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A Review of Variety Release Procedures and Related Issues
with Recommendations for Good Practice

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Acknowledgements

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List of Abbreviations Used

CIMMYT	International Center for Maize and Wheat Improvement
DUS	Distinctness Uniformity and Stability (of varieties)
EU	European Union
FSCRD	Federal Seed Certification and Registration Department (Pakistan)
CGIAR	Consultative Group on International Agricultural Research
IARC	International Agricultural Research Center
ISTA	International Seed Testing Association
NARS	National Agricultural Research Service
NGO	Non-governmental organisation
NVRC	National Variety Release Committee
PVP	Plant Variety Protection
UPOV	International Union for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
VCU	Value for Cultivation and Use (of varieties)

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EXECUTIVE SUMMARY

1. This working paper is a synthesis of experiences gained from studies carried out in Egypt, Ethiopia and Pakistan in 2011/12. The main purpose is to analyse the issues that arise in variety release and to make recommendations for 'good practice' that may be useful to those who manage the variety release system. In the context of this paper, the term variety release refers to the full range of activities that occur from the identification of promising lines by the breeder until early-generation seed is available for multiplication.

2. Funding for these studies came from a project of the USAID Famine Fund and was motivated by concerns about the possible impacts of new virulent disease races such as the Ug99 stem rust. That threat still exists but the objective of accelerating variety release for all crops is a high priority, regardless of a specific disease dimension. Moreover, with the entry of private companies in many countries, the breeding environment is becoming more competitive. This requires that the variety release system should be more responsive to a wider range of users (clients) than was the case when all these activities took place within the public sector. This study considers variety release in a broad perspective and with the goal of accelerating farmers' access to improved varieties.

3. The management of varieties is a key component of the seed regulatory framework in most countries and is usually included in the national Seed Law. It involves the evaluation of candidate lines by a prescribed trials system, the review of data by a technical committee, and ultimately the registration of the variety in an official list. Registration provides an endorsement that the variety has merit for cultivation and confirms its eligibility for certification, based on a recognised name linked to a description. Variety release is therefore a key stage in the formal 'seed chain' which links plant breeding to farmers.

4. The justification for these controls is that farmers need guidance on the varieties that are made available, and should be protected from inferior materials that might be offered by unscrupulous traders. However, in practice the technical and administrative procedures are often slow and complex, thus causing a delay in the delivery of new varieties. Each year of delay represents a loss of the benefit that farmers can achieve from the genetic gains made by plant breeding.

5. This study recognises the fundamental principle that a variety testing system can never be perfect. It is always a compromise which aims to provide a service to farmers and breeders within the resources available. The ultimate test of the system is that it provides this service efficiently and does not become a bureaucratic exercise in its own right. To achieve this goal, the regulations and procedures involved should be periodically reviewed, to ensure that the system is efficient and meets the needs of all stakeholders.

6. The target time for completing variety assessment should be two years (or seasons) using a standard protocol that enables all available results to be incorporated in a single statistical analysis package. If there are uncertainties about a variety after two years of testing, then the variety could be provisionally registered/listed pending further information. Delays in testing and release may lead to unofficial 'leakage' of varieties from the research system, or to smuggling in the case of varieties that are in use in other countries.

7. It should not be necessary to assess specific agronomic responses, for example concerning sowing rates or fertiliser response, as part of the variety registration system. This will increase the cost and duration of testing without significant benefit. Details of this kind will become evident once the variety is released and enters general cultivation.

8. During the period of official testing, early generation seed multiplication should continue and provisional seed certification of these crops should be allowed, on the condition that no seed is sold to farmers before variety registration is completed. If this approach is adopted, sufficient basic/foundation seed should be available to initiate large-scale production of certified seed at the time when the variety is officially released.

9. The 'National Variety Release Committee' (NVRC) must be an independent body and it should represent a range of stakeholder interests, not being dominated by breeders or official institutions. The NVRC is often constituted as

a technical sub-committee of the National Seed Council (or Board) which has general oversight of the seed sector and its development within the framework of a seed policy. Apart from reviewing the registration and release of new candidates, the NVRC should manage the national variety list in a proactive way, by monitoring the uptake and performance of recently-released varieties and by deleting those that have become obsolete.

10. The official variety list should be recognised as a working document containing both key information about the origin and characteristics of varieties and useful agronomic details about their adaptation. To avoid the high cost of annual reprinting and distribution, this list should be made available on a website where regular updates can be made and users can easily find the specific information they need.

11. One fundamental dilemma in any testing and registration system is how to recognise different 'recommendation domains' within the list. Multi-locational trials in a range of environments naturally favour those varieties of wide adaptation, even though they may not be the best variety in specific locations. On the other hand, where quite localised environmental conditions exist, farmers should be aware of these varieties and be able to access them. In countries with very diverse agroecology, the variety release system needs to be sensitive to the possibility of niche varieties and should avoid discriminating against them.

12. Variety maintenance and early-generation seed production are common constraints in national seed programs, because public breeders do not have the resources or incentives to undertake this routine technical work. Special efforts should be made to address this problem by allocating resources for this purpose and/or by devolving responsibility to a separate unit, under the supervision of the breeder. The availability of a sufficient bulk of basic/foundation seed can be made a condition for variety registration.

13. Running a variety testing and registration service has significant cost implications and this is usually provided from the government budget. Charging users for this service is a good idea in principle but it may have little practical benefit if the majority of breeders work in the public sector and are already short of resources. However, breeders can be required to provide good trial data and variety descriptions when they submit a candidate in order to reduce the work of the official testing service.

14. Where similar agroecologies extend across national boundaries, the use of trial data from other countries should be encouraged in order to reduce the duration (and cost) of official testing procedures. Ideally, this should be formalised in bilateral or regional agreements leading to 'regional variety lists', provided the participating countries have standardised procedures for testing and registration.

15. Many varieties of the major staple crops have their origins in the international agricultural research centers. As a result, identical or very similar genetic material is often tested simultaneously in many different countries and this provides a large body of information on variety performance and adaptation. In these cases, a fast-track procedure should be established for the registration and multiplication of such well-documented material, particularly in view of the possible need to respond rapidly to the challenge of new disease races, which was the original motivation for this project.

16. Seed certification is a widely-used system of quality assurance and it is normally available only for varieties that have been officially released and are included in the national list. However this requirement may exclude older varieties that still have merit but have not passed through the formal testing system. The variety registration system should be sufficiently flexible to accommodate older or traditional varieties that are well-known and used by farmers. The same should apply to varieties that originate from participatory breeding or selection programs. If necessary, a separate list could be established for these varieties using more flexible DUS criteria, provided that their merit has been clearly demonstrated.

17. The variety testing and release system is always designed for the staple crops of the country that contribute to national food security. It is unhelpful if this same system is applied directly to other crops such as vegetables, in which the plant breeding and market conditions are completely different. The international seed trade can provide a huge range of varieties of these crops and a more open system of declaration should be considered for these crops so that stakeholders can easily find the seed

material and information they need.

18. Many seed industries are in transition from a public sector model to a more diverse structure in which the private sector has much greater role in commercial seed production, and sometimes in plant breeding as well. Variety release may be affected by these changes as the seed sector becomes more competitive. In this situation, it is helpful to have a national seed policy to guide all aspects of seed industry development in a coordinated way and to ensure that the interests of all stakeholders are represented in this process. The National Seed Board (or Council) mentioned above would have overall responsibility for monitoring the implementation of this policy.

19. Although this paper addresses the problems of variety testing and release as carried out in many countries, it is should be acknowledged that there are quite different opinions on this subject. Advocates of de-regulation would say that all these technical and bureaucratic processes of variety release should be set aside so that 'the market can decide' once the variety is made available. While this approach may be valid in countries with advanced agricultural systems and highly competitive markets, it does have risks in less developed commercial environments. Companies may compensate for any defects by launching a vigorous marketing campaign to promote a variety and sell seed stocks, knowing that it may have a limited life. Moreover, where farming practices are diverse and often lack resources, it may take time for farmers to reach an objective conclusion about performance.

1. INTRODUCTION

1.1 Origins of the study

This working paper is an output of the project 'Accelerating seed multiplication to combat the threat of stem rust in wheat' and is based on visits to Egypt, Ethiopia and Pakistan between November 2011 and February 2012. This project was primarily a response to the new wheat stem rust race Ug99 that originated in Uganda and was considered to present a threat to global wheat production. Besides the urgent priority to identify resistant varieties, ensuring efficient mechanisms for the rapid multiplication and dissemination of these varieties was a key element in this project. In view of their long experience in seed sector development the three countries can thus provide interesting case studies. In each country, the variety release system was reviewed through consultation with a wide range of stakeholders and a report was prepared to summarise the key features of the variety release system and related issues. These reports were shared with the national contact persons in each country shortly after the visits were completed and some further information was collected by correspondence.

As predicted, the Ug99 race of stem rust has continued to spread but it has not yet had such a devastating effect at regional or global level as was feared ten years ago. Nevertheless, the objective of transferring new varieties rapidly from plant breeders to farmers remains a high priority and deserves attention regardless of a specific or acute disease problem.

1.2 Scope of the study

Considering the rust disease context outlined above, this study has it origins in wheat and that crop remains a key focus of the paper because of the threat still posed by new rust races with potentially devastating effects. However, the procedures for variety release apply to all crops, although with some variation between different groups. This paper therefore takes a broad view and includes examples or experiences from other crops when appropriate. Crops propagated by vegetative methods are not considered as they require quite different multiplication procedures. Another specific exclusion is the release of varieties having genetically-modified traits which would be subject to additional biosafety regulations. These require a separate or additional regulatory process that often belongs to the Ministry of Environment rather than the Ministry of Agriculture. However, the agronomic evaluation and registration of a genetically-modified variety should follow the same procedures as for conventional varieties, once biosafety issues have been addressed.

The paper does not look in detail at plant breeding procedures except from the time where promising lines are identified by breeders for possible release and are prepared for entry into the official testing system. On the other hand, it does consider the initial downstream multiplication and commercialisation of varieties because that is closely linked to, and often dependent on, the release procedures. In fact, the initial diffusion and uptake of varieties after release is a major concern of this review.

Systematic variety release procedures are a defining feature of the formal seed sector in which new genotypes originate from breeding programmes and are transferred ultimately to seed companies or similar entities for multiplication and commercialisation. The control of varieties is one major facet of the regulatory framework that is commonly defined in a national seed law, the other being the control of seed production, quality and marketing. The process of certification combines all these aspects by assuring the varietal identity and the quality of seed lots offered for sale and by providing traceability of material between named generations.

This review does not consider the products of participatory plant breeding or other local improvement efforts that are outside the formal sector. However, there are cases where new material has been deliberately channelled though the informal sector to accelerate adoption and diffusion and these are noted when they provide interesting examples.

While the main focus of the study is on the release of varieties from public institutions, which are still the main breeders in the three countries studied, comparisons with the private sector breeding are instructive because of the different financial conditions that prevail there. The paper deals mostly with regulatory, institutional and policy issues, rather than with technical procedures and standards and it may therefore be of particular interest to policy makers who oversee the seed system.

2. BACKGROUND INFORMATION AND CONTEXT

2.1 Defining variety release

For the purpose of this study, the term 'variety release' is used to cover all the procedures and actions that take place from the time when a breeder decides to enter a promising new line/variety for official testing until the time when the new variety is made available for multiplication as a first step on the road to general cultivation by farmers. In this context, variety release can be seen as the point of transition of new genetic material from its place of generation (in research) to its place of utilisation (in agriculture) and within which the following main stages and activities may be identified.

