

Report of the First External Review of the HarvestPlus Challenge Program

Review Panel: Ricardo Uauy (Chair)

Markus Palenberg Abdul Hamid Zakri

AUGUST 2007

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August 15, 2007

Dear Drs. Rabbinge and Wang:

On behalf the External Review Panel of the HarvestPlus Challenge Program (A.H. Zakri, M. Palenberg and R. Uauy) I submit the report of our review of the program. This work was undertaken by mandate of the Scientific Council of the CGIAR and represents the first review of the program.

We are particularly grateful for the collaboration of Dr Howarth Bouis, Program Director and to the HarvestPlus Management Team for their interest and willingness to contribute to the review; our task was also made easier by the contribution of the Chair, Vice Chair and members of the HarvestPlus Program Advisory Committee (PAC), the staff of organizations providing financial support to the program (USAID, World Bank and The Gates Foundation) members of CIAT Laboratories and field staff and other partners of the HarvestPlus CP; finally to multiple others that provided opinion to the review team members (see Annex 5 for full listing of contributors and interviewees). We have circulated the document to the HarvestPlus PMT and received input from the Director on factual errors that have been corrected in the attached final version. We look forward to your comments or request for clarifications of specific issues.

Best regards.

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Chair Review Panel HarvestPlus Challenge Program

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH SCIENCE COUNCIL AND CGIAR SECRETARIAT

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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 identifyied 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. Futhermore, 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 braking 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.

1 PROGRAM RELEVANCE

The Overview of the HarvestPlus Challenge Program (CP) presented below was extracted from the CP's Medium Term Plan (MTP) 2008-2010:

Micronutrient malnutrition, primarily the result of diets poor in bioavailable vitamins and minerals, affects more than one-half of the world's population, especially women and preschool children. The costs of these deficiencies in terms of lives lost, forgone economic growth, and poor quality of life are staggering.

The goal of HarvestPlus is to reduce micronutrient malnutrition among poor populations in Africa, Asia, and Latin America, by breeding and disseminating nutrient-dense staple food crops thereby improving food security and enhancing the quality of life.

HarvestPlus focuses on three micronutrients that are widely recognized by the World Health Organization as limiting: iron, zinc, and vitamin A. Full-time plant breeding programs are under way for six staple foods—rice, wheat, maize, cassava, sweetpotato, and common beans—that are consumed by the majority of the world's poor in Africa, Asia, and Latin America and for which feasibility studies have already been completed. Breeding feasibility and germplasm discovery studies are being undertaken for 10 additional staples: bananas/ plantains, barley, cowpeas, groundnuts, lentils, millet, pigeon peas, potatoes, sorghum, and yams. In 2007, with most gene discovery and screening activities complete, HarvestPlus crop improvement work is well underway with several varieties set to enter nutrition testing trials in 2008.

The primary objectives of HarvestPlus' 10-year plan (2004–2013) are to:

- select and breed nutritionally improved varieties of six major staple food crops with superior
- agronomic properties that make them attractive to farmers to grow;
- carefully test promising varieties under development to establish that sufficient nutrients are
- retained in staples as consumed, and that these nutrients are sufficiently bioavailable so that
- micronutrient status in undernourished people is improved;
- develop efficient, accelerated mechanisms for testing promising materials with farmers, consumers, and other end users, including those in the most nutritionally disadvantaged areas, to identify varieties with superior agronomic, socioeconomic, and end user-acceptable traits; and
- measure the nutritional impacts of these improved varieties in community-based studies where these varieties have been adopted.

Main Accomplishments of HarvestPlus CP 2003-2007 in the opinion of the panel.

Within the first three years of its existence, the conventional breeding component of HarvestPlus has been able to achieve a number of important milestones towards the stated goals. These include identifying nutrient-rich germplasm in rice, wheat, maize, beans, sweet potato, pearl millet and potato. This activity is being assisted by research efforts in assaying the bioavailability of Fe in breeders' lines (using in vitro cell cultures and piglet models) and through an upstream research program to identify more efficient ways of enhancing the nutritional value of staple foods. The research issues linked to this latter objective include breeding for increased levels of factors that promote bioavailability and/or breeding for decreased levels of substances that inhibit bioavailability. The Nutritional Genomics and Biotechnology research efforts complement this strategic approach by increasing the efficiency of conventional breeding, research is also

focused on identifying the genes that synthesize pro-vitamins A and that translocate Fe and Zn from the soil, through the plant, to the seed. The anticipation is that the results of this research will provide a strong foundation for the development of nutritionally enhanced crops through conventional breeding, genetic modification or eventually transgenic crops should the need arise in the future.

The program has also contributed to enhancing the awareness for improved food quality in addressing nutritional problems. Renewing and enhancing the interest of donors in food based approaches to the prevention and control of micronutrient deficiencies. Identifying gaps in our methods to assess nutrient bioavailability from staple crops and contributing in developing new approaches to evaluate it. The application of low cost high throughput methodologies to screen crops at various levels for nutritional content, starting from the field to the refined analytical labs (especially for carotenoids) has been an important contribution of HarvestPlus. Attracting agricultural development centres of large countries (China, India and Brazil) to invest in research and development of nutritionally enhanced staple crops. The expectation is that other national agricultural research centers will play important roles in reaching end users with the support in terms of training and demonstration projects spearheaded by the CP.

The panel considers that the problem of micronutrient deficiencies is indeed important and that more than one approach is needed to adequately control and prevent these conditions under different conditions and contexts. We are extremely excited by the promise of the HarvestPlus CP of contributing in the control and prevention of micronutrient deficiencies by providing nutritionally enhanced staple crops. We view the program as one of several potentially effective strategies that should be considered depending on context. The HarvestPlus program offers an excellent 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 and provides an example for innovation, illustrating the strength of multidisciplinary approaches, serving as a model for greater interaction between centers and contributes in fulfilling the CGIAR's mission. The Panel considered that overall the CP is well managed, has as strong governance structures that link it to the CGIAR system and excels in terms of obtaining financial support and keeping donor's interest.

The panel unanimously agreed that in their best judgment the HarvestPlus Challenge Program is an exciting and important initiative with major potential impact on the nutrition and health of populations living under poverty conditions in low and middle income countries. Moreover there are significant benefits in supporting nutritional security in industrialized countries alike. Our recommendations are essentially addressing areas where we as an external review panel consider there is room for improvement. The balance between the impressive progress and the areas in need for improvement may not be reflected by the corresponding text in our report, in terms of length since our task as a review team was to critically examine the program, more than to summarize the progress and achievements. We understand that the SC has received progress reports and detailed information on the HarvestPlus program over the past years.

1.1

The Panel first considered if there was a need for the program, it analyzed the nature of the micronutrients deficiencies in terms of the causal web, the consequences and the potential contribution the HarvestPlus CP could have in terms of impact. There is clearly international

consensus that global collective action is required to address the problem of micronutrient malnutrition. The problem has been recognized by the UN and international agencies addressing food and nutritional problems. There is an extensive network of agencies and academic research centers addressing the problem, the topic of micronutrient malnutrition from a public health perspective is being highlighted by a Lancet Series on Malnutrition to be published later this year, material relevant to the topic has been abstracted in Annex 7.

The existence of micronutrient deficiencies is well known by the international and bilateral health and nutrition/food organizations. For the past decade, the three micronutrients (Vit A, Fe and Zn) selected by the HarvestPlus CP are amongst the top priorities in the international nutrition agenda. The approach to the prevention of other critical micronutrients has been food fortification, in the case of iodine, salt and water have been used as vehicles by adding small amounts of Iodine. Iodine fortification of salt has contributed in the significant decline in Iodine deficiency disorders (goiter, abnormal growth and development, mental retardation, decrease educational performance and work productivity). The micronutrients of interest selected by HarvestPlus play important roles in defining child survival in the first years of life and also are key for normal physical growth and mental development of those that survive the early childhood years. These micronutrients affect infant and child mortality rates, ability to learn and capacity for physical work, thus also have an important impact in human capital formation and in overall socio-economic development. The WB has considered micronutrient fortification programs amongst the most cost effective interventions. Economists at the Copenhagen Consensus Center have concurred with this.

The latest estimate on the burden of death and disability from micronutrient deficiencies to be published as part of the Lancet series on malnutrition later this year (Lancet Malnutrition series) indicates that close to one third of all death and disability [lost disability adjusted life years (DALYs)] for children under 5 yrs of age can be attributed to child and maternal undernutrition. More than 20% of global deaths and DALYs lost in children less than 5 years old can be attributed to stunting, severe wasting and intrauterine growth restriction. Of the micronutrients, vitamin A and zinc deficiencies, by far have the largest remaining disease burden. In the case of Vitamin A 7.5 % of all death and 6 % of all DALYs; for Zinc 6.4 and 5.5 % and for Iron 0.2% and 0.5 % respectively. The geographic distribution of these deficiencies is well known; although in many cases mean national figures underestimate the degree of deficiency present amongst populations marginalized because of social, economic, ethnic or religious reasons. However, the fact that these deficits exist should not be equated with stating that these problems will be resolved by enhancing the micronutrient content and the bioavailability of the nutrients from the food sources. Even if the Panel is able to secure the basic nutritionally enhanced food crops there is at the very least a need to secure access to appropriate preventive and curative health, and to maintain vital care practices for young children and women of reproductive age. The latter is particularly critical in the first 6 months of life, exclusive breast feeding for the first 6 months of life, followed by continued breast in combination with appropriate micronutrient rich complementary foods is the most efficacious way to prevent death and loss of healthy life years of children below 2 years of age. Complementary foods need to provide adequate energy, protein, as well as all essential micronutrients, and be free from microbial and chemical contaminants.

Based on the recognition of this problem over the past 15-20 years major global initiatives trying to prevent and when necessary treat vit A and iron deficiencies have been undertaken; more recently zinc has been included. The present interventions are directed at targeted or universal

supplementation for the severely affected and to fortification of staple foods; results demonstrate varying degrees of success depending on the specific nutrient and the context of the intervention. In some cases the delivery of the supplement is done within the health services (vit A capsule at time of immunization) to secure uptake, since it is virtually impossible to deliver the necessary dose with regular or even fortified foods. Often, those who most need the critical micronutrients (the urban and rural poor) have the most difficulty in having access to the fortified foods or in some cases may be excluded from the benefit since they have difficulty accessing the health services. There is clear recognition that further action to address micronutrient deficiencies is required, particularly in those under 3 years of age; what is definitely less well defined is which of the alternative strategies available is most effective, and most cost effective in different settings. Since the micronutrient needs of infants and children below two years of life are much higher on a body mass basis (per kg of body weight) or even relative to energy needs (per kcal consumed) it is very unlikely that foods modeled to meet the needs of adults or older children; can provide sufficient micronutrients within the constrained volume of food consumed by young children. Even if foods have increased micronutrient density small children are limited by the volume of food they can ingest because of small stomach capacity. In general unless flesh foods are included (ruminant meat, fish, poultry, liver or flesh from other small animals) it is virtually impossible to meet the micronutrient needs of small children. Thus, the approach has been to fortify these foods centrally (low cost manufactured processed foods as provided by many governments of Latin America and some countries in Asia) or in various modes of home level fortification (condiments, vegetable oils or fat spreads, sprinkles, or tablets to be crushed and mixed with the food prior to serving it).

1.2

The Panel next analyzed if the CP could realistically achieve the goal of reducing the prevalence of micronutrient deficiencies, namely (vit A, iron and zinc). The Panel has provided the brief summary above and additional information in the Annex 7 describing of the nature of the problem being addressed by the HarvestPlus CP and the multi factorial nature of the causal web since this is necessary to assess whether the objectives have been set realistically and the promise of impact can be fulfilled assuming the program was implemented perfectly. The view of the Panel is that if the expectations are that " the CP will have a significant impact in decreasing the burden of death and disability of young children (< 2 yrs of age) in terms of death and DALYs" this will not be achieved by the CP even if it is successfully implemented. The Panel considers 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. In addition based on the latest available information, the consequences have been overestimated since it is extremely difficult to single out the relative benefit of solving micronutrient deficits in isolation of overall improvement in food supply, access to health and care.

The Panel chose to examine the capacity of the CP to impact the group under 2 years of age for this assessment, since this age represents the critical target group. It accounts for the largest fraction of the total death of children < 5 yrs; moreover, mortality for those below 1 year of age accounts for two thirds or at least one half of the total death for those under 5. The Panel based its judgment on the available evidence reviewed or in what can be projected based on progress to

date. The Panel has used the most recent estimates for malnutrition related death and disability to be published later this year in the Lancet (see appended data from the Lancet series on Malnutrition). Even in an optimistic scenario, in terms of the capacity to achieve the stated objectives, the anticipated short and medium term expected results are not in accordance with the theoretical expectation proposed in the HarvestPlus CP documents and presentations. It is true that the CP has avoided making clear commitments in terms of exact age of the target group, the magnitude of the reduction or the time it will take to have a measurable effect on death and DALY's. The Panel agrees with the concern expressed by the CGIAR SC in terms of the urgent need to clarify goals and purpose of the CP since this vagueness limits the capacity to evaluate the program and our task of assessing potential for impact.

However, despite the vagueness in the final objective against which to assess impact and progress, the considerations the Panel presents remain fully valid for the purpose of assessing the value of the ex-ante cost effectiveness evaluations being conducted by the HarvestPlus CP program (i.e. impact of specific micronutrients provided by given crops). The Panel is well impressed by the methodological approaches taken; indeed they are of interest since they provide an idea of maximum potential impact. However as noted in the short summary provided in the previous sections the causal web for death and disability due to each micronutrient is extremely complex and is also context specific (see figure in Annex 7 adapted from the Lancet series in press). Thus in the absence of empirical evidence and based on the latest information available the estimates of impact provided by HarvestPlus CP are considered by the Panel to be overly optimistic and have great uncertainty.

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. Moreover, as pointed out previously, the proportion of death averted and DALYs saved can not be derived from overall figures since the proportion of young children contributing to both death and disability burden is much greater and the relative benefit obtained in relation to the total population benefiting from HarvestPlus CP is much smaller than those derived from the average estimates of impact. In fact the evidence summarized to date indicates that the effect is maximal when interventions target children ≤2 yrs of age and have much less impact in those over 3 yrs of age in terms of linear growth and mental development. Thus, the real efficacy and effectiveness of the HarvestPlus CP for younger children remains unknown. It is even possible, that this critical age group has no direct gain at all. The worst case scenario is that only, children who are born from mothers who received carotenoid rich foods and were exclusively breast fed during the first 6 months of life, are the ones to benefit. The program benefit would be based on their chance to receive the extra carotenoid and vit A from human milk. In this case, provided the unstated assumptions of the HarvestPlus CP are proven correct, the differential gain in DALYs and risk of death should consider that breast fed infants whose mothers did not received the HarvestPlus benefit but are comparable in all other aspects is the valid comparison group. Comparisons should not be derived contrasting the results from breast fed HarvestPlus beneficiaries with observed risk of death and disability using non breast fed infants as comparison groups.

Appropriate ex ante impact is considered desirable, empirical evidence should be collected to define a model that allows context specific estimates and to test if the assumptions are proven correct. 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. This would allow for extrapolations and a scaling up process that may be able to address the critical barriers that impede effectiveness. Until this is obtained, the extrapolation of the ex-ante analysis is unwarranted and potentially misleading. The present approach for the ex ante evaluation has undoubtedly merit and technical rigor; it represents what can be done with the existing information. Unfortunately there are problems that limit the validity of the estimations, the assumptions need to specified, the uncertainties acknowledged, and there is a need to incorporate the age related factors and the confidence estimates for the results provided. The ex ante cost effectiveness evaluation model can serve as a template to define the type of data that will be needed to conduct an appropriate evaluation of cost effectiveness of the CP.

