

AUSTRALIAN WINTER CEREALS PRE-BREEDING ALLIANCE (ALLIANCE)

GUIDANCE FOR RESEARCHERS/PRE-BREEDERS and BREEDING ENTITIES IN WINTER CEREALS IN AUSTRALIA

1. Background

- 1.1 Researchers (Pre-breeders) undertake strategic research and development in germplasm pre-breeding (Pre-breeding) to:
 - (1) identify novel and valuable Traits for use in breeding;
 - (2) develop efficient and reliable methods and markers to phenotype and track these Traits;
 - (3) characterise the value of these Traits in key winter cereals production regions;
 - (4) determine the epistatic interactions between novel and existing Traits;
 - (5) develop ways of stacking complex Traits to reduce negative associations; and
 - (6) release enhanced germplasm for use by all Breeding Entities as either parental stocks or segregating material for further reselection.
- 1.2 Pre-breeders do not undertake winter cereals breeding or develop competing winter cereal varieties except in areas of market failure. Alliance members are expected to discuss proposals for variety development with the Alliance prior to undertaking such work.
- 1.3 Pre-breeders wish to develop guidance about arrangements with Australian winter cereals Breeding Entities (Breeders) so that Pre-breeding activities are adopted with optimal arrangements for the Australian grain industries ensuring speed to market.
- 1.4 Breeders are driven by commercial imperatives to achieve competitive advantage through releasing varieties that are successful in the market.
- 1.5 This Guidance Sheet is aimed at publicly-funded Pre-breeding including GRDC supported Pre-breeding projects. Separate arrangements would apply for high-risk, specialist and/or GM technologies, for specialized quality traits of limited market size where closed-loop arrangements are necessary, or where outcomes are constrained by existing contractual arrangements and privately funded Pre-breeding.
- 1.6 It is expected that technologies covered by this Guidance Sheet would be made available to all Australian Breeders on an equivalent basis. Competitive advantage would be achieved through the combination of Traits and technologies with proprietary germplasm and breeding lines, efficiency of operation and speed to market.

2. Currency of Guidance Sheet

- 2.1 Given the current state of continuing change in the industry, these principles in this Guidance Sheet will apply for four years from 1 July 2009 and cover all relevant material transferred to Breeders in that time. Six months prior to 1 July 2013, the principles will be

reviewed in the light of the effectiveness of the EPR scheme, the number of breeding companies and their profitability.

3. Contractual Documentation

- 3.1 It is proposed that the principles outlined in this Guidance Sheet would be implemented through separately negotiated licence agreements and material transfer agreements.

4. Field and Territory Covered

- 4.1 This Guidance Sheet covers use of germplasm, technologies (including molecular markers) and Traits in winter cereals breeding including for the commercial release of new varieties.
- 4.2 It is only relevant to Australia for planting and production.

5. Desired Outputs

- 5.1 It is hoped that implementing the principles in this Guidance Sheet may contribute to greater and faster adoption by commercial Breeders of publicly funded Pre-breeding research in order to benefit the Australian grains industry with the provision of new winter cereal varieties with superior performance and yield. To this end this document provides non-binding guidelines and recommendations for negotiations with Breeders about conditions of access to Pre-breeder's germplasm, technologies and genetic solutions in relation to Traits of interest.

6. Desired Activities

- 6.1 In relation to Traits for new winter cereal varieties there should be regular interactions with Breeders to share data and information on:
- (a) market drivers;
 - (b) defining national and regional priorities;
 - (c) germplasm and technology being worked on;
 - (d) research results;
 - (e) timing of availability to Breeders;
 - (f) current and future issues facing Breeders;
 - (g) trial results on Pre-breeder's Traits; and
 - (h) third party Traits for the Australian grains industry.
- 6.2 The Pre-breeder should provide the Breeder with Pre-breeding IP i.e. new Traits of interest, Trait-related know-how and selection methods, and Trait-related germplasm developed by the Pre-breeder, to be used in conjunction with or incorporated in the Breeder's germplasm. These would include (but not be limited to):
- (a) simple genetic solutions for Traits of interest available to the Breeder for crossing at earliest stage after research and proof of concept trials;

