Framework of Understanding between Trait Developing Companies (TDCs) and Plant Breeding Companies (PBCs) within the Seed Industry

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Background

India signed TRIPS agreement as a part of WTO and amended the Patents Act, 1970 and promulgated Protection of Plant Varieties and Farmers Rights Act, 2001 (PPVFR Act) to encourage innovations and benefit Indian agriculture and ultimately the farmers. There were differences of opinion regarding the interpretation about the scope of the sections of the Patents Act and the PPVFR Act among the members of the Seed Industry. Such differences led to delay in commercializing path breaking research in biotechnology and plant breeding and their availability to the farmers through seeds. After several rounds of discussions, to achieve speedy and broad based access of traits to the breeders leading to development of superior plant varieties, leaving the interpretation of the sections of the Patents Act and PPVFR Act open, the leading Industry bodies NSAI and FSII arrived at a consensus for working in India, so that the fruits of innovation both in biotechnology and plant breeding are integrated for the benefit of Farmers by enhancing crop productivity through enhanced availability of seeds of superior plant varieties ultimately to enhance farmer's income.

Objectives:

1. To encourage Plant Breeding Companies (PBC) to breed better varieties by providing access to new traits on the principle of "Nondiscriminatory access but not for free".

2. To encourage development of new traits by Trait Developing Companies, National & International public research institutions (TDC) by providing models for return on investments made for trait development, environment approval, stewardship etc. It is agreed that the trait value should facilitate recovery of these investments for further research investments by the TDCs for continuous development of traits.

3. To bring a framework towards adherence of stewardship guidelines by all PBCs so as to ensure the delivery of the full agronomic potential of the trait for a longer period.

4. All the above objectives are towards not only to the welfare of the Industry but also to ultimately make farming easier and profitable to the farmer.

Scope:

The agreements reached under this framework are an interim arrangement among the diverse Industry players in the background described above. These agreements shall not be interpreted as any party ceding their statutory rights. All rights as provided by the respective legislations to the parties shall remain intact.

Operational Guidelines

It is agreed that the framework should allow nondiscriminatory access to the qualifying PBCs for various traits like GM, non GM traits brought into cultivated species, Genome Editing based traits etc., which are having agronomic value to farmers, whether or not the

technology used is patented, for development of superior varieties and production and distribution of seeds of such varieties to the farmers.

There is a lot of opportunity to stack traits from different sources and manage resistance better. For example two traits that are available from different developers (TDCs) which can control Pink Boll Worm in cotton can be stacked to provide an effective solution to the farmers. The mechanics of responsibility for regulatory approval, cost of deregulation, ratio of trait value sharing, responsibilities & liabilities of different parties, etc., should also get covered in this framework.

There is a vast opportunity to use Genome Editing technology but there would be a challenge of collecting trait value from many OP crops in which the Crispr Cas technology may be potentially used. If we make a framework and implement, it will help in bringing benefits of modern technology to the vast number of farmers growing large acreages of OP crops across the country and will benefit everyone.

It is agreed that based on the interactions so far, the following aspects are accepted as broad elements of the framework by all participants.

1. The rights of the TDCs and the rights of the PBCs developing new plant varieties with the traits, have to be mutually respected.

   The TDC shall provide Non transferable access on a nondiscriminatory basis to the traits developed by them to PBCs qualifying as per following three criteria for developing superior plant varieties.

   a) Adhere to stewardship guidelines to deliver the intended benefits as well as to sustain the efficacy of the trait.

   b) Agree to pay the trait value/benefit share as determined in accordance with the guidelines set out below as long as the trait is delivering the intended benefit to the farmers.

   c) Possess financial capacity with a net worth of Rs. 5 Crs, annual sales of above Rs. 12.5 Crs and a profit making company with a minimum of Rs. 0.60 Crs profit per year for last 3 years. If the PBC is not a profit-making company, the net worth may be higher at Rs. 10 Crs. The PBC shall also have plant breeding expertise, research infrastructure with a farmland of 15-20 acres (own or with long lease for a period of at least 5 years), a poly house in case of need of containment facility, seed quality management infrastructure with well-defined quality protocols, IBSC and other statutory requirements to handle biotech traits.