Despite these concerns the Panel thinks that the CP can contribute to improve the nutrition of those living under conditions of poverty and nutritional insecurity depending on the context in which the program is implemented. The Panel unanimously agrees that the HarvestPlus program has worthy objectives and progress to date is significant; thus it recommends to the PACChair and CGIAR Director that the challenge program should continue in advancing its work towards the stated goal. This will require not only that the CP delivers the nutritionally enhanced staple crops and demonstrates that they are efficacious under controlled conditions in improving the nutritional status of individuals studied; but also that the non food factors that contribute to micronutrient deficiencies in practice are being addressed in conjunction with the CP. These include: access to adequate health, clean water and healthy environment, good governance, promotion and protection of the rights of women and children (including caring practices such as breast feeding), participation and empowerment of communities in their quest to fulfill their right to food (sufficient in amount and quality). It is likely that in order to do this, the CP will need to prioritize crops where major progress in the breeding has been achieved and where the impact of enhanced crop on micronutrient malnutrition of the target group is potentially greatest. This will also require that sites to test the effectiveness of the HarvestPlus should have in place programs that contemplate the other essential health, nutrition and care interventions.

The fact that the Panel considers that these intrinsic limitations are significant; by itself, does not decrease our interest in the HarvestPlus CP. 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.

1.3

The Panel next examined potential alternative goals in order to assist the CP in defining their main objective, the following three alternatives (not mutually exclusive) were considered of greatest interest and are detailed below.

The Panel first considered the broadest possible impact, which has the greatest applicability since it affects virtually all humankind. This would be, enhancing the nutritional quality of the

human food supply. If this is achieved it could contribute significantly in fulfilling, not only the right to adequate food (sufficient in micronutrient quality to prevent deficiency), but also generate the science base for a food supply that would promote lifelong health and well being for humankind. This goal, in fact has wider implications than the present important but narrow focus of preventing micronutrient malnutrition. This broader goal "to contribute to lifelong health, freedom from hunger and malnutrition in all its forms" has been the fundamental contribution of agriculture to humankind from its origins. The strategy proposed and tools developed under the HarvestPlus CP can serve equally well to address the suggested goal as a key issue facing humans now and in their evolutionary trajectory. Our biological evolution from its beginnings has been shaped by the available food supply; the presence of plant and animal life has influenced the hierarchy of the various species (including *Homo sapiens*) in a given ecological niche.

The nutritional needs and the corresponding foods available to humans have been intimately linked throughout evolutionary times. Heterotrophic life evolved based on the capacity of using autotrophic forms of life or other heterotrophic forms occupying a lower place in the food web. Humans within their evolutionary tree/web are unique in being able to gain from successive individual and social experiences not only in the selection of foods consumed; but also defining what foods are produced, how they are processed and preserved. Humans as hunters, scavengers or gatherers were able to pass to others and to the next generation their dietary patterns including food processing, preservation and culinary preparations. Agriculture made food culture possible and allowed the species to expand in relation to the amount and quality of the foods produced, it permitted larger human settlements, made cities and urban settlements possible. In fact modern man evolved thanks to agriculture. Presently we are not only able to choose our foods from naturally occurring forms of life, but are also able to select and modify our food supply, or even design new foods that have selective advantages in the production process or in the desired nutritional properties. Up to now the planning of our food supply has been based mainly on optimizing the energy supply necessary to assure the survival of an ever growing human population. In fact, FAO continues to define hunger solely on the food energy available merely considering the effect of income on the access to energy by the poor [see SOFI 2006 (State of the Food Insecurity in the World)]. The HarvestPlus CP has now incorporated the need to secure micronutrients (vit A, iron and zinc), these nutrients should clearly be considered in shaping the future of our food supply. Perhaps it is time that we expand our vision and consider which traits in plants and animals we use as foods contribute to our life long health or to the burden of disease at every stage of the life course in a broad manner. Nutrition not only affects the growth, mental development and survival of young children but also determines the risk of chronic diseases we will suffer as adults, accounting for nearly 50 % of the premature death burden of adults (WHO/FAO TRS 916 Diet Nutrition and the Prevention of Chronic Disease 2003). The present estimates for maximum human life span suggest that we can potentially live to slightly over 100 years. The data from both epidemiological and controlled interventions suggests that most cardiovascular diseases and a significant proportion of cancers can be prevented or significantly delayed by optimizing diet and physical activity patterns. There is also growing evidence that the macronutrients in the foods (quality of carbohydrates and fats) affect the prevalence of obesity, diabetes, cardiovascular diseases, some forms of cancer and age related functional losses. It is time that we consider what diet and activity patterns are needed to preserve muscle, bone, immune, and brain function in older people. Thus the objective of HarvestPlus is relevant in the development, enhancement, and preservation of human capital at all stages of the life course. This may sound a bit farfetched but indeed the marriage of agriculture and health was the inspiration that lead Lord Boyd Orr to propose in 1943 the

creation of the Food and Agriculture Organization before there was a UN. We are at the dawn of a new era in which humans may in fact actively contribute in the reshaping of their food supply and be able to modify their life course health/wellbeing; possibly affecting their evolutionary trajectory.

A second possibility would be to target the nutritional enhancement of foods for groups that are highly vulnerable to micronutrient deficiencies, as presently proposed but to limit the role of HarvestPlus CP in developing the micronutrient rich foods with demonstrated efficacy (can improve the nutritional status of those deficient) under controlled conditions. The focus would remain future mothers and young infants, but would not promise having a significant impact in the control of micronutrient deficiencies. Rather it would secure that what is "on the plate" meets the nutritional needs of these groups. As pointed out previously vulnerable groups lack not only access to the nutritional enhanced foods but have multiple other factors that condition their vulnerability, making it extremely difficult to judge, in a general way, the contribution of the access or lack of access to micronutrients in the end result. For these groups the promise of HarvestPlus needs to be seen in combination with other interventions that are context specific.

A third alternative, less ambitious and more immediate as an objective for the HarvestPlus CP, would be to contribute in meeting the MDG goals expanding the definition of hunger beyond the narrow FAO undernourishment (based on energy available), proposing the need to secure that the micronutrient needs of those who are poor or food insecure be adequately met. This comprises the large masses of urban poor in low and middle income countries and the subsistence farmers in developing countries. These two groups should be considered as complementary. The HarvestPlus CP would have as a goal filling the food micronutrient gap between the present level of micronutrient intakes and the existing nutritional recommendations. The impact would be assessed by the added micronutrient content delivered by the HarvestPlus CP, basically what is in the plate being consumed. How can nutritionally enhanced foods contribute to meeting the existing food based dietary guidelines (FBDGs), defined based on present dietary patterns, food composition information and prevalent social and environmental conditions that affect the fulfillment of nutritional requirements in practice. In this scenario HarvestPlus would contribute in meeting FBDGs for a given country or region in a context specific manner that would include the full agronomic cycle.

The Panel recommends that the program consider the three options detailed above and clearly defines 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.

As a team the Panel considers it is essential that the objectives be clearly specified, since this defines the framework of our work as evaluators. It is difficult to evaluate the present achievements unless the Panel has these boundaries in place. The assessment of activities, products to date and overall direction require clearly defined objectives, especially at a time the program is planning to expand in its scope and level of funding. The Panel recommends that the CP undertakes a self-assessment of its progress including a SWOT analysis and clearly states, objectives, identify end users, specifying where it adds value; where it can partner with existing national and international centers, and in what specific areas it should be held accountable in

terms of expected impact in a given time period. This should help in defining two or three potential future scenarios depending on projected level of funding. This recommendation is in agreement with guidance provided previously by the SC.

1.4 The Panel considered the question of who is the end user/beneficiary of HarvestPlus CP?

Based on the documents examined it appears that the CP evolved from an initial narrowly focused idea of providing the potential benefits to subsistence farmers, who would be in great need, and at the same time could produce and consume the bio-fortified foods themselves. This option is indeed attractive, but in many parts of the world, the urban poor are equally affected or possibly more vulnerable than the rural farmers. Moreover the IFPPRI data indicates that the rural poor relative to the urban poor are a shrinking group, thus the CP rightly expanded to consider the needs of farmers and non farmers who have limited access to foods naturally containing essential micronutrients or fortified with these. If fortification strategies were successfully implemented across all levels there would be limited space for the HarvestPlus program. This is clearly recognized by the HarvestPlus CP in presenting itself as a superior alternative in terms of running costs once installed, and for long term sustainability. On the other hand, the HarvestPlus as it presently stands, even if successful will not meet the promise of reducing micronutrient malnutrition in young children; the most significant target group in terms of death and disability.

The Panel considered who where the potential end users of the CP and identified two potential groups: individual farmers and agricultural organizations (public or private) charged with supplying of advising on crops selection to farmers. Potentially, individual farmers can be seen as end users; however, the alternative is to have national governments and specifically the existing or projected NARS as the real end users. In pondering the two alternatives the Panel decided that individual farmers should be considered end users only in the pilot phase of implementation mainly to prove the efficacy and or effectiveness of the crops developed by HarvestPlus. The Panel considered that the sustainable adoption of the HarvestPlus program requires that the suppliers or those that influence the selection of crops by farmers take up the new crops as part of their program activities. If national organizations, NARS or their equivalent are weak, their strengthening could be assisted by the HarvestPlus CP in conjunction with other funders and in partnership with government national agricultural research and development centers is the best way forward. The early experience of HarvestPlus partnerships with India, China and Brazil are excellent examples of this approach.

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. The fact that there is a need for supporting the implementation process to the farmer does not mean that the CP should be the one to do it. The HarvestPlus should consider where it adds most value for money and where it should work with others that have the responsability to support farmers and disseminate inovations at the national level

2 PROGRAM EFFICACY AND EFFECTIVENESS (IS THE PROGRAM DOING THINGS RIGHT?)

2.1

The Panel agreed that based on the information provided by the program and our review of the documents describing the program the overall goal of the HarvestPlus is the amelioration of micronutrient deficiencies. However, there is no specific target population or magnitude of the expected reduction ascertained. For the purpose of the assessment exercise as a review team, the Panel has taken what is stated by the HarvestPlus CP as a reasonable working definition... Develop micro nutrient dense staple crops using the best traditional breeding practices and modern biotechnology to achieve provitamin A, iron, and zinc concentrations that can have measurable effects on nutritional status...this served to orient our deliberations and to conduct our evaluation.

The Panel has taken this statement using it as a guide in assessing the purpose, objectives and strategies being implemented by the program; independent of the potential uncertainties that result from it. The Panel considers that the principal strategy/approach that is essential and specific to the HarvestPlus CP goal is achieving the nutritional enhancement of staple food crops. That is, unless the CP is able to deliver the promise of nutritionally enhanced staple food crops it has no reason to exist. The Panel concurs with the CP's vision that this area of discovery is fundamental but yet may be insufficient, if the Panel accepts that the working definition of purpose in the previous paragraph specifies that the crops need to have a measurable impact on nutritional status; this places additional demands in the implementation phase.

The CP needs to further emphasize examining what are the necessary steps for crops to go from the breeding phase to actual adoption in an economically sustainable manner, ideally with both nutritional and agronomic enhancements. These latter two conditions are essential to achieve success in terms of having a measurable effect on nutritional status. The next steps taking the crop from the farm to the mouth of the end user is important but can and should be done in clear partnerships with existing national institutions. The Panel considers that funding allocations and evaluation of progress should reflect this relative prioritization.

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 CP should consider where it adds value in a sustainable manner and it can do things better than others. This does not imply that implementation is less important, but rather that sustainability of implementation will depend on the buy-in of national government and development partners. There are many ways other than the HarvestPlus to facilitate implementation. HarvestPlus needs to clearly demonstrate efficacy of nutritionally enhanced crops, effectiveness is the desired final product, but the CP should take it to the proof of concept and not to the national coverage and final impact. The latter are best done in partnerships with national institutions. Since the Panel considers partnerships to be of crucial importance the Panel has generated a specific chapter in our report to address partnerships as crucial elements for the success of the HarvestPlus.

In terms of evaluation and accountability the Panel considers that the CP should be measured by the results of the breeding and equally important as facilitators and enablers for final implementation of the nutritional enhanced crops in terms of nutrient utilization, food consumption, and nutritional impact at the various levels.

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. The eradication of micronutrient malnutrition and its consequences in terms of death and disability is indeed extremely important but will require at the very least effective actions to prevent and treat infections and parasites, adequate care of mothers and infants and appropriate access to preventive and curative health care. In the final analysis it will relate to overall human, social and economic development. Undoubtedly the HarvestPLus CP has the potential to contribute to this process by breaking the chain of events that leads to poor human capital formation, but clearly its core expertise and scope are insufficient to achieve this most ambitious goal.

2.2 The Panel examined the program design in terms of its strategic approach and if the priorities were appropriate in achieving the objectives of the program?

The Panel considered that the overall approach is reasonable; within the first three years of its existence, the conventional breeding component of HarvestPlus has been able to achieve a number of important milestones towards the stated goals. These include identifying nutrient-rich germplasm in rice, wheat, maize, beans, sweet potato, and cassava, and phase II crops pearl millet, banana/plantain sorghum, potato, lentil, cowpea, barley and yams. This activity is being assisted by research efforts in assaying the bioavailability of Fe in breeders' lines (using in vitro cell cultures and piglet models) and through an upstream research program to identify more efficient ways of enhancing the nutritional value of staple foods. The research question posed for this later issue includes breeding for increased levels of factors that promote bioavailability and/or breeding for decreased levels of substances that inhibit bioavailability. The Nutritional Genomics and Biotechnology research is intended to complete this strategic approach by increasing the efficiency of conventional breeding, research is also being directed to identify genes that synthesize pro-vitamins A and that translocate Fe and Zn from the soil, through the plant, to the seed. The anticipation is that the results of this research will provide a strong foundation for the development of nutritionally enhanced crops through conventional breeding, genetic modification or eventually transgenic crops should the need arise in the future. The Panel examined progress for each of the 4 key HarvestPlus CP objectives based on the information available to us including peer reviewed publications, phone interviews with collaborating centers and visits to IFPRI and CIAT.

Select and breed nutritionally improved varieties of six major staple food crops with superior agronomic properties that make them attractive to farmers to grow.

This is the key objective of the HarvestPlus CP (Nutritional enhancement of staple food crops) and could be used to assess overall impact in a generalizable manner. The scientific developments necessary to achieve this objective are already at hand, and available to the CP. They include genetic mapping of relevant traits for specific crops, QTL or specific gene locus identification, markers for QTLs or genes, molecular assisted selection. With these tools the efficacy of breeding could be significantly enhanced.