1. The technical decision by a breeder (institute or company) to submit a candidate variety for official testing based on internal trial data. At this point, the breeder should have a purified nucleus stock of the variety that is genetically uniform and stable for submission to the trials organisation and to initiate multiplication.
2. The independent assessment of the variety to determine its 'Value for Cultivation and Use' (VCU) by means of multi-location field trials and (when appropriate) tests for end-use quality attributes, followed by preparation of all the data from these assessments. These trials normally take two or three years and there is a requirement for new candidates to show clear advantage in one or more respects over existing varieties. The actual criteria for VCU vary between countries but would normally include field attributes such as yield, disease resistance, maturity time and standing ability followed by post-harvest assessment of quality. It should be recognised that these 'formal' trials do not necessarily predict the ultimate reaction of farmers to a particular variety under their precise conditions and needs. For this reason, official variety trials can never be perfect, and there is no reason to make them more lengthy or complex in the pursuit of perfection.
3. Many testing systems also require an examination of the variety to establish that it is Distinct (from other varieties), Uniform (within the population) and Stable (between successive generations of multiplication). These 'DUS tests' require only small numbers of plants that are characterised using a standard list of descriptors. Pathological and biochemical tests may also be included to supplement the list of morphological characters. 'Genetic fingerprinting' may be used to characterise varieties in specific cases but is not a standard procedure required for release, nor is it necessary because sufficient morphological characters are normally available to differentiate candidate varieties from all others. This issue is discussed in more detail in section 4.3.
4. The administrative decision by an official committee to formally register the variety in an official list and release it for multiplication within its area of responsibility. Registration is intended to maintain order in the market by giving official recognition to a variety name linked to a description; this also provides a basis for certification. Official release also implies a recommendation to farmers that the variety is suitable for cultivation within a certain geographical domain, that it meets the requirements of the market and/or consumers and has some specific merit/advantage over the existing varieties. The precise relationship between registration and release is discussed in detail in the following sections and depends on the procedures of individual countries.
5. The decision by an institution or company to multiply seed of a variety in order to launch it in the market. In the case of a company, this decision will be strongly influenced by judgements about the prospects for the variety in the market, based on its merit and other competition factors. Public sector breeders may be less concerned about the market response but are still interested in the uptake of their varieties for reasons of professional recognition and status. Not all registered varieties are finally released into the market by their owners and many of those that are released do not find a place in the market.
6. The promotional (extension) activities needed to bring the variety to the attention of farmers and thus stimulate demand for seed. Although not strictly part of the 'release process', from a commercial perspective these market-related activities are equally important since there should be an obligation to deliver the new variety quickly in order to obtain some return to the breeder. Public breeders are not under the same financial pressure to actively promote new varieties and may lack the resources to do

it. However, without some promotional effort, good varieties may still languish and fail to take off, especially if there is a competitive private sector in the marketplace. This lack of direct linkage to the market is a weakness in public breeding for two reasons. First, there is often a lack of resources for early generation seed production which initiates the seed chain and second, there may be little direct engagement with client farmers to discuss their needs and receive feedback.

The ideal release system should accomplish all the above stages and activities in the shortest possible time so that farmers can benefit from the genetic innovations achieved by breeders. If the breeder has enough seed available for VCU trials, and simultaneously submits a pure stock for DUS testing, then the official examination and release should take only two years. Factors that may lengthen this period include: submission of impure material by the breeder, incomplete trial data, (requiring further years of testing) and failure to carry out DUS and VCU testing simultaneously. There may also be bureaucratic inertia or very stringent requirements so that, in the worst case, varieties may spend four to five years in the testing system.

2.2 Registration and release

These terms may appear synonymous but in practice they may be interpreted in different ways depending on the legislative procedures and the national context. Registration would normally refer to the inclusion of the variety in an official list, which thereby legitimises it for certification and marketing. Release, on the other hand, may relate more to the physical activities associated with a multiplication program or a promotional campaign. In the case of public sector varieties, registration would normally be followed directly by release, provided sufficient early generation material is available to initiate multiplication. However, in practice seed supply is often a constraint, resulting in a gap between registration and release. If there is no requirement for VCU testing, then registration may be based solely on the criteria of DUS, thus validating the status of the variety and its name without implying any recommendation of its merit. This is the case for vegetable crop varieties in the European Union.

2.3 Breeders' role in variety release

At an early stage in the life of a variety, and if it appears to have agronomic potential, the breeder must initiate variety maintenance and early generation seed multiplication to ensure the availability of seed with high genetic purity to feed the multiplication system. If this work begins when the first pure stock is produced (stage 1 in the list mentioned above), then two generations of multiplication should have been completed by the time the variety is officially registered and basic seed is available at that time to start large-scale production of seed for sale.

When a variety is identified as a candidate for testing and release, the breeder must:-

- purify and maintain a nucleus seed stock of the variety,
- send a small sample of that seed stock for DUS testing, possibly with harvested plant material,
- send a bulk of seed for VCU testing,
- produce breeder and/or pre-basic seed to initiate the multiplication process,
- produce sufficient seed to promote the variety in demonstration plots and similar activities before/when it is released.

Fulfilling all these requirements places a considerable obligation on breeders and competes for their creative time, and their resources. In practice, public breeders are usually judged on their output of varieties and may be reluctant to use their limited resources for maintenance and seed multiplication. Consequently, at the time of official registration, very little seed may be available to initiate multiplication and moreover, the quality of that seed in terms of genetic purity is often not as high as it should be. To summarise, accommodating all the activities in the release process requires careful management of the initial seed stocks in terms of both their quantity and quality.

2.4 The concept and purpose of variety lists

In most countries, the regulatory system establishes lists of varieties that are available and approved for multiplication and marketing. Except for traditional varieties or landraces that are still in use, all varieties in current use are officially listed and this also serves as a source of reference for extension staff. Likewise, only listed varieties are able to enter the certification system because crop inspection requires a name and a description.

Variety evaluation and listing is therefore a key element in the formal seed system. However, there is a valid concern that traditional varieties should be eligible for registration and certification provided that they meet certain criteria; this is discussed in section 4.30.

Three different kinds of variety lists can be recognised, based on their purpose and legal status, as follows:-

The permitted list (often called a National List) contains all the varieties that are eligible for formal marketing and certification within a country; it may be considered as a filter to 'protect the farmer' from inferior varieties or unscrupulous marketing. By registering the name of the variety, preferably linked to a description based on DUS tests, such a list brings order to the market since variety names that are not on the list are illegal. This should eliminate or at least reduce the practice of 'renaming' imported varieties, or creating spurious synonyms for commercial advantage.

The recommended list is a subset of the permitted list containing supplementary information about the performance, cultural requirements, regional adaptation or other matters that farmers or extension staff may need to know. This list would normally be based on more extensive trials and it should be regularly reviewed in the light of experience, for example, if a variety shows signs of disease susceptibility. It is more a working document for agronomists and farmers whereas the National List is a fixed list of names.

In practice, these two lists may not be separate; the agronomic and adaptation information may be presented as part of the National List although this will make it a larger document that is more expensive to revise and reprint.

The protected list is a subset of the permitted list for varieties that have been granted plant breeder's rights. This only exists in countries having a Plant Variety Protection (PVP) law. It is common to find that certain crops with high commercial value figure prominently in the protected list, while other crops are absent.

Other lists may be established for specific purposes, for example, for varieties intended only for seed production and export, but which are not registered for local use. Likewise, a special list may be made for traditional/local varieties that do not meet standard DUS criteria but are still useful for farmers and should have the opportunity to be certified in order to assure their seed quality standards.

Some countries, notably the USA, have no requirement for official evaluation or registration of varieties. In this case, release is an internal decision by the breeding institution or company. The merit of the variety is established by its performance in farmers' fields and the benefit they obtain from growing it. Although this approach allows more varieties into the market, it is vulnerable to high-pressure marketing techniques that may not reflect the true value of the products. In practice, agronomic trials may be carried out by the extension services, farmers associations, or other independent groups in order to provide information on new varieties.

The majority of countries with developing seed industries have opted for the more regulated approach in the belief that farmers should be given objective information about varieties and do need to be 'protected'. This concern reflects the fundamental problem with seed marketing because the buyer cannot ascertain the identity or the quality of seed at the time of purchase, and is therefore vulnerable to malpractice. In more developed commercial markets, the importance of brand reputation, backed by internal quality assurance and ultimately by consumer protection laws, is generally sufficient to ensure that only good quality products are offered to farmers. Unfortunately, some developing countries have seen an upsurge in 'fake seed' in the market during the past few years and efforts are being made to introduce systems to counteract such fraudulent practices.

2.5 Public versus private breeding

The institutional and financial context in which breeding takes place has a profound effect on variety development and release. Breeders in the public sector (research institutes and universities) do not usually have a direct conduit to the market and depend on intermediaries for this work. This also means that there is no revenue link between the market and the breeding program consequently public breeders have often been criticised for pursuing their own research interests and theories without sufficient regard for farmers' actual needs.

That situation has probably improved in recent years but there is still no direct accountability, apart from the prestige that comes from releasing varieties that are widely adopted by farmers. Much therefore depends on the extent of breeders' involvement with farmers and their responsiveness to feedback.

In commercial companies the context is quite different because the breeding program is ultimately supported out of sales or royalty income on current varieties. Therefore, there is a strong pressure on breeders to produce marketable varieties and this may be reflected directly through incentive schemes based on market share. All decisions about varieties during the development/ release period are conditioned by the prospects of generating income and there is no prestige attached to releasing a variety unless it gains market share. In fact, releasing varieties that do not gain market share may damage the reputation of a company.

In developing countries, wheat breeding remains largely a public activity because in the absence of a functioning royalty collection system, there is little commercial incentive to make a long-term investment with uncertain returns. Moreover, there is no immediate prospect of a significant shift to hybrid wheat, which would provide a biological protection for varieties and ensure a revenue stream from annual seed sales. In marked contrast, private companies are now actively involved in breeding rice since the technology of hybrid seed production has been mastered. Maize breeding has long been a private sector activity because of the relative ease of producing new hybrids, followed by large-scale seed production with guaranteed annual sales.

2.6 Institutional context of variety release

Although variety release is normally considered as a technical and administrative matter, in practice it can be subject to controversy and political influence. This is understandable because it is the point at which several vested interests converge namely:-

- breeders - keen to show that they are successful and are helping farmers (or are generating sufficient income, in the case of the private sector),
- seed companies - wanting new improved varieties to increase sales,
- extension services - wanting new improved varieties to promote to farmers,
- regulatory authorities - concerned to protect the public interest,
- governments - concerned about policies to improve crop productivity and food security, and
- international agencies – soliciting to liberalise regulatory frameworks and trade.

Considering these diverse interests, it is not surprising that there is sometimes mistrust of one group by another. Breeders in particular are not passive observers of the variety testing system; they typically have a very strong belief in the merit of their own varieties and may criticise the testing system if it does not provide the results they expected. It is the task of policy makers in ministries and government to balance all these interests with the ultimate goal of maximising benefit for farmers, rural development and the national economy. Ensuring that the variety testing and release system is independent, efficient and well-managed is important for safeguarding the confidence of the stakeholder community. It should also contribute to an increase in productivity by providing reliable information.

In countries where government organisations were the main players in variety development, the entire release process could be managed within the Ministry of Agriculture, although it was not necessarily efficient. With the entry of the private sector into breeding and seed production, there is a more competitive environment in many countries, thus creating new policy issues between the various parties. This situation is unlikely to change since government resources continue to decline and there is a general acceptance that the private sector should play a stronger role. However, there are limits on what they can do unless an effective variety protection and royalty collection scheme exists. In many crops, especially self-pollinating cereals and legumes, strategic advances will continue to depend on publicly-funded research.

