcross breeding, mutation breeding, transgenic, gene editing and other breeding methods. However, whether it is an EDV cannot be judged solely on the basis of the breeding method or the level of genetic similarity, and a comprehensive judgment is also required. It should be noted that if the parent of the hybrid is an EDV, the combined hybrid is not an EDV. However, in the process of producing and propagating the hybrid, due to the repeated use of the parent, the permission of the owner of the parent's IV is also required. If the parent is an authorized variety, the parent's right holder's permission is also required.

10. How to protect the rights and interests of farmers in using seeds when implementing the EDV system?

The fundamental purpose of establishing an EDV system is to establish a reasonable benefit sharing mechanism among variety rights holders, which has no direct impact on the price level of seeds and will not damage the rights and interests of farmers in using seeds. In the long run, the implementation of the EDV system is conducive to promoting initial innovation in breeding and upgrading of varieties, and is conducive to increasing agricultural production and farmers' income.

The Seed Law stipulates that the propagating materials of authorized varieties for selfpropagation and self-use by farmers may not be permitted by the owner of the variety right, and no user fee affiliated to this case. However, other rights enjoyed by the owner of the new plant variety right in accordance with relevant laws and regulations shall not be infringed. According to the relevant judicial interpretations of the Supreme People's Court, farmers' self-propagation of the propagation materials of authorized varieties within the scope of land agreed in the household rural land contract management contract does not constitute infringement. However, new business entities such as large contracting households, family farms, and farmers' professional cooperatives do not belong to the scope of farmers who enjoy the right to self-propagation and self-use.

END TRANSLATION

Attachments:

No Attachments.