Breeding activities include:

Additional evaluation of germplasm to identify additional micronutrient-dense progenitors
for crosses to use in breeding of parent building and germplasm with potential for short-term
impact through fast-tracking (new information in this area is not yet reflected in the

- publications, however ongoing work at CG centers and partners particularly for phase I crops are advancing).
- Implementation of molecular markers for large-scale selection programs (Not documented by publications but evidence that this is occurring at IRRI, CIAT CIMMYT, Univ of Illinois, U of Adelaide, USDA-Baylor for phase I crops was documented including during the visit to CIAT and phone interviews).
- Genetic and QTL analyses to determine loci involved in micronutrient content (based on publications 1 QTL study in rice after 5 years using a population characterized and developed by others, additional work in this area was documented for beans and cassava during site visit to CIAT).
- Development of varieties with high micronutrient concentration and superior agronomic traits, in collaboration with NARES and farmers' groups. (Unclear how much progress in this area, specifically reported in MTP and reports but not reflected in publications. Work on drought resistance and disease resistance in this area documented during the visit to CIAT for beans and cassava; similar work for other phase 1 crops is ongoing)
- Leverage and integrate new methods in genomics, genetics, and molecular biology to identify and understand plant biosynthetic genes of nutritional importance, specifically those related to zinc, iron, and vitamin A; (Scientific 'nutritional genomics' group has excelled especially in the area of carotenoids, work in progress on iron and zinc)
- Demonstrate proof of concept nutritional enhancements by engineering genes involved in the
 biosynthesis of essential vitamins and accumulation of essential minerals (no publications in
 this area provided in the report, however excellent recent progress published in 2007 on
 carotenoid biosynthesis in potatoes in collaborating laboratories and important work being
 carried out at CIAT in this area documented during the site visit relative to carotenoids in
 cassava)
- Analyze the consequences of proof of concept enhancements on nutrients and bioavailability,(apparently limited progress in modifying crops to increase bioavailability of key micronutrients no specific publications in this area)
- Transfer proven materials to partner breeding centers for implementation in Phase 1 and 2 crops (For OFSP a agronomically superior high carptempod variety has been released in Uganda and deployed to African partner NARS. For bean, high Fe final products with superior drought tolerance developed under HarvestPlus are tested by several African NARS and entered variety registration trials. (State-of-art, progress and projections regarding the transfer of micronutrient dense crops are documented in MTP and donor reports. Given the short lifespan of the project, publications regarding breeding can not be yet expected, but will be forthcoming)
- Assist with analysis of micronutrient composition and agronomic traits (extensive work in this area including standardization of methods, implementation of new methods for rapid assessment of micronutrient composition of crops. Practical Manuals and dissemination material produced. Less evidence of productivity from agronomic traits work, however this is expected given the limited lifespan of the project, publications likely will be forthcoming since several articles have been submitted in 2007 and 1 recently published)
- Aid breeders in identifying and developing molecular markers for nutritionally important genes, in order to incorporate into molecular breeding programs (No publications supporting this objective which is critical for the success of the CP are reported yet, however the visit to CIAT revealed that the potential for this is available and is being explored in collaboration with the University of Freiburg for cassava and work at CIAT on beans, parallel activities reported from other CG and partner research centers for phase I crops).

The Panel agrees that in order to be able to perform breeding for mineral content, the availability of genetic variation is essential. However, in order to conduct efficient breeding, the scientific knowledge on the genetic components of the observed variation and insight into the genotype by environment (G x E) interaction are highly relevant and of practical importance. Recent developments in quantitative genetics making use of molecular markers allow the determination of genetic maps and using map positions one can establish the relative contribution of the different loci to the observed trait variation. The obvious application of this knowledge is the use of marker-assisted breeding (MAS), where molecular markers linked to the loci determining variation for the trait can be used to select the most favorable genotypes with a reduced need for assays in all breeding generations. In addition, this approach allows the incorporation of multiple genes at a time into the breeding lines as 3-4 markers can be used to "pyramid" 3 or 4 genes of interest. Markers can help select initially those that have the desired combination of 3-4 genes and then advance these lines gaining efficiency.

The CP has confirmed that there is abundant genetic variation for the concentrations of Fe, Zn and other minerals in the germplasm of major crops to justify selection. Despite some reported G x E interactions, mineral traits are generally stable across environments in the above mentioned crops, and it is feasible to combine high micronutrient traits with high yield varieties or combine these genes with other potentially useful agronomic properties more efficiently and rapidly than what the CP could achieve with markers not yet available or can achieve unless it incorporates the MAS and uses genetic modifications as tools to test the interactive effects of the desired traits. There is a clear need to reinforce the present strategy by creating the mechanisms necessary for a closer interaction between biotechnologists and breeders..

The Panel is somewhat concerned that the novel mechanistic insights being produced will not translate into HarvestPlus CP products (nutritionally enhanced crops) in the short/medium term unless they are applied in collaboration with the breeders. Unless the scientific knowledge is used to determine if the novel genes have an effect on the desired phenotypic traits in agronomically sustainable crops and to develop robust genetic markers to allow molecular assisted selection in breeding programs the program will unlikely be able to fulfill its promise. The Panel recommends that the science discovery laboratories component of the project should be responsible for generating genetic maps, new markers, 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 our opinion this needs strengthening in order to meet the timeline for the delivery of nutritionally enhanced crops.

Carefully test promising varieties under development to establish that sufficient nutrients are retained in staples as consumed, and that these nutrients are sufficiently bioavailable so that micronutrient status in undernourished people is improved;

For now the HarvestPlus CP has made significant advances in upgrading methods to test bioavailability and to assess nutrient interactions that affect vit A, Fe and Zn utilization from foods. This is being done in partnership with major international research groups in the North but with a global scope. The exploration of in vivo methods to define bioavailability is of interest but of limited value since the human model has multiple dietary and physiologic interactions that can not be appropriately modeled by the in vitro studies. Work in this area should be based in developing strong collaborations with existing established laboratories as is being done more recently.

Develop efficient, accelerated mechanisms for testing promising materials with farmers, consumers, and other end users, including those in the most nutritionally disadvantaged areas, to identify varieties with superior agronomic, socioeconomic, and end user-acceptable traits.

This is clearly an important area and one in which the CP is clearly making progress in identifying the natural variability and the gene/environment interactions that define the nutrient content and nutrient utilization in the end product as consumed by humans. However unless the breeding efforts are effective in providing nutritionally enhanced crops that are agronomically superior and economically advantageous the stated objective will not be met. The requirements for successful and effective breeding include genetic mapping of desired traits (gene identification or QTLs), molecular markers to assist crop selection. Progress in this area would have been greater if the breeding effort had been guided by modern molecular biotechnology rather than by phenotypic characterization

Measure the nutritional impacts of these improved varieties in community-based studies where these varieties have been adopted. Is there beneficiary ownership?

Since for now most of the potential products are still in the development stage, it is difficult to have evidence of direct ownership by beneficiaries. In the case of the carotenoid rich sweet potato, the implementation phase contemplates intensive efforts at generating demand; in some ways this is worrisome. The fact is that the program has to spend money and efforts doing this, rather than responding to existing demand. The process of generating end user interest should establish a demand that is sustainable over time based on consumer preference, agronomic superiority and farmers' economic interest; otherwise it will be a waste of resources. On a more positive note, the fact that 3 major governments (India, China and Brazil) are partnering with the CP is strong evidence that there is a clear interest in the program, this is a pre requisite for effective demand for the approach taken by the CP; the Panel considers that in this case governments are an excellent proxy for social demand.

The Panel examined the scientific productivity relative to objectives and whether the science in the CP overall and in the different components is of high quality and recognized by peers? The scientific productivity of the CP has been mixed in some areas it has an excellent productivity while in others is of limited value in terms of original scientific findings, multiple publications to increase awareness and disseminate the potential of biofortification. Methodology reviews and manuals to disseminate existing knowledge are of value for the dissemination efforts but do not substitute the need for scientific research necessary to achieve the main objective of the HarvestPlus, that is to deliver nutritionally enhanced crops that are agronomically superior and economically sustainable.

Science discovery (excellent collaborators and publications in the carotenoid field) less strong on mineral content of crops (reasonable scientific output)

Translating scientific discovery to enhanced breeding methodology. This particular area needs to be strengthened (limited productivity based on publications record related to mapping, QTLs and MAS as evidenced from phone interviews; however observations during the visit to CIAT suggest that the work is on ongoing but can be enhanced if a specific effort in terms of prioritizing human resources and funding to this area is made).

Improving bioavailability and utilization of nutrients from crops. Extensive collaborations with Nutrition Research Centers has great promise for enhancing knowledge and methods with widespread applications. (Emerging publications in this area in mid to low impact journals, but there is evidence from abstract that there is potential for increased impact).

Facilitating uptake by end users. Publications in this area are emerging for now in the studies document efficacy in relevant groups, but not quite addressed to the target group, as a recent publication in this area by Jan Low shows.

We encourage the HarvestPlus CP to consider including genetically modified or transgenic crops as necessary tools to improve the effectiveness of the breeding program. We will discuss this later in our report, the panel views of genetic modified crops for direct human consumption and agree with the HarvestPlus CP cautious approach to this; however we firmly believe that genetic modification is an important tool to enhance breeding process of nutritionally and agronomically enhanced cultivars. It would be important for the HarvestPlus CP to have a clear idea of who to partner with to be able to effectively link modern genomics into the breeding efforts; this may be related to the limitations that are intrinsic to the CGIAR centers. This limitation should be resolved as soon as possible. In fact the latest evaluation of CIMMYT expressed that the center lacked the critical mass in the area molecular genetics, which is essential to the present and future needs of the CP. 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 using the relevant biotech tools (Genetic mapping, QTL and MAS).

2.3 The Panel examined the potential use of transgenic methods as research tools or in final products as way to improve nutritional value of stable crops?

The Panel concurs with the prevailing philosophy of HarvestPlus and its three prerequisites, namely that research on transgenics be initiated only and only if: (a) natural variation does not exist in the crop germplasm for the targeted nutrients, (b) the micronutrient levels in the crops in question are not sufficient enough to have a nutrition-biological impact; and (c) transgenic breeding materials would only be sent to countries having in place national biosafety regulatory systems.

The panel considers that the use of gene transfer should be seen as an important tool to achieve nutritionally enhanced staple crops. The addition of genes foreign to a given species (transgenic) to nutritionally enhance crops has been well documented by the success of Golden Rice in addition gene transfer allows for proof of principle by expressing the gene products of interest with certainty. It is now over five years since Golden Rice was first discovered/engineered based on transgenic methods; yet it is still not available to meet the needs of target populations. Many years of regulatory hurdles have to be overcome before the promise of golden rice is finally fulfilled; it may be 4-5 yrs before golden rice is available for common use. This shows that despite the obvious advantage of transgenic varieties in the time required to develop them relative to conventional breeding, the time to reach market might actually be comparable (+/- 10 years).

From the breeding perspective, use of transgenic techniques can facilitate the work in various ways.

Taking the example of enhancing carotenoid content, since the pathways are relatively well known, transgenics can be used to modify components in the metabolic pathways. The use of RNAi (i for interference) serves to selectively silence particular genes in this pathway. Recent examples in potato show that silencing of lycopene epsilon cyclase (LCY-e) responsible for alpha carotene synthesis and the beta-carotene hydroxylase (CHY) responsible for transforming betacarotene to zeaxanthin will induce a dramatic increase in total carotenoid and beta-carotene contents of potato tubers (Diretto et al. 2007). Although these potatoes cannot be used for human consumption the experiments show that by decreasing the activity of genes responsible for synthesis of other carotenoids (in this case alpha carotene and zeaxanthin), the beta-carotene can be significantly increased. These results indicate that in some cases it may be useful to develop knockout alleles for genes responsible for breakdown of the product of interest, rather than trying to increase the product itself (in this case beta carotene) by conventional breeding. The knockout alleles can then be introgressed into adapted germplasm and expanded using conventional breeding strategies, but with the advantage of demonstrated effectiveness in terms of increased nutrient content from the transgenic experiments. In the case of zinc and iron relatively less is known compared to the carotenoid metabolic pathway. In fact the HarvestPlus nutritional genomics group is engaged in studies of genes regulating metal-homeostasis in rice. Studies to define the specific functions for the genes of interest are underway with promising results in a few cases. The use of transgenics would greatly aid in assigning specific functions and could allow for a better understanding of their specific roles. This might lead to a purposeful manipulation of the genes regulating the metabolic pathways for mineral transfer between roots, plant and seeds for the purpose of enhancing the storage in the endosperm. The definition and understanding of the metabolic pathways hopefully will lead to the identification of specific alleles that might enhance nutrition.

However, this process has limitations, you can only do gene transfer, enhanced expression or silencing of candidate genes you already know. Thus, it is important to identify the QTLs in order to characterize the specific genes affecting the traits of interest. QTLs will lead to the identification of candidate genes, which can then be used in gene transfer experiments to validate the gene and define its function in the plant. As in the case of carotenoids, once a gene is identified in species A, the homologous genes in species B,C and D can be studied promptly using transgenics to see if the similar mechanisms are in operation. In the case of carotenoids, much of the information has been gained from the study of Arabidopsis, this information then can be used in studies of the cultivated staple crop species of interest.

The analysis of whether to use transgenic methods should also consider cost related to regulatory processes and intellectual property rights. Given the mission-oriented nature of the HarvestPlus CP, and the state-of-the-art knowledge on transgenics, it would be prudent to assess the contribution of transgenic experiments in increasing the likelihood of achieving the target of developing nutrients-dense food crops within the stipulated timeframe. This is especially relevant with the recent success in the beta carotene enhancement using genetic modification which serves as proof of concept.

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 assumes that HarvestPlus fully subscribes to the Guiding Principles on Genetically Modified Organisms released by Bioversity International and the CGIAR Centres' Position Statement on Biotechnology. It is important that HarvestPlus in the course of its work declares its adherence to the five primary principles which refer to the need to ensure transparency in all activities related to GMOs.

"GMOs will only be used to produce global public goods; that HarvestPlus take into account socio-economic implications, intellectual property rights and environmental and health impacts; observe the highest standards of safety in the conduct of laboratory and field experiments, meeting national and international legislation and codes of conduct, and working with partners to study the impact of potential and actual gene flow from GMOs to local varieties and wild relatives."

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.

Need to consider local regulatory and biosafety guidelines will be necessary for field studies? In the absence of such local regulations, it is incumbent on the part of HarvestPlus to embark on a program of capacity-building on biosafety and risk assessment and management specific to the nutrients-dense traits of interest. As this is an area of interest among many governments including those in the developing countries, it is pragmatic for HarvestPlus to collaborate with NARS and to identify other relevant partners at the national level such as the National Focal Point for Biosafety (normally residing at the Ministry of Environment by virtue of its jurisdiction over the Cartagena Protocol on Biosafety).

2.4 In response to whether the HarvestPlus CP will have health and nutrition impact?

The health and nutrition benefits are directly linked to achievement of program objectives. This is why the Panel thinks it is crucial to have clearly established goals in order to judge program effectiveness over the short and long term. The Panel considers that it is most realistic to achieve the first potential objective stated under 1.3 that is "contributing in securing an adequate micronutrient intake from staple food crops for most people". This will have a likely benefit on health over the long term. If the CP focuses in closing the gap for vulnerable groups it can expect short term and long term benefits in terms of preventing deficiencies. What the Panel considers most difficult is to effectively impact young children who are presently deficient and in greatest need; the limitations in this case are intrinsic to young children or others living under poverty as already outlined.

The Panel considers the HP 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. The alternatives strategies (food fortification at a central and home level; and micronutrient supplements) have greater possibility for short term impact, the dose of supplement or level of

fortification can be adjusted to level of deficiency and to the specific target populations depending on the context specific needs.

