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

Background

India signed the TRIPS agreement as a part of the WTO and amended the Patents Act, 1970 (Patents Act) 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 of the scope of the sections of the Patents Act and the PPVFR Act among the members of the Seed Industry. Such differences led to a 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 the Objectives as set forth herein below including 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 (both represent PBCs and TDCs operating in India) along with the industry stakeholders have arrived at an understanding to promulgate this framework to ensure broad based access to traits and to arrive the trait fee payable by a Plant Breeding Company (PBC) to a Trait Developing Company (TDC) so as to enhance the availability of superior plant varieties and ensure that the interests of all stakeholders are equally protected (Framework).

Objectives:

A. To encourage PBCs to breed better varieties by providing access to new traits on the principle of "Nondiscriminatory access but not for free".

B. To encourage development of new traits by TDCs, national & international research institutions 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.

C. 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.

D. To ensure that 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.

E. 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:

This Framework is an arrangement agreed among the diverse industry players in the background described above. Any party adopting this Framework shall not be considered to be ceding their statutory rights. Further the adoption of this Framework shall not prejudice any rights available to the parties under applicable laws. For avoidance of doubt, this Framework is voluntary and each party shall be free to act in their best interest.

Operational Guidelines

It is agreed that the Framework should provide for nondiscriminatory access of various genetically modified (GM) traits and non-GM traits developed through biotechnology, genome editing etc.in cultivated species, which are having agronomic value to farmers, whether or not the technology used for the development of such traits 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 assessing responsibilities for seeking regulatory approvals, cost of deregulation, ratio of trait value sharing amongst the respective TDCs, responsibilities & liabilities of parties to the trait access agreement, etc., will be further deliberated and decided by the Industry Governing Body (IGB) proposed under this Framework.

There is a vast opportunity to use genome editing technology but there would be a challenge of collecting trait value for many OP crops in which the Crispr Cas technology may be potentially used. The Framework when implemented, 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.

Based on the discussions and deliberations so far amongst the key industry bodies and other industry stakeholders, the following aspects are accepted as broad elements of the Framework by all participants.

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

   Every PBC qualifying as per the criteria given in the Appendix shall have access to the traits developed by TDCs on a non-discriminatory and non-transferable basis for developing superior plant varieties. However, such PBCs should:

   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 in accordance with the guidelines set out below as long as the trait is delivering the intended benefit to the farmers.

   c) Demonstrate adequate 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, adequate financial capabilities and other statutory requirements to handle biotech traits.

2. Trait Value

2.1 Trait value will be arrived based on the agronomic value the trait is expected to deliver to the farmer. The trait value for each trait should be 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 A TDC will make presentation with relevant information and supporting statistics, costings etc., to the IGB proposing the trait value on the basis of the indicative factors mentioned in Paragraph 2.1 above. 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 proposed trait value will be discussed in the IGB meetings and finalized.

2.3 While dealing with the trait value proposed by the relevant TDC and arriving the trait value, the IGB will observe the guideline that the trait value should be between 5% and 20% of the seed value, for which the rational is given in the Appendix unless there are extraordinary reasons or circumstances (like abnormal changes in crop economics, transformational changes in mechanization and digital technologies, increases in labour costs, climate change related changes or very niche technologies like ancillary traits which are needed to effectiveness of main trait, etc.) which justify the trait value to go below or above the range. The crop 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 A trait value, in absolute value (and not as a % of price) as arrived, once recommended by the IGB through the above process, shall be uniformly applicable to all PBCs irrespective of their individual seed prices. Though the PCBs are at liberty to access or not to access the trait from the respective TDC as recommended by IGB.

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 trait value every year as recommended by the IGB. The IGB may also recommend 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 industry bodies/two associations (the representatives of which are members of the IGB) may take the expert opinion of an independent technical body to assess whether the trait is continuing to deliver the intended agronomic benefit or not.

3. Calculating seed value for arriving 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 companies in each of the three buckets categorized as large sized (PBCs with above INR 500 Crs annual revenues), medium sized (PBCs with INR 100-500 Crs annual revenues) and small sized (PBCs with below INR 100 Crs annual revenues) PBCs in the crop shall be considered, the average price of each of the three buckets will be calculated and the mean of those three averages will be calculated 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". The discounting percentage of 25% on billing price is based on an estimated average of various discounts and / or the trade margins offered by PBCs to trade channel partners consisting of retailers / wholesalers / distributors.

c) This seed value will be the basis for the IGB as detailed under 2.3 above to arrive at the absolute trait value as a % of seed value only for once at the first instance.