- (b) complex genetic solutions for Traits of interest available as early as possible in adapted germplasm for crossing or at a later stage incorporated in advanced breeding lines as agreed with the Breeder;
 - (c) appropriate methods or know-how for the selection of the Trait of interest.
- 6.3 Where the Breeder requires the Pre-breeder to help with the incorporation of a Trait of interest into the Breeder's germplasm the Pre-breeder should be able to work with the germplasm carrying the new Trait of interest to carry out further research and development on the Trait of interest, and be able to share any Trait-related research results (but not germplasm) with other researchers and breeders unless the parties have agreed otherwise.

7. Pre-breeder's Contributions

- 7.1 It is intended that the Pre-breeder would:
- (1) provide Trait-based germplasm not necessarily well characterised;
 - (2) provide information on Trait value, germplasm and breeding methodology;
 - (3) provide technology and technical advice for screening and assembly of complex Traits; and
 - (4) incorporate other Pre-breeders' Background IP where applicable.
- 7.2 Progression of fixed lines through selection would only be undertaken under negotiated arrangements on a fee-for-service basis and is outside the scope of these guidelines.

8. Pre-breeder's Responsibilities

- 8.1 The Pre-breeder is expected to:
- (1) take all reasonable measures to ensure freedom to operate issues are clearly identified; and
 - (2) maintain integrity of all advanced breeding lines provided by the Breeder; and
 - (3) maintain confidentiality on information derived for those lines as agreed with the Breeder. Separate non disclosure agreements may be required.

9. Breeder's Contributions

- 9.1 It is intended that the Breeder would:
- (1) evaluate Pre-breeder's material and Traits through national evaluation by the Breeder as appropriate for the material;
 - (2) share results and information of trials and evaluation with the Pre-breeder; and
 - (3) provide breeding populations or advanced breeding lines as Background IP, when and as suggested by the Breeder.
 - (4) Provide information on market drivers, defining national and regional priorities.

- 9.2 The Breeder may also contribute a proprietary Trait that is not yet in the public domain. In this instance the Breeder is likely to be treated for licensing purposes as if it were a Pre-breeder.

10. Breeder's Responsibilities

- 10.1 The Breeder would be expected to:
- (1) provide Background IP in the form of know-how where applicable; and
 - (2) provide information on performance of released varieties, particularly that which is perceived to be relating to the Pre-breeders contribution.

11. Breeder's Rights

- 11.1 The Breeder should be entitled to negotiate confidential fee for service arrangements with the Pre-breeder where appropriate.

12. Intellectual Property

- 12.1 It is expected that:
- (1) the Pre-breeder would own the Pre-breeding IP;
 - (2) the Breeder would incorporate the Pre-breeding IP licensed from the Pre-breeder into their proprietary genetic material for plant breeding purposes including commercial variety release;
 - (3) the Breeder would own all genetic material which they generate in the process including any commercial varieties other than those that are essentially derived from third-party varieties;
 - (4) Pre-breeders, Breeders and GRDC would retain ownership of their Background IP;
 - (5) any Background IP, including Pre-Breeding IP, contributed by one party would not be made available to another party without the prior agreement of the owner except as incorporated in a released variety;
 - (6) protection of Pre-breeding IP would be at the Pre-breeder's discretion.

