International Seed Federation
Seed is Life

ISF Submission to the ITPGRFA Notification "**Invitation to submit views and other information on "Digital sequence information""**

28 MARCH 2019

A CONTRIBUTION PREPARED BY THE INTERNATIONAL SEED FEDERATION
ITPGRFA REFERENCE: NCP GB8-016 MYPOW/DSI

The International Seed Federation (ISF) is pleased to submit its views and other information relating to "Digital Sequence Information" (DSI) in accordance with Notification NCP GB8-016 MYPoW/DSI.

In accordance with the Notification, we provide views on the four elements listed:
- *terminology used in this area*
- *actors involved in DSI on PGRFA*
- *the types and extent of uses of DSI on PGRFA, such as: characterization; breeding and genetic improvement; conservation; identification of PGRFA*
- *relevance of DSI on PGRFA for food security and nutrition.*

SUMMARY

ISF continues to fully support the effective implementation of the Treaty in a way that mutually supports the conservation and sustainable use of Plant Genetic Resources for Food and Agriculture (PGRFA) as well as the fair and equitable sharing of benefit resulting from the utilization of PGRFA. We believe that achieving conservation, sustainable use and access and benefit sharing objectives hinge on facilitated access to and utilization of PGRFA in the Multilateral System (MLS).

ISF recognizes that the issue of DSI is complex in many ways. First, there is no consensus definition for the term digital sequence information. We agree with many who have stated that non-material information and data are not equivalent to genetic resources as defined in the Convention on Biological Diversity and the Treaty. Second, many diverse actors in industry and academia are involved in the generation, storage, curation, dissemination, interpretation and use of DSI. These "users" work in well-functioning systems that have been established for a long time. Many of these systems have operated under the principle of "open access" to promote information exchange, which we believe is a fundamental principle of the Treaty. Third, the types and extent of uses of DSI are equally diverse, ranging from public and private breeding to conservation work. Beneficial research has been accelerated by public and private actors as sequencing PGRFA has become more common and affordable. Finally, and with the wider use of sequencing, DSI has become a critically important tool in food security and nutrition especially through faster breeding cycles, more effective control of agricultural pests in farmers' fields.

Within the context of the broader discussion on DSI, ISF supports having a constructive debate with the goal of enhancing the fairness and equity elements of access and benefit sharing under the Treaty. However, ISF is concerned that the current attempts to create an international DSI regulatory regime will undermine the access and benefit sharing objectives of the Treaty. We believe that there is also a high likelihood for DSI regulation to disrupt on-going conservation, exploration, collection, characterization, evaluation and documentation of PGRFA, and to create an entry barrier for capacity building for smaller market segments and for new users.

TERMINOLOGY

ISF notes that the issue of DSI is complex due in large part to the fact that a consensus definition has not been agreed upon. This may be due to the technical complexities around "sequences" which include defining minimum length requirements, homology levels, epigenetic attributes, data quality metrics, and handling of sequencing artefacts (to name only a few). Importantly, neither "digital", "sequence" nor "information" are defined in the Treaty. Rather, the Treaty adopted definitions of plant genetic resources

for food and agriculture, genetic material, and Traditional Knowledge that were harmonized with definitions in the Convention on Biological Diversity. ISF agrees with Parties that have determined that these definitions refer only to physical material and not non-material information. In fact, within Articles 5.1, 7.2, 12.3 of the Treaty, PGRFA and "[descriptive] information" are listed side by side suggesting information and PGRFA are distinct from each other. As such, an amendment process would be required for DSI to fall within the scope of the Treaty.

ISF believes that the Treaty (and Convention) require collaborative and cooperative exchange of information among Parties. In particular, we note that conserving PGRFA (Article 7), provisioning of technical assistance (Article 8), and sharing of benefits through the exchange of information, access to and technology transfer, capacity building, and the monetary and other commercial benefits (Article 13) often have linkages to the use of information including genetic sequence data. It is logical that open access to publicly available genetic sequence data should be seen as facilitating the cooperation called for in the above-mentioned articles of the Treaty.

Looking to the future, ISF is willing to explore the approach proposed by several Parties to the Treaty to use "genetic sequence data" as an initial reference when discussing DSI.

ACTORS INVOLVED IN DSI ON PGRFA

Regardless of how DSI is defined, many actors within industry and academia are involved in the generation, storage, curation, exchange, interpretation and use of DSI on PGRFA. These "users" work within well-functioning systems that have been established for a long time. Many of these systems have operated under the principle of "open access". As sequencing costs have fallen exponentially over the years, the availability and use of DSI has grown among breeders and other plant scientists. Use of DNA sequence information is becoming one of the cheapest forms of high through-put phenotyping/genotyping[1], and supports taxonomic identification and protection against pests and pathogens. Actors in the area of breeding, pest and invasive species control, and in-situ and ex-situ conservation see DSI and genetic sequence data as an invaluable tool for conservation and sustainable use of PGRFA. Even some farmers are using DSI for pest detection and identification.

A specific group of actors maintain publicly and internationally available gene banks with sophisticated data storage and sharing systems. These databases were developed with public funds for the purpose of making sequence data freely available. ISF would also like to remind Parties that Article 17.1 of the ITPGRFA encourages the development of a global information system that has been launched. ISF encourages users of the MLS to exchange information and make it available through the GLIS, to support the Programme of Work to provide "capacity development and technology transfer opportunities for the conservation, management and use of PGRFA and associated information and knowledge paying special attention to the needs of developing countries."[2] This gives visibility and value to PGRFA by adding information necessary to help researchers and breeders' choice when choosing a PGRFA according to their needs.