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 trait value shall be adjusted / reduced to the extent of 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 subsequent Govt. intervention (after decision by IGB as above) 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 at the first instance.

4. Once the trait value has been assessed and recommended by the IGB (basis the process specified above in this Framework), it will be communicated (in writing) to the Ministry of Agriculture, Government of India by the two associations (namely NSAI and FSII). Such communication will carry both the absolute value of the trait and the % of the average seed value considered to arrive at the trait value.

5. The PBC which willfully entered into a trait access agreement shall: (a) comply with stewardship guidelines provided by the TDC and the IGB; (b) maintain the quality of the seed and the trait purity in the seed as per applicable laws; and (c)make payment of trait value to the TDC as per this Framework.

6. PBCs will have a right to register their seed varieties with the trait under the PPVFR Act duly acknowledging the presence of the trait accessed from the TDC. The TDC shall not make any intellectual property claim on plant varieties with the trait or enforce any intellectual property right on the plant varieties of the PBCs who are paying trait value in accordance with this Framework. The PBC shall not make or enforce any intellectual property claim on the trait *per se*.

   The PBCs are free to license their proprietary seed varieties with the trait to other seed companies including companies who might not qualify under clause 1(c) above.

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

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

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

8. **Periodic revisions:** The Framework will be subject to periodic revisions as considered necessary.

Formation of Industry Governing Body.

The Industry stakeholders may mutually agree and create an independent body (called as Industry Governing Body, IGB) comprising of members who will be 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 based on percentage of average seed value 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 amongst the IGB members based on the guidance in this Framework.

   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 amongst the IGB members based on the guidance in this Framework to arrive at a commonly acceptable formula.

2. Thought leadership role of the IGB:

   Since it is a platform where all the industry stakeholders can participate, IGB should endeavor to discuss various issues affecting the industry and stakeholders (the IGB can invite some experts if needed) and create industry position papers on various subjects including, the needs of the farmers in respect of 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., submissions to the Government, engaging with the Government to find solutions (in the form of regulatory reforms/guidelines) to address these industry requirements satisfactory positions.

3. Principles that will be followed by the IGB:

   a) Principles of Fair, Reasonable and Non-Discriminatory Access (FRAND) shall be followed by the IGB to ensure that there are no accusations of or potential for cartelization/anti-competitive practices in trait access agreements.

   b) The underlying principle of protecting the interest and rights of all stakeholders, including the interest and rights of PBCs, farmers and the TDCs without undermining the rights of any other stakeholders 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, Ministry of Environment & Forests and the Ministry of Agriculture & Farmers Welfare to ensure that the PBCs are not required to repeat biosafety evaluation. However, the PBCs shall absolutely and meticulously follow the applicable conditions for biosafety approval of the trait. Approvals of new variety of seeds with the biosafety approved transgenic traits shall be as per the provisions of the Seeds Act, 1966.

4. Industry GoverningBody

4.1. The proposed composition of the IGB:

Non Voting Members of the IGB

a) President of NSAI or his nominee;
b) Chairman of FSII or his nominee;
c) One Representative of TDC group nominated by the members of AAI (Alliance for Agri Innovation) which is a sub group of FSII representing all the TDCs;
d) Two representatives of large sized PBCs nominated by the board of NSAI and FSII respectively;
e) Two representatives of medium sized PBCs nominated by the board of NSAI and FSII, respectively;
f) Two representatives of small sized PBC nominated by the board of NSAI and FSII, respectively;
g) Two representatives of the PBCs, who have a major market share in the crop under consideration. (one each from FSII and NSAI), if needed;

Independent, Voting Members of the IGB

h) An independent person of eminence who will Chair the IGB;
i) Two scientists with qualifications and/or experience in biotechnology/ seed/ regulatory industry;
j) One agricultural economist or a professor from any leading management institute teaching agricultural economics or marketing to agriculture management students; and
k) [One additional independent person of eminence].

5. All meetings of the IGB are to be attended by One external Advocate observer, who must be well versed and have experience in competition law and ensure that the deliberations before the IGB are in compliance with competition law.