2. Trait Value determination

   2.1 Trait value will be determined based on the agronomic value the trait is expected to deliver to the farmer. The determination of trait value for each trait will be guided based

on the trial data, the value delivered to the farmer, the agronomic value of the trait, the prevailing price of the seed without the trait and such other parameters like crop economics as they deem relevant to a specific trait.

2.2 The TDC will make a presentation to the Industry Governing Body (IGB) proposing the trait value. The proposal for trait value will have to be supported with scientifically robust field agronomic trial data generated at multiple locations which clearly establishes the additional agronomic value the trait is expected to deliver to the farmer. The trait value will be a portion of additional agronomic value. This will be discussed in the IGB and finalized.

2.3 While determining the Trait value the IGB will observe the guideline that the trait value should be between 5% and 20 % of the Seed Value (defined hereinafter) unless there are abnormal reasons to go below or above the range. The Trait with smaller potential (sales volume due to small area of a crop or narrow use of the trait leading to limited sale volume) will have a higher % while traits with large potential for business will have slightly lower %.

2.4 Such trait value, in absolute value (and not as a % of price) as determined through the above process, shall be uniformly applicable to all PBCs irrespective of their individual seed prices.

2.5 The trait value will be on a telescopic scale of time (assuming that the volume of business will go up with time and then will stabilize before eventually coming down). The trait value would be at its highest in the first 5 years after introduction and then will have a sliding scale with a reduction up to 5% of the value every year as decided by IGB. The Industry Governing Body (IGB) may decide the exact percentage of annual reduction based on data on changes in crop economics, penetration of the trait, etc

2.6 However, the trait value shall be paid only till the trait is delivering the intended agronomic benefit to the farmers. The two associations will take the help of an independent technical body to assess whether the trait is continuing to deliver the intended agronomic benefit or not.

3. Determining the Seed Value and thereafter the Trait value

Before the IGB decides the trait value and the percentage of seed value to arrive at the trait value to be paid by PBCs to the TDCs as described under 2 above, the following steps required to be undertaken to arrive at a uniform trait value payable by all PBCs:

(a) The list price (not the MRP) of the top five to ten companies in the crop shall be considered to arrive at the average list price of the crop (average price of hybrids / varieties constituting at least 50% market share).

(b) 25% discount on the average list price, as arrived above, to be deducted to arrive at the "seed value".

(c) This seed value will be the basis for the IGB as detailed under 3.3 above to arrive at the absolute trait value as a % of seed value.

(d) Such trait value shall be uniformly applicable to all PBCs for the first five years after commercialization. The seed value increment, during this five years period as may be changed by PBCs due to inflation of cost of production, shall not alter the trait value. In other words, even if the list price goes up subsequent to arriving at trait value during the first five years period, it shall not impact/alter the trait value.

(e) After five years, the trait value shall reduce as per the framework. While increasing the seed value to adjust inflation, the reduction of trait value shall be adjusted / reduced from the increment in seed value from the 6th year onwards so that the benefit of reduced trait value shall be passed on to the farmers.

(f) If there is any Govt. intervention to regulate the seed prices, the trait value shall be corrected and adjusted accordingly by the IGB.

(g) It is clarified that PBCs shall always be at liberty to individually set seed prices for their products and that the reference to seed prices in this framework is only for the purpose of calculating trait value.

4. Once the trait value is determined it will be communicated to the Ministry of Agriculture, GOI by the two associations through a written communication. Such communication will carry both the absolute value of the trait and the % of the seed value to arrive at the trait value.

5. The PBC is responsible for maintaining stewardship guidelines provided by the trait provider and the regulatory body. The PBC is responsible for maintaining the quality of the seed and the trait purity in the seed as per the regulations under the appropriate legislations. The PBC has to make payment of trait value to the TDC as per the access agreement signed. In case of delay in payment of trait value, the PBC shall pay interest @ 12% per annum. Prolonged delay in making payments may attract cancellation of the Access Agreement and recovery proceedings with the support of the IGB. The associations will make sincere efforts to persuade such errant PBCs to make timely payment of the trait value.

