

# Elements for a National Legal Framework implementing Access to PGRFA and related Digital Sequence Information consistently with ITPGRFA preamble, Articles 9 and 12.3d, as well as the CBD and its Nagoya Protocol

## **Objective**

To establish a national legal framework implementing the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), specifically regarding the use of plant genetic resources for food and agriculture (PGRFA) and access to those held in *ex situ* collections of the Multilateral System, and to ensure that Digital Sequence Information (DSI) related to PGRFA cannot be used to undermine farmers' rights through patents or other Intellectual Property Rights.

#### **Definition**

"Digital Sequence Information (DSI) means any digital representation of PGRFA, their parts or components, including nucleic acid sequences, amino acid sequences, or any other associated information, whether derived from physical genetic resources, from public and private databases or computer-based calculation (including so-called 'artificial intelligence' – IA)".

### **Key Principles:**

- Implement key ITPGRFA provisions, including Articles 9, 12.3d, and 12.3e.
- Prevent extension of patent and other IPR scope from DSI to physical PGRFA.
- Prevent that facilitated access to PGRFA in ex situ collections is restricted by IPR claims.

### **Recommended Legal Provisions:**

1. **Non-Patentability of Natural Sequences and Traits**: "No patent or other Intellectual Property Rights shall be granted on traits from naturally occurring genetic sequences or their artificial copies (particularly those derived from genetic engineering), including corresponding DSI, contained in PGRFA accessible from public collections or the Multilateral System. The same applies to PGRFA held by farmers in their fields, in community or private seed banks. Any patent or Intellectual Property rights covering the above mentioned PGRFA, their genetic parts or components, including DSI, shall be deemed null and void".

- 2. **Prohibition of Patent Scope Extension**: "The presence of a patented sequence or trait in any PGRFA shall not constitute patent infringement, nor shall it restrict facilitated access to or use of such PGRFA. The incidental or unintentional presence of patented sequences or traits in PGRFA found in *in situ* conditions, and in particular in farmers' fields, including DSI contained therein, does not constitute infringement. In case of contamination, the burden of proof rests entirely with the patent holder, and farmers' are entitled of reparation".
- 3. **Limitation of the scope of patents on technical processes:** "Where a naturally occurring trait is transferred into an organism through a patented process, the scope of the patent is limited to the process and does not extend to the organism".
- 4. **Disclosure and Transparency**: "Patent applications involving DSI must disclose the origin and source of the information, including the physical genetic resource(s) from which it was derived or the database(s) used, and the related Material Transfer Agreement if the PGRFA has been obtained through the ITPGRFA Multilateral System or the Free Prior Informed Consent of Indigenous Peoples or Local Communities who selected and conserved those PGRFA. Failure to provide such disclosure shall be sufficient grounds for rejection".
- 5. **Invalidation Mechanism**: "Any patent or other Intellectual Property Rights granted in violation of these provisions shall be subject to administrative nullification or judicial revocation".
- 6. **Prevalence of Farmers' Rights**: "In cases of conflict between private intellectual property claims and farmers' rights recognized under this law and the ITPGRFA preamble and article 9, as well as in article 8(j) of the CBD and 7 of the Nagoya Protocol, the rights of farmers shall prevail".

#### **Conclusion**

National access legislation implementing the ITPGRFA must include robust safeguards against the misuse of DSI in patent or other Intellectual Property Rights systems. Legal measures should firmly protect public access to PGRFA and the rights of farmers, ensuring that DSI cannot be used to privatize and expropriate what belongs to the farmers.