



**Report of the
First Challenge Program External Review
of the
HarvestPlus Challenge Program**

Overview Documents

1. CPER Report Summary and Recommendations
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SUMMARY

The goal of HarvestPlus CP is to reduce micronutrient malnutrition among poor populations of Africa, Asia, and Latin America, by breeding and disseminating nutrient-dense staple food crops thereby improving food and nutrition security in vulnerable populations. HarvestPlus focuses on iron, zinc, and vitamin A; these nutrients are widely recognized by the UN system, multi- and bilateral development agencies as the key micronutrients given the high prevalence of deficiency and their impact on population health and well being. The causal web for this form of malnutrition includes inadequate access to food of sufficient quality or quantity, limited access to health and inappropriate caring practices; affecting close to 2 billion people, especially women of reproductive age and preschool children. The impact of these deficiencies in terms of the burden of death and disability is staggering; with direct impact on human capital formation, restricting economic growth, human and social development.

HarvestPlus has been able to achieve a number of important milestones towards the stated goals in its first years of existence. HarvestPlus researchers have identified nutrient-rich germplasm in rice, wheat, maize, beans, sweet potato, pearl millet and potato. Nutritional Genomics and Biotechnology research complement conventional breeding efforts by identifying the genes that synthesize pro-vitamins A and that translocate Fe and Zn from the soil, to the plant and edible parts to improve the breeding efficiency and add other desirable traits providing agronomic superiority and potential enhanced economic productivity. Thus the challenge program is uniquely placed in offering an opportunity to support food base approaches in the control of micronutrient deficiencies in a sustainable manner with long term impact.

The panel's view is that the HarvestPlus program contributes in making the CGIAR Centers more effective, providing an example for innovation, illustrating the strength of multidisciplinary approaches, and serving as a model for greater interaction among CGIAR Centers and with those outside the System. The panel unanimously agreed that in their best judgment this Challenge Program is an exciting and value-added initiative with major potential impact on nutrition and health of populations especially those living under poverty in low and middle income countries. **The Panel considers that HarvestPlus is well managed, has strong governance structures and excels in terms of obtaining financial support and keeping donor's interest; concluding its review with a firm approval for continuation of its work towards the stated objectives.** However, the panel also identified areas in need for improvement and made specific recommendations which the main ones will be presented briefly.

Program Relevance, Efficacy and Effectiveness: The Panel agrees there is clearly international consensus that global collective action is required to address the problem of micronutrient malnutrition; the topic is being highlighted by a Lancet Series on Malnutrition to be published later this year. However, in light of existing data on effectiveness of micronutrient interventions and the limitations of providing sufficient micronutrient rich foods for children < 2 years of age, the Panel considers that the program will unlikely be able to have a significant impact in this most significant age group. The panel expresses concern that the CP strategy and impact pathways insufficiently recognize the multifactorial nature

of the factors that condition micronutrient deficiencies. Moreover the panel suggests that the attributable risk reduction, for death and loss of healthy life years, derived from the provision of nutritionally enhanced staple foods needs to be derived from objective data on effectiveness of the HarvestPlus intervention under real life conditions.

The Panel considers that achieving the nutritional enhancement of staple food crops is the essential and specific strategic approach for HarvestPlus. Thus it needs to further examine what are the necessary steps for crops to go from the breeding phase to actual adoption with the concomitant nutritional and agronomic enhancements that assure the economic sustainability of the new crops. The Panel recommends that the science discovery laboratories component of the project should be responsible for generating genetic maps, new markers and QTL studies to link markers with phenotypes, and thus guide the breeding process. This is essential for the program to accomplish the combined breeding of nutritional enhancement with agronomic superiority, disease resistance and equal or improved economic productivity. In the Panel's opinion this needs strengthening in order to meet the timeline for the delivery of nutritionally enhanced crops. The Panel strongly recommends that the CP focuses its next phase (2-3 yrs) in demonstrating its capacity to deliver nutritionally enhanced crops that will have measurable effects on nutritional status of vulnerable populations. Expanding to Phase II crops will not resolve the urgent need to enhance translational research, taking discovery to products that fulfill the promise of improved nutrition.

The program needs to examine how to make conventional breeding more effective through judicious use of molecular biology techniques, such as developing and applying molecular markers, both in terms of money and time; and prove that it can deliver what it has promised. The Panel recommends that the management team of the CP clearly define what realistically can be expected from the CP and examine what should not be expected from the CP in the next 2-3 years. The implementation activities should mainly take the form of "proof of principle", and in terms of overall investment should remain a small fraction of the effort. The Panel considers that establishing partnerships with NARS or equivalent national bodies at an early stage is the best way to assure a cost effective and sustainable implementation.

Partnerships

Up to now, HarvestPlus has developed mainly by directly commissioning research instead of using competitive bids. The original proposal indicated a benchmark of 25% of the funds to be awarded through competitive bidding, today only about 5% of the overall budget has been allocated competitively. **The Panel recommends that the original benchmark of 25 % of funds allocated by competitive bids be restored in order to guarantee transparency and best value for money of the research program. Furthermore, the panel suggests for large scientific research projects, an external panel with specific expertise in the field of the contracted research to periodically evaluate the progress and cost effectiveness of the work conducted.**

Governance, Management and Finance: The Challenge Program's lean governance and management arrangements have worked well in the past. Hosting by CIAT and IFPRI has kept costs at bay, while allowing for program autonomy since no center can make decisions

unilaterally. The Program Advisory Committee (PAC) is a productive and high quality governance body acting as a steering committee; the PAC independent Audit Committee serves to provide financial oversight and monitoring exemplifying principles of good governance. **The panel recommends to further clarify the role and the accountability of the PAC vis-à-vis the boards of CIAT and IFPRI, including the specification of the role of center representatives on the PAC and the recommendation that the PAC Chair be responsible for the Program Director's performance evaluation in order to prevent duality in the vertical chain of command of the Challenge Program.**

HarvestPlus is in good financial health and has exceeded its original budget targets but still needs to ensure future funding. As the uncommitted cash reserve will melt down with the end of the first program phase at year-end 2007, the Panel endorses a recent PAC decision to establish a cash reserve sufficient to guarantee program stability at the end of phase I but that acknowledges the limited lifetime of HarvestPlus.

RECOMMENDATIONS

Recommendation 1. The Panel unanimously agrees that the HarvestPlus program has worthy objectives and progress to date is significant; thus it recommends to the PAC Chair and CGIAR Director that the challenge program should continue in advancing its work towards the stated goal.

Recommendation 2. The Panel recommends that the management team of the CP clearly define what realistically can be expected from the CP and examine what should not be expected from the CP. The Panel concurs with the views expressed by the SC on the need for the CP to be explicit in defining the justification and rationale for the planned activities and recommend that the CP reexamine and more clearly define its objectives based on a realistic assessment of potential impacts. This should include defining the scope of the program at various levels of potential funding.

Recommendation 3. The Panel recommends that the implementation strategy be based mainly by establishing partnerships with NARS or equivalent national bodies at an early stage. The Panel considers that this model is the best way to assure a cost effective and sustainable implementation. The Panel considers that the CP should not primarily be concerned with implementation; the CP should stay within the proof of concept testing mode, evaluating and facilitating the actual implementation by national partners.

Recommendation 4. The Panel recommends independent evaluations of quality and cost-effectiveness of such major activities as discussed in the governance section of this report. While the Management Team should assist implementing these evaluations, the PAC should be responsible for them. A corresponding recommendation has been presented in the governance section of this report.

