ACQUISITION AND USE OF CIMMYT MAIZE HYBRIDS AND OPVs FOR COMMERCIALIZATION

The main purpose of CIMMYT's Germplasm development work is to provide improved, adapted and stress-tolerant varieties with particular benefit to resource-poor farmers. CIMMYT has produced both open-pollinated varieties (OPVs) and hybrids of maize suited to various agro-ecological zones across Latin America, Asia, and Africa. Institutions (both public and private) may apply for permission to register and subsequently commercialize CIMMYT maize varieties in specific countries within the framework of the applicable laws, rules and regulations of those countries, harmonized regional seed laws, the Multilateral System of the Food and Agriculture Organization's International Treaty on Plant Genetic Resources for Food and Agriculture, the Standard Material Transfer Agreement (SMTA), CIMMYT and CGIAR guidelines and policies, and their CIMMYT maize licensing agreement. In granting permission to an institute to register CIMMYT maize hybrids, CIMMYT retains all legal rights which it currently has in such varieties, including parental lines, and since CIMMYT germplasm is an International Public Good, the partner institution may not acquire any ownership interest in the varieties or parental lines. In many instances, seed of CIMMYT varieties, and their parents, is already in the possession of parties other than the institution to which permission is granted, and therefore such varieties may continue to be used for testing and research purposes, or commercialization in other countries.

In some cases, CIMMYT receives project funding from donors to sponsor the varietal release process according to the national release/registration scheme; in such cases CIMMYT will allocate maize hybrids and OPVs that have been released typically on a non-exclusive basis, following the process and principles outlined below.

In other countries, CIMMYT relies on public- and private-sector partners (especially NARS and seed companies) to sponsor CIMMYT maize products through the release/registration process, and therefore a geographically limited exclusive licensing arrangement is required. The approach used by CIMMYT in granting permission to institutions to register CIMMYT maize varieties also differs depending on whether the variety is an OPV or hybrid: by their nature, hybrids are more difficult to produce than OPVs, and it is not economical to recycle the grain harvested from hybrids as seed, because it is inherently less productive than the original hybrid seed. Consequently, permission to register hybrids is granted to particular institutions on a confidential basis and hybrid parental combinations are also considered confidential information, to prevent unlicensed production and commercialization of the product in contravention of national varietal registration schemes.

The licensed institution is responsible for maintaining the hybrid variety and its parents. They are normally granted the right to apply their own branding and product name, although a CIMMYT-generated Varietal Identification Number (VIN) will be assigned to each hybrid or OPV, and this will need to be included on each bag/package of certified seed intended for commercial sale. The institution is not otherwise obligated to publicly reveal the source of the variety nor provide parental seed to other interested parties.

Product Allocation Principles

When allocating products to partners, CIMMYT strives to:

- Give preference to applicants from National Agricultural Research Systems (NARS). Because of their mandate to work in the public interest and their knowledge of their local seed industry and regulatory framework, NARS partners are generally the preferred candidate for ensuring improved maize hybrids reach the target beneficiaries. Upon the successful release of a hybrid, many NARS routinely make the improved hybrids available on a non-exclusive basis to multiple partners, which CIMMYT is normally unable to do without the NARS' involvement.
- 2. Avoid allocating the same hybrid to more than one partner within a given country (maintain geographic exclusivity).

This principle aims to maximize the value of a given hybrid within a given market by ensuring that it can be more easily differentiated from competing varieties, and is therefore a more worthwhile investment for the successful applicant. Though licensees may apply their own branding, CIMMYT insists that all packaging also display the CIMMYT-assigned VIN to facilitate tracking of CIMMYT products on the market.

- 3. Ensure equity and fairness in access to products, while also maximizing potential for impact. This may be achieved by applying the Allocation Criteria listed below, along with the following best practices:
 - Whenever possible during a given round of allocations, try to allocate at least one product to every deserving applicant, especially those who have either demonstrated progress with the earlier-allocated products, and those who show eagerness and capacity to scale-up and deploy new products from CIMMYT.
 - Ensure broad dissemination of product announcements and ensure that <u>only</u> products that have been publicly announced are allocated to partners.
 - Seek to ensure that especially high-potential hybrids are allocated across broad geographies (whether by allocating to many smaller organizations or to a small number of regional or multinational companies with broader reach), and ensure that these products are given to reliable partners with proven track records (based on Allocation Criteria outlined below).

4. Ensure uninterrupted access to seed by farmers.

CIMMYT's partners should have a proven track record, or in the case of new partners, be reasonably capable of registering, producing, and marketing hybrid maize at scale within their target markets.