Policy makers are another important set of actors who must listen to all voices in the discussion on DSI. In addition to the views of ISF, some negotiators alleged that unregulated access to DSI will allow users to

[1] Today BGI offers to sequence any human genome for $600 while the first human sequencing project in 1990 cost $2.7 billion. BGI Beijing Genomics Institute is a publicly traded company that has become a major powerhouse in DSI generation, and they receive millions each year from the Chinese government.

[2] http://www.fao.org/3/a-bq638e.pdf

further circumvent benefit sharing obligations under the Convention on Biological Diversity (CBD), the Nagoya Protocol and the Treaty. Some policy makers may be disadvantaged due to the technical complexity of the topic when trying to view this issue in a balanced manner. For example, descriptions of "rematerialization" of PGRFA solely from accessing DSI are grossly overstated and misleading. Material PGRFA will be essential in commercial breeding for the foreseeable future. ISF is concerned that overly simplistic arguments for regulation overlook the serious, broad and negative impacts of regulation. We urge policy makers to recognize that the societal value of keeping DSI out of scope of any regulation is typically underestimated by the proponents of regulation.

TYPES AND EXTENT OF USES OF DSI

As noted above, the current discussions on DSI are complex for many reasons. For example, some technical complexities arise around "sequences" including defining minimum length requirements, homology levels, epigenetic attributes, data quality metrics, and handling of sequencing artefacts. DSI is being extended broadly to include DNA, RNA and protein sequence information without limit all of which may apply to PGRFA. Some assume that "information" is equivalent to "data", but this creates a number of key questions, such as: does DSI include metadata? Annotated data? Raw data? Gene expression data? And what about data errors? Should we only include "natural sequences" or include synthetic sequences?
With more information being shared by experts in the collection, storage, curation, and dissemination of sequence data, it is becoming clear that the proponents of regulation fail to grasp the intractable complexities. The free access and use of public sources of DSI benefits everyone from conservationists to farmers, from researchers to consumers, and anyone concerned about climate change. The benefits are threatened now by proposed increased regulation of DSI. Regulating access to DSI will create an entry barrier that hinders the capacity building and technology transfer and sustainable use for smaller market segments (orphan crops and market segments with less financial value). It will increase the divide between sophisticated users and others.
The dissemination and transfer of know-how and innovations around the world will be impacted by any regulation affecting DSI as the ability of scientific publications to publish and grant access to information containing DSI will be impaired. Information drawn from scientific publications are accessed by millions of users on a daily bases around the world and constitutes the backbone sustaining science and technology advances; impairing this fundamental right of researchers and breeders and directly contradicts the benefit sharing spirit of the Treaty.

Areas where DSI contributes include:
• In conservation: Use of DSI continues to increase both in taxonomic research and in the monitoring and protection of ecosystem biodiversity e.g., control of pathogens and invasive species. Genetic information is also used to enhance knowledge of ecological communities, which is important for environmental remediation and restoration. In addition, DSI is used to enhance agricultural efficiency which mitigates against the conversion of land for food, feed and fibre production.
• In exchange of genetic resources: applications of DSI in diagnostic tools e.g. virus, identification improve the safe international movement of plant materials and commodities.
• In exploration, collection, documentation, DSI is used in breeding and basic research.
• In characterization and evaluation: DSI can facilitate the development of plant varieties that contribute to more sustainable agriculture. DSI is also used to monitor pest and diseases on farm, as well as for quality control, food safety and other customer-oriented services.

• Basic researchers: collect and extensively use DSI to advance science and scientific understanding of biological systems. The rate of scientific advancement and technological development is heavily dependent on the ready availability of unburdened DSI.

THE RELEVANCE OF DSI TO FOOD SECURITY AND NUTRITION

ISF emphasizes that open (unregulated) access to DSI (genetic sequence data) is critical for food security, nutrition and sustainable agriculture – the primary objectives of the Treaty. This is because DSI is a universal tool in research used globally to solve problems related to food security and nutrition. Present day advancements have been facilitated by the dramatic reduction in the cost of sequencing and the availability of sequence data made possible through multiple public data bases.
ISF feels that more emphasis should be placed on capacity building and enhancing the ability of all scientist around the world to access DSI (sequence data) in support of their conservation and sustainable use efforts. Capacity building for the conservation and use of PGRFA will bring more social benefits than increased regulation of characterization information. The public accessibility of vast sequence databases and the ever-diminishing costs of tools to generate DSI will improve food security and nutrition across the globe if capacity building is prioritized over bureaucratic regulation.

CONCLUSION

In conclusion, if DSI were regulated, anyone and any institution (e.g. a national research unit, a company, or a university) that generates or uses genetic sequence data, and/or accesses non-confidential sequence information would be negatively impacted. The proposed administrative and financial barriers to the sharing and use of DSI would discourage innovation and add to existing disparities. Most institutions would have to add administrative staff to attempt to ensure legally compliant DSI exchange. As we noted above, the task of tracking and defining what data are in scope would likely be an intractable exercise. Users and providers of DSI would have to ensure that prior informed consent (PIC) and mutually agreed terms (MAT) account for the information acquired. Again, extensive, if not impossible, tracking and tracing would be needed; ultimately making both downstream products and other utilizations more expensive and less accessible in the future.
ISF is concerned about the increasing burdens on access and use of germplasm and other genetic resources at a time when plant breeding should be a priority. Impeded access to genetic resources has been growing for over 30+ years. Additional barriers to information access and sharing would further threaten food security, as well as basic research to conserve biodiversity. It would also have a distinctly negative impact on plant breeding programs that strive to sustainably meet the needs of farmers and their customers.