2.5 In response to the Panel's opinion of whether the CP's key assumptions/ expected impact pathways concerning critical scientific and technological constraints, socioeconomic conditions, adoption, markets, researchers' motivation and donors' interests appropriate?

The Panel has reviewed extensively key assumptions and impact pathways and consider the assessment to date has been overly optimistic both in terms of overestimating the contribution of nutritionally enhanced crops as one of multiple factors that condition micronutrient malnutrition (population attributable risk fraction) and also in terms of overall potential impact in terms of the number of lives and loss of healthy life years potentially averted (public health effectiveness).

The donors' interest so far have been very favorable to the program as an exciting opportunity to test a novel approach, however as will be discussed in chapter 3 there is danger of losing support if the program is not able to deliver products in a timely fashion or if the expectations have been overstated and the real impact does not meet what the donors perceived would be the likely impact.

2.6 Is the program aligned with the beneficiaries' needs, priorities and strategies?

The first 4 years of the CP have been guided and oriented by the needs of beneficiaries as they are perceived by those involved in the program and the related professional technical staff. Despite this, the Panel found no evidence of direct input from beneficiaries being incorporated in the design of the program or of processes in place that would allow for this to occur. Indirectly the NARS might fulfill this role since they are both partners and beneficiaries of the CP and will surely play a key role in making the new crops available to farmers. Ideally input from NARS should be brought in to the planning of the work well before final products are ready for field testing. In fact, the ideal crop cultivar to be bio-fortified is the one that is presently preferred by farmers as considered in the breeding strategy of the CP, because of their properties relative to the soil where it will be planted. The best way to secure uptake would be to improve the varieties that are already being planted, this minimizes the need for behavioral change of farmers and consumers.

On the other hand, if by beneficiaries we mean the children or women who will benefit from the program, we should think of ways of incorporating both the small farmers and urban poor who might end up consuming these products. There is ample experience that the social, cultural and economic determinants of food choices are more powerful than the nutritional benefits. Even in famine conditions people might starve because their preferred food is not accessible (as the Irish farmers faced starvation because of the potato blight, corn was being fed to the pigs).

In response to a specific question on the potential significance of work on QPM (Quality Protein Maize) presented to the panel. The panel agrees that while neither protein nor amino acid deficiencies are presently priorities as global problems in human nutrition, QPM is recognized as superior food relative to other maize varieties that can benefit some individuals, specifically young children, at risk of severe malnutrition. The greater direct impact of QPM is on increased availability of some amino acids (lysine and tryptophan) on animal production. This could

potentially benefit human nutrition at the population level. The experience in the past with high lysine opaque corn and multiple efforts at developing novel protein sources (fish protein concentrate, single cell protein etc) have demonstrated that modifying consumer behavior is extremely difficult, access to nutritious food is clearly necessary but insufficient to secure nutritional impact.

In discussing this issue with the HarvestPlus Program director the panel was informed that QPM and protein or essential amino acid concentration in the context of QPM are not breeding target traits and are not part of the research agenda. The PAC has been strict and explicit in not allocating any funds in QPM. Consequently HarvestPlus does not invest in QPM. Breeders use their best elite germplasm in developing biofortified crops by combining those genotypes with micronutrient dense sources. Frequently the best elite locally adapted germplasm is in QPM backgrounds, particularly in countries such as Ghana or Mozambique which concentrated on developing QPM germplasm. Based on the above information, we make no recommendations or suggestions on QPM other than the need for the SC to acknowledge that this issue has been satisfactorily clarified.

2.7 Is the global level the most appropriate level for the program?

An international or even better global level for this CP is essential, the need for foods with enhanced nutrient content is not only a problem for those who suffer deficiencies, the crops that will be derived from this effort will benefit humankind as a whole. Virtually all major countries fortify their staple foods with iron to prevent anemia, and many foods in industrialized countries have vitamin A added. The product of this CP is clearly a global public good, thus legitimately the initiative should be global. However, the program clearly needs to work with regional, national and local partners to avoid duplications, unnecessary conflicts and to promote synergies both in the science and in the implementation of actions that result from the CP.

- 3 PROGRAM EFFICIENCY (IS THIS PROGRAM THE BEST DELIVERY ALTERNATIVE RELATIVE TO ALLOCATED RESOURCES?)
- 3.1 The Panel examined the progress of the HarvestPlus CP in advancing the strategic objectives relative to overall resources and also examined resource allocation relative to productivity in advancing the key objectives of the program.

The Panel notes the substantive effort of the Nutritional Genomics group and the need to better integrate its work into the breeding activities. With the exception of sweet potato which already has a high level of beta carotene in its germplasm, work in support of the development of marker related activities has been undertaken for most of the Phase 1 crops. The characterization of populations in terms of phenotyping for nutritional content of crops under various environmental conditions has been undertaken. This will support the mapping of the desirable traits and identifying the QTLs or the specific genes of interest. After four years of work, the HarvestPlus teams have the characterized populations of beans, rice, maize and cassava with enhanced nutritional components and in some cases advanced in collaboration with other research centers in identifying the genes responsible for these traits. In rice, for example, a set of 43 genes putatively related to metal homeostasis have been identified by 2006, several QTLs of interest have been characterized A recent collaboration between researchers in IRRI and CIAT has resulted in the design of SNP primers to assist in a high through put markers assisted selection breeding scheme. The Panel is assured of the prudence and pragmatism of the Nutritional Genomics Group to utilize the modern tools available on hand to speed up the breeding process and the willingness to expand its collaborative network to include expertise which originally may not have resided in HarvestPlus. The Panel recognizes progress in several areas notably in identifying the multiple elements and interactions of factors that determine bioavailability and utilization of key nutrients in food crops.

The CP has contributed in defining the variable spectrum of nutritional content of carotenoids, iron and zinc in food crops, thus setting the stage for the development of novel varieties with enhanced nutrient content; it has also examined gene environment interactions that should facilitate the nutritional enhancement of staple food crops in a sustainable manner.

Notable progress from the nutritional genomics group relative to the support received is detailed below

Peter Beyer (Freiburg University) US\$1.349.475

- Co-inventor of golden rice with Ingo Potrykus.
- Proven track record and leader in his field, specifically related to carotenoid enhancement of plants.
- Outstanding quality (and quantity) of publications in leading journals (Science, Plant Physiology, etc) over last few years
- International team working with him including private sector

Dean Dellapenna (Michigan State University) US\$1.098.726

- Has discovered several key enzymes in the carotenoid pathway of plants, including novel members and is also leader in vitamin E metabolic pathways
- Also has outstanding publication record and is the leader in his area.
- Also has international team with multiple collaborations.

These researchers are two of the top people in their field working in very similar areas, with significant complementary overlap. Dellapenna research scope includes tocopherols/vitamin E; both are outstanding scientists and provide excellent scientific support to HarvestPlus in the field of carotenoid metabolism in plants.

Michael Grusak (USDA, Baylor College of Medicine) US\$1.081.600

- Plant physiologist specializing in iron and zinc status in the plant.
- Many of the publications listed in the HarvestPlus summary are for Medicago truncatula, a model legume species and there is some work in crops.
- Publication record is very good category; Abstracts presented at recent meetings show that he
 is currently working on several projects related to Zinc and Iron uptake and remobilization.
 Also currently working with Gpc-B1.
- All in direct relationship with the needs of the HarvestPlus program

Naoko Nishizawa (Japan Contract- University of Tokyo) US\$200.000

- Expert who has helped elucidate the role of nicotianamine in the transport of Zinc and Iron in xylem and phloem.
- Very productive lab that is doing high quality research in zinc and iron transporters in rice, barley and other agronomic species.
- Publication record is top-notch in high impact journals (Nature Biotech, PNAS, Plant Journal)
- Excellent scientist to have in project since he has worked in this area full time over his career.

Janette Fett (Brazil Contract-FAURGS) US\$200.000

- Working on Iron-Zinc transporters in rice, few recent publications.
- Most of important publications have come in collaboration with Mary Lou Guerinot (Dartmouth); small contract in an important topic, resources allocation in line with initial phase of her contribution.

General Comments: The group should generate basic scientific knowledge to allow new target genes to be identified. The scientists on the list are some of the leaders in nutritional genomics worldwide (specifically Beyer, Dellapenna and Nishizawa). Major contributions are in carotenoids and zinc/iron uptake and transport in plant. This is in close agreement with HarvestPlus priority nutrients (Vitamin A, Zinc and Iron).

The focus in terms of funding level up to now has been mainly on breeding objectives and bioavailability of critical nutrients from relevant crops, some resources are funding nutrient utilization studies and nutritional assessment but little has been spent on testing best practices to facilitate end user uptake. This is not unreasonable given the stage of development of the program.

The specific details of partnerships within and beyond the HarvestPlus CP will be addressed in chapter 4 (Partnerships) including the relative contributions to the progress of the project of the main collaborating centers. The breeding objective group productivity is analyzed under 4.2 and the productivity of the breeding of Phase I crops under 4.2 (see these sections for further details).

The focus will most likely will change as new crops come to the implementation face. For now the orange flesh sweet potato is serving to test the CPs capacity to implement a vegetatively propagated crop with a visible micronutrient trait at the farmer's level. In this case the CP benefits from having an experienced team that has been working on this for nearly 8-10 yrs, well before the CP came into being.

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.

The Panel is concerned that despite the excellent scientific knowledge being generated by the nutritional genomics group the breeding process and the final products could not yet benefit sufficiently from the science. HarvestPlus has established linkages between the high level science and what is being done by breeders but additional efforts will be required to ensure that the science and new knowledge related to mechanism of uptake, metabolism, distribution and transport of nutrients by plants is being translated into breeding the new crops. Efforts by specific members of the scientific team with the capacity to contribute in the translational phase of the work to the breeding process need to be strengthened. The level of science being conducted is likely too complex for traditional breeders to utilize directly unless there is an effort of translating this into practical methods to follow and tools to utilize. Breeders may have difficulties in the incorporation of molecular markers for MAS. This issue was further discussed at the time of a visit to CIAT by one of the panel member. The CIAT scientists and managers acknowledged the need for strengthening the interface between biotechnology and breeding.

3.2 The program has contributed indirectly to the achievement of other important objectives, these include:

- Enhancing the awareness for improved food quality in addressing nutritional problems.
- Identifying gaps in our methods to assess nutrient bioavailability from staple crops and contributing in developing new approaches to evaluate it.
- Applying low cost high throughput methodologies to screen crops at various levels for nutritional content, starting from the field to the refined analytical labs (especially for carotenoids). Near Infrared spectrometry (NIRS): high precisions calibrations has been developed for minerals and pVAC and NIRS implemented at CGIAR Centers; calibrations developed for Phase II crops. Colorimetric high-throughput staining techniques will be further developed and implemented at ICRISAT, CIMMYT, IRRI and selected collaborating NARS.
- Renewing and enhancing the interest of donors in food based approaches to the prevention and control of micronutrient deficiencies.
- Attracting agricultural development centres of large countries (China, India and Brazil) to invest in research and development of nutritionally enhanced staple crops.
- Simulation/modeling: in a joint project with Generation Challenge Program and Chinese Academy of Agricultural Sciences, Beijing. Simulation will be applied to assess the cost/benefit of conventional and molecular marker assisted breeding for minerals in comparisons of different breeding strategies.

3.3 Is there competition with regional, national or local programs (subsidiarity principle)?

There are clearly multiple actors in the field of provision of micronutrients, several in the area of food fortification in various manners, directly included during processing of foods such as wheat

during milling or sugar during packing while others prefer the home level fortification by adding micronutrients to condiments such as salt or use a combined micronutrient mix to be added before the food is consumed.

This is a crucial issue, since there are indeed successful universal fortification and targeted supplementation programs in place which in many cases are doing a good job at delivering the micronutrients. However the CP is intended to reach where these do not reach and in the future to be an option that in some cases might be more cost effective. The cost effectiveness of the alternatives proposed by the CP in the long run may be as or more effective for less money. Presently the theoretical models indicate that bio-fortification may be less costly and more effective than supplementation provided it can deliver the necessary amounts in a way that the micronutrients are well absorbed and safe.

The tables provided in Annex 8 provide the type and amount of nutrients that can delivered by fortification considering for each food matrix the level of fortification and type of fortificant used the proportion of daily need that is provided for each nutrient and the cost per year. For example the costs of providing 100% of the mean requirement for retinol as fortified oil is about US 5 cents per person per year, while for sugar is almost double that amount. The costs of adding (Retinyl Palmitate, Thiamin, Riboflavin, Niacinamide, Pyridoxine, Folic Acid Vit. B-12 iron as ferrous fumarate and Zinc as oxide) to refined wheat flour to cover 50-90 % of needs according to the nutrient is about 3 cents for each nutrient per person per year, similar costs are given if maza/maize flour is used as the food matrix. An alternate approach is based on the use of reconstituted micronutrient fortified cereal grains (rice) [Nutririce or Ultrarice] providing 50 % of daily needs Vitamin A, Vitamin B1, folate, Niacin, Vitamin B12, and Iron in 200 g of rice at a cost of an additional 2-3 % the cost of the rice or 0.3 to 0.7 US\$ per person per year.

International (WHO/FAO) public and private (GAIN Global Alliance for improved nutrition funded by Gates) and national initiatives supporting micronutrient fortification of staple foods are in place in most countries. HarvestPlus should work in close interaction with these programs, since they will be competing at the national level for the limited human resource base needed to support local actions and potential would compete for government resources in terms of scaling up to cover the population at large.

Of greater concern is the apparent parallelism and potential for antagonism between the HarvestPlus CP and the Bioversity International Initiative (former IPGRI), part of the CGIAR system. The proposal from IPGRI is the use of agrobiodiversity for dietary diversity and poverty reduction. Integration of food-based approaches based on diverse plant genetic resources can move beyond the single nutrient, staple food, interventions that in the past have made health, nutrition, and food security programs difficult to sustain and manage locally. With the perspective of bioversity, biofortification strategies can be considered as a component of the solution when they are practical, cost effective, ethical, and culturally appropriate to address the fundamental determinants of undernutrition.

In order for bio fortified foods to have a positive impact, the introduction of enhanced genotypes must be complemented with conservation and greater use of traditional forms of biodiversity that needs to take into account:

- 1. broader nutrition and health needs,
- 2. the sociocultural, economic and political context in which people undertake their development and livelihood decisions,

- 3. the need to promote improved economic self-sufficiency of poor farmers,
- 4. the need to secure long term sustainability of agricultural and food systems.

During the visit of one of the panel members to CIAT there was an opportunity to review within the same institution, CIAT complementary activities related to the HarvestPlus CP, the Bioversity initiative, and a specific Canadian CIDA program AgroSalud (AgriHealth) in Latin America with close or nearly identical objectives but run in parallel. AgroSalud involves the work of CIAT, CIMMYT, CIP and Embrapa and NARS in Latin America and is a linkage program to HarvestPlus reviewed by an external panel commissioned by HarvestPlus every 18 months. In addition a panel member had the opportunity to see at a recent nutrition meeting in Africa respective parallel symposia by the Bioversity and HarvestPlus program and clearly in competition with each other. Since these programs are all within the scope of the CGIAR system, they should at the very least be harmonized, ideally sufficiently coordinated to gain in their synergy and avoid unnecessary confusion and competition for the national or community partners.

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.