Recommendation 5. The Panel recommends that the program clearly define the overall objective considering this is fundamental in order to assess if the implementation strategies, fund raising efforts, resource allocations, level of scientific productivity, efficacy/effectiveness and cost effectiveness of the HarvestPlus CP are in line with the objectives. The

Panel appreciates the difficulty of trying to restrict or place boundaries in what is up to now an exciting and highly successful program. However, the Panel thinks it is best to do it now than risk the future of the CP because of vagueness and lack of focus.

Recommendation 6. The Panel recommends that the CP strengthen collaborations with others or explore tripartite arrangements (CGIAR Centers, extra CGIAR Centers and HarvestPlus CP). The Panel considers that there is clear need to strengthen the breeding program, in terms of applying the use of modern biotechnology in assisting the breeding process. The progress reports need to include key milestones indicators that serve to document the achievements necessary to further increase breeding efficiency by using the relevant biotech tools (Genetic mapping, QTL and MAS).

Recommendation 7. The Panel recommends that the science base effort necessary for efficient breeding methodology should be strengthened. This is essential to secure crops with enhanced nutritional traits that will also combine superior agronomic traits, this approach is needed to establish a clear economic advantage in growing the new crops and thus assure sustainable use of the crops developed by HarvestPlus.

Recommendation 8. The Panel recommends that further steps be explored to ascertain that the final product be eventually acceptable to the target groups, namely the farmers that are going to be growing the crops and the consumers of such nutrients-rich staples. Without their early buy-in, there is always the prospect of such products not being acceptable to the intended users.

Recommendation 9. The Panel strongly recommends that the CP consider the NARS as the end users of its product (nutritionally enhanced crops) and thus include the NARS from the early stages of development to the implementation in pilot projects with farmers.

Recommendation 10. Concerning gender and citizenship balance in the PAC, the Panel recommends that the PAC works towards a gender and origin-balanced membership. This should be pursued as a strong 2nd priority. The first priority should remain the PAC members' expertise and background.

Recommendation 11. In order to shield the institutional representatives – and in consequence HarvestPlus – from any alleged conflicts of interest, the Panel recommends to differentiate between external members and institutional representatives in the PAC terms of reference (as listed in the HarvestPlus Governance and Management Handbook), and to specify their respective roles and responsibilities. Institutional representatives should be full PAC members in all respects, but should not have formal voting rights.

Recommendation 12. The Panel recommends implementing the PAC membership rotation as defined in the HarvestPlus Governance and Management Handbook. In selecting new PAC members, the representation of HarvestPlus beneficiary groups should be increased.

Recommendation 13. The Panel recommends that the PAC agrees and formulates an explicit voting policy that specifies the meeting quorum, necessary majorities for different types of decisions, potential tie breaking processes and requirements for voting through

representatives or delegated votes. The independent nature of the PAC as an external expert Panel should be strengthened without damaging the present achievements in terms of process and working relationships with the host centers. While remaining active PAC participants, the overall role and the "ex-officio" status of the four institutional representatives of CIAT and IFPRI should be clarified and they should not have formal voting power in the PAC.

Recommendation 14. The Panel recommends that the PAC commission and oversee external assessments of output, relevance and cost-effectiveness for major HarvestPlus activities contracted to major HarvestPlus partners. The periodicity of this outside evaluations should be yearly or more frequent depending on specific situations.

Recommendation 15. The Panel therefore agrees with the PAC's assessment and recommends tasking the Audit Committee to oversee that full compatibility of the HarvestPlus competitive mechanisms with CGIAR guidelines is verified or, if needed, established.

Recommendation 16. The Panel therefore recommends that the ultimate responsibility for the performance evaluation of the Program Director should be with the PAC chair. The performance assessment should be based on intense consultation with the Director Generals of CIAT and IFPRI, and other relevant observers. The Panel recommends that the PAC chair in consultation with the IFPRI and CIAT Director Generals conducts the performance evaluation of the Program Director and determines the terms of his employment.

List of suggestions

The Panel suggests that the attributable risk reduction, for death and loss of healthy life years, resulting from the provision of nutritionally enhanced staple foods needs to be derived from objective data on effectiveness of the HarvestPlus intervention under real life conditions.

The Panel suggests the model for the impact evaluation of the HarvestPlus program be based on empirical data from cluster randomized controlled trials in multiple sites to include the context specific components and thus strengthen the potential to have a true effectiveness measured under diverse conditions.

The Panel suggests that HarvestPlus take into consideration all factors that would come into play in its transgenic work, which includes the costs involved in embarking on such an undertaking. This reinforces the case for collaboration with centers of excellence in the developed and the developing world that are undertaking this type of work.

The Panel suggests that HarvestPlus incorporate the above principles in a Plan for Transgenic Outputs which include a detailed description of its strategies, rationale for transgenics use and a plan of work. This document should be shared with and preferably endorsed at the earliest possible time by existing and potential partners, taking into account local regulatory and biosafety guidelines.

The Panel suggests that the CGIAR Alliance establish the appropriate mechanisms to support synergy and complementarity of the CGIAR food based approaches to improve micronutrient nutritional status (HarvestPlus and bioversity) and generate the organizational structure to support these worthy objectives.

The Panel suggests that the reporting to donors be programed in a manner that is less disruptive of the work of the team leaders, ideally the donors should evolve into becoming development partners so that they fund components of the HarvestPlus CP that are in accordance with their planned investments in a sustainable manner. Having a set of pre scheduled meetings with developmental partners/donors (once or twice a year) with discussions that incorporate feedback from them may be in the long run beneficial in enhancing support and securing sustainable partnership.

The Panel suggests that the HarvestPlus program strengthen partnerships with research scientists conducting genomic research on the Phase I crops. This is needed to obtain the mapping of nutritional and agronomic desirable traits. The mapping of QTLs and or specific genes linked to these traits and the respective molecular markers should further increase the chances of success and the efficiency of the breeding effort.

The Panel suggests that the present target of 25 % of total funding should be respected and possibly expanded in areas where scientific breakthroughs that have potential bearing on the program objectives are foreseen.

The Panel suggests, subject to the availability of funds, that HarvestPlus develop a comprehensive capacity-building program based on the functional areas and impact pathway of the CP. The capacity strengthening activities need to be appropriately funded, planned and implemented in support of the HarvestPlus objectives.

For a better understanding of improvement potential in terms of these issues, a detailed analysis of perceptions and experiences of HarvestPlus program partners and stakeholders would be needed, e.g. through a survey with follow-up interviews targeted at these overlapping groups. Such a thorough assessment, however, exceeded the allocated capacity for this Review and has therefore not been undertaken. The Panel nevertheless suggests conducting such an assessment to further analyze improvement potential for these functions. Any statements made regarding these points in the report are based on the Panel's observations within HarvestPlus and selected stakeholder and program partner interviews.

The Panel suggests that the CIAT and IFPRI board further clarify the specific governance functions and level of authority delegated to the PAC in a document that is endorsed by PAC, the board of CIAT and the board of IFPRI. Legal and financial assessment of related risks should be examined for each governance function.

HarvestPlus Challenge Program Response

The HarvestPlus Program Management Team (PMT) thanks the Review Panel for their comprehensive analysis, based on the considerable time and effort that went into understanding how HarvestPlus organizes its activities and into writing the External Review. We are appreciative of their many complimentary remarks on progress made to date. Nevertheless, there are areas where improvements in science, implementation, and governance can be made.