6. The PBC will have the right to register their varieties with the trait under the PPVFRA duly acknowledging the presence of the trait accessed from the TDC. The TDC shall not make any IP claim on plant varieties with the trait or enforce any IP right on the plant varieties of the breeders/seed companies who are paying trait value under this framework. The PBC shall not make or enforce any IP claim on the trait *perse*.

7. **Performance failures and claims by the farmers**

   Any performance failures or claims based on performance related to trait shall be the responsibility of the TDCs whereas the performance related to the variety / hybrid shall be the responsibility of the PBC. However, both parties shall support each other as required from time to time while defending the claim.

A legally binding Access Agreement covering the above aspects will be signed by the TDC and the PBC when access is provided to the trait.

Formation of Industry Governing Body.

The Industry may consider creating an Independent Body (called as Industry Governing Body, IGB) through consensus involving the industry representatives (both PBC and TDC) and including an independent person of eminence (agriculture scientist or policy maker who served in the Govt. or someone similar) to discuss and decide on several actions including determination of trait value.

1. Facilitating Role of the IGB:

a) Facilitating the determination of trait value percentage by evaluating the data submitted by the TDC, the market situation, value being delivered to the farmer, seed companies views, etc and based on a detailed discussion in the IGB.

b) In situations where more than one trait coming from different TDCs will be stacked together, facilitate the formula for sharing of the overall trait value between the TDCs who are contributing the traits in the stack. This will be based on an evaluation of the value being delivered by each trait, trial data, the need of the farmer, market situation, costs incurred for environment deregulation, seed companies views etc., which will be discussed in the IGB to arrive at a commonly acceptable formula.

2. Thought leadership role of the IGB:

   Since it is a platform where all the industry is coming together this IGB should be able to have a discussion (the IGB can invite some experts if needed) and create industry position papers on subjects like what are the needs of the farmers in various crops which need technological interventions, which traits can be brought in which crop to meet these needs, what should be an overall biotech plan for crops in the country, regulatory guidelines for new technologies as they keep coming in, etc, submit them to the government and engage with the government to find satisfactory positions.

3. Principles that will be followed by the IGB:

a) The principles of Fair, Reasonable and Non-Discriminatory (FRAND) shall be followed by the IGB so that there are no accusations of cartelization/anti-competitive practices.

b) The underlying principle of protecting the rights of the PBCs and the TDCs without undermining the rights of each other shall be maintained and conserved by the IGB.

c) In case of transgenic traits, the IGB shall work towards acceptance of Event Based Approval Mechanism (EBAM) by the GEAC, the Ministry of Environment & Forests and the Ministry of Agriculture & Farmers Welfare so that the PBCs need not have to repeat biosafety evaluation. However, the PBCs shall have the responsibility to follow the conditions for biosafety approval of the trait meticulously. The new variety approvals with the biosafety approved transgenic traits shall be as per the provisions of the Seeds Act.

4. The possible composition of the IGB:

1. President of NSAI or his nominee
2. Chairman of FSII or his nominee
3. One Representative of TDC
4. Two Representatives of two PBCs out of which at least one shall be representing small and medium companies in the Industry identified by the two National Seed Associations
5. An independent person of eminence who will Chair the IGB

Invitees without voting

6. An independent biotech/seed scientist (if needed)
7. Two representatives of the PBCs, who have a major market share in the crop under consideration. (one each from FSII and NSAI)

This IGB will discuss the proposals in all the required detail and take suitable decision which will be fair to all parties concerned.

The IGB decision must be by consensus and voting shall be avoided unless it is absolutely necessary. The dissent in such cases will be recorded.

The President/Chairman of NSAI/FSII shall be Member Secretary of the IGB by rotation for one year at a time.

M.RAMASAMI
Chairman, FSII

M. PRABHAKAR RAO
President, NSAI