3. OVERVIEW OF THE THREE COUNTRIES STUDIED

Three separate country studies were prepared and shared with the key local counterparts but as background information for this paper, a brief overview of the seed industry situation in each country is provided. A chronology of the seed industry in each country is presented in Annex 2.

3.1 Egypt

Of the three countries studied, the seed system in Egypt is the easiest to describe and understand. There is a relatively uniform and intensive agriculture based almost entirely on irrigation along the Nile Valley. There are no variations in altitude that would give rise to agroecological complexity except some temperature gradient from south to north. The seed system has changed little in terms of the structure and function of the formal institutions and there has been no move towards decentralisation of the testing or decision-making procedures. However, there is a strong representative association for the private sector and they have maintained a persistent dialogue with the regulatory authorities to progressively improve the position of private seed companies and thus create a 'level playing field' for their members. Consequently, the private sector has come gradually into the market but is still in a minority position in all crops except hybrid maize and vegetables. Large public institutions retain a dominant position and are secure for the time being because it would be too difficult or sensitive to reduce or privatise them on account of their huge staff payroll. However, this does represent a substantial cost to the government and may be unsustainable in the long-term.

One interesting feature of the legislative system in Egypt is the frequent issue of Ministerial Decrees that make changes in the regulations. Thus, although the underlying 'Agriculture Law' dates back to 1966 and surely requires revision, the details have been regularly updated to reflect the needs of an evolving private seed sector.

3.2 Ethiopia

In comparison with Egypt and Pakistan, the major challenge for both plant breeding and seed supply in Ethiopia is to meet the needs of very diverse agroecologies and difficult topography. Although there has been a long history of seed industry development reaching back to the late 1970s, for many years formal sector penetration was limited mostly to large state farms due to strong central planning of the economy.

Since the early 1990's, the country has embarked on a policy of regionalisation in which most activities, including agricultural research, seed production and quality control, are devolved. This has created uncertainty about the fate of the long-established federal institutions, such as the Ethiopian Seed Enterprise, while raising the prospects of duplicating specialist services at the regional level. A federal regulatory authority (The National Seed Industry Agency) was abolished some years ago, thus weakening the quality control system in the country. This function now belongs to the Federal Ministry of Agriculture, although it has limited facilities at its disposal for this important task.

Unlike Egypt and Pakistan, there has been relatively little participation by the private sector, perhaps due to lingering fears about government intervention, and the lack of indigenous capital for investment. There has been much analysis of the seed sector in Ethiopia, and that process continues under the aegis of the Agricultural Transformation Agency, established in 2011 to drive a major increase in productivity. However, changes in the formal seed supply system are progressing, while the influence of central planning and control persists.

A new Seed Proclamation, No 782/2013 was approved by Parliament in 2013. Similarly, the revised Biosafety Proclamation (No 896/2015) was approved in 2015. The Plant Variety Protection law (No 481/2006) is still under review pending approval.

3.3 Pakistan

Development, release and multiplication of new varieties were originally in the hands of closely associated public institutions. In the past twenty years, the private sector has expanded rapidly but in a rather uncontrolled way, which has caused some confusion in the market. This has been exacerbated by the fact that the regulatory framework has not kept pace with these developments and is now in urgent need of updating. The main regulatory body lacks resources to do its work and its role needs to be re-defined to take account of the changed institutional and market environment. Strategic oversight of the seed sector has also been weak, despite the fact that there are many issues that need to be addressed.

The regulatory framework is further complicated by the dynamics between federal and provincial responsibilities, and the disparity between the provinces with regard to their capacity for agricultural research and the extent of crop production, the province of Punjab being overwhelmingly dominant in all these matters. In

2011, the Federal Ministry of Food, Agriculture and Livestock was abolished, which had serious implications for the seed regulatory services. This has subsequently been addressed by the creation of a new Ministry of Food Security and Research to which the seed regulatory authority now belongs. With regard to agroecology, Pakistan has some cool mountainous areas in the north and west, but the majority of the agricultural production takes place on the vast irrigated plain extending from the Punjab, through the province of Sindh to the Indian Ocean, with relatively uniform conditions, apart from a gradient of increasing temperature from north to south.

3.4 Summary of project experiences

The USAID-funded regional (seed) project aimed to establish a mechanism for the rapid replacement of existing commercial varieties with new rust resistant (Ug99) and high yielding wheat varieties in Egypt, Ethiopia and Pakistan. Variety development, evaluation and release has often taken many years in these countries and the project therefore demonstrated a faster model with an element of flexibility for emergency situations. In Ethiopia, Ug99 resistant lines received from IARCs were screened for stem rust at the 'hot spot' during the off-season and evaluated for agronomic performance in multi-location trials across wide geographical regions of the country during the main season; and they were then fast-tracked for release within one year. In Egypt, the project enabled both the DUS and VCU tests to be conducted at the same time which is not always the case in order to speed up the release of resistant varieties.

Under normal circumstances, seed multiplication begins only when a variety is officially released and the lack of breeder seed at that time is often cited as an impediment to rapid delivery of seed to farmers. Pre-release multiplication was adopted to provide sufficient basic seed of the new varieties to commercial seed suppliers and/or farmer groups and thereby accelerate the delivery of seed to farmers. In Ethiopia, fast-track testing, release and pre-release seed multiplication was adopted as a strategy, both during the main and off-seasons. In Pakistan, the Seed Act 1976 did not allow pre-basic and basic seed multiplication by private companies.

However, following dialogue with Federal Seed Certification and Registration Department (FSCRD), they granted permission for agricultural research institutes to produce pre-basic and basic seed with qualified private companies to increase the availability of basic seed. In Egypt, promising lines were entered simultaneously in DUS and VCU tests and pre-release seed multiplication and were provisionally released for an extensive promotional campaign. Pre-release seed multiplication has now been adopted as a strategy within the breeding programs of the three project countries and this positive experience will hopefully influence the regulatory authorities elsewhere.

Fast-tracking of variety release and accelerating seed multiplication, combined with a vigorous program of demonstrations, were the key strategies adopted to achieve these goals and funds were provided to drive the process. At the same time, the project created awareness among policy makers, researchers, seed producers, development agencies, extension services, NGOs and farmers. During the first year, hundreds of demonstration plots were planted in target districts and thousands of farmers attended the field days. These activities not only created awareness of the new varieties but also a demand for seed from public and private seed suppliers. Likewise, farmers who hosted demonstrations fuelled the lateral diffusion of varieties through the informal system.

As a result of these coordinated and intensive efforts supported by the project, a total of eight rust resistant varieties were released in Ethiopia, two in Egypt and five in Pakistan from 2009 to 2012, through fast-track testing and release. The threat of a serious wheat disease epidemic certainly helped to raise awareness about the various activities involved in variety release and focused attention on the need to accelerate the overall process. These lessons should be used to inform and adjust the standard practices and schedules for variety testing and release.

3.5 Political context of variety release

It should be noted that there is often a political dimension to variety release. This is especially true in Ethiopia where the strong policy of regionalisation implemented by the government has raised issues about division of responsibility between the Federal and Regional administrations in the seed sector. The same applies to Pakistan, where there is a decision making process at both provincial and

national levels, though an effective coordination mechanism exists. Egypt is not affected by such internal complexities and maintains a single national authority in matters related to seeds and varieties and with close coordination among the concerned public sector organisations.

4. DISCUSSION ON ISSUES RELATED TO VARIETY RELEASE

4.1 The purpose of variety testing and release

The overall aim of the release system should be to transfer new varieties rapidly from research stations to farmers' fields, while making a reliable assessment of their value for farmers. In practice, however, there is always a compromise because formal trials do not reflect the production conditions and needs of farmers. Ideally the testing system should represent 'average farming' conditions but this is difficult because farmers exhibit a wide range of competence and expertise. Consequently, aiming for greater accuracy in the variety testing system may simply make the process longer and more expensive without significant benefit. This is discussed in the next section.

The variety testing and registration system also provides guidance to some key intermediaries in this process, notably seed companies, who introduce new varieties to the market after their release, and extension services, who provide front-line information to farmers. From a regulatory perspective, it aims to bring order to the market by stabilising variety names and preventing the opportunistic promotion of varieties that have no intrinsic merit.

4.2 Duration and scale of testing

To avoid the effects of an atypical season, the minimum time for VCU trials is two years (or seasons) of testing. The number of trial locations depends very much on the research station sites that are available with suitable land and facilities. Some systems use very large numbers of sites (30-40) which is questionable on statistical grounds, but the National Variety Trials System is often highly institutionalised and difficult to change. The inclusion of an on-farm site at each location is desirable to balance the effects of 'over-management' on research farms, especially if breeders are directly involved. On-farm testing varies greatly in character; it can range from full-scale replicated trials carried out in farmer's fields, down to simple comparisons of a few varieties managed entirely by farmers. Both approaches have their own merits.

DUS testing is a small-scale activity (effectively a botanical examination) but it still requires two years (seasons) in order to confirm the stability of a new variety between generations. To keep the testing time to a minimum, the assessment of VCU and DUS should be carried out simultaneously, although this introduces the risk of doing the DUS tests on varieties that may not pass the VCU requirements and will finally be rejected. Public breeders may be reluctant to accept this risk since it represents a waste of resources.

In some countries, there may be a requirement to carry out agronomic trials, for example on fertiliser responses, as part of the VCU process. However, this is of doubtful value because it increases the scale and cost of testing without revealing any substantial differences between varieties that have not been shown by the main VCU trials. Such agronomic testing should be used to provide supplementary information for extension purposes after the variety has been listed.

4.3 Role of molecular techniques in variety registration

The technique commonly known as genetic fingerprinting can provide a very precise definition of a variety and it has been suggested that this should be used to supplement morphological characters when testing for distinctness. However, in practice this could create problems if an apparently uniform and stable variety is shown to contain genetic variability that is not manifested in any obvious morphological differences. In this case, separate lines within the variety could be registered individually based on their molecular profile. Moreover, a molecular profile cannot be used to distinguish varieties in the field, so a conventional morphological description would still be required for certification purposes. At present, the lists of descriptors compiled by UPOV and Bioversity International provide sufficient resolution to identify almost all varieties and molecular techniques can therefore be kept in reserve for especially difficult cases. They may also be used to settle legal disputes about variety ownership, for example in some vegetable crops where a limited number of morphological traits are available.

4.4 Negative effects of slow or restrictive release procedures

It is a basic assumption that a formal variety testing and registration process is a net benefit to farmers because it provides information and maintains good order in the market. However, if the process is very slow, it may lead to the unofficial 'leakage' of new material from research stations into nearby farming communities before official release. The precise mechanism of this leakage varies and is difficult to investigate. It may be a well-intentioned attempt to allow farmers to test the variety unofficially, or it could be an unofficial gift (or sale!) of a small quantity of seed to a company for trial purposes. In any case, it can be difficult to trace such material once it starts to circulate within the informal system and this can cause confusion.

Breeding programs in private companies are less prone to leakage because breeders are more concerned about ensuring the success of their varieties and to benefit from the income. In addition, companies are more alert about the security of their material and private breeders are normally paid more than their public counterparts.

In general, there is a balance between the complexity of regulations and their effectiveness, since total control of the seed market is difficult especially where small farmers predominate. Ideally, the system should be based on a consensus among the stakeholders that encourages them to lean towards respect for, and compliance with, the official release system rather than trying to subvert it. In much the same way, complex import controls encourage smuggling and that also leads to confusion in the marketplace if foreign varieties are offered to farmers unofficially.