It is important to indicate here that the responses to the recommendations below are those of the PMT, i.e. this is a response of the HarvestPlus management. The timing of the submission of the External Review and the schedule of bi-annual meetings of the HarvestPlus Project Advisory Committee (PAC) did not permit an official response from the PAC. The PAC will meet next on October 29-30, 2007, at which time the report, the management response, and the recommendations will be thoroughly discussed. The Boards of CIAT and IFPRI also will review the report and, in particular, the governance-related recommendations at their next meetings.

Below we state where we concur with the Panel's recommendations and, as appropriate, how we feel we can address those recommendations and suggestions within the program. In some cases, we did not fully concur with issues raised. We provide discussion and explanation which are intended to provide further insight for the Review Panel, the Science Council, and the PAC on the activities of HarvestPlus and justification for them.

The Panel's sixteen recommendations can be divided into four broad areas (the discussion of breeding strategy and dissemination strategy are closely interconnected in the External Review):

1. Project Objectives and Justification – Recommendations 1, 2, 5
2. Breeding Strategy – Recommendations 6, 7
3. Dissemination Strategy – Recommendations 3, 8, 9
4. Governance – Recommendations 4, 10, 11, 12, 13, 14, 15, 16

We chose to organize our responses according to the above four groupings.

RECOMMENDATIONS

1. Project Objectives and Justification

Recommendation 1. The Panel unanimously agrees that the HarvestPlus program has worthy objectives and progress to date is significant; thus it recommends to the PAC Chair and CGIAR Director that the challenge program should continue in advancing its work towards the stated goal.

HarvestPlus appreciates these comments from the panel and also feels that progress to date under the CP has been significant and positive, thus justifying continued advancement in developing this strategy for reducing micronutrient malnutrition.

Recommendation 2. The Panel recommends that the management team of the CP clearly define what realistically can be expected from the CP and examine what should not be expected from the CP. The Panel concurs with the views expressed by the SC on the need for the CP to be explicit in defining the justification and rationale for the planned activities and recommend that the CP reexamine and more clearly define its objectives based on a realistic assessment of potential impacts. This should include defining the scope of the program at various levels of potential funding.

Recommendation 5. The Panel recommends that the program clearly define the overall objective considering this is fundamental in order to assess if the implementation strategies, fund raising efforts,

resource allocations, level of scientific productivity, efficacy/ effectiveness and cost effectiveness of the HarvestPlus CP are in line with the objectives. The Panel appreciates the difficulty of trying to restrict or place boundaries in what is up to now an exciting and highly successful program. However, the Panel thinks it is best to do it now than risk the future of the CP because of vagueness and lack of focus.

Recommendations 2 and 5 can best be addressed simultaneously. We accept the recommendation of the Panel to be more explicit about the objectives of the HarvestPlus CP.

Objectives, Activities, Justification

In Chapter 2, the Review Panel describes very well the intended **objective** of HarvestPlus in reaching the general population:

‘We consider the CP will have the greatest long term impact in the general population by contributing in securing adequate critical micronutrient intakes, if we are able to improve the micronutrient content of the food supply we will have sustained long term impact.’

2.4 External Review Report

The primary **activities** of HarvestPlus are to:

- i) breed micronutrient biofortified staple food crops which (i) are high in nutrient content (as eaten) to the extent feasible and (ii) are high yielding/profitable when grown in target regions -- in collaboration with National Agricultural Research institutions (NARS)
- ii) test the feasibility of these biofortified crops to provide adequate levels of increased micronutrient contents, through food science and human nutrition studies
- iii) measure the efficacy of biofortified staple foods to improve micronutrient status, thus providing the justification for a larger scale dissemination activities
- iv) demonstrate the ability to successfully disseminate biofortified crops (in 2-3 target countries for each biofortified crop) with reasonable rates of adoption by farmers and consumption by key target groups (in particular, women and children); this entails conducting research to identify successful implementation strategies; rates of adoption should generate public health benefits which significantly exceed costs incurred under (i) through (iv)
- v) advise other countries on successful ways to disseminate and promote biofortified crops, and thus to achieve effectiveness in reducing micronutrient malnutrition
- vi) assist with some level of capacity building (as funds permit) in key countries, and development of enabling technologies, which ultimately contributes to the likelihood of sustainability of a biofortification program

We believe that the overall **objective** of HarvestPlus, to contribute to improved health by reducing micronutrient deficiency prevalence rates in selected target countries, is achievable and its potential will be fully demonstrated when the above **activities** are accomplished. Biofortification’s complementary niche with respect to fortification, supplementation, and nutrition education is that it will be particularly effective in reaching rural populations, who typically do not rely on centrally-processed, purchased foods and who may not be reached by supplementation programs.

Target countries by crop under (iv) and target populations within those target countries will be further refined under an assessment process (to be completed by December, 2007) in which HarvestPlus is currently participating, funded by the Gates Foundation in preparation for a new four-year proposal (2009-2012). The extent to which prevalences of micronutrient deficiencies can be reduced by biofortification among various age and gender groups is still speculative, but some evidence on which to base these estimates is emerging from HarvestPlus nutrition research. Potential for benefit has already been demonstrated through an efficacy study showing the impact of iron-rich rice on the iron stores of iron deficient Filipino women, and the effect of provitamin A rich sweet potato on vitamin A status of children has been demonstrated in both efficacy studies and an effectiveness study.

With respect to **justification**, HarvestPlus has made a major investment in developing and applying a methodology for *ex ante* benefit-cost analysis of biofortification. Using conservative assumptions which we believe generate significant **underestimates** of potential benefits, the analysis shows that biofortification is highly cost-effective relative to fortification and supplementation. Because of the inherent uncertainty of *ex-ante* impact assessment, the analysis uses a range of assumptions to assess impact (not just on area coverage, but other key parameters including enhanced micronutrient content, and retention in processing and cooking), so that the robustness of the results to alternative assumptions can be checked. The methodology and its application for selected case studies have been published in peer reviewed journals.

We believe that these objectives, activities, and justification are implicit within, and reflected by, the activities and results produced by the HarvestPlus CP, as documented in proposals, annual donor reports, and the Medium Term Plan. Nonetheless, we recognize that these have not been explicitly stated as such.

Specific Target Populations and Expected Extent of Impact

In one section of the review report (2.1.2) the Review Panel perhaps misunderstood the goal of HarvestPlus to include **eradication** of micronutrient malnutrition:

‘2.1.2 However, the panel considers that the eradication of micronutrient malnutrition as a goal is beyond the CP’s mission, the boundary should remain in improving access to micronutrient rich foods that have a measurable effect on nutritional status.’

This has never been a stated goal of HarvestPlus and we are uncertain why it was considered by the Panel. Complete eradication of micronutrient deficiencies is not at all implied by the *ex ante* benefit estimates made for biofortification. As stated above, conservative assumptions as to potential benefits have been used.

The Review Panel expresses concern about other underlying expectations of the HarvestPlus CP that may not be met. One is the potential impact on the most vulnerable age group, those < 2 years of age. A second is that the causes of morbidity and mortality are multifactorial in nature and solving micronutrient deficiencies alone will not be sufficient to reduce morbidity and mortality. As a result, they believe the estimated impact of biofortification has been overestimated:

“We consider that the program will not be able to impact significantly [on] micronutrient deficits in the group < 2 years of age; and that the potential biological impact of vit A, iron and zinc enhanced food has been overestimated. Our view is in line with the SC expression of concern that the CP strategy and impact pathways fail to identify the multifactorial nature of the factors that condition the consequences of micronutrient deficiencies.” 1.2.1 External Review Report

Under Two’s

Can biofortification have an impact?