5. Avoid "locking" of good products.

It may happen that a partner may withhold an allocated CIMMYT hybrid from the market, either as a ploy to keep it out of competitors' hands, or due to poor capacity. CIMMYT therefore requires licensees to report annually on efforts and progress towards commercialization of their licensed products. Companies who fail to make such efforts may have their licenses revoked and may be restricted from future product allocations. These reports also help CIMMYT to understand and enhance the adoption and impact of our products.

6. Strongly encourage accelerated varietal turnover.

When evaluating applications, CIMMYT seeks opportunities to replace known old/obsolete products with new/improved CIMMYT hybrids. During the application period, they may also actively encourage partners who continue to market old varieties to submit applications for viable alternative replacement products.

Allocation Process

After identifying one or more CIMMYT elite maize hybrids or OPVs that may be of commercial interest (for example, by browsing <u>CIMMYT's Maize Product Catalog</u>¹), institutions may submit an application to obtain a commercial license via CIMMYT's <u>Maize Licensing Portal</u>². If more than one partner is interested in registering a particular product in a given geography, CIMMYT reserves the right to allocate the variety on a non-exclusive basis (where permitted under local varietal release/registration schemes) OR on a geographically limited exclusive basis to only one partner based on an evaluation of the following criteria:

- 1. Investment by the applicant in variety testing and seed production.
- 2. Likelihood that seed will become widely available to smallholder farmers.
- 3. Likelihood that seed will become widely available as soon as possible.
- 4. Diversity among the partners' suppliers of improved genetics.
- 5. Diversity of regions where the variety will be marketed.
- 6. Capacity, viability and track record as a CIMMYT collaborator in deployment of improved varieties (especially the applicant's progress in commercializing any previously licensed CIMMYT products).
- 7. Relative importance of a variety for the variety portfolio or success of an applicant.
- 8. When all else is equal, public-sector institutions are granted preference over private sector institutions.

If the supply is far less than the demand for a specific type of product (for e.g., Fall armyworm-tolerant maize hybrids), the preferred path is to license the product to the key NARS partner in each of the target countries for varietal release/registration, and further sublicensing of the released variety to interested seed companies within the country on a non-exclusive basis and/or according to the NARS partner's standard licensing scheme.

Once the CIMMYT Product Allocation Committee has reviewed and approved the allocation of a particular product to an applicant, CIMMYT will forward a CIMMYT Maize Hybrid Registration & Commercialization License Agreement for signature by the applicant. Upon signature by both parties, the licensee (partner institution) will need to submit a formal seed request. CIMMYT will provide small quantities of breeders' seed of the hybrid and its parents to enable the institution to begin testing and multiplication of the product (see Table 1, below). The partner institution will need to submit advance payment for any applicable shipping costs. Seed may not be immediately available in sufficient quantities for immediate shipment, in which case it may take up to one growing season, or up to two growing seasons in case applicable phytosanitary regulations require a quarantine period. Upon receipt of the seed, the licensee will be responsible for further testing, registration, and commercialization of the allocated product in the target geographies for which the product has been allocated.

¹ http://maizecatalog.cimmyt.org/

² https://cimmyt.inteum.com/cimmyt/agreementportal/login.aspx

Table 1: Details of seed supply for commercially licensed CIMMYT maize products

Limits on seed supply ³				
Breeder's seed	Inbred parent	CIMMYT can provide up to 1 kg of seed of each Parent Line upon allocation on cost-recovery basis. If a licensee requires additional seed, CIMMYT will provide up to a maximum of 10kg per line, subject to advance payment and lead time of at least one crop season.		
	Single-cross parent	It is the partner's responsibility to produce single-cross parent seed; CIMMYT does not provide.		
	OPV	CIMMYT can provide up to 1 kg of seed of each OPV upon allocation on cost-recovery basis. If a licensee requires additional seed, CIMMYT will provide up to a maximum of 10kg per OPV, subject to advance payment and lead time of at least one crop season.		
Basic seed	Inbred parent Single-cross parent	It is the partner's responsibility to produce basic seed; CIMMYT does not provide.		
Hybrid seed	For National Performance Trials (NPTs), registration, testing, and/or demonstrations	CIMMYT can provide up to 4 kg of seed of each Hybrid upon allocation on cost-recovery basis. If a licensee requires additional seed, CIMMYT will provide up to a maximum of 10 kg per hybrid, subject to advance payment and lead time of at least one crop season.		
Indicative Cost Recovery Rates (values in USD) ⁴				
Seed origin	Seed production costs	Other Charges (as applicable)		
Ethiopia	\$10.00 per kg	 Phytosanitary certificate and processing: \$120.00 per shipment Shipping: Varies by destination, weight, and available courier options Shipments to MLN non-endemic countries⁵ will be routed via Zimbabwe after passing through a Plant Quarantine Site (PQS); in such cases, Zimbabwe rates will be applied. 		
India	\$12.00 per kg	 Phytosanitary clearance: \$17.00 per hybrid, per pathogen (number of pathogens varies depending on destination country) Shipping: Varies by destination, weight, and available courier options 		
Kenya	\$10.00 per kg	 Phytosanitary Certificate: \$20.00 per shipment MLN-free certification: \$70.00 per sample Non-GMO certification: \$90.00 per sample Seed Health Lab analysis: \$6.00 per sample Shipping: Varies by destination, weight, and available courier options Shipments to MLN non-endemic countries will be routed via Zimbabwe after passing through a Plant Quarantine Site (PQS); in such cases, Zimbabwe rates will be applied. 		