3.4 Is there a value added, comparative advantage of this programs compared to other global or regional programs?

The overall value added by the program is in principle reasonable, although some components are clearly not as competitive as others. The two highest budget items in the breeding objectives are provided as direct unrestricted grants, their productivity over the past years is relatively low, in low/middle impact journals and refers mostly to topics unrelated to the key breeding objectives of the CP. The Nutrional genomics component adds good value and has excellent scientific productivity. Overall judgment is that there is great promise but not much in concrete output to date in terms of high impact scientific developments. The potential value added from the application and end user side are yet unrealized, the initial studies in school children provides great expectation that the high carotenoid orange flesh sweet potato will demonstrate the CP's capacity to impact community level nutrition, specifically mothers and young children. The work on testing bioavailability and final impact of the nutritionally enhanced crops is in progress so a final judgment on whether the HarvestPlus CP will deliver the expected results must be left pending.

3.5 Donors' perspective on overall program (strengths and weaknesses).

The Panel had the opportunity to discuss strengths and weaknesses of the HarvestPlus CP with the three major donors by personal visits and discussions and in other cases by phone conversations. All donors considered that the problem of micronutrient deficiencies was indeed important and that more than one approach was needed to adequately control and prevent these conditions under different contexts.

Most were extremely excited by the promise of the HarvestPlus CP of contributing in the control and prevention of micronutrient deficiencies by providing nutritionally enhanced staple crops.

Most donors saw the program as one of several potentially effective strategies that should be considered depending on context.

Relative Strengths:

The program offers an exciting opportunity to support food based approaches to control micronutrient deficiencies in a sustainable manner with long term impact.

The World Bank (WB) valued the CP and thought it helps make the CGIAR more effective, as new way of doing things, in multidisciplinary approaches, and serves as a model for greater interaction between centers and contributes in fulfilling the CGIAR's mission.

Gates expressed continued interest in supporting the CP in its future development considering the potential impact and the outstanding leadership of the CP. What is pending is defining the appropriate level of support especially given the various competing alternatives strategies to improve micronutrient nutrition. Gates has recently shifted the management of the HarvestPlus CP from health to agriculture. This may modify the strategic value of HarvestPlus and the level of support in the future. Gates considered that the level of support would most likely be similar to present levels.

The Panel considered that overall the CP is doing extremely well in terms of fund raising and in keeping donor's interest. However the interviews serve to document the need for the program to define more clearly what it can be held accountable for in terms of deliverables and impact over the short and mid term. If expectations for short term impact in terms of controlling micronutrient deficiencies are not fulfilled there could be a critical disenchantment with the CP and potential loss of interest and support. This is discussed in more detail under finance section.

Presently there is great dependence of the CP on one or two major donors, there is need to diversify the funding for the program spending more efforts in diversification, this may require that the fund raising effort be shared by several of the program leaders and not dependent on any one person exclusively.

Relative weaknesses

There was concern expressed by some on the capacity of the program to deliver on its promise, others were concerned on the expansion to phase two crops without clearly demonstrating efficacy on phase I crops. The possibility of limited uptake by farmers and national level end users was also an issue for others; historically multiple "high tech fixes" have failed because of lack of uptake by end users.

The behavioral issues that define the foods consumed were according to some not fully acknowledged in the program design and implementation. Past failures in changing people food cultures were brought into the discussions. Most considered that fortification of staple foods at the household level for rural populations and at the central level for urban populations was not only most effective but also most cost effective on the short term considering there were immediate needs that required urgent attention. The capacity of delivering the required levels of nutrients by bio-fortification was also questioned by several donors' technical staff members.

USAID expressed the need to incorporate donor input more effectively, provide feed back on progress and to enhance interactions with other complementary approaches to improving micronutrient nutrition. The Nutrition Group at USAID was concerned with the HarvestPlus

timeline to deliver products, nutritionally enhanced crops, which could in fact fulfill the promise of measurable nutritional impact. There was concern that the program might be siphoning resources in a disproportionate manner and restricting available support to other alternatives of established effectiveness. On the other hand the agricultural group at USAID was pleased with the ongoing relationship with the HarvestPlus program.

The Panel suggests that reporting to donors be programd 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 meeting 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 partnerships. This is perhaps a more difficult approach to raising funds than presently being used but is likely to be more secure over time.

3.6 To what extent should resources be applied to completing the work with Phase I crops versus expanding to Phase II?

This is an important point that needs to be assessed relative to overall objectives and the strategy. As indicated in preceding sections this project is predicated on the ability to produce nutritionally enhanced staple crops with additional agronomic advantages.

So far this objective has not been achieved by the HarvestPlus CP, the OFSP as a source of pro vitamin A was developed prior to HarvestPlus. Thus it would seem sensible to first demonstrate to its fullest the capacity to address Phase I crops since they constitute the main crops feeding humankind. Resource allocation should focus on strengthening the science base for breeding and into translating this knowledge into products. The solid approach to this is mapping of desired traits (related to nutritional enhancement and agronomic advantages), establishing QTLs, identifying genes and markers to be used in MAS. The HarvestPlus CP should demonstrate its capacity to deliver the main object of its work.

It is true that the CP has succeeded in attracting funding to undertake efforts in both Phase I and Phase II crops, but this by itself should not be considered a measure of success. Expanding a yet unfulfilled promise may potentially backfire since the CP sooner rather than later will be accountable to stakeholders in its capacity to deliver. This is why it is also important to clearly state what are the main goals of this program; if it is the first alternative posed under 1.3 (enhanced nutrition security for all) or the second 1.3 (contribute in filling the micronutrient gap in vulnerable populations); these are achievable goals. If the promise is conquering micronutrient malnutrition then the Panel considers it will be unfulfilled based on the available evidence and progress to date.

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 Advancing in Phase II crops will not resolve the urgent need to enhance translational research, taking discovery (by HarvestPlus or in partnership with others) to products that fulfill the promise of improved nutrition. The program needs to examine how to make breeding more effective, by developing and applying molecular markers, both in terms of money and time; and prove that it can deliver what it has promised. The Panel thinks that it is time the CP effort concentrates in phase I crops and demonstrate what

the program will do to its fullest in these, rather than expand thinly and broadly without a clear focus on deliverables.

4 PARTNERSHIPS

Considering the critical nature of partnerships for the HarvestPlus CP the Panel has placed several of the key issues relative to partnerships in a separate chapter. In general these items address the need for stronger partnerships in order to allow the CP to concentrate in where it adds value. The Panel also examined potential need for partnerships beyond the CGIAR system that can provide synergies and help advance the HarvestPlus objectives in a cost effective way. The need to strengthen monitor and evaluation is included under chapter 5.

4.1 Should the program reach out more to new partners, eg NARES and outside CGIAR?

HarvestPlus has a total of 46 institutional partners that, at some point in time, have collaborated with (and received funds from) the Challenge Program (Annex 9).

Based on total cash disbursements for research from 2003-2006, the following ranking in terms of research funds received per institution can be compiled. As can be seen from this chart, HarvestPlus focuses its funding on a group of 5 to 10 key partners, receiving 52% (top 5) and 80% (top 10) of the total research funding of 25.2 million US\$ from 2003-2006.

Table 4.1. Partner ranking in terms of funding for research

Rank	Name of Institution	Research disbursement share 2003 – 2006	Research disbursements 2003 – 2006 In million US\$
1	IFPRI	16%	4.1
2	CIP	10%	2.5
3	CIAT	9%	2.3
4	CIMMYT	9%	2.2
5	USDA	8%	2.0
6	IITA	7%	1.8
7	IRRI	6%	1.5
8	University of Adelaide	6%	1.4
9	Michigan State University	5%	1.2
10	University of Freiburg	4%	0.9

The Panel suggests that the HarvestPlus program strengthen partnerships with research scientist 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.

There are several research networks in place addressing exactly these topics (the USDA is investing on wheat and rice, addressing mainly agronomic properties see section 4.3). The CP could contribute by adding the corresponding nutritional traits to these crops and gain in the process since there is no need for exclusivity since the research is funded with public resources it should be made available to those in greatest need.

The value for money of this CP should be more specifically targeted to the breeding of nutritionally enhanced crops that are effective in improving nutritional status and in defining the best way to reach end users mainly NARES and farmers only to facilitate the uptake as proof of principle. Partnership with NARES in the breeding effort would be ideal, as appears to be the case for India, China and Brazil. This will help to achieve sustainable results. The USDA wheat and rice (Coordinated Agricultural Projects) CAPs, which have similar objectives in terms of the science and the application of genomics to breeding programs offer a unique opportunity to increase value for money since the USDA effort at present is not focused on nutritional objectives.

The Panel considers that the effort to recruit the best science within the CGIAR but also make use of every possibility to synergize with existing efforts outside the CGIAR, promoting partnerships in competitive bidding (about 1.25 million or 5 % is done by competitive on the basis on cash disbursement of 25 M to the end of 2006) helps to strengthen the science. If the ground rules are set appropriately, the bidding process can help to establish partnerships that include developing countries, thus contributing to capacity strengthening and greater uptake by the end users.

4.2 What has been the added scientific value from the CP; in particular, by the partnerships represented by the CP?

"Breeding Objectives Subprogram": US\$ 3.388.960

This subprogram was originally conceived as an upstream research effort that would investigate new strategies for optimizing the constraints to achieving HarvestPlus goals of breeding nutrient-dense staple crops. Specifically, first, it was intended to assist breeders to assay the bioavailability of Fe in breeders' lines using in vitro cell cultures and animal models; its second objective was to identify more efficient ways for breeders to enhance the nutritional content of crop plants such as exploring, among others, the role of inulin and carotenoids in promoting the bioavailability of Fe and Zn.

The key researchers are Graham and Stangoulis from Univ. of Adelaide (\$2.047.415) and Welch from USDA-Cornell (\$2.258.208). Ross Welch and Robin Graham are both distinguished researchers who have championed the case for biofortification since the 1990s and the Panel was informed that their work has been a source of inspiration and provided the scientific underpinning for HarvestPlus CP.

It is in that context that at the outset of the program, a significant amount of non-competitive funds was disbursed to the PSNL in Cornell and the University of Adelaide respectively. Welch is leading an active research group trying to develop tools to make breeding more efficient by incorporating the two strategies mentioned above. His scientific leadership of the project is demonstrated by multiple key review articles on the subject and also by a steady publication record from the inception of the project until the present time; more than 20 articles have been published in reputable journals by this group. The Cornell Group under Welch is also involved in technology transfer and training of researchers particularly from developing countries such as China, Colombia, Nigeria, Thailand and Peru.

The Adelaide group (Graham and Stangoulis) list 20 publications in the 5 year period, many are not fully related to the HarvestPlus objectives. Twelve of them have to do with selenium toxicity, or selenium accumulation in wheat, with no mention of zinc, iron or carotenoids. Two of them are reviews or proceedings from meetings. Six publications address the HarvestPlus objectives. These publications are on the right track, with a QTL study on zinc/iron content in rice, screening methods for zinc/iron and carotenoids in crops and general diversity studies. However six out of

twenty publications directly related to the HarvestPlus mission over 5 years is considered insufficient taking into account the over US\$2 M in funding.

Subsequent phone interviews with the Cornell and Adelaide groups reported that additional papers directly related to the HarvestPlus CP are in press or have been submitted for review. In addition the Adelaide Group is active in developing capacity building analytical laboratories for HarvestPlus collaborators in India, Nigeria, China, Mexico, Colombia and the Philippines. The technical assistance and support to the HarvestPlus crop leaders has been an important part of their effort. For instance, they have contributed to the establishment at CIAT of a laboratory to analyze minerals and contributed to the design of the equipment necessary to ensure there was no contamination of Fe and Zn during the sample preparation process. The Panel is appreciative of the scientific and leadership inputs from the Cornell and Adelaide Research Groups since the beginning of the HarvestPlus CP and looks forward to their contribution as the program expands and enters its new phase. These groups could play a pivotal role in training and capacity building of young researchers from developing countries.

Partnerships for breeding of "Phase I Crops"

Each major crop has received between US\$1.5 and US\$2.5 M over 5 years to enhance its nutritional quality. This is roughly ~\$400.000 year/ crop to the different CGIAR institutions. The funds provided for each crop studied by the CP seems very reasonable for the objectives, considering that additional funding sources likely exist for each crop. Therefore, the US\$400,000 /year should be used specifically to implement strategies to increase carotenoids, zinc and iron contents in the grains.

While scientific output is not outstanding based on publication records, the measure of success in this case should not be research papers but the actual new crops, product of the breeding effort. The Panel is somewhat concerned with the limited documented novel scientific output over the initial 4 years. The publications of original research over this period directly linked to the HarvestPlus CP are limited in quantity and of rather low scientific impact if one assesses the ISI impact rating of the journals where these are published [wheat (5), maize (1), cassava (4), rice (0), beans (0) and sweet potato (1)]. There are multiple other outputs of research information such as proceedings from meetings, and abstract but these represent outreach and dissemination efforts that contribute little to the science base needed to support the breeding objectives and implementation of novel methods required by the breeding centers. After several years of funding, there should be more visible results for the different crops such, as QTL analysis and molecular/genetic maps with markers linked to the traits that will allow more efficient breeding.

This serves to highlight a potentially significant weakness in the science base of the CP, that is the clear need to strengthen the link between the basic research described under 'nutritional genomics' with the application tools necessary for a more effective breeding process. The Panel considers there is a need to incorporate molecular markers to assist the breeding process and make if more effective. A stronger link between the nutritional genomics and the breeding effort will strengthen the ambitious breeding objectives in terms of nutritional enhancement, agricultural superiority and economic productivity can be met without strengthening the link between the nutritional genomics and the breeding effort.

4.3 How do program costs (or cost per achieved output/outcome/impact) relate to other benchmarks? Is the cost per output/outcome/impact reasonable?

For comparison of this CP the Panel examined and reviewed the USDA wheat and rice (Coordinated Agricultural Project) CAPs, which have similar objectives in terms of the science and the application to breeding programs http://www.uark.edu/ua/ricecap/http://maswheat.ucdavis.edu/. The USDA finances wheat and rice CAP projects in the US at a level of US\$ 4-5 Million over a 4 year period (~\$1.25 M per year/crop). This is divided into 15 laboratories, receiving less than US\$100.000 per year if you consider overhead (indirect costs):

- The CAP programs have 16 and 14 publications respectively in 2006-07, all directly related to
 breeding of wheat and rice respectively, QTL analysis, phenotypic characterization of
 accessions and generation of novel markers for traits of interest. This type of work is vital for
 the effective translation of basic science into breeding as it generates the necessary tools
 required for a more targeted breeding.
- For the wheat CAP project, there are currently 17 groups mapping populations, each looking at multiple phenotypes in to achieve an acurate mapping of the QTL linked to the specific traits. This is parallel to germplasm release and other work being carried out. These maps serve to yield new markers for yield, disease resistance, quality, etc that can be used directly in breeding within the next few years. Nutritional quality is not seen in the CAP program as a major aspect and was has not been incorporated in the objectives. This offers a unique opportunity for the HarvestPlus CP to explore synergism.

4.4 What has been achieved by the CP that could not have been achieved without it, through Center activities or SWEPs?

The Panel noted that HarvestPlus CP has several innovative features which sets it apart from other undertakings in the CGIAR system. For example, the governance and matrix management structure in place facilitates the flow of information across crops, disciplines, cultures and institutions thus minimizing duplications, learning from best practices developed elsewhere within the program and enabling the sharing of new scientific findings derived from cross-disciplinary exchange of perspectives and methods. The Panel agrees that measures of cost-effectiveness could be enhanced by closer coordination of work on several crops. for example relating the gene discoveries on the regulation of Fe and Zinc translocation from plant to seeds in wheat to those in rice and vice versa.