We agree with the general consensus in the nutrition community that the < 2 years age group is a critical period which accounts for a high proportion of the Disability Adjusted Life Years (DALYS – a commonly used metric of the burden of morbidity and mortality) lost due to micronutrient malnutrition. We agree that interventions other than biofortification will be needed to substantially reduce micronutrient malnutrition among this group, especially the < 1 year olds because of their low food staple consumption. Many in the nutrition community are focused on under two’s and the potential for impact of biofortification in having a major impact on this age group is perceived as being relatively small.

However, we feel that biofortification can have **some** impact on this group through direct consumption of biofortified staples, especially for the 1 year olds. Although no such benefits are assumed in the benefit-cost calculations, it is also possible that the < 2 years age group could be helped through better micronutrient status of their mothers (during pregnancy and lactation), after an extended period of consuming biofortified staples (e.g. iron stores in young women increased in the efficacy trial involving high iron rice conducted in the Philippines).

There is a need for research in this area to quantify the effects of biofortification. Some evidence is already available from a published effectiveness study involving orange-flesh sweetpotato (OFSP) (Jan Low et al, Journal of Nutrition, 2007). Children 1 year of age reported 80 grams of consumption of OFSP and the prevalence of vitamin A deficiency was reduced.

Has ex ante impact on under two 's been overestimated?

To the extent that intakes vary by age group, so does the impact of a biofortified food; that is, the larger the intake of a food vehicle the larger the impact. The *ex ante* impact analyses do take account of age disaggregation, and the corresponding age-specific food intakes. For example for zinc, the age categories are children 6 months to 1 year, children 1 to 3, and children 4 to 5 years.

Obtaining information on intakes of food at this level of disaggregation for a large number of countries is difficult, and information on current intakes of micronutrients from all food sources is scarcer still. While assumptions were involved, these data were always checked by in-country nutritionists for their reasonableness, and sensitivity analysis was undertaken as to level of consumption of the biofortified food. The sensitivity analyses suggest that even with very low levels of staple food consumption by very young children, biofortification continues to have the potential for impact.

Multi-factorial nature of the factors that condition the consequences of micronutrient deficiencies

Should HarvestPlus simultaneously address such issues during dissemination?

HarvestPlus agrees that programs that, for example, improve breastfeeding and child feeding practices, prevent infectious diseases, improve sanitation, or reduce parasitic infections – all would have an interactive effect with increasing vitamin and mineral intakes and are all necessary for the eventual **near eradication** of micronutrient malnutrition.

In any given country, it is hoped that public health officials, working with NGOs and other partner institutions, will implement (and to the extent possible coordinate) national or appropriately targeted programs in all these areas. Biofortification is one tool that may be included in such a comprehensive health and nutrition program. HarvestPlus believes that, in any given context, biofortification can contribute to improved micronutrient status of the population in a cost-effective way (as outlined above under steps (i) through (vi) above) **without the need for simultaneous introduction/expansion of such types of public health programs (i.e., the benefits observed should not be conditional on the presence of all other public health interventions).** Fortification, supplementation, and dietary diversity programs currently operate under this same presumption.

Nevertheless, HarvestPlus will look for cost-effective, opportunistic ways to coordinate with such public health programs. For example, in the case of OFSP (where pro-vitamin A carotenoids are visible to consumers) it is necessary to create demand for OFSP through nutrition education which are targeted at mothers of young children. Additional messages may be combined with messages surrounding the consequences of and ways to overcome vitamin A deficiency.

Should HarvestPlus undertake research to quantify the interactions between biofortification and other public health interventions?

While we agree that addressing all of the many causes of death and disability is the ultimate goal of development, the purpose of HarvestPlus is to develop and test the tools of one specific intervention. Therefore, HarvestPlus does not believe that it should bear responsibility to define and measure the benefits of comprehensive packages of interventions, encompassing micronutrients, prevention of infectious disease, safe and adequate water supplies, and so on. Research on the combination of these interventions would best be designed and tested in the context of national health and welfare programs.

Again, it may be possible to be cost-effective and opportunistic in investigating the magnitude of these interactions in the design of particular studies. Additionally, the HarvestPlus nutrition research program has already begun to include, and will continue to include, considerations of other health conditions that may modulate the impact of biofortified staple foods on nutrient absorption and status (e.g., infection status of individuals, and markers of intestinal health and permeability).

Specifically, we believe that HarvestPlus **should not** be expected to:

- i) quantify the contribution of other causes of morbidity and mortality in addition to micronutrient malnutrition
- ii) demonstrate the effectiveness of biofortification only if other public health strategies are also implemented; the latter may not be feasible to implement on a sustainable basis and could therefore result in unrealistic benefits.
- iii) demonstrate the long term effectiveness of biofortification programs to reduce national rates of infectious disease or mortality once implemented on a national scale.

It is noteworthy that attributable risk due to micronutrient deficiencies and the impact of interventions such as fortification have been derived using empirical data largely from controlled **efficacy** trials of **single** micronutrient interventions. Thus far these have not relied on effectiveness studies, nor have they included multiple public health interventions such as improved breastfeeding, and prevention of infectious diseases. True effectiveness studies of micronutrient interventions are as yet uncommon, yet micronutrient interventions such as supplementation and fortification are still considered to be cost-effective interventions to reduce morbidity and mortality in at risk populations (1.1.1, and Annex 7 of the External Review report).

Has the ex ante impact been overestimated due to these interacting factors?

To repeat, HarvestPlus agrees that micronutrient malnutrition has multiple cause and have therefore taken care to be conservative in quantifying the DALY burden of malnutrition (which we consider to be **underestimates**) that can be attributed to insufficient intakes of iron, zinc, and pro-vitamin A.

For example, recognizing that anemia has multiple causes, only one-half of the prevalence of **moderate and severe** anemia is assumed to be attributed to insufficient iron intakes (and it is only these populations, therefore, who are amenable to improved iron status through a food-based intervention). That is, zero benefit to increased iron intakes from biofortified crops is attributed to anyone (i) who is iron deficient but not anemic, nor to anyone (ii) who suffers from **mild** anemia. A similar approach has been taken with pro-vitamin A and zinc as outlined in HarvestPlus Technical Monograph #4.

2. Breeding Strategy

Recommendation 6. The Panel recommends that the CP strengthen collaborations with others or explore tripartite arrangements (CGIAR Centers, extra CGIAR Centers and HarvestPlus CP). The Panel considers that there is clear need to strengthen the breeding program, in terms of applying the use of modern biotechnology in assisting the breeding process. The progress reports need to include key milestones indicators that serve to document the achievements necessary to further increase breeding efficiency by using the relevant biotech tools (Genetic mapping, QTL and MAS).

Recommendation 7. The Panel recommends that the science base effort necessary for efficient breeding methodology should be strengthened. This is essential to secure crops with enhanced nutritional traits that will also combine superior agronomic traits, this approach is needed to establish a clear economic advantage in growing the new crops and thus assure sustainable use of the crops developed by HarvestPlus.

Recommendations 6 and 7 can best be addressed simultaneously. We concur with these recommendations of the Panel. Several of the points raised already are part of the HarvestPlus agenda.

HarvestPlus is endeavoring to develop and integrate molecular tools into the breeding process. Activities include (i) simulation/modeling of marker assisted selection (MAS) and assessment of cost/benefit of molecular marker development, and (ii) implementation of (MAS) for selected HarvestPlus crops.