³ All seed quantities are subject to availability. Especially for newly announced products, at least one growing season advance notice may be required, or two seasons in case applicable phytosanitary regulations require a quarantine period.

⁴ All costs are indicative. Rates are subject to periodic revision without notice. Applicability of "Other Charges" may vary depending on phytosanitary requirements at destination, special requirements of the recipient, and other external factors; similarly, additional costs not captured in Table 1 may also apply. All payments must be received in advance of shipment. In some cases, partners licensed to commercialize certain products in countries targeted by specific donor-funded projects may be eligible to receive project-subsidized rates, e.g. limited quantities of seed at no or reduced cost.

⁵ As of August 2021, MLN-endemic countries include Kenya, Ethiopia, Tanzania, Uganda, Rwanda, and D.R. Congo. For more information about MLN disease and its status in Africa, visit the CIMMYT MLN Information Portal at <u>https://mln.cimmyt.org/</u>.

Mexico	\$25.00 per kg	 Seed Distribution Unit, international shipments: up to 5 kg \$34.80 plus \$3.65 per each additional kg Seed Distribution Unit, domestic shipments: \$3.65 per kg Phytosanitary Certificate: \$42.15 per shipment Phytosanitary Verification Opinion: \$94.02 per shipment (applies to shipments ≥ 15 kg) Seed Health Lab analysis: \$54.00 per sample Transgene analysis: \$243.63 per sample Non-GMO letter: No cost Shipping: Varies by destination, weight, and available courier option
Nepal	\$7.00 per kg	 Phytosanitary clearance: \$2.00 per sample (number of samples varies depending on destination country's phytosanitary requirements) Export certificate: \$2.00 per shipment Shipping: Varies by destination, weight, and available courier options
Zimbabwe	\$10.00 per kg	 Phytosanitary clearance: \$30.00 per shipment Testing for specific pathogens charged upon request based on government rates GMO-free certificate from National Biosafety Authority (if required): \$70.00 per shipment PQS surcharge (for seed originating from Kenya or Ethiopia): \$12.00 per kg Shipping: Varies by destination, weight, and available courier options

What does the Standard CIMMYT Maize Hybrid/OPV Registration and Commercialization License Agreement entail?

The standard CIMMYT Maize Hybrid Registration and Commercialization License Agreement establishes the terms and conditions under which CIMMYT grants permission to our partners to pursue registration/release and eventual commercialization of our maize hybrid and OPV products within a specific country or group of countries. <u>CIMMYT does not charge royalties or licensing fees</u> under the standard License Agreement; all we ask in return is that our partners make sincere efforts towards commercializing these hybrids and provide CIMMYT with <u>information</u> that we can take back to our donors to demonstrate that their investments are creating real impact for resource-poor farmers who otherwise would have no access to our improved maize products.

What rights does the standard agreement grant to CIMMYT partners?

- In cases where CIMMYT is offering a license to commercialize a hybrid in a country where it has
 not been released, the agreement gives the CIMMYT partner <u>exclusive permission to produce</u> (or
 have produced) the parental lines and hybrid seed <u>and to register and commercialize</u> (directly or
 indirectly) the hybrid(s) <u>only in the specific countries</u> identified in the agreement. In these cases,
 CIMMYT will not knowingly give similar licenses to anyone else in the same specified countries as
 long as the agreement remains valid.
- If CIMMYT is offering a license for a product that CIMMYT has registered or plans to register, or if the product is an OPV, then the agreement gives the CIMMYT partner <u>non-exclusive</u> permission to produce, register and/or commercialize, as the case may be.