HarvestPlus mission-oriented research focus on concurrently using conventional plant breeding and molecular biology on one hand and human nutrition and food science on the other to bring about nutrient-dense staple foods for the under privileged of the world is a path-breaking approach that is worthy of emulation by other researchers working on issues of pressing global importance. This mission oriented work, taking the best science has to offer in improving human nutrition, health and well being should serve as a model for others to follow.

The Panel views positively the extensive network of some sixty research and implementing organizations in over forty countries developed by HarvestPlus since its establishment. It is also noteworthy that this network is multidisciplinary in nature bringing together diverse disciplines ranging from human nutrition, food science, plant breeding, molecular biology, economics, farm extension, and communications.

4.5 Is there any evidence of synergies and/or new modes of operation of the Centers involved in the CP? Can these *synergies be improved?*

Synergies among the Centers involved are already built-in early on with the core management structure of HarvestPlus - the Program Management Team (PMT) being based at the two cooperating centers, namely IFPRI (Nutrition, Impact, Communications) and CIAT (Plant Breeding, Nutritional Genomics, Reaching End Users). The Program Director is based in IFPRI.

These strategies are further strengthened by the coordinating roles of the functional research leaders of the above disciplines across the six Phase 1 crop groups. One facet of the CP that would ensure the delivery of the final product is the 10-phase HarvestPlus Impact Pathway which includes phases of research, development and dissemination. While such strategies and new mode of operation are commendable, 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.

To what extent and when should NARS be involved in adaptive and participatory breeding activities of the promising varieties?

As discussed under who should be the end users of the CP, 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. This partnership is essential to enhance potential for sustainability of the effort and is most cost effective. An early and on-going engagement of HarvestPlus with stakeholders and target recipients of its research outputs is not only desirable but absolutely crucial.

The Panel considers the partnership with the NARS as an essential component of implementation process; interaction with NARS should start early incorporating members of the national agricultural research community in the design of the new crops and training NARS staff so they can adequately support the implementation during the pilot phase and in the expansion phase. NARS should also be involved wherever possible in the evaluation of the nutritionally enhanced crops for agronomic properties and in gene/environment optimization processes.

4.6 Policies regarding intellectual property?

As the products of HarvestPlus are global public goods, all intellectual property arising from the CP must be freely available for use in developing countries. Participating institutions must agree and sign such Agreements prior to receiving any funds. The Panel takes note that a PAC committee has been formed to consider a reformulation of the HarvestPlus IPR strategy which would be based on many elements of the Generation Challenge Program structure.

HarvestPlus, and specifically the PAC, has spent considerable effort on clarifying the International Public Goods (IPG) nature of its program outputs. The original program proposal also addressed this point. While recognizing that the absence of a legal HarvestPlus entity would not allow direct Intellectual Property (IP)-related agreements between HarvestPlus and IP-owners in the private and public sector, the original proposal defined a series of requirements on

how Intellectual Property Rights (IPR)-protected program outputs owned by one or more collaborators would be handled, including publication and royalty-free and unrestricted access to the outputs through a licensing agreement. Subsequently, the PAC has revisited and updated the HarvestPlus IP-policy in almost every PAC meeting, leading to the currently valid HarvestPlus IP-policy (see Governance and Management Handbook) that is largely in line with the original policy but contains a few adjustments.

Firstly, while IP-ownership remains with the collaborators that developed it, the royalty free, irrevocable, perpetual, worldwide, non-exclusive license (for non-commercial purposes only) allowing access is restricted in a first step to CIAT and IFPRI who then also obtain the right to sublicense to all other present and future HarvestPlus collaborators under the same conditions.

Collaborators obtain the right to commercialize the Challenge Program IP in one or more of the "More Developed Countries and Territories". In this case, a royalty fee needs to be negotiated and is payable to HarvestPlus.

The Panel did not assess the current HarvestPlus IP-policy in great detail. It seems, however, obvious that the IPG character of HarvestPlus outputs has been clear from the outset, albeit reduced to Regional Public Goods (RPG) targeted primarily at less developed countries in the case of commercialization. As recommended in the governance and management sections of this report, the Panel encourages HarvestPlus to update the Governance and Management Handbook (that contain the current IP policy) because recent PAC meeting minutes indicate that the discussion has moved further forward since the Handbook was last updated (in May 2005).

4.7 Are the rules and mechanisms for commissioned research transparent? Is there a wellestablished, clearly defined and transparent internal control environment on implementing competitive grants?

The HarvestPlus original proposal differentiates between commissioned activities and competitive grants. Commissioned activities include those undertaken by collaborators in areas central to the core program pillars of nutrition, nutritional genomics, genomics, breeding, and policy analysis. Some central program services, such as sample analysis and plant nutritional pathway elucidation, will also be commissioned by the program to ensure consistency of results and obtain efficiencies of scale. Competitive grants are awarded in open competitions. An important aim of these competitive grants is to widen the pool of developing-country institutions and networks participating in the Challenge Program, thus building national and regional capacity in the target regions of the program. The PAC will determine a process for administering these open competitions, including peer review mechanisms, to ensure independence and transparency in the awarding of the grants within the Challenge Program.

The original proposal sets a target that 25% of overall program funds to be awarded through competitive mechanisms. Currently, HarvestPlus commissions most of its overall programmatic funds. In fact if the estimation of proportion of open bid funding is applied to the overall program funds the competitive mechanisms accounts for only 5 % of the total budget.

There is clear dominance for commissioned activities in the HarvestPlus program and management strongly supports the present model. The arguments supporting commissioned research are that it is easier, leaner and more efficient to administer and that it helps in building real partnership. However on the down side the fact is that much of the commissioned research

remains within the CGIAR centers or the initial universities/research centers that originated the HarvestPlus CP thus the opportunity to attract others is limited. Commissioned research at the very least needs careful monitoring and evaluation in place since it is difficult to have proper accountability in place when the contracted are also the owners of the program. It is crucial that the products to be delivered by the contractor be clearly established at the outset.

Competitive grants have been implemented more recently for the work on nutritional genomics and for specific methodological aspects to assess bioavailability of nutrients and interactions within the food matrix.

The Panel considers that the best way to secure the highest quality scientific products needed by the HarvestPlus CP to reach its key objective is to deliver nutritionally enhanced staple crops is to have a competitive award research program with clearly defined terms on both what is required and how it is delivered. 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.

4.8 In what ways has the CP contributed to capacity building of partners?

The Panel did not identify a specific capacity-building effort or program at the start of the HarvestPlus program. The Panel acknowledges that capacity-building is a long-term investment and requires substantial financial resources. So far there has been no specific funding allocation for capacity-building during HarvestPlus I but it was budgeted in HarvestPlus II.

While it is understandable that a research of this kind may not have capacity building as its prime consideration at the outset, at this phase of its development, it is imperative that such a scheme be set in motion. It is evident from the documents provided that HarvestPlus has contributed to training efforts and educational programs conducted by others. The recent development and upgrading of methods and protocols used in the area of nutrition research, food analysis and nutrient content of plants have served to generate manuals and other materials that serve to disseminate knowledge, This is a clear contribution to training and capacity development workshops held in Brazil, China and Tanzania.

Training also took the form of post-doctoral fellowships on 'Breeding Objectives' at Cornell University or the University of Adelaide. While they may have been useful, such instances are 'ad hoc' at best. If the CP is to live up to its promise of being seen as a major research effort at tackling micronutrient deficiencies for the benefit of the poor in the developing countries, a major component of its future program should be capacity building.

While conventional breeding may be taken for granted in many places, it would be opportune to include this component in any training program besides food processing and human nutrition. Undoubtedly, high on the priority list would be training on nutritional genomics. Such training is preferably organized in situ in recipient countries with the active participation of NARS but it should not preclude training exchanges with training components in advanced laboratories in developed countries. Eventually, this CP program may spawn hands-on training on how to initiate, manage and coordinate a multidisciplinary program on research on issues of innovation of crops either for enhanced nutrition, agronomic superiority and possibly multiple uses of crops with particular traits deemed useful for human food production, animal feeds and other economic uses.

The Panel is in agreement with the view expressed in the SC's comments on HarvestPlus 2007-2009 Medium Term Plan that "capacity building, which is of great importance for the implementation and carrying forward of the outputs... (should involve)...Program-wide human resource development and infrastructure support at the NARS levels, specifying the training components with detail on numbers and people targeted." The Panel notes the expressed interest of HarvestPlus to focus on training opportunities for agriculture and nutrition scientists in the area of biofortification for improved nutrition and to explore the prospect of strengthening laboratory facilities and upgrading equipment to conduct biofortification research. HarvestPlus is also looking into the feasibility of using the web as a virtual tool for training scientists.

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.

5 GOVERNANCE AND MANAGEMENT

The CGIAR defines Challenge Programs as follows¹:

"A CGIAR Challenge Program (CP) is a time-bound, independently-governed program of highimpact research, that targets the CGIAR goals in relation to complex issues of overwhelming global and/or regional significance, and requires partnerships among a wide range of institutions in order to deliver its products."

Since Challenge Programs have a finite lifetime, it seems reasonable to avoid heavy setup and close-down investments, e.g. related to the establishment of a independent legal entity and the buildup of administrative back office capacity within Challenge Programs themselves. Instead, the present Challenge Programs have opted for virtual organizations that outsource key operative functions such as human resources management (employment of program staff), accounting, handling of funds, legal services (contracting) and the provision of office and meeting facilities to participating institutions.

In the absence of a legal Challenge Program entity, the boards of the participating institutions are ultimately responsible – and accountable – for governance. The present Challenge Programs have set up diverse Challenge Program governing bodies, ranging from advisory panels to steering committees that should advise and/or take decisions in the Challenge Programs' best interest. In order to allow for "independent governance" of Challenge Programs, the boards of the host institutions have delegated (some of) their authority to the CP governing bodies.

This setup is common to all present Challenge Programs and leads to a certain intrinsic ambiguity both on the governance and on the operational management level that can be summarized by the following questions.

- How independent is the CP governing body, i.e. how far does the delegation of authority go? Has accountability been transferred accordingly?
- How independent is CP management from the host institutions?

The HarvestPlus Challenge Program has chosen a pragmatic and lean governance and management arrangement that has proven to work well in the past.

HarvestPlus is based on a joint venture agreement² between two CGIAR Centers, namely CIAT and IFPRI. The boards of these centers bear the ultimate governance responsibility and accountability for HarvestPlus, but no single center can make unilateral funding decisions for the program³.

The centers themselves employ the program management staff, provide for legal representation (including contracting), execute all financial transactions, deliver accounting and auditing

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¹ CGIAR website, visited on 28.07.2007.

^{2 &}quot;Cooperative Research Agreement", CIAT, IFPRI, March 14, 2003.

³ In 2003, IFPRI consulted with its external auditors (KPMG) on the matter. An extract of their opinion reads: "IFPRI, by itself, does not have the unilateral power to redirect the use of the transferred funds without the approval of the PAC. The PAC is not controlled by IFPRI but jointly controlled by IFPRI and CIAT, and ultimate resolution of conflicts does not rest with IFPRI but with an external mediator.

services on behalf of the Challenge Program and physically host the Program Secretariat. For these services, the centers receive an administrative fee from HarvestPlus.

This arrangement has served HarvestPlus well in the past. The Panel has observed a powerful, productive and high quality governance body – the Program Advisory Committee (PAC) – as well as a well performing and professional Management Team. Both CIAT and IFPRI management and governance have shown a high degree of sensitivity in terms of letting HarvestPlus act as an independent program.

In what follows, the Panel analyzes the HarvestPlus governance and management structure and performance in more detail and will present some recommendations. Most of these comments do not intend to remedy lack of performance but rather to render high governance and management performance sustainable.

5.1 HarvestPlus Governance

Overall Governance Performance

The governance bodies with direct relevance for HarvestPlus are the CIAT and IFPRI Boards of Trustees, and the HarvestPlus Program Advisory Committee (PAC).

As far as the Panel could determine, both the CIAT and the IFPRI boards have refrained from interfering with any PAC recommendation or decision in the past. Because of this hands-off governance approach, the Panel has focused on analyzing the PAC rather than examining the center boards. Information from center boards has only been requested about the type and degree of authority delegated to the PAC.

To this end it might be advisable for the center boards to assess risks related to the delegation of authority to the Challenge Program from the centers' perspective and to study related risk mitigation mechanisms. This is, however, not within the scope of this review and has not been studied further.

Concerning the PAC as HarvestPlus' main governance body, the Panel has been positively impressed by the degree of involvement and expertise of PAC members, as well as of the performance of the PAC as a whole. The quality and devotion of the PAC chair and other PAC members, as well as the institutional independence of most of its members has helped to create a working style characterized by the right to dissent, open and constructive discussions, and a hands-on problem-solving approach.

PAC Composition and Processes

In the original HarvestPlus proposal⁴, the PAC was designed as an external expert body, consisting of 12 individuals, selected according to the following criteria:

- Widely recognized expertise in various disciplines (as defined in the proposal),
- Gender balance,

• Balanced developing- and developed-country citizenship.

The current⁵ PAC comprises of 17 individuals, 13 of which are external experts in the sense that their institutional affiliation does not contain any direct link to either CIAT or IFPRI⁶. Compared

 $^{^{4\}prime\prime}\mbox{Biofortified Crops}$ for Improved Human Nutrition", CIAT, IFPRI, August 21.

to the original layout, one additional external expert (the chair of the PAC Audit Committee) and four institutional representatives have been added to the PAC.

While the inaugural PAC members had been chosen by CIAT and IFPRI, subsequent PAC members are chosen by the PAC itself.

Currently, a total of five PAC members – or about 30% – are women and most PAC members have a developed country citizenship, only about 30% come from ODA-receiving countries⁷.

External expert PAC members represent a wide range of scientific disciplines and professional experience.

Table 5.1. PAC members' expertise

Name	Function	Expertise
Peter McPherson	PAC Chair	Administration
Barbara Underwood	PAC Vice Chair	Nutrition
Mark Wahlqvist	External expert member	Nutrition
Ruth Oniang'o	External expert member	Nutrition
M.S. Swaminathan	External expert member	Breeding, Biotech
Richard Flavell	External expert member	Breeding, Biotech
Qifa Zhang	External expert member	Breeding, Biotech
Maria Jose Sampaio	External expert member	Breeding, Biotech
Estrella Alabastro	External expert member	Food Science
Michael Lipton	External expert member	Economics
Jeroen Bordewijk	External expert member	Private Sector, Food Marketing
Peter Sandoe	External expert member	Ethics
Patrick Murphy	Chair Audit Committee	Finance

The Panel finds that, in general, PAC member expertise fits the Challenge Program's needs well. The PAC has chosen its new members with care, following a process that first identified needs and then proposed and screened candidates involving the Nomination Committee, a PAC subcommittee.

While the present selection of PAC members has been primarily based on scientific expertise, the Panel finds that the representation of the program's beneficiaries could be improved. As pointed out in the programmatic part of this review, both early strategic planning and the concrete "reaching the end user" approach strongly depend on thorough understanding of the beneficiaries' situation. The PAC should therefore seek to increase the beneficiaries' representation on the PAC, ideally finding candidates that combine this role with solid management skills, as currently the case for most PAC members.