Simulation/modeling of marker assisted selection

HarvestPlus initiated a project in 2005 with a leading group in this area of research at the Chinese Academy of Agricultural Sciences (CAAS), Beijing, in collaboration with the Generation Challenge Program (GCP). The objective was to discover and define novel and optimal MAS strategies, and to evaluate their cost/benefit compared to conventional and combined conventional/MAS strategies. Simulations consider realistic assumptions regarding, for example the number of genes, variation explained by QTLs, population size, timing of MAS in the breeding process. Recovery of superior adapted genotypes is also considered.

Assessment of cost/benefit of molecular marker development

Related HarvestPlus research is then addressing cost assessment in germplasm product development, a major knowledge gap in public sector breeding efforts. HarvestPlus teamed with John Brennan, a leading expert in this field, to develop a program for Cost Assessment of Research and Plant Breeding Options (CARBO H+), building on a previously developed program applied for wheat at CIMMYT. The program is expected to cover all crops, breeding stages, and conventional and marker assisted selection. Prototype versions for wheat, rice, maize, bean and cassava are already available.

CARBO H+ in combination with simulation allows consideration of all primary factors related to breeding efficiency (not only nutrient content) and development of strategies based on their contribution to genetic progress and benefit/cost. MAS must take into account **all** breeding goals (high yield, pest resistance, etc) in defining crop biofortification strategies which maximize genetic gains and breeding effectiveness -- which combine **all** the attributes which are critical for adoption by farmers such as agronomic performance and by consumers such as sensory traits. For most, if not all the range of traits relevant for farmer adoption, molecular markers are not yet available at CGIAR Centers and may not be available in the near future.

Consequently, effectiveness in product and impact oriented crop biofortification is also driven by genetic knowledge gains for these traits and strategies to reduce time to market such as rapid generation advancement techniques, high-throughput screening techniques/diagnostics, generating micronutrient environments, computer-assisted design of crosses, and spatial experimental designs. For example, NIR high-throughput diagnostics allows, at low cost, estimation of micronutrient levels in crops and a wide range of other traits and compounds (among these compounds associated with bioavailability) and permit using selection indices and taking into account correlations among these compounds in selection. The NIR technology for micronutrient pre-screening has been further developed under HarvestPlus, and implemented for several crops at CIP, CIAT and CIMMYT. Plans are in place to expand the use of the NIR technology to all HarvestPlus crops, and participating CGIAR Centers and NARS partners.

Defined milestones are on target to be met in 2008 and will be highlighted in future reports. A publication on CARBO H+ is planned for Crop Science.

Collaborative Arrangements For MAS

Several teams are currently collaborating on MAS for specific crops with the CGIAR Centers responsible for these crops. In some cases, output from the collaborative research eventually can also be directed to development of transgenics:

Wheat - MAS

Ismail Cakmak, Sabanci University, Turkey
Preben Bach Holm, University of Aarhus, Denmark
Hugh Wallwork, University of Adelaide, Australia

Maize - MAS

Torbert Rocheford, University of Illinois, USA

Rice - Gene Discovery for MAS and/or Transgenics

Janette Palma Fett, University Federal do Rio Grande do Sul, Brazil
Naoko Nishizawa, University of Tokyo, Japan
Alex Johnson, University of Adelaide, Australia

More upstream and cross-cutting genomics research by Peter Beyer (provitamin A carotenoids), Michael Grusak (iron and zinc), and Dean Dellapenna (provitamin A carotenoids) contributes to MAS for several crops. Such collaborative arrangements can be strengthened in the future as required, for example for cassava.

Implementation of MAS for HarvestPlus crops

During the first three years of HarvestPlus, the crop breeding teams focused on identifying the appropriate micronutrient trait(s) sources and donors, developing the needed mapping populations for the target traits and the phenotypic characterization. Existing mapping populations were also screened regarding their suitability to develop molecular markers for micronutrients to accelerate the trait discovery.

Depending on the crop, 1-2 years were needed to validate results from screening and to finalize the list of superior donor parents; a two-year time frame was needed for the development of the recombinant inbred lines for mapping. At the end of 2006 the HarvestPlus teams had developed mapping populations for beans, rice, maize and cassava. In the case of wheat, due to lack of genotypic variation in populations initially developed, and the wild species donor source, the populations for zinc will be available only in 2007.

With these preparatory activities in place, implementation of MAS activities will take place during HarvestPlus II (2008-2012).

In the current strategy, molecular marker development, routine MAS, and marker assisted back-crossing are intrinsic parts of the breeding strategy (a crucial enabling technology). Due to the integration of HarvestPlus crop teams with breeding and MAS at the CGIAR centers, the program is able to leverage complementary activities. Therefore, the present strategy reinforces the mechanisms necessary for a closer interaction between biotechnologists and breeders.

Key milestones describing the above activities have been defined, met, and summarized in reports. Publications are being prepared. In future reports, more detailed milestones and accomplishments towards these milestones will be highlighted and communicated.

The Need For Superior Agronomic Traits

Central to HarvestPlus strategy is the incorporation of micronutrient density into adapted, superior agronomic backgrounds with added-values from higher productivity, better tolerance to abiotic and biotic stresses, better end-use quality characteristics and production economics, and combinations of those. For example, biofortified elite bean lines combine high iron with drought tolerance in commercially accepted market classes. This has resulted in the selection of more than sixty lines by farmers in Kenya, DR Congo, Rwanda, Burundi, Malawi, Madagascar, Uganda and Tanzania and the promotion of lines developed as part of the HarvestPlus program to National Performance Trials in Kenya and National Variety Trials in Ethiopia.

HarvestPlus research thus far indicates that micronutrient density and yield can be combined. Micronutrient-dense breeding products developed under HarvestPlus outperformed or were competitive with commercial checks for maize (Nigeria), cassava (DR Congo, Brazil), bean (several African countries) and orange-fleshed sweetpotato (Uganda); further evidence exists for rice (the Philippines), soft wheat (China), Lentil (Syria, Ethiopia, Bangladesh) and pearl millet (India).

3. Dissemination Strategy

Recommendation 9. The Panel strongly recommends that the CP consider the NARS as the end users of its product (nutritionally enhanced crops) and thus include the NARS from the early stages of development to the implementation in pilot projects with farmers.

Recommendation 3. The Panel recommends that the implementation strategy be based mainly by establishing partnerships with NARS or equivalent national bodies at an early stage. The Panel considers that this model is the best way to assure a cost effective and sustainable implementation. The Panel considers that the CP should not primarily be concerned with implementation; the CP should stay within the proof of concept testing mode, evaluating and facilitating the actual implementation by national partners.

Recommendation 8. The Panel recommends that further steps be explored to ascertain that the final product be eventually acceptable to the target groups, namely the farmers that are going to be growing the crops and the consumers of such nutrients-rich staples. Without their early buy-in, there is always the prospect of such products not being acceptable to the intended users.