Management and funding of the testing system

4.5 The need for an independent variety release committee

The conventional mechanism for making decisions about variety release is a National Variety Release Committee (NVRC), established according to an article of the Seed Law. In the past, public sector breeders were strongly represented in these committees and this could raise concerns about favouritism for particular institutes, or bias against candidate varieties originating from private companies or foreign countries. There could also be a desire to increase the number of varieties released by public sector institutions in order to demonstrate the productivity of breeders. As plant breeding becomes more competitive, the need for independence in all aspects of the trial system becomes very important to ensure that there is no influence on the decision making process. Ideally, the national variety release committee should be constituted as an independent body with broad representation from stakeholders. This may also increase the success rate in identifying the best varieties by bringing different perspectives to the decision-making process.

4.6 Management of the testing system

The Variety Release Committee will normally prescribe the trial procedures for each crop in an official manual but the actual trial sites may belong to a range of institutions including the research service, the extension service or universities. Consequently, there may be a need for some oversight to ensure that all trial sites follow the correct procedures. This task could be assigned to members of the NVRC who would arrange a program of assessment visits when the crop is in full growth. An alternative approach, adopted in some European countries, is to delegate the entire trial system to a third party on a contract basis. It is logical and convenient for DUS tests to be carried out by the certification agency because they require good variety descriptions for the purposes of field inspection. This is the case in Egypt and Pakistan. However, VCU trials are more expensive and would not fit so easily with the work of the certification agency so they could be carried out by any independent organisation that has research farms, such as Agricultural Universities.

Besides the overall administrative management of the testing system, there is also a need to manage trial data in the most efficient way. This requires the use of standard testing protocols that enable data from different sites to be assimilated into the same statistical program. Field work is expensive and to achieve cost effectiveness it is important that all available information should be used to assist decision makers. Modern statistical programs can help in achieving this objective.

4.7 Management of National Variety Lists

The requirement for a variety to be included in a National List is a bureaucratic tool to regulate the varieties that are made widely available to farmers. It can be considered as a filter between

breeders and farmers, the coarseness of which varies according to the criteria applied for listing. Besides addition of new varieties, the removal of obsolete ones is equally important to ensure that the list is a useful working document. Old varieties often remain in the list because there is no official mechanism for review and deletion, or because breeders are keen to show the productivity of their work. However, this leads to a situation in which most of the varieties on the list are obsolete and of purely historical interest.

In developed countries, where charging for official services is commonplace, this problem is overcome by charging an annual fee to keep a variety on the list. As soon as the variety falls below a certain volume of sales, the company may cease to pay this fee and the variety then drops out of formal production because basic seed is no longer available for multiplication.

4.8 Funding the testing system

A comprehensive variety testing system incurs substantial costs. In developing countries, these are normally paid by the government through its funding of the testing organisation or program. Fees may be charged but these are usually a token amount that may cover the administrative costs but not the costs of carrying out the physical testing activities. Moreover, if most of the breeders are in the public sector, charging a fee only places additional demands on their limited resources and there is no overall benefit.

In developed countries, for example in the European Union, the principle of full-cost recovery has been pursued for many years with the costs of trials being broadly covered by the fees charged. This approach therefore regards the testing system as a service to breeders for which they must pay, although they are obliged to use the service if they wish to market their varieties! These fees therefore become a recognised cost of the breeding program which must ultimately be covered by seed sales. Where smallholder agriculture predominates, there is a natural reluctance to place any further burden on farmers. Testing and registration are then supplementary services to the plant breeding effort, which is still mostly public.

Some savings in the overall cost of testing can be made by requiring breeders to provide information when they submit a new candidate to the system. For example, the breeder can be required to complete a draft description of the variety for the DUS test, and to provide one year of trial results in comparison with the standard control varieties. A more significant step would be to require the breeders to grow the first year of VCU trials themselves according to a standard protocol and for the testing authority to inspect these trials and use the results. However, there may then be concerns about the impartiality of breeders in making an objective assessment of their own material.

Meeting the needs of farmers

4.9 Responding to the needs of diverse agroecologies

The challenge of variety testing is to match promising new genotypes with the environments in which their maximum potential can be expressed. This applies both to the selection process used by breeders for their advanced lines, and to the official testing system for variety registration and release. Since plant breeders generate huge amounts of new material, there is always a risk that an outstanding genotype is overlooked because it is not tested in the right location or in the right way. This has no doubt happened countless times in the history of plant breeding. However, as breeders gain a deeper understanding of their parent materials at the genetic level and techniques of rapid assessment become more sophisticated, the success rate should improve.

Multi-location testing intrinsically favours varieties having wide adaptation that give a good average performance under diverse environmental conditions. Moreover, wide adaptation may also imply a tolerance of below-average conditions that will always be found within the broad spectrum of the farming community. Conversely, varieties with specific adaptation to niche environments (sometimes called pocket varieties) may be overlooked unless a special effort is made to identify them in the VCU trial results. In reality, the main thrust of breeding programs is towards wide adaptation because that gives the best return on investment. Identifying varieties with specific adaptation is more complicated and will benefit fewer farmers. Furthermore, the mainstream formal seed system may be reluctant to multiply these varieties because of the relatively high cost and less return. This is a justification for participatory approaches to breeding and selection that can target specific locations or farming systems, although it is

still necessary to define a system for maintenance and diffusion of these varieties.

4.10 Recommendation domains

The biological justification for a recommendation domain is very clear; all varieties have a physiological or developmental adaptation to certain environmental conditions in which they perform best. That is reflected in a geographical area in which they are recommended for cultivation. This is not necessarily a contiguous area, particularly where altitude is a major factor. A country such as Ethiopia, with its very complex topography, presents a much greater challenge for variety evaluation and recommendation. For this reason, breeding activities have been partially devolved to the regions in Ethiopia, although this approach does have cost implications and there is also a risk of duplication. In contrast, Egypt has no significant altitude variations and the main environmental influence is the temperature during critical phases of growth, particularly flowering and grain filling. Therefore, the recommendation domains for varieties are Lower, Middle and Upper Egypt, which reflect the decreasing duration of the spring season due to the rapid rise in temperature.

In Pakistan, the vast Punjab plain likewise provides a relatively uniform environment in which the same varieties can be used over a very wide area, and this enabled the Punjab Seed Corporation to become a dominant force in the national seed industry since its establishment in the 1970s. Private companies that have entered the seed market latterly are also focussed on this market. In contrast, the Khyber Pakhtunkhwa province (ex. North–West Frontier Province) presents a diverse agroecology that is more challenging for breeders, and less attractive for companies.

This emphasises the fact that companies have to make strategic decisions about the sectors of the market they wish to enter based on a range of considerations, both technical and commercial. In contrast, public breeders may be driven by scientific or social motivations that do not necessarily translate into commercial products. To summarise, it is difficult for a commercially-driven breeding system to address small agroecological domains or niche products because the final return is insufficient to cover the investment costs. Client-oriented breeding is an excellent approach but there must be a critical mass of clients who will become customers for the product when it is released. When this is not the case, participatory breeding and local seed enterprises may be able to fill the 'market space' with seed at moderate cost, provided that the organisational arrangements for production and marketing are sustainable.

4.11 The dilemma of variety choice

In principle, farmers should have a good choice of varieties within the National List to meet their particular needs. In practice, the attraction of high yield is very powerful and varieties that combine high yield potential with acceptable quality tend to occupy most of the market. Consequently, the general belief in the benefit of offering a wide range of varieties to farmers is questionable because the majority of the released varieties do not gain wide acceptability. In practice there are a few clear winners in the variety race and many that 'also ran', or fell at an early stage! There are good examples of enduring or dominant wheat varieties in all three countries studied; Sakha93 in Egypt, Kubsa in Ethiopia and Seher06 in Pakistan, the latter two have now succumbed to rust diseases.

The commercial reality for seed companies reinforces this position because from every point of view, it is easier to produce large quantities of a few popular and widely- adapted varieties. What then are the prospects for commercialising varieties with specific adaptation or having a 'niche market' status? The answer is not very promising, unless local seed enterprises or cooperatives can gain market advantage by offering such varieties within a defined target area. Even then, the farmers who want these specific varieties may be less inclined to purchase seed regularly and sales volumes may remain low.

The Integrated Seed Sector Development Project (ISSD) in Ethiopia is supporting local production initiatives and small enterprises to test the viability of this approach for seed supply. It will be interesting to observe whether the regional agricultural research institutes in Ethiopia can successfully identify these location specific varieties and if the regional seed enterprises, or other local players, can commercialise them on a sufficient scale to increase the range of varieties available to farmers.

4.12 Factors determining the success of a variety

There are many examples of released and apparently promising varieties that do not succeed

in the market. Several factors may contribute to this, including:-

- Insufficient seed to launch the multiplication or promotional program,
- Lack of farmer awareness due to insufficient promotion,
- Too many varieties released in the market to launch a new one,
- Preference of seed companies to focus on a few 'high-volume' varieties rather than offering a more diverse list, as noted in 4.11,
- Farmers purchase the variety initially but with experience, they see no great advantage, or identify a weakness, so the demand rapidly declines,
- Varieties succumb to major diseases after their release, this is particularly true for wheat in which rust resistance is often short-lived,
- Poor end use quality leading to consumer resistance or low market prices.

Closely linked to the question of variety uptake, is the understanding of farmers' purchasing behaviours. On the one hand, there is the 'novelty interest' in new varieties by farmers who are natural innovators; on the other, there may be a strong loyalty to a known and trusted variety by farmers who are more conservative and risk averse. These different patterns of adoption behaviours exist in all farming communities and they make the dynamics of variety adoption quite complex. Moreover, long-established varieties will be easily available from informal sources and farmers may see that as a convenient low cost option rather than making a fresh purchase of certified seed to try a new variety.

Although difficult to analyse and quantify, there is probably also an 'experience effect' by which a farmer who has grown a variety for several years, learns how to exploit its potential and thereby gains some additional yield. This is lost each time a new variety is introduced to the farm. In many countries, there are examples of old varieties that have maintained a substantial market share and have proved difficult to displace even when there are new varieties with superior characteristics on offer. This is frustrating for breeders, but farmers generally have sound practical reasons for such loyalty and it can be difficult for the testing system to reflect all of these factors.

4.13 Decentralisation of variety release

Decentralisation is now favoured by many governments and development agencies, driven by the principle of devolving responsibility for decision making closer to those who are affected by them. This has a clear relevance to variety evaluation and release because of the need to reflect diverse agroecological conditions and farming systems in the recommendations made. However, in practice political considerations may intervene in scientific matters and breeders feel obliged to demonstrate their commitment to their particular province or region. Pakistan has had a province-based research system for many years, while in Ethiopia, the regions are still in the process of establishing their agricultural research capabilities, often with limited resources. In these cases, it is desirable to ensure that there is a strong national body with responsibility for overall coordination of the research system in order to avoid duplication of effort.

In Pakistan, some provincial research institutes conduct their own variety testing for release through a Provincial Seed Council (PSC) but they also send their material to the nationwide trials coordinated by the National Coordinated Wheat Program while the DUS testing is conducted centrally by the FSCRD. The National Uniform Wheat Yield Trials are conducted across the country for two years followed by spot examination by a technical evaluation committee to be presented to the PSC. In both cases, the eventual responsibility to release a variety rests with the PSCs, and varieties are only referred to the National Seed Council if they are to be released at a federal level. Coordinated trials would help reduce duplicate lines from being tested both at provincial and federal levels.