13. Equity Sharing Principles

- 13.1 While it is recognised that technology licence fees will not pay for the full cost of pre-breeding during the life of this agreement, and hence these activities are largely funded publicly, there is considerable value in a clear market signal to share an equitable proportion of net endpoint royalty (EPR) income with Pre-breeders who have materially contributed to the genetic success of a variety.
- 13.2 **At all times it should be remembered that the value of a trait is ultimately determined by the gain it provides to the grower. This will not necessarily directly correlate with the effort expended by pre-breeders in making the trait available to breeders**
- 13.3 When the Pre-breeder seeks a return for Pre-breeding IP:

(a) the principles in Attachment A are recommended as guidance for licence negotiations with Breeders; and

(b) the parties will take into account any relevant laws and applicable government policies and practices related to commercial activities and/or the pricing of goods and services.

- 13.4 In the Attachment, Traits are divided into Tiers, which may attract a range of licence fees. This is to recognise that different genetic solutions for Traits of interest and associated technologies represent a significant range of complexity and investment in their development to the point of useful application in a breeding program. Notwithstanding this, it is recognised that it is impossible to provide Tier definitions that are totally exclusive of one another.
- 13.5 If in doubt about Tier identity or licence terms, the Pre-breeder should use their own judgement as to what propositions may be appropriate but should always act to preserve the principle intentions of this Guidance document – the development of optimal technology transfer arrangements ensuring fast technology adoption for the benefit of the Australian grains industry.

14. Confidentiality

- 14.1 Separate non disclosure agreements are likely to be required.
- 14.2 It is expected that results obtained with breeding lines and/or germplasm developed using any of proprietary germplasm of a Breeder that is not available publicly e.g. not a PBR-protected commercially released variety, would not be shared with other Breeders without approval.

15. Publication

- 15.1 It is expected that the Pre-breeder and where applicable the GRDC would retain rights to publish all IP generated in the Pre-breeding activities.

1. Aim

- 1.1 The overriding objective of this guidance document is to enhance the adoption of Pre-breeding technologies by the Australian breeding sector and hence the effectiveness of public investment in Pre-breeding research.
- 1.2 Any recommendations in this document are non-binding. However, Pre-breeders are encouraged to use them as guidance in their negotiations with Breeders.
- 1.3 The recommendations are directed at Pre-Breeding IP whether protected by patent or not, but do not apply to GM embodiments of patented IP, nor to the other exemptions listed in paragraph 1.5 of the Background section to this document.
- 1.4 The recommended structure of Trait tiers and technology licence fees is hoped to promote and speed the adoption of Pre-breeding technologies by:
 - (1) providing equitable, non-exclusive access for all Australian Breeders;
 - (2) representing realistic, non-prohibitive expectations on returns from technology adoption, which acknowledge the public good nature of public investment, the contributions of public pre-breeding research to the development of commercial varieties, the need for Breeders to use and stack multiple Traits for optimal variety performance, and the relatively small and still maturing Australian market both with regard to the breeding sector and to the endpoint royalty model as a means of value capture;
 - (3) providing Breeders at the time of technology transfer with a degree of certainty about the total cost of technology adoption relative to Breeder's future income from endpoint royalties.

2. Tier 1 Trait

2.1 Meaning

- (1) A validated genetic solution derived from naturally occurring genetic variation in the primary gene pool including synthetics. The qualifying criterion of a genetic solution for a Tier 1 Trait is that it is relatively simple to discover and deploy.

2.2 Trait Examples (non-limiting; non-binding)

- (1) Aluminium tolerance, salinity tolerance, some disease resistances

2.3 Availability

- (1) Tier 1 Traits would be available with appropriate selection methods (e.g. molecular markers) either as Trait-based germplasm that may not be well characterised, or in Breeder-supplied breeding populations.

2.4 Licence Fees

- (1) A technology licence fee is not recommended.

3. Tier 2 Trait

3.1 Meaning

- (1) A validated genetic solution derived from outside the primary gene pool, or from the primary gene pool if considerable effort is required to discover and deploy the genetic solution due to its complex nature or to lack of a simple selection methodology.