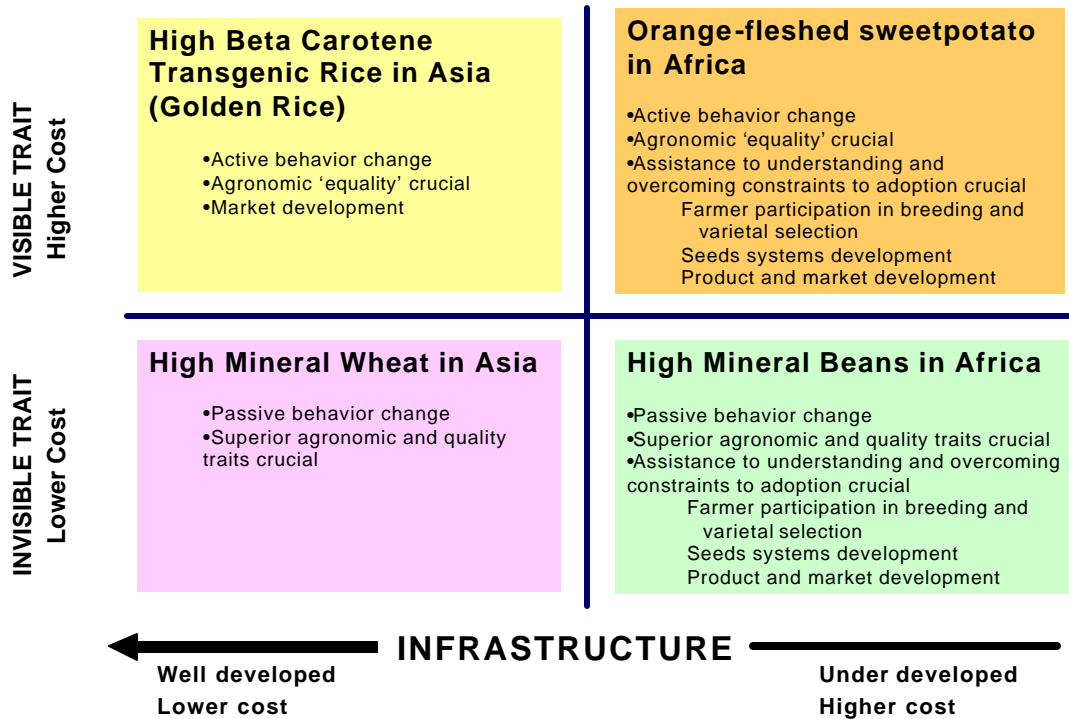
Recommendations 9, 3, and 8 can best be addressed simultaneously. We accept all of the points in these three recommendations, with the possible exception of the last sentence of recommendation 3 as discussed below.

The “Reaching End Users Conceptual Framework

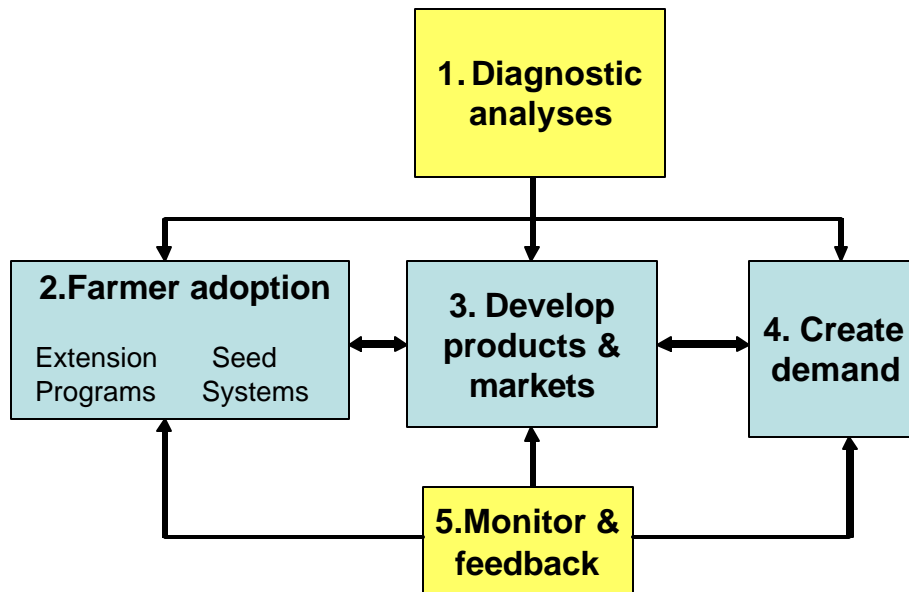
In broad terms, three things must happen for biofortification to be successful. First, the breeding must be successful as defined in step (i) above under **1. Project Objectives and Justification**. Second, the retention, bioavailability, and efficacy studies as defined under steps (ii) and (iii) above must be successful, and third the biofortified crops must be adopted by farmers and consumed by those suffering from micronutrient malnutrition. In HarvestPlus, this third step is addressed under the rubric of “Reaching End Users,” or REU.

HarvestPlus has developed four REU typologies, as outlined in the diagram below. REU will be more difficult and expensive depending on (i) whether or not the nutrient trait is invisible or visible and can piggyback on a superior agronomic trait and (ii) the extent to which institutions and markets are strong and conducive to the rapid spread of new crop technologies.

REU Typologies



REU Framework for Visible Nutrients



In the case of visible nutrients (that is, where provitamin A carotenoids change the color from white to orange), it is recognized that some type of nutrition education program (in conjunction with high profit, good agronomic qualities) will have to drive adoption (“demand creation” in the diagram above). The above framework is being applied to the dissemination of OFSP in Uganda and Mozambique. The cost-effectiveness of alternative means to provide information on the consequences of and ways to overcome vitamin A deficiencies are being assessed. Lessons learned/best practices will be derived from a comparison of these two contrasting case studies.

With this as background, we very much concur that all steps be explored “to ascertain that the final product be eventually acceptable to the target groups, namely the farmers that are going to be growing the crops and the consumers of such nutrients-rich staples.”

Participation of NARS

We recognize that a particularly vital element of any REU strategy is that the biofortified varieties are just as high-yielding and profitable as the best lines otherwise available to farmers. Therefore, they must be well-adapted to local growing conditions. In this regard, we agree that it is important to work with NARS as collaborating partners and as key entry points for delivery of the biofortified crops.

However, in each country it must be a coalition of implementing agencies in agriculture *and health* and their “enablers” (those who at higher levels administer those who implement) who must work together to make the third step happen of adoption by farmers and intake by malnourished consumers.

NARS have been included in early stages development in projects with farmers since HarvestPlus commenced. Deployment and implementation strategies are an integral part of product concepts.

On the following page is a list of collaborating NARS who have received HarvestPlus funding and who have attended HarvestPlus crop meetings:

Degree of Participation of HarvestPlus in Dissemination

A key question raised in recommendation 3 is the extent to which HarvestPlus should get involved directly in the REU process. The second part of recommendation 3 implies that HarvestPlus should focus on breeding and nutrition studies, and be marginally involved in REU. We think we have some disagreement here with the Review Panel.

First, it must be emphasized that collaborating partners (CGIAR Centers, NARS, and a number of other institutions) do *all* the work of development and dissemination of biofortified varieties -- activities which the relatively small HarvestPlus staff endeavors to coordinate through contracts which are funded by a consortium of donors and which are issued to partner institutions. This cuts across the three broad steps described above of breeding, establishing efficacy, and dissemination.