The transition of varieties to commercial seed production

4.14 Management of variety maintenance and breeder seed production

It is the responsibility of breeders to maintain the nucleus material of their varieties and to generate a bulk of the first named generation (normally breeder seed) each year, to initiate the sequence of multiplication. This responsibility usually extends through to pre-basic and basic (= foundation) seed but routine technical work of this kind can absorb a lot of effort and resources.

In the past public breeders often produced relatively small amounts of seed of a new variety, often just a few kilograms and this was a common constraint on the initial multiplication. To address this problem, the testing authority in Ethiopia has

introduced a requirement that the breeder must have a minimum seed stock (sufficient to sow one hectare) of a new variety in order to complete its registration.

In practice, the large-scale work of pre/basic seed production is normally delegated to a department of the breeding institute. However, the primary maintenance work, using ear to row techniques to maintain nucleus material, is under the breeders' control and even this task can absorb a considerable amount of time and land. The establishment of a separate 'Breeder Seed Unit' with a defined budget and resources provides a way to manage this important work without jeopardising the main breeding program. The scale of the maintenance system, in terms of the number of ear-row and progeny plots varies widely between different research organisations and is often very large. However, these procedures have been developed over many years and become embedded in the culture of the research station, making any change difficult to implement. In order to devise an efficient system, it would be beneficial to review these procedures and experiences.

The Seed Unit (now Section) at ICARDA is a unique example within the CGIAR system where special attention has been given to seed issues like variety purification, maintenance, and breeder seed production in order to accelerate and facilitate the transfer of promising varieties to NARS and ultimately to farmers. The Unit also provides a source of elite material for national programs to kick-start seed multiplication or to renew nucleus material if the maintenance program is imperfect. Despite the value of such 'back-up' support, the best solution to this problem is to strengthen the capability of NARS to undertake the technical tasks that underpin variety release and maintenance.

4.15 Financing early-generation seed production

The activities of variety maintenance and early generation (breeder and pre-basic) seed production are labour intensive and costly. It is impossible to recover these costs in the price charged for pre-basic or basic seed, since that would make them far too expensive. The real value of this seed is expressed in its downstream multiplication.

There are two ways to address this problem. Either early-generation seed production can be accepted as an essential service to the seed industry and farmers, which must be covered by public funds, or a royalty can be charged on subsequent seed sales to support the breeders' work, including variety maintenance. This latter approach would normally work only if there is a plant variety protection system to enforce and collect royalties. However, in Egypt a royalty system has been implemented for many years for public varieties and this is based on an agreement with the Central Administration for Seed Production (CASP), a closely associated government enterprise operating under the agricultural research system.

In the absence of such a mechanism, or a straight government subsidy, the financial status of 'foundation/basic seed organisations' is very precarious, despite the vital role they play in the seed chain. It is impossible to generate sufficient revenue to maintain these operations without charging a very high price for the seed and thereby making it less attractive for the private sector. In Morocco, with the dissolution of the Seed Unit within INRA, the public seed production organisation (SONACOS) reverted to importing early generation seed from Spain for local multiplication and marketing. The company found that the cost of early generation seed production was prohibitive and found it cheaper to import seed of generic varieties.

To address this problem, early generation seed producers often try to retain some certified seed sales in order to provide additional income as a way to subsidise the more expensive work on early generations. This is contrary to the conventional wisdom that public seed enterprises should completely vacate the retail market but it does provide an additional source of revenue to sustain their activities. For the same reason, breeding institutes sometimes have a small retail business selling seed of their varieties.

Some countries (e.g. Tanzania) have established an independent organisation to undertake pre/basic seed production as an intermediary between the NARS institutes and the commercial seed sector.

Although this provides a convenient institutional solution, it does not solve the underlying financial problem of obtaining sufficient revenue from sales to cover the high cost of producing such seed, unless a royalty system exists. The experience of the National Seed Development Organisation (NSDO) in the UK provided an interesting case study, although it was

dependent on royalty income (Box 1).

The same need that lead to the establishment of NSDO still exists in many countries that have a significant public breeding sector but where the private sector is the main supplier of certified seed to farmers. The challenge is how to bridge the gap between the public and private sectors in the most effective way, while generating sufficient revenue to support breeding activities.

Box 1: The National Seed Development Organisation (NSDO) in the UK – an example of an intermediate seed multiplication agency for public sector varieties

In the UK, Plant Breeders Rights were introduced in 1964 and the first rights were granted in 1966. At that time, the government was by far the largest breeder at a network of long-established agricultural research stations. The government therefore had to make a policy decision about how to handle PVP for its own varieties. It was not an option to exempt them because that would have made seed of public varieties cheaper than those from the private companies that would carry a royalty cost. It would also have been inefficient to expect each research station to set up its own programme for the commercialisation of their own varieties, some had many but others had rather few. It was therefore decided to establish the 'National Seed Development Organisation' (NSDO) to handle all the activities between the breeder and the commercial seed sector. These were:-

- Variety maintenance and breeder seed production, done in close collaboration with the breeder but with dedicated resources for this work,
- Two generations of seed multiplication, namely breeders to pre-basic and pre-basic to basic,
- Arranging and providing seed for trials and demonstrations of new varieties,
- Initial promotion of new varieties to create awareness in the market,
- Licensing of varieties to companies,
- Allocation and sale of pre-basic or basic seed,
- Monitoring certified seed production and collection of royalties.

Apart from variety maintenance, NSDO carried out all these activities using its own facilities; it owned a large processing plant and hired land for contract seed production, all funded out of revenue from basic seed sales and royalties. While these activities were initially conducted in the UK, they were soon extended to other countries where commercial opportunities existed. This was normally done by appointing national agents for NSDO varieties.

NSDO became an independent, free-standing organisation that could gain expertise in the technical and commercial activities at the interface between breeders and the private seed trade, especially the licensing of varieties. It was a limited company wholly-owned by the Ministry of Agriculture and did not pay any money directly to the breeding stations that provided the varieties, although later a revenue-sharing system was agreed. Consequently, it made a large annual profit because it received the income from varieties without having any breeding costs. NSDO functioned effectively in this role from 1967 to 1987 but was then dissolved when large sections of the state plant breeding activity were privatised.

Many university staff undertake plant breeding activities as an adjunct to their teaching responsibilities. However the fate of these varieties is very uncertain because there is seldom any allocation of funds for maintenance and development of the products, regardless of their merit. A survey of these experiences of university breeders in releasing and commercialising their varieties would be interesting.

4.16 Acceleration of early generation seed multiplication

Some practical measures can substantially accelerate early generations and certified seed availability, depending on the environmental requirements of the crop. First among these is the use of off-season multiplication, usually by exploiting a location where warmer or cooler conditions prevail. This is a routine procedure for wheat breeders in the northern hemisphere who use a southern hemisphere location both for selection and for small-scale multiplication. Considering the three countries studied, this could be achieved during the 'summer' in the northern mountains of Pakistan, or in the irrigated lowlands of Ethiopia during the dry season in the highlands. Egypt does not have an option of this kind due to its lack of significant climatic or altitude variation.

In some environments there is also scope for increasing the multiplication factor of wheat by using very low sowing rates. This works best where there is a long cool growing season and ample moisture that increases early tillering and the total number of seed bearing heads per plant. Cooler areas of Northern Pakistan could provide such conditions whereas in Egypt, the rapid onset of high temperatures during or soon after flowering limits the grain filling period.

4.17 Allocation of new varieties and early generation seed

When all major activities in the seed sector were under government control, there was a single delivery channel from research centers to the national or state seed organisation. This was the case in the three countries studied: Pakistan (mostly with the Punjab Seed Corporation), Egypt (with

the Central Administration for Seed Production) and Ethiopia (with public seed enterprises). Once the market diversifies with the entry of competing companies, then the allocation of basic/foundation seed becomes a more sensitive issue, especially if a new variety has special merit and market potential.

The allocation procedures for early generation seed between government entities and private companies need to be open and transparent but there should be a 'pre-qualification' to ensure efficient use of this valuable seed. Pakistan is currently going through this process because companies are pressing for access to seed at an earlier stage in the multiplication program and this would also reduce the burden on public breeders. However, it is essential for companies to have the competence and facilities to do this work properly and with adequate supervision by the certification authority. If poor quality seed is marketed, the prospects for the variety may be jeopardised.

With the declining role of public enterprises in many countries, there is a need to consider the licensing of public varieties to the private sector in a way that ensures proactive development of the variety. However, this raises complex issues about the type of licence that is offered, whether exclusive, restricted or completely open. This topic deserves further attention as public breeders are under increasing pressure to commercialise their varieties but may lack the skills to make the most suitable arrangement to benefit both the research system and the client farmers.

4.18 Pre-release seed multiplication

It is a well-recognized problem that public breeders often wait until a variety is formally registered before launching the multiplication program, and they then start from a very small seed stock. Breeders are reluctant to commit resources to seed multiplication until they are certain that the variety will be registered and released. This may cause a delay of two to three years in the availability of certified seed, or even more if the testing system is also protracted. By starting multiplication simultaneously with the testing cycle, this delay can be reduced or eliminated but there is a risk that the effort may be wasted if the variety does not ultimately satisfy the requirements for release. The seed stock may then have to be diverted to the grain market with a consequential loss of investment by breeders. In fact, the actual financial loss in such cases may be quite small; the more serious aspect is the competition for limited resources if breeders devote more time and space to seed production.

Private breeders working in a competitive environment have to make these judgements constantly, in consultation with their marketing departments; the better the prospects for the variety, the more confident they are to boost early multiplication. Likewise, the seed production plan for each new variety would be adjusted after the first year of official trials, or if any other relevant information becomes available, such as the entry of a rival variety.

Another key issue in starting pre-release multiplication is the ability or willingness of the certification agency to inspect and certify crops/seed lots of a variety before it is officially registered. This can be a bureaucratic obstacle but in fact there is very little risk involved if it is agreed that no certified seed would be sold to farmers until the registration process is completed. If the regulatory authority can adopt a pragmatic approach in consultation with the breeders, it would facilitate pre-release multiplication, and potentially save two years in the production chain.

4.19 The link between variety release and certification

There is a close technical linkage between these two activities because:

- only officially registered varieties are normally eligible for certification,
- registration in a list requires a name and a description to establish the identity of a variety,
- a good variety description is a requirement for crop inspection.

From this viewpoint, certification can be considered as a downstream management system to ensure the maintenance of the characters defined in the DUS description and in the initial release of (pre)-basic seed by the breeder. Certification thus safeguards the genetic purity of the variety as the scale of multiplication increases and also provides an assurance of seed quality to the purchaser.

One sensitive issue arising in this connection is the stage in early generation multiplication at which the certification agency should first inspect a seed crop. There must be a point at which the breeder transfers material to another party but breeders

are often reluctant to have their crops inspected by an official agency. In fact, it is not uncommon that there are problems in the quality of material released by breeders. Purchasers may have to do some roguing of the basic/foundation seed crop to rectify this. In practice, the inspection of crops that are producing pre-basic seed from breeder seed is probably adequate, since this reveals the quality of the breeder seed and roguing can be done if necessary. If delayed to the next multiplication (pre-basic to basic) the scale of the task becomes much larger and more costly.

The changing context of plant breeding

4.20 Impact of competitive breeding on the variety release system

When breeding was entirely a public activity, there was little competition between breeders or research institutes, except with the intention of enhancing scientific reputation. With the entry of new private sector players, the picture has changed dramatically because they have to compete for market share by all possible means in order to fund their breeding activities. This is shown very clearly in Pakistan when the Bt gene became available in cotton and many companies rushed to get on this market 'bandwagon'. The same was observed in India, where it was also linked to the widespread adoption of hybrid cotton[1].