6. While IGB deliberations can and should include discussion and inputs from the IGB members, the final decision on average seed value and determination of trait value will be taken only by persons listed at 4(h), (i), (j) and (k) (Independent Voting Members). All decisions amongst the Independent Voting Members must preferably be by consensus and voting shall be avoided unless it is absolutely necessary. However, where a vote is required, the decision of the majority Independent Voting Members shall prevail. To further transparency, the dissent in such cases will also be recorded along with reasons.

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

The rationale behind some of the elements of this Framework is explained in the appendix.

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Chairman, FSII

M. PRABHAKAR RAO
President, NSAI

WITNESS (P.RAM KAUNDINYA) WITNESS: (R. K. TRIVEDI)

Appendix

Rationale for certain elements in the Framework

PBC eligibility criteria.

As per the biosafety guidelines under Environment Protection Act, 1986, the PBCs who handle GM traits are required to have certain basic infrastructure such as:

a) a greenhouse admeasuring min 900 sq mt needing an investment of INR13 lakhs
b) capability to test the quality of the GM material in a laboratory, etc.

In addition to the above, the development of a new plant variety, duly incorporating the trait accessed, takes 4-5 years and may cost above INR 1.5-2 Crs. The varieties that have been developed have to be tested in green houses followed by open field tests under the ICAR system for a minimum period of 2 years. This testing process is likely to cost at least INR 5 lakh per year per zone per variety. Assuming that a PBC would develop 5 varieties for testing every year, the expenditure for the same would be above INR 25 lakh per year per zone and for 3 zones it is INR 75 lakhs/year.

In light of the above, that a PBC shall have adequate financial ability to undertake the necessary trait introgression, and consequently, meet the regulatory requirements for the varieties they develop.

However, to ensure unhindered access to all the PBCs, which do not have adequate financial ability, the framework proposes the option of licensing such traited varieties from a PBC which has entered into a trait access agreement with a TDC. This will ensure that no eligible PBC is potentially left out of the process.

Range of trait value as 5-20% of seed value.

- All traits are not equal in the value that they deliver to the farmers, and, therefore, their value may differ basis:

a) the problem that would be potentially addressed in a crop by adopting a certain trait; or
b) the economic impact of the trait on the crop on which it is operated; or
c) the potential increase in the acreage/volume of sales.

- Further, it is important to note that certain traits are intended for very niche applications and have very low potential of use while certain others have a wider spread application on broad acre crops. The price of the seed in each crop varies from as low as INR 50 per kg (Rice) to INR 20,000/kg (Tomato) or even higher in certain other cases.

- The trait value also has to be supported by the cost savings or losses prevented or additional yield that the farmer derives from using the trait and this would vary from trait to trait. Keeping in mind these vagaries, the trait value is being benchmarked as a percentage of seed price and hence such percentage should also be factored in the price of the seed. Therefore, all these considerations need to be accommodated in the suggested range, and consequently, the range of 5-20% has been recommended.

- In addition, guidance has been drawn from the pricing pattern of "Bt." Cotton seeds which is the only genetically modified crop approved in the country so far. Since the

only crop where the Government has fixed seed prices is 'Bt Cotton', illustratively the following trend can be observed in relation to the MRP and the trait value of Bt Cotton:

(Price per 450gr packet of Bt.Cotton)

	Before price control was announced by Government through CSPCO	After price control was announced by Govt through CSPCO			
	2015	2016	2018	2019	2020
MRP	1000	800	740	730	730
Trait value	175	49	39	20	0
% of MRP	17.5	6	5.2	2.7	0
% of assumed seed value with 25% discount	23	8	7	3.6	0

It is observed that prior to price control introduced by the Government of India, the trait fee was approximately 23% which was reduced to 8% for the intervention by the Government of India and eventually reduced to zero. This provides an indication of the range of movement of value of a trait that has widespread application on a large acreage as time progresses and it gains market share.

Determining the seed value - Application of 25% discount on average list price to arrive at the seed value.

List price is decided by all companies for each seed variety to market the seeds every year. This price is published through a price list and several discounts are offered on this by different companies. The prices of companies are different from each other, and they are revised every year. On the basis of current market practices and prevailing discounts and trade margins offered to various channel partners, 25% discount (which is the average discount offered) on the seed prices has been considered as reasonable to arrive at the net seed value as against published price list.