For each biofortified crop, HarvestPlus believes that it is important to demonstrate feasibility and success in 2-3 target countries. We believe HarvestPlus should assist in coordinating, identifying and relieving bottlenecks, and learning lessons from dissemination efforts. Importantly, this involves taking leadership in raising the funds (only a part of which may be channeled through HarvestPlus to collaborators) so that national-scale REU activities can be realized in selected target countries.

| Type of Collaboration | Phase 1 Crops | | | | | |
|--|---------------|--------------|------------|--------------|------------|--------------|
| | Rice | Maize | Wheat | Sweet-potato | Beans | Cassava |
| Received HarvestPlus Funding for Breeding (Attended HarvestPlus Crop Meetings) | | | | | | |
| | Bangladesh | Ghana | India | Mozambique | Kenya | Ghana |
| | Indonesia | Guatemala | Pakistan | Uganda | DR Congo | DR Congo |
| | Philippines | Zambia | Kazakhstan | Kenya | Burundi | Togo |
| | Vietnam | Ethiopia | Turkey | China | Malawi | Guinea |
| | China | Brazil | China | | Uganda | Brazil |
| | | China | | | Tanzania | |
| | | | | | Brazil | |
| Funded for Germplasm Evaluation/Receive Germplasm and/or Attend HarvestPlus Crop Meetings | | | | | | |
| | India | Angola | Uzbekistan | Tanzania | Rwanda | Benin |
| | Nepal | Nigeria | Kyrgyzstan | Ghana | Madagascar | Sierra Leone |
| | Thailand | Kenya | Tajikistan | Ethiopia | Angola | Nigeria |
| | | Malawi | Azerbaijan | Rwanda | Lesotho | Colombia |
| | | Mozambique | Georgia | Nigeria | Cameroon | |
| | | Zimbabwe | | South Africa | | |
| | | Mexico | | India | | |
| | | South Africa | | Indonesia | | |
| | | Cameroon | | Zambia | | |
| | | India | | Madagascar | | |
| | | Nigeria | | | | |
| Co-Funding from National Sources | | | | | | |
| | India | India | India | | | |
| | | Brazil | Brazil | Brazil | Brazil | Brazil |
| | China | China | China | China | | |

4. Governance

Recommendation 10. Concerning gender and citizenship balance in the PAC, the Panel recommends that the PAC works towards a gender and origin-balanced membership. This should be pursued as a strong 2nd priority. The first priority should remain the PAC members' expertise and background.

Agreed.

Recommendation 11. In order to shield the institutional representatives – and in consequence HarvestPlus – from any alleged conflicts of interest, the Panel recommends to differentiate between external members and institutional representatives in the PAC terms of reference (as listed in the HarvestPlus Governance and Management Handbook), and to specify their respective roles and responsibilities. Institutional representatives should be full PAC members in all respects, but should not have formal voting rights.

The institutional representatives are the Directors-General and one Board member each from the CIAT and IFPRI Boards of Trustees. CIAT and IFPRI have been entrusted with the legal responsibility for managing HarvestPlus' financial resources and activities to attain project objectives. It would in our view be inappropriate to dilute their responsibilities by excluding them from key decisions of the program.

Recommendation 12. The Panel recommends implementing the PAC membership rotation as defined in the HarvestPlus Governance and Management Handbook. In selecting new PAC members, the representation of HarvestPlus beneficiary groups should be increased.

Agreed.

Recommendation 13. The Panel recommends that the PAC agrees and formulates an explicit voting policy that specifies the meeting quorum, necessary majorities for different types of decisions, potential tie breaking processes and requirements for voting through representatives or delegated votes. The independent nature of the PAC as an external expert Panel should be strengthened without damaging the present achievements in terms of process and working relationships with the host centers. While remaining active PAC participants, the overall role and the "ex-officio" status of the four institutional representatives of CIAT and IFPRI should be clarified and they should not have formal voting power in the PAC.

Agree to first two sentences. Third sentence repeats Recommendation 11 which is addressed above.

Recommendation 4. The Panel recommends independent evaluations of quality and cost effectiveness of such major activities as discussed in the governance section of this report. While the Management Team should assist implementing these evaluations, the PAC should be responsible for them. A corresponding recommendation has been presented in the governance section of this report.

Recommendation 14. The Panel recommends that the PAC commission and oversee external assessments of output, relevance and cost-effectiveness for major HarvestPlus activities contracted to major HarvestPlus partners. The periodicity of this outside evaluations should be yearly or more frequent depending on specific situations.

Recommendations 4 and 14 are similar. We agree with the concept of ongoing evaluations for contracted research work. Indeed this is why contracts with collaborating institutions are written on a calendar year basis. Funding tranches are released based on contracted deliverables every six months. The PMT reviews the results and determines whether the next tranche of funding should be released and, at the end of the calendar year, reviews a proposed workplan and budget for the following calendar year. The PAC is informed on the overall progress of contracts at its meetings. The audited financial statements of HarvestPlus clearly indicate what amounts are being disbursed under each contract. Through these mechanisms, PAC and its audit committee satisfy themselves of

the quality of the research being undertaken. If the PAC were unsatisfied with progress, it could commission a quality assurance review. Lead researchers from collaborating institutions have attended and presented at PAC meetings.

Recommendation 15. The Panel therefore agrees with the PAC's assessment and recommends tasking the Audit Committee to oversee that full compatibility of the HarvestPlus competitive mechanisms with CGIAR guidelines is verified or, if needed, established.

Agreed.

Recommendation 16. The Panel therefore recommends that the ultimate responsibility for the performance evaluation of the Program Director should be with the PAC chair. The performance assessment should be based on intense consultation with the Director Generals of CIAT and IFPRI, and other relevant observers. The Panel recommends that the PAC chair in consultation with the IFPRI and CIAT Director Generals conducts the performance evaluation of the Program Director and determines the terms of his employment.

Agreed. In practice this how the process currently operates. We will ensure that the process is more clearly documented.

HarvestPlus Response Addendum

Mr. P. McPherson, Chairperson PAC, sent the following additional comments

The External Review and the management response to the recommendations were shared with the full HarvestPlus Project Advisory Committee (PAC) shortly before the Science Council meeting. These documents will be discussed fully at the next PAC meeting on October 29-30. I am in concurrence with the management response, as I think are most of the PAC members who have now been given a chance to provide comments informally, although on short notice. There are further comments which I would like to make on Recommendations 11 and 12.

Recommendation 11. In order to shield the institutional representatives – and in consequence HarvestPlus – from any alleged conflicts of interest, the Panel recommends to differentiate between external members and institutional representatives in the PAC terms of reference (as listed in the HarvestPlus Governance and Management Handbook), and to specify their respective roles and responsibilities. Institutional representatives should be full PAC members in all respects, but should not have formal voting rights.

Management Response:

The institutional representatives are the Directors-General and one Board member each from the CIAT and IFPRI Boards of Trustees. CIAT and IFPRI have been entrusted with the legal responsibility for managing HarvestPlus' financial resources and activities to attain project objectives. It would in our view be inappropriate to dilute their responsibilities by excluding them from key decisions of the program.

My comments:

In my view, the balance on the one hand of empowering the PAC to take strategic, management, and budget decisions, and on the other hand of ensuring that CIAT's and IFPRI's (who have legal responsibility and liability for HarvestPlus) perspectives are taken into account, has worked very well. I would not want to upset this balance.

The PAC has recognized the potential conflict of interest with respect to CIAT and IFPRI receiving funding annually for managing HarvestPlus and for undertaking research. The PAC will continue to monitor these expenditures closely.

Recommendation 12. The Panel recommends implementing the PAC membership rotation as defined in the HarvestPlus Governance and Management Handbook. In selecting new PAC members, the representation of HarvestPlus beneficiary groups should be increased.

Management Response:

Agreed.

My comments:

The PAC has discussed and agreed that HarvestPlus should have a finite life span, and cease its activities within a reasonable period of time, on the order of perhaps 10-12 years. In this context, maintenance of a sub-group of core PAC members throughout the existence of HarvestPlus is consistent with the most efficient operation of HarvestPlus. However, I agree that there needs to be some rotation of membership to bring in new ideas and perspectives.