While such competitive breeding would normally be considered as beneficial for farmers, if the primary gene pool is limited, it can quickly lead to the churning of the same genetic material to produce a lot of similar varieties whose main merit is novelty but with little agronomic gain. This also becomes a problem for the testing authorities who are required to differentiate between these varieties, under intense scrutiny by the breeders. As an example, the market for cotton seed in Pakistan became chaotic at one time with many varieties under test and some unregistered varieties being marketed informally.

If these introductions are of good quality, there may be no serious threat to farmers but disorder in the market may increase the opportunity for deliberate malpractice by unscrupulous companies who could exploit this lack of control.

The financial incentive for competitive breeding varies greatly between crops; private companies have largely taken over the market for hybrid maize in Egypt with several active breeding programs, while in Ethiopia (a more difficult market) the only long-established private sector company is Pioneer, although SeedCo has also entered the market recently. In Pakistan, maize was traditionally a minor crop but it is increasing rapidly, with active private sector participation.

Teff, the dominant grain crop in Ethiopia, is notably difficult to breed and also presents challenges for pure seed production, so it is of little interest to the private sector. This is a clear example in which public breeding programs will remain the main source of improved varieties for the foreseeable future.

4.21 Incentives for public breeders

As already noted, the working environment of public and private breeders is very different, although both are motivated by the same underlying desire to create new superior genotypes. Private breeders are, by definition, directly connected to the market on which they ultimately depend for their funding. Consequently, the market share occupied by varieties provides a clear measure of breeding success although this is only translated into revenue if there is a regular sale of seed and/or a royalty collection scheme. For this reason, private breeders must focus their attention on the more productive commercial sector of agriculture and on goals that are likely to bring short-term gains. In contrast, public breeders have the freedom to address whatever constraints will bring the greatest overall socio-economic benefit to farmers, or to pursue more strategic breeding objectives. They may be acclaimed for widely-adopted varieties, or even receive an official award but this is not normally reflected in the revenue of breeding programs. Given these financial realities, the need to provide some incentive for public breeders is often raised. However, the mechanism for achieving this is problematic and could prove divisive within the scientific community of a research station. Breeding involves various supporting services and disciplines and the allocation of income in a fair way could be difficult. There is also an element of chance in breeding, such that one program may be more successful than another due to a particular line of crossing that was undertaken.

[1] Despite its rapid spread and predominance in India, hybrid cotton has not yet been widely adopted in Pakistan. This may be due to the lack of development of seed production system which requires intensive hand labour, and also the rather different cultivation status of the cotton crop in the two countries.

In many developed countries, breeding of major crops has moved decisively from public to private sector in the past 30 years, driven both by government policies and robust variety protection laws. This has enabled private breeders to collect sufficient royalty income to support their activities and this is a clear indicator of their success. However, public sector institutions may still undertake more strategic research, often in partnership with private companies.

In many developing countries, private sector breeding has gained momentum in the past decade and this has been achieved by recruiting experienced breeders from the public sector. While this ensures that their skills are put to good use in a commercial environment it has depleted the pool of public breeders, who will still be needed for the foreseeable future. In fact there is a general shortage of practical breeders who understand both the genetics and the agronomy of the crops they work on. The new generation of breeders have been mostly trained in lab-based molecular techniques, divorced from fieldwork. Many practical breeders feel there is an urgent need to recombine these different skills.

4.22 Impact of plant variety protection on variety release

Any significant private investment in plant breeding of non-hybrid crops depends on some form of legal protection. This gives breeders a 'property right' and enables them to collect a royalty on the use of the variety by farmers and thus provides revenue to support the breeding program. Variety protection also impacts on variety release because granting a Plant Breeders Right requires an accurate morphological description of the variety, based on a DUS examination. This obliges the breeder to produce a purified and uniform nucleus stock of the variety as the starting point for testing, maintenance and multiplication. Although this is not difficult technical work, there is a tendency to under-estimate the requirements for the DUS criteria and to revert to more 'agronomic' descriptions of varieties that are not adequate for legal protection.

After obtaining a breeders right, the owner is under strong commercial pressure to multiply the variety and get it into the market place as quickly as possible in order to create and exploit a 'novelty premium' on the seed price for the first two to three years. Therefore the existence of an effective variety protection and royalty collection system is a key driver of rapid variety release. However, this situation applies mostly in countries with a largely industrial agriculture where annual seed purchase by farmers is done routinely.

In countries where the informal sector predominates as the default seed source for small farmers, sales of new varieties commonly show a brief peak followed by a rapid decline once the variety is in general circulation. In these cases it can be said that the primary (and essential) function of the formal sector is to inject new varieties as quickly and widely as possible, after which the informal sector takes care of diffusion. The social and economic benefits of the variety are still achieved but the breeder cannot easily obtain a royalty from the informal sector.

This explains the common observation that, in developing countries, the formal sector accounts for only 10-15% of the seed supply in self-pollinated crops and this is a major disincentive for the private sector to invest. On the other hand, a public breeder may be very pleased to know that a variety occupies a large proportion of the total area with significant yield impact and may not be concerned about the actual channel of seed supply. Such different perceptions again emphasise the contrasting positions of public and private breeders.

4.23 Impact of seed replacement rate

The scenario outlined above is completely contrary to the private sector goal of maximising the annual sale of certified seed but in reality, companies find it difficult to maintain seed sales of well-established varieties, unless there are legal constraints on the informal sector, as in EU countries. The concept of replacement rate, that is the percentage of the annual seed requirement that is purchased each year as certified seed, is relevant here. In some countries there is often an expectation, particularly among policy makers, of an unduly high level of certified seed production and purchase with the belief that this will increase the national yield. Subsidies may be used to reduce the seed price and which increase the volume of sales but in practice the quality of this large scale production is uncertain. This reflects a fundamental confusion between the national seed requirement (how much seed of a particular crop is sown each year) and the 'effective seed demand'

(how much seed farmers are prepared to purchase on a regular basis at a market price).

Unfortunately, there is no automatic yield gain from the purchase of certified seed. Everything depends on the effectiveness of the seed production and quality assurance system, especially crop inspection and post-harvest handling. It would be better to aim for a more modest replacement of say 25-30% annually for established varieties, and then to emphasise high seed quality in the market and good seed practice on the farm. In fact, seed specialists and extension services commonly recommend the repurchase of fresh seed every three to four years in order to overcome the effects of variety admixture and the build up of seed borne diseases in a farm-saved stock. This strategy also encourages farmers to consider testing a new variety that might have entered the market.

4.24 Variety release and the informal seed sector

The concept and procedures of variety release are, by definition, key features of the formal seed sector since they involve regulatory bodies and serve the interests of the organised commercial seed industry. However, some important linkages to the informal sector should be noted.

First, for public varieties, the use of an extensive promotional campaign with demonstration plots is an effective technique to launch a new variety. This was clearly demonstrated by the large-scale production of the wheat variety Misr1 in Egypt, where about 100 such demonstrations were grown in 2009 using project funds. Moreover, farmers were encouraged to use part of the harvest crops as seed for distribution/sale to raise awareness. Many farmers responded and achieved a good premium over the normal seed price. This was a very effective way to stimulate interest in/demand for the variety, from which the formal seed sector later benefitted when certified seed became available in the market. However, such a large informal promotion at the start of the variety life may ultimately reduce the total seed sales because many farmers may see no reason to return to purchase certified seed for the next two to three years. This again highlights the problem of achieving regular seed sales of a crop like wheat (or rice) when faced with a dominant informal sector.

Regional dimensions

4.25 Release of imported varieties

Although the main theme of this review in the release of material from within national research systems, it is appropriate to consider the procedure for imported varieties. When a variety has been registered in another country and has entered general cultivation, it is wasteful to start the entire release procedure from a zero baseline. This is a strong argument for establishing regional lists so that varieties could move easily between nearby countries having similar agroecologies. In this case, the DUS description could be obtained (or even purchased) from the country of first registration and the VCU trials could be reduced to a single year of verification since there would be very little risk associated with a variety that is already in use elsewhere.

4.26 Introduction of lines and varieties from the International Research Centers

The IARCs provide the core breeding effort for their respective mandate crops across the developing world. In the case of wheat, this work is done by CIMMYT and ICARDA and they target the major agroecologies where the crop is grown.

These centers conduct comprehensive programs of crossing, screening and yield trials to identify promising lines that are sent to collaborators in national research systems for evaluation. Some of this material is used for further crossing while other advanced lines may be selected directly for release and multiplication. Because of the coordinated nature of this system, there is a large body of trial data from many locations. In practice, closely-related or identical lines may be selected for use in different countries having similar agroecological conditions.

It is the responsibility of national research programs to identify and submit material to their variety testing system but in the case of advanced CGIAR lines, the characteristics and performance are often well-known. In fact, there may be specific trial data from a neighbouring country so again the risk of releasing an unsuitable variety is very small. In these cases, it is a waste of resources and time for this material to go through the full evaluation process. A 'fast-track procedure' should be devised in consultation with CGIAR centers and the NARS.

4.27 Regional harmonisation of variety lists

Political boundaries seldom correspond with agroecological zones and in many parts of the world, similar production environments extend across several countries. This provides a strong justification for a coordinated regional approach so that a variety tested in one country could be added to the list in another, or could be registered after one year of testing. Ideally, a regional variety list would comprise varieties in each of the national lists once they have been in general use for two years without any obvious problems.

However, for this system to work effectively, the procedures for testing and listing must be of similar standard in all the participating countries. Agreement among the technical representatives is necessary to ensure uniformity of these standards, and ultimately it must have the approval of politicians. In practice it is proving difficult to achieve this regional harmonisation despite the benefits it could provide in terms of cost saving in the trials system and wider/quicker availability of varieties to farmers.

The case for review and renewal of variety release

4.28 Updating national variety release systems

Considering the many issues raised in this discussion, there is a strong case for national authorities to review both the technical and administrative procedures relating to variety release. In many countries these procedures have become institutionalised over the years and do not reflect the current realities of national and international plant breeding efforts, and the movement of seeds and varieties in a more globalised world. While there is still a need to 'protect farmers' from unsuitable material, it is also true that varieties of proven merit, and presenting no risk, may progress slowly through testing to full registration. A more sophisticated and sensitive system should provide for:-

- Pre-release seed multiplication of varieties under test,
- Conditional release of promising new varieties, followed by full release when they have been grown by farmers for one or two years,
- Fast-track testing and release of varieties that have already been listed in nearby countries, or have a common origin in material from international research centers,
- Automatic review of each listed variety every five years to assess its value and status within the farming community,
- Deletion of obsolete/unsuccessful varieties from the list, and
- Development of more regional variety lists where the similar agroecology extends across several national boundaries.

Achieving these objectives would imply a more proactive role for National Variety Release Committees, not simply to review and approve new varieties but also to manage the overall variety portfolio, at least in the major crops. On the other hand, a more flexible approach is needed for vegetable crops because of the huge number of varieties available from the international trade.

4.29 Efficiency of variety testing

As with all public services, the costs of variety testing and registration are seldom calculated in detail and it is difficult to carry out a true benefit/cost analysis on the overall process. Consequently, the testing system may continue unchanged without its technical or economic efficiency being scrutinized or challenged. There are some who would advocate that the entire edifice of variety testing should be swept away as part of 'de-regulation' but that may lead to market confusion, over which it may be difficult to regain control. However, in the interests of efficiency and value for money, it would be desirable for national authorities to review their variety testing and release systems to reflect the issues discussed here. In particular, any delay in delivering new varieties to farmers does represent a cost in terms of extra administrative work and loss of the genetic gain achieved by breeders. This becomes more acute if disease resistance is 'lost' while the variety is moving slowly through the testing system.