- Partners may not register or commercialize (nor provide sublicenses to organizations for registering or commercializing these hybrids), in any country <u>outside</u> of the specific countries listed in the agreement.
- <u>Public</u> institutions may collect a reasonable royalty from their sublicensee(s), but <u>private</u> (including parastatal) companies may <u>not</u>. CIMMYT must be informed of any sublicenses.
- CIMMYT treats the pedigrees of the licensed hybrids as confidential information and may provide this information to other partners <u>only</u> if they have also signed a similar license for registration and/or commercialization of the same hybrid in <u>other</u> countries (if the licenses were granted on the basis of geographically limited exclusivity) or possibly in the same country (if the licenses are being offered on a non-exclusive basis). In all cases, all licensees are expected to maintain pedigrees confidential.
- CIMMYT will provide <u>limited</u> amounts of the breeder seed and hybrid seed, but some costs may apply (see Table 1).
- Partners have the option of ending the agreement with six (6) months' prior written notice to CIMMYT. So if for example a partner is unable to register and/or commercialize one or more of the CIMMYT hybrid(s), they may simply terminate or amend the agreement with respect to any such hybrid(s).
- SME partners owe CIMMYT no royalties on the commercialization proceeds, but are invited to make a voluntary contributions to support CIMMYT's R&D programs.
- Partners may also use the parental line and hybrid seed for their own research, breeding and training purposes, and may develop new germplasm from any of it. Partners will own such newly derived germplasm, but <u>obligations of the SMTA continue to apply to any germplasm derived</u> <u>from that transferred under the SMTA.</u>

What are the Partner's responsibilities and obligations?

- Once CIMMYT has provided the initial breeder seed, it is the partners' responsibility to produce (multiply) and maintain their own stock of seed of the parental lines for producing the hybrids. If the partner is unable to produce sufficient seed of the parental lines, they may contract with one or more third-party seed producers to have it produced on their behalf.
- Licensees are responsible for maintaining the genetic purity of the parental lines.
- Licensees are required to <u>submit annual reports demonstrating that they are making efforts</u> in good faith to try and register and commercialize their licensed hybrids/OPVs within a reasonable timeframe. The content and format of those reports will be determined by CIMMYT.
- Partners must keep confidential all information that CIMMYT specifies as confidential information, including among other things the pedigree for the CIMMYT hybrid(s) licensed under the agreement and the specified countries in which the partner has been given license.
- If a partner or CIMMYT terminates the agreement for any reason, their obligations to keep the pedigree of the CIMMYT hybrid(s) confidential continue for 10 years after the expiration or ending of this agreement.
- Partners may not give or transfer any parental line seed to any other person or organization, with the exception of any seed producers whom they have contracted for assistance with seed production.
- If a partner uses one or more of the parental lines to develop new germplasm, they will own that new germplasm, but because it incorporates genetic material from the seed CIMMYT will have transferred under an SMTA, when transferring the new germplasm to any other person or

institution for research, breeding or training, it must be under a new SMTA.⁶ <u>Other SMTA</u> obligations continue if a partner or others commercialize germplasm created from the original germplasm transferred under the SMTA.

What are CIMMYT's rights?

- CIMMYT retains ownership rights to the parental lines, single-cross hybrid parents, hybrids and OPVs.
- CIMMYT may give (or may have already given) similar licenses to register and commercialize the same hybrids; if the licenses are offered on a geographically limited exclusive basis, CIMMYT will ensure that there is no overlap of territory between licensees. The other partners are bound to the same confidentiality rules and other obligations.
- CIMMYT may make, use and distribute to others (i) the parental lines, (ii) the CIMMYT hybrid(s) and/or (iii) OPVs licensed to a partner for research, breeding and training purposes only in any country.
- As a member of the CGIAR, CIMMYT has annual reporting obligations that may require disclosure of certain confidential information relating to licensees. This confidential information is not further disclosed.
- CIMMYT may use information we gather from licensees to develop reports and communications
 materials that reveal <u>in aggregate</u> (without revealing confidential information) the impact of our
 work.
- If CIMMYT believes that a partner is not acting with diligence to commercialize their licensed hybrids or OPVs, CIMMYT may terminate the agreement and re-allocate the same hybrid(s) to one or more other partners in the specified country/ies. This outcome could also negatively affect that organization's prospects for receiving licenses from CIMMYT in the future.
- Once the agreement ends, CIMMYT may re-allocate the CIMMYT hybrid(s) to another institution for commercialization in the same specified country.

⁶ Partners can create a new SMTA, available in six languages (Arabic, Chinese, English, French, Russian and Spanish), at this website: <u>https://mls.planttreaty.org/itt/index.php?r=site/index&lang=en</u>