3.2 Trait Examples (non-limiting; non-binding)

- (1) Secondary gene pool: alien disease resistance gene
- (2) Primary gene pool: transpiration efficiency (TE), milling yield, some disease resistance

3.3 Availability

- (1) Tier 2 Traits plus effective selection method would be provided to Breeders in a generally adapted material.
- (2) Should individual Breeders require the Trait in their material, a service agreement between the Pre-breeder and Breeder may be established. The terms of the agreement would be the same for all Breeders requesting this service.

3.4 Licence Fees

- (1) Tier 2 Traits may attract a technology licence fee to be set as a percentage of Breeders' net income from EPR.
- (2) If a technology licence fee is charged for a Tier 2 Trait it is recommended that the fee be capped at 5% per annum of net EPR income.

4. Tier 3 Trait

4.1 Meaning

A genetic solution that is:

- (1) Validated in the field,
- (2) Unique, not previously demonstrated in Australia,
- (3) Highly significant and commercially valuable (typically total EPR >\$5m pa per variety from Australian production),

4.2 Trait Examples (non-limiting; non-binding)

- (1) Efficient fertilizer use; herbicide tolerance; general consumer benefits

4.3 Availability

- (1) Tier 3 Traits plus an effective selection method that explains at least 50% of the genotypic variation of the Trait would be provided to Breeders in a generally adapted material.
- (2) Should individual Breeders require the Trait in their material, a service agreement between the Pre-breeder and the Breeder may be established. The terms of the agreement would be the same for all Breeders requesting this service but may differ between pre-breeders (pre-breeders may compete in providing the service as long as they offer it on the same terms to all breeders).

4.4 Licence Fees

- (1) Tier 3 Traits may attract a licence fee to be set as a percentage of Breeders' net income from EPR.
- (2) If a technology licence fee is charged for a Tier 3 Trait it is recommended to:
 - (a) cap the licence fee at 15% per annum of net EPR income; and
 - (b) consider a stepwise increment of licence fees up to that point.

For example, a Breeder could be required to pay a licence fee set at 5% of net EPR income for the first \$5M followed by a licence fee set at 15% of EPR net income for any net EPR received beyond \$5M per annum.

5. Stacking of multiple Tier 2 Traits

- 5.1 When multiple Tier 2 Traits are combined in a single variety it is recommended to cap the total of licence fees to 5% per annum of net EPR income independent of how many Tier 2 Traits are bundled together. This is to recognise the great number of Traits which are typically combined in any one variety.
- 5.2 The licence fee should be shared between all Pre-breeders who have contributed Tier 2 Traits to that variety.

6. Stacking of Tier 2 and 3 Traits

- 6.1 When Tier 2 and Tier 3 Traits are combined in a single variety it is recommended to cap the total of technology licence fees at the highest Tier level, i.e. at 15% per annum of net EPR income, independent of the number of Traits that are bundled together.
- 6.2 The licence fee should be shared between the contributing Pre-breeders of Tier 2 and Tier 3 Traits.

7. Additional Principles

- 7.1 It is expected that all Australian breeding programs will have equitable, non-exclusive access to Tier 1, 2 and 3 Traits. This will maximise the benefits of technology adoption on a national scale.
- 7.2 The division of the licence fees among contributing Pre-breeders will need to be negotiated by the respective pre-breeding organisations in the first year of commercial release of the variety in question.

- 7.3 If a Tier 1, 2 or 3 Trait is only protected by PBR, payment of a technology licence fee will discontinue after the point of commercial release of a third party variety that does not attract a Trait-related technology licence fee because the Trait was incorporated from a commercially released variety.
- 7.4 If a Tier 1, 2 or 3 Trait is protected by patent, premiums to the Pre-Breeder may apply to reflect the additional value that can be captured by the Breeder due to the fact that licensing arrangements would provide on-going protection beyond the release of the first variety/ies.
- 7.5 Where germplasm is progressed, under contract with a Breeder, by the Pre-breeder to fixed lines or beyond, a separate service fee arrangement is likely to be negotiated