4.30 Registration and listing of traditional varieties

As noted elsewhere in this review, variety testing, registration and release are key elements in the formal seed system, which is often represented as a chain linking research to farmers. Varieties produced by organised plant breeding programs normally have to pass through this process and thereby become eligible for seed quality control procedures, such as certification. However, this highly structured process discriminates against

traditional varieties that may have genuine merit but lack the official status to qualify for certification.

If the regulations for testing and listing are rigorously applied, such varieties may even be regarded as 'illegal', despite being widely known, and there may be a reluctance to improve them if there is no way to gain official recognition.

This situation undervalues such varieties and, in addition, it may antagonize groups who support more devolved and farmer-based approaches to plant breeding and seed supply. For these reasons, it is appropriate to consider establishing a separate procedure to recognise traditional and locally improved varieties. This would have less stringent requirements for DUS and allow for some variability while still ensuring that the variety is a recognisable and manageable entity. The possibility of protecting such varieties has been widely discussed in the context of 'farmers' rights' but this is difficult because of the need to define the variety accurately and determine its true origins and ownership within rural communities.

4.31 Registration of varieties from participatory plant breeding or selection

A similar concern arises with varieties originating outside the mainstream research system, for example from participatory breeding or selection activities. This approach has been strongly promoted as a parallel or complimentary breeding strategy, especially for more diverse or marginal environments where varieties with wide adaptation may not perform as well as those selected within the community. The problem is that the formal testing and release system was developed for varieties originating from the national research system and there may be a reluctance to accept material from other sources. Such discrimination, whatever its basis, may restrict the wider multiplication and distribution of promising varieties. To address these concerns, testing system should be open to varieties from different sources in order to provide an objective assessment of their merit and thus make them eligible for certification. It must be accepted that the concept of 'release' is rather different for varieties that have originated within communities because farmers may have already saved seed from the trials they carried out. However, this should not prevent the 'formalisation' of a successful variety, provided its origins are recognised.

4.32 Registration of non-cereal crops

In all countries, the variety testing and release system was designed primarily for staple cereal crops such as wheat, maize or rice that are of strategic importance for food security. Sometimes the same procedures have been transferred to other crops such as vegetables in which the variety supply context is quite different. With such a large number of crops and varieties available from the international trade, it is unrealistic to undertake variety testing and registration on the same scale because the volume of seed marketed for each variety does not justify such a large investment. In practice, it is common to find many imported vegetable varieties on sale in the market, only a few of which have been formally tested and released while the majority have been imported unofficially.

Since most of these international varieties are marketed in many countries, it is unlikely that they represent a serious threat to growers. However it would be advantageous if they could be included and described in a central registration system (or database) so that extension staff and others could access this information. This approach could be adapted to a website format whereby companies pay a modest fee to register their varieties with a description of their key characteristics and (if possible) strengthen their position as the primary importer.

4. 33 Role of a seed policy in variety release

A national seed policy is a declaration of intent by the Ministry and Government on how the seed sector as a whole should develop with a long-term vision. It should provide guidance to all stakeholders and ensure consistency in decision making. To support the process of transition to a more liberalised seed industry, many countries have prepared or revised a seed policy to define the responsibilities of participants, particularly the contributions of the public and private sectors. Variety release is a key element in such a policy because of its importance to the seed industry and the many sensitive issues that need to be clarified for the benefit of all stakeholders. While official testing, registration and listing would be defined briefly in the seed law, many of the issues discussed in this review are matters of implementation. The time-frame for variety release relates more to the way in which the law is implemented, and should therefore be addressed in the policy to avoid undue delays.

5. RECOMMENDATIONS FOR GOOD PRACTICE

1. Variety release is an integral part of the formal 'seed chain'. The overall purpose is to identify those varieties that have real value for farmers or consumers and to exclude those that do not. It may be considered as a 'filter' to exclude unsuitable varieties from the market. To achieve this objective, candidate varieties are entered into a standardised programme of field trials, usually followed by post-harvest assessment of quality in order to establish their Value for Cultivation and Use - commonly abbreviated as VCU.

It is also important to establish the identity of a new variety by means of a detailed examination to confirm that it is Distinct, Uniform and Stable - commonly referred to as DUS. This description, linked to a registered name, is required for seed certification and it also helps to manage the market by ensuring the validity of variety names.

2. Variety release involves a number of separate technical and administrative stages leading to the official recognition of named varieties in a national list. It is important to establish a clear timeframe for this process so that the genetic gains achieved by plant breeders can be transferred quickly to farmers. If the process becomes too lengthy and bureaucratic, the impact of plant breeding on national productivity is reduced. Moreover, slow evaluation and release procedures may lead to the unofficial leakage of varieties into the farming community, or in some cases, smuggling of seed from neighbouring countries.

3. Both VCU and DUS tests require a minimum of two seasons or a maximum of three if there are problems in either test. It should be a requirement of the testing system that the DUS and VCU evaluations are carried out simultaneously and that the results are reviewed after two years or seasons.

4. A standard testing protocol should be prepared for each crop so that the results from all trial sites can be incorporated in a single analysis that makes best use of all the data collected. The use of good statistical packages can greatly increase the efficiency of variety testing.

5. It is very difficult for a variety trial to exactly predict the performance and uptake of a variety when it enters general cultivation by farmers. The testing process is therefore always a compromise between achieving reasonable precision with the limited resources available. Extending the trials with more seasons or locations does not guarantee better results and delays the time when farmers can purchase seed and make their own decisions. On-farm trials should conducted in parallel with official trials and these should, as much as possible, be managed by farmers under their normal conditions.

6. Coordinated national trials favour varieties that show adaptation to a wide range of conditions and may overlook those with more specific adaptation or uses. The testing system should be alert to the needs of farmers in locations with different needs and should arrange more targeted trials to assess their merits. This must be linked to a viable means of multiplication through local seed enterprises that will ensure diffusion and uptake.

7. It is not necessary to carry out more detailed agronomic evaluation, for example on fertiliser response or planting dates, as part of the variety release process. This can be done at a later stage as part of an extension activity to provide more information for farmers.

8. The decision making body for variety evaluation and release is normally a National Variety Release Committee, often working as a technical sub-committee of the National Seed Board. This committee should be composed of a range of stakeholders including the private sector and should not be dominated by one particular interest group. Varieties that are approved by the NVRC should be included in the National List and should then be eligible for certification.

9. The NVRC should meet regularly at specific times each year to review the trial results and at the same time it should consider the status of existing varieties and decide whether any should be removed because they are no longer in production. The committee should therefore play a proactive role in managing the National List.

10. The National List of Varieties should be readily available to all stakeholders as a working document and it should be updated annually. However, the printing and distribution of such a document entails a considerable cost and this may lead to

delays in publication. To address this problem, it is recommended that the National List is maintained on a website and updated regularly. Agronomic information about each variety can then be added in a separate section of the list.

11. Breeders should be required to inform the National Variety Release Committee about the quantity of seed they will have available for multiplication when the variety is registered. The Committee may require that breeders have a specified quantity of seed before the variety can be registered. However, this is an expensive task and breeding institutions should allocate some funds specifically for early generation seed production so that this work does not compete for resources with the main breeding program.

12. To facilitate the production of early generation seed while a new variety is being evaluated, the certification authority should be authorised to inspect and approve these seed crops so that, at the time of registration, there is sufficient basic (foundation) seed available to start large-scale production.

13. Varieties that are already released and cultivated in a country with similar agroecological conditions should be allowed a 'fast-track' release after one year of evaluation because they present very little risk to farmers. Likewise, when varieties or lines released by the International Agricultural Research Centres are submitted for testing, the trial data from other locations should be accepted as evidence of their performance.

14. National variety testing authorities should enter into bilateral agreements with neighbouring countries in order to share data and prepare joint variety lists. Ideally this process should extend to include several countries, which would share a regional list. However, in this case, it is essential that the testing procedures and standards are similar in all the participating countries.

15. Given the increasing role of the private sector in seed supply, it is essential that governments and public breeding institutions gain experience in the licensing of their varieties in a way that maximises the return to breeders and the benefit to farmers.

16. The introduction of plant variety protection is a recognised stimulus for private sector investment in plant breeding but it will also increase the pressure from companies for speedier and efficient variety release procedures, so that they can recover their investments as quickly as possible from seed sales.

17. The testing and release system devised for staple cereals crops is not suitable for vegetable crops because of the very large number of varieties and the diversity of production requirements. A different procedure should be devised for these crops, based primarily on the registration of the name, a description of the variety and confirmation of its breeder/supplier. This would support the orderly marketing of such varieties and offer some element of protection to breeders/agents without the need for extensive testing procedures, which are costly and delay the wide availability of improved material.

18. The testing and release system should be open to varieties from alternative sources, for example, those obtained by purification of traditional/local varieties or arising from participatory activities involving farmers. If necessary, more flexible DUS criteria could be established for such materials provided their merit had been demonstrated for specific locations, purposes or client groups. If these varieties gain recognition in an official list, they could then be eligible for certification and more organised marketing. The guiding principle of the testing system should be to assess candidates objectively, regardless of their origins and to facilitate their transition into the market.

19. The breeding, release and multiplication of improved varieties are key strategy issues for increasing national productivity and promoting food security. Considering the many changes that have taken place in seed industries over the past two decades, particularly the increased participation of the private sector and the globalisation of trade, it is recommended that governments and Ministries review their variety release procedures to ensure that they are 'fit for purpose'. Based on this review, the regulatory framework for varieties and seeds should be adjusted to ensure a more efficient and streamlined system of variety release.

20. Many countries are preparing a National Seed Policy to guide the development of the seed sector and the procedures for variety testing and release should be a key element in these policies.

The policy should reflect not only the regulatory procedures but also the broader principles of accelerating farmers' access to improved genetic material and increasing choice in the market.