⁵ Documentation of the PAC meeting on June 14-15, 2007

⁶ In addition, according to the HarvestPlus "Conflict-of Interest Policy" (Annex of the Governance and Management Handbook), all direct or indirect involvement of PAC members with HarvestPlus operations need to be disclosed by PAC members.

 $^{^{7}}$ Based on the "OECD DAC list of ODA Recipients", effective from 2006 for reporting on flows in 2006 and 2007.

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.

The PAC has been meeting twice per year, starting from its first meeting in March 2003. All meetings have been in person meetings, lasting generally two days.

Meeting attendance has generally been high, as shown in the table below.

Table 5.2. PAC meeting attendance analysis

	-								
	1	2	3	4	5	6	7	8	9
			May/		May/				
			-		-		-		Jun
	2003	2003	2004	2004	2005	2005	2006	2006	2007
Chair	1	1	1	1	1	1	1	1	1
Vice Chair	1	1	1	0	1	1	1	1	1
Audit Chair		_		1	1	1	1	1	1
	1	1	1						
_	0	0	0	0					
			1	0	1	1	1	1	1
									1
	0	0	0	(1)	0	(1)	(1)	(1)	(1)
	1	1	1	1	0	1	1	0	1
	1	1	1	1	1	1	1	0	1
	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	0	1	1	0
	1	1	1	0	1	0	1	1	0
	0	1	1	1	0	0	0	0	1
									1
CIAT board			1	1	1	1			
FPRI DG	1	1	1	1	1	1	1	1	1
CIAT DG	1	1	1	1	1	1	1	0	0
FPRI board									1
FPRI board	1	0	1	1	1	1	1	1	
CIAT board							1	1	1
	11	11	12	12	11	11	11	11	13
	8	9	10	8	8	8	10	8	11
	73%	82%	83%	67%	73%	73%	91%	73%	85%
	13	14	16	16	15	15	15	15	17
	10	11	14	12	12	12	14	11	14
	77%	79%	88%	75%	80%	80%	93%	73%	82%
	CIAT board FPRI DG CIAT DG FPRI board FPRI board	Chair 1 Vice Chair 1 Audit Chair 1 0 0 1 1 1 1 1 1 1 1 0 CIAT board FPRI DG 1 CIAT DG 1 FPRI board FPRI board CIAT board CIAT board 1 11 8 73%	Chair 1	Mar Nov Jun 2003 2004 Chair 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Mar Nov Jun Nov Jun Nov Jun Nov Jun Nov Jun 2003 2004	Mar Nov Jun Nov Jun Sunction 2003 2003 2004 2004 2005 Chair 1	Mar Nov Jun Nov Jun	Mar Nov Jun Nov Jun	Mar Nov Jun Nov Jun Nov Jun Oct

Legend:

1 = not PAC member at that time

1 = present at PAC meeting

(1) = represented by other person at that PAC meeting

0 = not present or represented at that PAC meeting

The lowest attendance was 73% (or 11 out of 15 PAC members) during the 8th PAC meeting in October 2006 and the highest attendance was 93% (or 14 out of 15) during the 7th PAC meeting in June 2006. Apart from PAC members, the Program Director, the Management Team as well as selected other guests attend PAC meetings.

Most PAC members have attended meetings regularly, missing meetings only occasionally. In one case, however, a PAC member has never attended a PAC meeting in person and has send a representative in 5 out of 9 meetings. MS Swaminathan absence to all PAC meetings is

problematic, considering the major rol he plays in the field of interest of HarvestPlus and additionally in Bioversity International. His contribution in addressing need for stronger collaboration between these two initiatives could be significant. In another case, a PAC member has only attended 4 out of 9 PAC meetings without sending a representative.

The Panel finds that PAC meeting attendance should be further encouraged. PAC members are selected according to their expertise and background. Missing several meetings in succession can therefore result in certain aspects being underrepresented in PAC decision making. Since PAC members are identified on an individual basis, their roles and responsibilities should include personal attendance and continued absenteeism should be a reason for rotating that PAC member off.

According to the Governance and Management Handbook, PAC members serve for a 3 year term, starting from March 2006, after which one third of the PAC membership will be replaced each year. New members are hired for a 3 year term with one option for renewal and staggered departures. In the original proposal, membership was planned for a 4 year, non-renewable term.

In its 6th meeting (November 2005), the PAC decided to prolong membership for all PAC members for a second term. The main reasons reported for this decision were the perceived good performance of the PAC, the preservation of institutional memory that had been built up over time and the limited life span of the Challenge Program. As a result of this decision, 9 of the original 11 external experts or 11 of 13 original PAC members (including the institutional representatives) currently serve on the PAC, 4 years after its inception.

While agreeing with the positive self-assessment of the PAC in terms of general governance performance and the importance of preserving institutional memory, the Panel finds that PAC membership rotation should commence in line with original plans, for example based on a 3 or 4 year, one time renewable term and staggered departures. A special weight should be laid on the search and selection process of new members, as well as on a staggered rotation plan that guarantees an adequate level of experience with the Challenge Program within the PAC at all times. In the Panels' view, this approach will sustain and potentially further energize the good current PAC performance.

As far as the Panel could determine, PAC decisions are taken on a consensus basis. Surprisingly, no formal voting rules have been defined in the original proposal or in the Governance and Management Handbook, or seem to be in place.

The Panel finds that the definition and agreement on a set of voting rules, including the quorum needed to constitute a valid PAC meeting, voting rights, necessary majorities to constitute a valid PAC decision, and potential tie-braking, e.g. by the chair, would increase validity of PAC decision-making.

Since the first PAC meeting, the Director Generals of CIAT and IFPRI have participated as "exofficio" members at PAC meetings. In the second PAC meeting, an IFPRI board representative was added as full PAC member. Similarly, a CIAT board representative became an additional PAC member in the third PAC meeting. Since then, a total of four institutional representatives from CIAT and IFPRI have been members of the PAC.

In the Panel's view, the presence of institutional representatives of CIAT and IFPRI in the PAC has the clear advantage of facilitating communication between the host centers, their boards, and PAC. On an operational level, this provides on-time information on whether potential PAC decisions can be implemented by the centers as planned. On a governance level, it allows for a timely feedback from the center boards concerning critical PAC decisions.

On the other hand, the PAC perceives that its independence is diminished by the presence of institutional representatives. In a survey done for this review, 92% respondents from the PAC either slightly or strongly agreed that "The presence of IFPRI and CIAT representatives on the PAC introduces some institutional interests into PAC recommendations/decisions."

While the Panel has observed a high degree of sensitivity and professionalism amongst the institutional representatives with regard to the independence of the PAC, it is of the opinion that HarvestPlus governance would benefit from a further clarification of the roles and voting rights of the institutional representatives. E.g., in the absence of documented PAC voting rules, it has not become clear to the Panel whether institutional representatives in the PAC have formal voting rights or not.

External experts on the PAC, apart from their main roles as scientific advisors and decision-makers, guarantee the independence of all PAC decisions from real or perceived illegitimate institutional interests, such as interest of increasing a program partner's budget share without programmatic arguments.

Institutional representatives in the PAC should primarily represent legitimate institutional interests, i.e. act as "host center representatives" by advising the PAC on matters relating to the legal representation, as well as contractual, financial, HR-related and other services the centers provide to the Challenge Program. Institutional representatives should also continue to provide their expert input when appropriate, but should not formally take part in PAC decision making.

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 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.

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 braking 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.

Functions of HarvestPlus Governance

The last version of the HarvestPlus Governance and Management Handbook (May 2005) describes the responsibilities of the PAC as follows (numbering has been added for later reference).

Under the leadership of the Chair, the PAC exercises shared responsibility for:

- 1. Reviewing progress toward meeting HarvestPlus' objectives and overseeing the Program Management Team (PMT) in fulfilling its responsibilities.
- 2. Discussing and approving HarvestPlus' strategic research priorities as proposed by the PMT.
- 3. Reviewing and approving the annual work plans and budgets presented by the PMT.
- 4. Ensuring an independent and transparent competitive grants process for specified components of HarvestPlus; approving peer review committees to referee submitted proposals.
- 5. Assisting in advocacy and communication on behalf of HarvestPlus.
- 6. Nominating new members of the PAC—as required—to the Boards of CIAT and IFPRI for approval.
- 7. Reviewing and approving the annual financial reports prepared by CIAT and IFPRI on Sources and Disbursements of HarvestPlus Challenge Program funds.

This PAC TOR closely resembles a "standard" steering committee TOR for global partnership programs. In fact, it covers most functions⁸ of governing bodies of global and regional partnership programs:

- *Setting strategic direction*⁹: is covered by PAC TOR 2) and 3).
- *Management oversight*¹⁰: is covered by PAC TOR 1).
- Stakeholder participation¹¹: is not covered, although PAC TOR 5) contributes partly.
- *Risk management*¹²: is partly covered by PAC TOR 7) and by the responsibilities of the PAC Audit Committee.
- Conflict management¹³: does not appear in the PAC TOR. The HarvestPlus Governance and Management Handbook only defines that arbitration will be sought if conflicts about new PAC members persist between the boards of IFPRI, CIAT and the PAC.

⁹ Exercising effective leadership that optimizes the use of the financial, human, social, and technological resources of the program. Establishing a vision or a mission for the program, reviewing and approving strategic documents, and establishing operational policies and guidelines. Continually monitoring the effectiveness of the program's governance arrangements and making changes as needed.

¹⁰ Monitoring managerial performance and program implementation, appointing key personnel, approving annual budgets and business plans, and overseeing major capital expenditures. Promoting high performance and efficient processes by establishing an appropriate balance between control by the governing body and entrepreneurship by the management unit. Monitoring compliance with all applicable laws and regulations, and with the regulations and procedures of the host organization, as the case may be.

¹¹ Establishing policies for inclusion of stakeholders in programmatic activities. Ensuring adequate consultation, communication, transparency, and disclosure in relation to program stakeholders that are not represented on the governing bodies of the program.

¹² Establishing a policy for managing risks and monitoring the implementation of the policy. Ensuring that the volume of financial resources is commensurate with the program's needs and that the sources of finance are adequately diversified to mitigate financial shocks.

⁸ See Sourcebook for Evaluating Global and Regional Partnership Programs (Independent Evaluation Group, OECD/DAC Network on Development Evaluation, 2006); adapted from the OECD Principles of Corporate Governance (2004).

Audit and evaluation¹⁴: the PAC has set up an Audit Committee that fulfills the audit function.
The evaluation function is not explicitly addressed by the PAC TOR and will be discussed separately.

In a survey, the Panel has asked the PAC and the Management Team about the level of satisfaction with the PAC performance along these governance functions.

Table 5.3. Survey results: satisfaction with governance functions

Core governance function	Highly satisfied	Slightly satisfied	Slightly unsatisfied	Strongly unsatisfied	Number of respondents (in percent of all survey respondents)
Giving strategic direction	88%	12%			N = 17 (94%)
Exercising management oversight	82%	12%	6%		N = 17 (94%)
Fostering stakeholder participation	29%	65%	6%		N = 17 (94%)
Risk management	65%	29%	6%		N = 17 (94%)
Conflict management	53%	47%			N = 17 (94%)
Audit and evaluation	88%	6%		6%	N = 17 (94%)

Overall, satisfaction levels were high and in general PAC and Management Team responses followed the same trend. For detailed survey results, please refer to the Annex 10.

From this self-assessment, the largest improvement potential – if any – can be identified for "Fostering stakeholder participation" and for "Conflict management". These functions coincide with those functions that were not – or not entirely – covered by the PAC TOR.

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

¹³ Monitoring and managing the potential conflicts of interest of members of the governing body and staff of the management unit. Monitoring and managing conflicting interests among program partners and participants, especially those that arise during the process of program implementation.

¹⁴ Ensuring the integrity of the program's accounting and financial reporting systems, including independent audits. Setting evaluation policy, commissioning evaluations in a timely way, and overseeing management uptake and implementation of accepted recommendations. Ensuring that evaluations lead to learning and programmatic enhancement.

these points in the report are based on the Panel's observations within HarvestPlus and selected stakeholder and program partner interviews.

One answer indicating "strong dissatisfaction" with the governance performance in terms of "audit and evaluation" has been followed up with an interview revealing dissatisfaction with financial management quality in some parts of the Joint Venture.

As pointed out before, the Panel shares the overall positive assessment on PAC performance. Apart from the functions highlighted above, some oversight functions of the PAC merit closer attention and will be discussed later in this chapter.

Role and Accountability of PAC vis-à-vis the Boards of CIAT and IFPRI

Since HarvestPlus is a hosted program, the center boards of CIAT and IFPRI share some of these governance functions with the PAC and carry the ultimate legal and fiduciary responsibility.

Rather than taking an active role in HarvestPlus related decisions, both center boards have chosen to have some representation on the PAC – and to delegate their authority up to a certain degree to the PAC. According to the Panel's observations, the center boards have never rejected a PAC decision so far.

This leads to the question on how the responsibility for governance functions, and the related accountability, is distributed between the PAC and the center boards, i.e. the role of the PAC visà-vis the role of the center boards.

The HarvestPlus Governance and Management Handbook describes the role of the PAC as follows.

"The HarvestPlus PAC is an external independent advisory body that provides governance and oversight to facilitate the Program's complex collaborative arrangements. The PAC is not a legal entity, but has been delegated authority from the CIAT and IFPRI Boards of Directors. (...)"

A similar statement can be found in the original program proposal, and in the Cooperative Research Agreement between CIAT and IFPRI.

In the HarvestPlus Governance and Management Handbook, the role of the CIAT and IFPRI boards are described as:

CIAT and IFPRI have entered into a Cooperative Research Agreement (March, 2003) with the objective of cooperating with each other in the development and implementation of the BCP, now known as HarvestPlus, to achieve the objectives set out in the BCP proposal.

Both the CIAT and IFPRI Board of Directors have delegated their authority and related responsibilities to the Program Advisory Committee (PAC) to undertake their mandate as an independent expert body. The Director-Generals of CIAT and IFPRI are responsible for reporting to their respective Boards on progress made under HarvestPlus.

From these statements alone, the degree of delegated authority does not become entirely clear. Does the PAC have a strict advisory role, i.e. can its recommendations be overruled by center boards' decisions? Does the PAC have governance authority for some functions and the center

boards for others? Or is the PAC the ultimate decision-making body for HarvestPlus – with full accountability for its actions and decisions?

As far as the Panel could determine, the IFPRI board has not decided to explicitly delegate certain of its oversight functions to the PAC nor specified the respective degrees of delegation, but has rather acknowledged that the PAC exists "as a mechanism of oversight from the Boards of IFPRI and the International Center for Tropical Agriculture (CIAT)" and that the PAC approves the HarvestPlus budget¹⁵.

Although requested, no information concerning delegation of oversight functions from the board of CIAT has been obtained.

The PAC itself is divided about its role. In the tables below, the PAC and the Management Team were asked about their level of agreement with the two following statements.

Table 5.4. Survey results: PAC as advisory body?

Respondent group	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree	Number of respondents from that group (in percent of all survey respondents from that group)
PAC	33%		17%	50%	N = 12 (100%)
Management			33%	67%	N = 6 (100%)
All	22%		22%	56%	N = 18 (100%)

[&]quot;De facto the PAC is a program steering committee with decision-making power"

Table 5.5. Survey results: PAC as program steering committee?