SCIENCE COUNCIL OF THE CGIAR

Commentary on the 1st External Review of the HarvestPlus Challenge Program

21 September 2007

The Science Council discussed the 1st External Program Review of the HarvestPlus Challenge Program and the Program's response at the 8th Science Council meeting, in Bioversity International, Maccaresse, Italy on 29 August 2007. The SC thanked the external review Panel for their constructive work, a well-written report, and a very clear presentation made by Professor Ricardo Uauy, Panel Chair. The Council thanked the Program Coordinator, Dr. Howarth Bouis for presenting a brief response to the Report.

The Report provides 16 recommendations: 3 on the objectives and justification of the Program, 2 on plant breeding strategies, 3 on dissemination strategies, and 8 on governance.

Program-related

The SC agrees with the panel that HarvestPlus is an exciting and value-adding initiative dealing with three major micronutrients essential to tackle micronutrient deficiency (Iron, Zinc and Vitamin A), with major potential impacts on nutrition and health, especially on the poor in low and middle income countries. The Council agrees with the findings of the report concerning need for more focus on the intended objectives, and strengthened collaborations with NARS as end users of HarvestPlus products, involving them early-on in research planning.

The SC endorses the Panel's recommendation to enhance the use of both conventional and transgenic breeding for biofortification of crops with Zinc, Iron and Vitamin A. The SC acknowledges that achieving similar enhancement results for Fe and Zn may be somewhat more difficult than the early successes achieved to date for Vitamin A. In particular, the SC strongly concurs with the Panel's exhortations that HarvestPlus make more use of QTL analysis, and apply state-of-the-art molecular markers to speed delivery of improved varieties. The SC also agrees with the Panel's concerns regarding intellectual property issues of the Challenge Program, especially in the case where both conventional and transgenic breeding are used. Such IP issues may be exacerbated because Harvest Plus has a large number of partners and is itself not a legal entity.

A major point of discussion has been Recommendation 3 of the Report which talks about the implementation strategy (i.e. the deployment, testing of adoption and the impact of nutritionally enhanced varieties). This has been an important part of the HarvestPlus Program from its inception. It is an integral part of the proof of concept of the biofortification approach. Whilst enhancement may be brought about through breeding research, in moving to deployment there will be a need to consider the whole chain, from production to consumption, as there are many steps at which the quality of foods can be affected either positively or negatively. The Panel urges the CP to involve NARS at an early stage of the development of the implementation and testing, a point with which the SC concurs. The Management Response notes that breeding and enhancement are carried out both through Centers and collaborating national members of the Consortium according to their strengths in different commodities. Reaching end-users will involve all parties in the target countries, including agriculture and health institutions. This is a major task for HarvestPlus in facilitating and evaluating actual implementation by national partners. The SC notes the Panel's concern that in order to have micronutrient-dense genetic material adopted, it will be necessary to forge stronger links with conventional breeding programs that add evident traits of value to farmers, to the cryptic micronutrient ones. The SC sees this as an important component of testing of the proof-of-concept. It agrees with the panel that delivering nutritionally enhanced crops in the field - that demonstrably

have measurable effects on the nutritional status of vulnerable groups - is a higher priority at this stage of the Program than adding phase II crops.

The SC agrees with the Panel's observation that the program will not impact significantly on the <2 age group, in terms of iron and zinc, as this age group has very high micronutrient requirements and consumes small amounts of food. Thus, the SC agrees with the Panel in cautioning HarvestPlus not to promise what it cannot deliver. Nevertheless, the Panel recognizes, and the SC concurs, that other groups at high risk for anaemia, such as pregnant and lactating women and older children and adolescents can be helped significantly through biofortified staples. The SC also requests clarification of the efficacy and feasibility of the Randomized Controlled Trial (RCT) approach in China, India and Brazil. This is a component of assuring donor confidence and support for the continuation of the program.

The SC notes that there is no inherent conflict between the approaches of HarvestPlus and Bioversity. Bioversity's approach is to increase the diversity of fruit and vegetables in the diet. The approach being followed by HarvestPlus on staple crops complements this because it is known that iron intake is significantly enhanced by consuming foods that are high in Vitamin C. In addition, while the SC concurs with the Panel's recommendation that the Program strengthen collaborations with other organizations, it agrees with the Panel that the Program undertake independent external evaluations for large contracts.

CGIAR SECRETARIAT

Commentary on the Governance and Management Aspects of the Report of the First External Review of HarvestPlus Challenge Program

September 24, 2007

The CGIAR Secretariat thanks the HarvestPlus Challenge Program External Review (CPER) Panel for its report. The Review Panel made 7 (out of a total of 16) recommendations on governance and management, most of which are on the governance body's (Program Advisory Committee or PAC) composition and functioning.

Governance and Management

- The Panel's recommendation regarding the composition of PAC supports the view that governance of HarvestPlus should meet the criterion of "independence" as specified in the definition of CPs. It recommends that the institutional representatives of the CPs host centers in PAC (i.e. the DGs of CIAT and IFPRI and one board member from each center) should not have voting rights. In its view, this is important in dispelling any perceived conflict of interest.

The HarvestPlus PAC Chair and Management disagree with the recommendation. We do feel it is important for the governing body to be independent of institutional interests. We note the Panel's survey of PAC members showed that 92% of respondents either slightly or strongly agreed that the "presence of CIAT and IFPRI representatives on the PAC introduces some institutional interests into PAC recommendations/decisions." While we acknowledge the Panel's observation that the current CIAT and IFPRI Boards have refrained from interfering with any PAC recommendation, and also that the current center representatives on PAC have been "sensitive and professional", we think that CIAT and IFPRI should conduct a serious analysis of risks, if any, of formalizing a distance between the Centers and the CP, as recommended by the Panel.

- In selecting the "independent" members of PAC, we agree with the Panel that it should be based primarily on expertise and background of the candidates. We are particularly pleased that an expert on financial management is currently serving as an independent member of the Committee. We also agree with the Panel that diversity in terms of gender and nationality, increased representation of beneficiaries, and membership rotation are also important considerations.
- We support the Panel's recommendation that PAC complements the Management Team's monitoring activities by commissioning external reviews of major commissioned research projects/activities.
- Consistent with the Panel's view on the level of independence that PAC should have, we support the recommendation that the ultimate responsibility for performance evaluation of Program Director should rest on the PAC Chair in consultation with the CIAT and IFPRI DGs.

Finance

- We compliment the HarvestPlus PAC and management for the Panel's assessment that the CP is in good financial health. HarvestPlus' achievement in fund-raising demonstrated its ability to attract new monies from both traditional and non-traditional donors.
- We endorse the suggestion to manage financial risk by diversifying funding sources. However, this must not result in less attention to important current ones such as the Bill and Melinda Gates Foundation. We support the effort to secure another multi-year commitment from the Foundation in preparation for the second phase of the program
- The idea of a cash reserve as recommended by PAC and endorsed by the Panel is a good one in theory. However, the amount and standard should not be the same as for the traditional Center since the CP does not have the same needs as a brick and mortar institution. Perhaps, a small "contingency fund" is what is actually intended, which, in our view makes sense. In a targeted, time-bound program, it can be argued that resources should be invested in activities/efforts aimed at realizing the objectives within the timeframe rather than being held back in reserves. Therefore, the real challenge is to come up with a reasonable size of "contingency fund."

Partnerships

- The Panel's report includes a chapter addressing some key questions on partnerships. The views and recommendations/suggestions made were based on interviews and document reviews. We fully appreciate the results of the analysis on this important issue. However, we think that a more comprehensive survey of partners at different levels (i.e. consortium of institutions, scientists/field researchers, and development partners) could have provided important additional insights on the quality and effectiveness of partnerships in HarvestPlus.