ANNEXES

Annex 1: Summary table of national procedures for variety development, evaluation and release

Stages in the process	Egypt	Ethiopia	Pakistan	Remarks
A. Variety development				
Crossing/ hybridization	F1	F1	F1	Local or introduced germplasm
Screening segregating population	F2-F6/F7	F2-F7	F2-F6/F7	Selection on-station using standard breeding protocols
Number of years	6-7 years	years	6-7 years	
B. Variety evaluation trials				
	Observation nursery (1 year)	Observation nursery (1 year)	Preliminary yield trials (1 year)	Mostly on-station and subjected to disease screening nurseries (e.g. Ethiopia)
	Preliminary yield trials (A-YT) (1 year)	Preliminary variety trial (1 year)	Advanced yield trials (1 year)	Main and sub-stations
	-	-	Regional (Micro) variety trials (1 year)	Main and sub-stations and subject to disease screening trials (e.g. Pakistan)
Number of years	2	2	3	
C. Variety release trials				
	Advanced yield trials (D-YT) (1st year)	National variety trial (1st year)	NUYT (1st year)	Parallel with DUS testing (e.g Pakistan), but after VCU testing (e.g. Egypt)
	Advanced yield trials (D-YT) (2nd year)	National variety trial (2nd year)	NUYT (2nd year)	Parallel with DUS testing (e.g. Pakistan), but after VCU testing (e.g. Egypt)
	Variety registration (DUS) testing (2 years)	Variety verification trial (3rd year)	Spot examination for final approval (2nd or 3rd year)	Final approval by NVRC
Number of years	4	3	2(3)	
Total number of years	12-13	12-13	11-13	
D. Variety approval				
Evaluation committee	Follow up Technical Committee for Varietal Registration, NVRC	Technical Committee	Variety evaluation committee	
Approval authority	Technical Committee for Varietal Registration PVRC, MoAL (Ministerial Decree)	NVRC, APHRD, MoA	Provincial Seed Council, National Seed Council	

Note: NUYT= National Uniform Yield Trials; APHRD= Animal and Plant Health Regulatory Directorate

Annex 2: A chronology of seed industry development in the three countries

2a. Egypt

1922 Seed production and distribution unit established for cotton; this subsequently evolved through Branch (1942), Section (1957) and Directorate (1980) of the Ministry
1926 Seed Law (No 5) - regulated cotton seed supply
1946 Seed Law (No 146) extended control to seeds of major field crops
1952 Egypt became a member of the International Seed Testing Association (ISTA)
1966 Agriculture Law (No 53) passed, covering all aspects of agriculture
1966 First Green Revolution wheat variety released (Giza 155)
1980 Central Administration for Seeds (CAS) established
1987 Pioneer Hybrid enters as joint venture with Ministry of Agriculture
1991 First National Seed Conference held; National Seed Council established
1995 Central Administration for Seed Certification (CASC) and Central Administration for Seed production (CASP) established as separate entities to replace CAS
1998 Egyptian Seed Association (ESAS) established
2001 Central Seed Testing laboratory at Giza gains ISTA accreditation
2003 PVP Office established within CASC by Prime Ministerial Decree (# 1366)
2006 Egyptian Seed Industry Association (ESIA) established
2008 First Plant Variety Protection Certificates issued
2009 Plant variety release protocol passed (by Ministerial Decree No 769)

2b. Ethiopia

1976 National Seed Council established by the National Crop Improvement Conference
1978 Start of the FAO Seed Production and Quality Control Project
1979 Establishment of the Ethiopian Seed Corporation under the WB project
1982 National Variety Release Committee established
1990 ESC forms joint venture with Pioneer for hybrid maize seed production
1992 National Seed Industry Policy and Strategy published
1993 National Seed Industry Agency established to handle regulatory matters
1993 Ethiopian Seed Corporation renamed as Ethiopian Seed Enterprise
1995 Policy of regionalisation introduced by the new Constitution
1996 Joint venture terminated; Pioneer becomes independent PLC
2000 Seed Proclamation by MoA (206/2000)
2002 National Seed Industry Agency abolished, responsibilities transferred to newly formed National Agricultural Inputs Authority (NAIA)
2004 NAIA abolished, responsibilities transferred to the newly formed Ministry of Agriculture and Rural Development (MoARD)
2007 Ethiopian Seed Growers and Processors Association established
2008 First Regional Public Seed Enterprise established in Oromia Regional State; (and Amhara RS in 2009 and Southern Nations, Nationalities and Peoples in 2010; and Somali RS in 2014)
2009 Integrated Seed Sector Development Project established with NL funding
2010 SeedCo enters hybrid maize seed market
2010 First regional quality control bodies established
2011 Agricultural Transformation Agency established, with seeds as one key focus area
2013 New Seed Proclamation promulgated by Federal Government
2014 Strategy and road map for seed sector development published by ATA (published online in 2015)

2c. Pakistan

1961 – 1972 Organized seed production started by West Pakistan Agricultural Development Corporation (WPADC), with a certification wing for quality control and regulatory functions
1965 First 'Green Revolution Wheat' released as 'Mexipak'
1966 Cotton Control Ordinance (included controls on varieties)
1972–1976 WPADC abolished, seed production transferred to provincial governments
1976 Seed Act passed by Parliament
1976 World Bank 'Seed Industry Development Project' started
1976 Provincial Seed Corporations established in Punjab and Sindh
1976 National and Provincial Seed Councils established
1976 Federal Seed Certification Agency (FSCA) established
1976 National Seed Registration Authority (NSRA) established
1981 World Bank Seed Project closed
1981 First private seed company established
1984 Entry of multinational seed companies (Cargill -1984, Pioneer-1989, Syngenta-1991, ICI-1996)
1994 Seed businesses granted 'industry status' for tax purposes
1997 Certification and Registration Agencies merged into FSCRD
2001 Amendment to Seed Act submitted to Ministry for authorization (still pending)
2004 Bt cotton varieties introduced unofficially
2005 Biosafety rules promulgated under the Environment Protection Act
2009 First Bt cotton variety officially released, following biosafety protocols
2010 Seed Association of Pakistan established to represent the private sector
2011 Federal Ministry of Agriculture and Livestock abolished and most responsibilities devolved to provinces;
Federal seed agencies and agricultural research transferred to the Ministry of Science and Technology;
Ministry of Food Security and Research established with responsibility for federal variety and seed control agency

Annex 3: Comparison of different systems of generation nomenclature

Definition	AOSCA	OECD	Egypt	Ethiopia	Pakistan
1st generation supplied by plant breeders	Breeder	Breeder	Breeder	Breeder	Breeder nucleus
2nd generation	Foundation*	Pre-basic	Foundation	Pre-basic	Pre-basic
3rd generation	Registered	Basic	Registered	Basic	Basic
4th generation	Certified	Certified 1	Certified	Certified 1	Certified
5th generation		Certified 2		Certified 2	Approved

AOSCA is the Association of Official Seed Certification Agencies (USA)

OECD is the Organisation for Economic Cooperation and Development, which operates an international seed certification scheme; the OECD terminology is also used in the European Union.

*In some countries, there is provision for two generation of foundation seed. This may be required to produce sufficient certified seed to meet the national requirement for popular varieties.

Annex 4: Glossary of terms used in connection with variety testing and release

This is provided as an explanatory note for those who are not familiar with the technical terms used in connection with variety testing and release

Certification: An officially recognised quality assurance procedure involving the inspection of seed crops in the field, the sampling and testing of seed lots after harvest, and a system of identification for seed crops and lots which provides traceability through successively named generations of multiplication. Post-control plots may also be grown to check the varietal purity of certified seed lots. There are different systems for naming the generations, as shown in Annex 3, but the principles are the same.

DUS (Distinctness, Uniformity and Stability): These are the standard criteria that determine the eligibility of a variety for registration in a National List and/or for protection. The test for DUS requires a detailed examination of growing plants and the preparation of a description according to a standard list of characters. This enables the variety to be defined and, hopefully, distinguished from any other known variety, thus confirming that it is 'distinct'. Uniformity refers to the population of plants that are examined in the test; if a variety is not uniform it may be more difficult to be certain that it is distinct. Stability refers to the maintenance of its characters when multiplied from one generation to the next. DUS tests are relatively small in scale but must be well-managed so that the plants can be examined properly; they must be carried out for at least two seasons in order to test stability.

F1 hybrid: A type of variety produced by the controlled cross-pollination of two parent lines (usually inbreds); F1 hybrids are characterised by high uniformity but they are not genetically stable if the seed is sown to produce further generations. They are therefore exempted from the normal requirement for stability in a DUS test. There are also more complex hybrids involving three or four parent lines but still with the requirement for controlled crossing to provide a defined and known combination of genes. Besides their agronomic benefits, F1 hybrids also provide a biological protection if the breeder can keep control of the parent lines required to create the hybrid. Consequently, the private sector is most active in breeding crops such as maize, sunflower, sorghum where F1 seed production is relatively easy.

Maintenance: The procedure by which the breeder, or another delegated person, maintains the nucleus stock of a variety with the same genetic composition as when the variety was originally bred, tested and registered. The term 'maintenance breeding' is sometimes used but this is misleading because it may imply that breeding activities continue after the variety has been initially defined by a DUS test. This should not be done because the variety should be fixed at the time it is registered and released.

National List: The official list of named varieties that have met the requirements of the DUS and VCU tests and are therefore considered as 'released' for multiplication and marketing. Only varieties on the national list are usually eligible for certification because they have an official description linked to a name.
Open-pollinated: Refers to varieties that are maintained by natural pollination without any specific control of pollination and therefore often showing some degree of genetic variability within the population. The term 'OP varieties' is commonly used to distinguish them from F1 hybrids in which pollination is controlled to ensure uniformity.

Plant breeders right (PBR): A property right given to the breeder of a new variety and which enables a royalty to be collected for commercial use of the variety by others. Plant breeders' rights are granted on the basis of a DUS test. There is no requirement to demonstrate agronomic merit in order to grant a breeders' right so there are no VCU criteria.

Plant Variety Protection (PVP): The system by which plant breeders rights can be granted and have legal authority based on a Plant Variety Protection Law. This enables the breeder to collect a royalty on the use of the variety by farmers and the revenue from this supports the breeding programme to produce further new varieties. A system of PVP and royalty collection is essential if the private sector is to participate in breeding

non-hybrid varieties of crops like wheat, rice, barley and grain legumes.

Registration: Normally refers to the inclusion of a variety in the National List after it has satisfied the DUS and VCU criteria. In some countries registration may mean the same as release because the variety can then be marketed. However, release should also imply the systematic multiplication of variety in order to ensure its availability to farmers as certified seed.

Variety: This term refers to cultivated varieties or 'cultivars' of a species which have been deliberately bred or selected; a variety is a population of plants clearly distinguishable by one or more characters, and which retains those characters through successive generations when multiplied in an appropriate way.

Variety release: The procedure by which a new variety is made available for general cultivation after passing through an official trialling system and (usually) being entered in a National List. In a commercial context, the term may also refer to the promotion and launch of a new variety into the market.

Variety Release Committee: A technical committee of the Ministry that reviews all the information available from DUS tests and VCU trials and makes a recommendation to register and release the variety. Formal approval of this recommendation may be made by the Ministry or by the National Seed Council, if such a body exists.

VCU (Value for Cultivation and Use): the criteria used to determine if a variety has sufficient merit to justify inclusion in a National List and be marketed. The actual criteria, and thresholds for approval, may vary between countries but they normally involve replicated field trials and examination of the harvested product to assess its quality. VCU requirements may be considered as 'filter' to keep out inferior varieties. VCU requirements are not normally applied to vegetable crop varieties because of the large number of agronomic considerations and specific consumer preferences in these crops.

About ICARDA and the CGIAR

ICARDA
Science for Better Livelihoods in Dry Areas

Established in 1977, ICARDA is one of the 15 centers supported by the CGIAR. ICARDA's mission is to improve the livelihoods of the resourcepoor in dry areas through research and partnerships dedicated to achieving sustainable increases in agricultural productivity and income, while ensuring efficient and more equitable use and conservation of natural resources.

ICARDA has a global mandate for the improvement of barley, lentil and faba bean, and serves the non-tropical dry areas for the improvement of on- farm water use efficiency, rangeland and small ruminant production. In Central Asia, West Asia, South Asia, and North Africa regions, ICARDA contributes to the improvement of bread and durum wheats, kabuli chickpea, pasture and forage legumes, and associated farming systems. It also works on improved land management, diversification of production systems, and value-added crop and livestock products. Social, economic and policy research is an integral component of ICARDA's research to better target poverty and to enhance the uptake and maximize impact of research outputs.

CGIAR

CGIAR is a global agriculture research partnership dedicated to reducing rural poverty, increasing food security, improving human health and nutrition, and ensuring more sustainable management of natural resources. It is carried out by the 15 centers who are members of the CGIAR Consortium in close collaboration with hundreds of partner organizations and the private sector. www.cgiar.org