Respondent group	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree	Number of respondents from that group (in percent of all survey respondents from that group)
PAC	58%	17%	8%	17%	N = 12 (100%)
Management	80%	20%			N = 5 (83%)
All	65%	18%	6%	12%	N = 17 (94%)

In both cases, a division of PAC members into a majority seeing the PAC as a steering committee with decision making power and into a minority perceiving the PAC as an advisory body without decision-making power can be observed.

The Management Team, however, clearly tends to see the PAC as the main HarvestPlus authority.

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[&]quot;The PAC is an advisory body without decision-making power"

¹⁵ Minutes of the IFPRI Board Executive Committee Meeting, December 10, 2003.

One Panel member has outlined these survey results during the 9th PAC meeting in June 2007. In the ensuing discussion, PAC members suggested to further clarify the role of the PAC vis-à-vis the boards of CIAT and IFPRI and to analyze potential implications, e.g. in terms of insurance coverage of PAC members and in terms of general HarvestPlus liability.

The Panel finds that the Challenge Program, CIAT and IFPRI would collectively profit from a further clarification of how authority and accountability are divided between the PAC and the center boards.

The Panel also considers the independence and authority of the PAC as important ingredients for continued HarvestPlus success and therefore encourages the boards of CIAT and IFPRI to strengthening PAC's independence up to the maximum level compatible with the present hosting arrangement. This implies a careful analysis of governance-related risks and risk mitigation mechanisms from both the PAC's as well as from the center boards' perspectives along all governance function relevant for HarvestPlus. The results of this risk assessment may well influence the exact distribution of authority between the PAC and the center boards.

Finally, after this clarification has taken place, a change of name for the PAC should be considered, since the current name clearly indicates an advisory function (Program *Advisory* Committee) that might not reflect the actual functions assigned to the PAC.

The Panel suggests that the CIAT and IFPRI board further clarifies 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.

Oversight over Commissioned Research Funding and Competitive Grant Mechanisms

As part of its strategy-setting and management oversight functions, the PAC oversees the implementation of HarvestPlus projects through commissioned and competitive mechanisms.

Commissioned activities are approved by the PAC as part of the annual HarvestPlus budgets. This includes, implicitly, the approval of the selection of partners for these activities.

Commissioned activities account for the vast majority of HarvestPlus activities. About 95% of funds are disbursed for such activities¹⁶. As detailed in the section on project monitoring in this report, the Management Team's oversight over commissioned major has natural limitations.

In view of the large budget share for these activities, as well as the limited penetration depth the PAC can possibly have in overseeing performance of single projects, even if large, the Panel recommends that the PAC complements the Management Team's monitoring activities by commissioning independent assessments of the quality and cost-effectiveness of results obtained by commissioned (and competitive) activities. These external reviews are not intended to replace or duplicate the current monitoring activities of the Management Team but to complement them by an independent, in-depth component.

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 $^{^{16}}$ Based on HarvestPlus Management Team estimate of 1.25 million US\$ for competitive bids and total disbursed cash of ca. 25 million for 2003-2006 for HarvestPlus Research (Addendum to IFPRI Financial Report 2006).

For competitive grants, the PAC carries a more direct responsibility overseeing the selection of independent reviewers, the content and target group of the competitive bid invitation and the selection of proposals following recommendations from independent experts. The HarvestPlus Management Team is responsible for the preparation and the implementation of this process.

Triggered by an external audit of another Challenge Program in 2006, the CGIAR Internal Audit Unit has begun to define a policy for competitive grants processes to guarantee full accordance with the CGIAR Financial Guidelines, specifically with the Financial Guideline 6 that covers procurement and under which Challenge Program competitive bids, somewhat surprisingly to the Panel, seem to fall. The recent audit of both the CIAT and the IFPRI component of HarvestPlus has also highlighted the importance of addressing this point, albeit without going deeper into the matter. In its October 2006 meeting, the PAC has tasked the PAC Audit Committee to ensure that best practices are followed for competitive bidding processes.

While, as far as the Panel could observe, the competitive process contains all necessary elements for independent selection and fair competition, it is not guaranteed that the current process is in full accordance with the CGIAR procurement guideline (CGIAR Financial Guideline Number 6), as required for Challenge Programs.

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.

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.

The PAC Audit Committee

HarvestPlus, as a hosted program, largely relies on the auditing functions of its host centers, CIAT and IFPRI. Both centers include an addendum detailing all HarvestPlus-related expenditures in their externally audited annual financial reports. In addition, since the host centers manage all HarvestPlus finance operations, the center-internal controls and audits apply to HarvestPlus as well.

In addition to the centers' internal and external audit capacities, HarvestPlus has set up a PAC Audit Committee in 2004. The committee consists of an independent chair who also became a PAC member and of the chairs of the CIAT and IFPRI Board Audit and Finance Committees.

The PAC Audit Committee provides an independent expert opinion on HarvestPlus finance and finance-related processes. It also oversees and reports to the PAC on the implementation of finance-related recommendations as far as HarvestPlus is concerned.

For example, in 2006, both the CIAT- and the IFPRI-components of HarvestPlus have been audited by the respective centers' internal auditors in collaboration with the CGIAR Internal Audit Unit. A total of 33 recommendations (16 in the CIAT-component and 17 in the IFPRI-component, with partial overlap) were contained in the audit reports in October (IFPRI) and November (CIAT) of 2006.

The Panel did not assess to what degree the recommendations have been addressed since progress will be verified by the centers internal audit units in August 2007. The Chair of the Audit Committee stated that most of the recommendations are currently being implemented by the host center management or by HarvestPlus.

Audit Committee meetings normally take place just before PAC meetings and are also attended also by the Program Director, as well as the CIAT and IFPRI Directors of Finance.

The Governance and Management Handbook describes the Audit Committee's tasks as follows:

"The Audit Committee provides assistance to the PAC in fulfilling its fiduciary responsibilities related to HarvestPlus' accounting practices, internal financial controls and reporting practices, and other administrative policies and procedures. Specifically, the Committee:

- 1. Reviews and recommends to the PAC for approval an audit plan (and objectives) for the subsequent year.
- 2. Maintains, through regular confidential meetings, a direct line of communication between the PAC and the external auditors of CIAT and IFPRI.
- 3. Ensures that financial transactions of HarvestPlus are properly audited by the external auditors of CIAT AND IFPRI and disclosed in the supplementary schedules to the audited financial statements of CIAT and IFPRI.
- 4. Reports to the full PAC on the supplementary reports on HarvestPlus activities prepared by CIAT and IFPRI.
- 5. Considers legal issues placed before it by counsel and recommends to the PAC appropriate

The Chairperson of the Audit Committee periodically reviews the Program Director's expenses and informs the PAC as to whether they are in order."

The Panel is of the opinion that the Audit Committee provides a valuable contribution to HarvestPlus Governance.

Firstly, it introduces necessary financial and administrative capacity into HarvestPlus governance. Amongst measures recommended by the Audit committee were, e.g. the introduction of a clause into HarvestPlus project contracts that protect the Challenge Program against liability risks from unplanned budgetary shortfalls.

Secondly, it contributes to HarvestPlus good governance through being an independent control mechanism for financial and planning matters.

Other PAC Subcommittees

The PAC has set up several additional committees, some of which have ceased to meet regularly or have been disbanded.

The *Executive Committee*, according to the Governance and Management Handbook, comprises of the PAC chair and vice-chair, the respective chairs of the Audit and Nominating Committees, the Director Generals of CIAT and IFPRI, and the Program Director and is chaired by the PAC chair. A valid Executive Committee meeting is constituted if four PAC members are present. The Executive Committee acts on behalf of the PAC in between PAC meetings.

In practice, HarvestPlus decision making in between PAC meetings is done in a more pragmatic way. According to the Panel's observations, the Program Director consults with individual Executive Committee members, or other PAC members, for decisions that exceed his authority. While not exactly observing the above rules for Executive Committee meetings, the Panel finds that the present pragmatic approach has worked well.

The *Nominating Committee* comprises of three PAC members. It prepares PAC membership rotation and proposes new PAC member candidates.

The *Scientific Committee* was originally set up to advise the PAC and the Management Team on specific scientific issues. It consisted of a sub-set of PAC members. In 2006, the PAC decided to provide the scientific advisory function through the entire PAC rather than through a subcommittee.

While the Governance and Management Handbook contains laudably specific terms of reference for the PAC subcommittees, they do not always match the actual practice. It might be advisable to update the Governance and Management Handbook accordingly.

5.2 HarvestPlus Management

Structure

HarvestPlus is managed as a matrix organization. The HarvestPlus Management Team has overall responsibility and manages the program along functional areas as shown in the table below.

Table 5.6. Management Team functions

Function	Responsible Manager	Crops or Area covered						
Breeding	W. Pfeiffer	Phase I Crops and program-wide						
Biotechnology	J. Thome	Phase I Crops and program-wide						
Breeding Objectives (Vitro Screening)	In C. Hotz	Phase I Crops and program-wide						
Human Nutrition	C. Hotz	Phase I Crops						
Food Processing	C. Hotz	Phase I Crops						
Reaching End Users	K. Ampofo	Program-wide						
Impact and Policy	J.V. Meenakshi	Phase I Crops						
Donor Relations as Communications	nd B. McClafferty	Program-wide						
Phase II Crops	W. Pfeiffer	Phase II Crops						
Country Programs H. Bouis Program-wide (Strengthening Regional NARES)								
Program Leadership at Administration	nd H. Bouis	Program-wide						

While mostly focusing on the breeding function, Crop Leaders organize the work for individual Phase I crops across all functions.

Overall management responsibility lies with the Management Team, consisting of 7 individuals

- the Program Director
- the Biotechnology Coordinator
- the Donor Relations and Communications Coordinator
- the Impact and Policy Coordinator
- the Nutrition Coordinator
- the Plant Breeding Coordinator
- the "Reaching the End User" Coordinator¹⁷

The Management Team is assisted by 7 assistants and 1 specialist, who provide support for specific or general functions. Most of these appointments are full-time positions, but some are part-time (e.g. the biotechnology Coordinator with a 25% appointment).

Overall Performance

The program management receives high performance rating from the PAC members. Table 5.7 shows the survey responses to the question: "Please indicate your satisfaction with the performance of the Program Management in terms of the following functions"

Number of

Table 5.7. Survey results: satisfaction with management functions

Management function	Highly satisfied	Slightly satisfied	Slightly unsatisfied	Strongly unsatisfied	respondents from PAC group (in percent of all PAC survey respondents)
Program implementation	75%	25%			N = 12 (100%)
Regulatory compliance	82%	18%			N = 11 (92%)
Reviewing and reporting	84%	8%	8%		N = 12 (100%)
Administrative efficiency	83%	17%			N = 12 (100%)
Stakeholder communication	50%	25%	17%	8%	N = 12 (100%)
Fostering learning	55%	18%	27%		N = 11 (92%)
Performance assessment	55%	36%	9%		N = 11 (92%)

The Panel has had the occasion to interact closely with the Program Director and the Management Team. It finds that the management consists of experienced professionals that show a considerable amount of dedication to the program and take full ownership of their respective functions.

The Panel also finds that the Management Team is operating at the limit of its capacity in terms of workload.

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 $^{^{\}rm 17}$ Staffed until year end 2007.

Accountability of the Management Team

The HarvestPlus Management Team is employed either by CIAT or by IFPRI or, as in the case of the Program Director, jointly by CIAT and IFPRI. As a consequence of this setup, HarvestPlus management is perceived to have responsibilities towards PAC as well as towards CIAT and/or IFPRI management. For example, the performance evaluation of the Program Director is jointly done between the Director Generals of CIAT and IFPRI and the PAC Chair and signed off by all three.

In a survey done for this review, the PAC and Management Team members were asked assess to what degree the HarvestPlus Director was subject to a "two masters problem", i.e. to a situation of unclear or overlapping responsibilities towards the PAC on the one hand and IFPRI/CIAT management on the other hand.

Table 5.8. Survey results: two masters problem?

Respondent group	100% responsible towards IFPRI/CIAT	Mainly responsible towards IFPRI/CIAT	Responsibi- lity evenly distributed towards IFPRI/CIAT and PAC	Mainly responsible towards PAC	100% responsible towards PAC	Number of respondents from that group (in percent of all survey respondents from that group)
PAC answers		9%	45%	36%	9%	N = 11 (92%)
Management Team answers			33%	50%	17%	N = 6 (100%)
All answers		6%	41%	41%	12%	N = 17 (94%)

The PAC essentially is of the opinion that the Program Director's responsibilities are split between the PAC on one side and CIAT and IFPRI management on the other side, with a tendency towards being perceived more responsible towards the PAC.

In the Management Team's opinion, the Program Director is more clearly responsible towards PAC rather than to the center management.

The same analysis has been repeated for the entire Management Team instead of the Program Director with comparable results, albeit with a perception of stronger focus on the PAC as dominant authority (see Annex 10 for complete survey results).

In the Panel's view, the perceived overlapping responsibilities towards the PAC and towards center management are a direct consequence of the organizational setup of HarvestPlus as a whole, having no legal entity on its own and being hosted by CIAT and IFPRI. As pointed out before, the Panel is of the opinion that the "virtual organization" arrangement serves the HarvestPlus purposes well and is an adequate setup for a time-bound program. The Panel therefore does not consider any fundamental change in this setup.

The Panel, however, finds that the degree of influence CIAT and IFPRI can or could exert on the HarvestPlus director is potentially problematic. The Panel sees two reasons for that:

Ambiguity in the vertical chain of command. On the one hand, the director reports to and
receives his instructions from the PAC. On the other hand, the responsibility for his
performance evaluation lies mostly in the hands of his superiors in center line management,

- i.e. with the Director Generals of CIAT and IFPRI. While in the Panel's observation both Director General's have exerted great care of not exerting any undue influence on the Program Director, the current setup does not represent a future structural guarantee.
- Reputation risk. The CIAT and IFPRI Director Generals are in a potential conflict of interest
 situation if HarvestPlus and host center interests do not match (e.g. in the hypothetical
 situation of a proposed decision that would serve the Challenge Program but hurt the
 centers' strategic or economic interests). While such potential conflict of interest is primarily
 an issue to be considered by the host centers, it does pose a reputation risk for HarvestPlus as
 well. It could be argued from an outsider's point of view that center management has the
 possibility of bypassing the PAC and to exerting direct influence on the Program Director.

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.

Concerning the program Management Team and the Program Secretariat, the Program Director seems to have a sufficient level of authority to guarantee coordinated management. According to the Panel's information, the Program Director is in charge of evaluating the performance of Management Team members, while specialists and assistants in the Program Secretariat are evaluated by their respective superiors in the HarvestPlus Management Team.

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.

Project Monitoring

Since most HarvestPlus activities are implemented as projects, one of the most important management tasks is project monitoring.

The HarvestPlus Management Team monitors program and project progress through a project-level reporting system. Most HarvestPlus projects are commissioned on an annual basis. HarvestPlus research contracts oblige the project partners to submit semi-annual and annual reports that consist, apart from introductory information, essentially of a financial and a programmatic progress report.

Semi-annual reports cover a period of 6 months and tend to be slightly lighter than annual reports that cover the entire year.

The financial reports contain actual expenditures to date for project activities along the different budget line items. If variances exceeds both 5,000 US\$ and 10%, a written explanation is required. Financial reports need to be certified by authorized individuals in the respective accounting/finance department.

Programmatic progress reports consist of a narrative that needs to cover objectives and activities, accomplishments, lessons learned, changes affecting project activities, challenges, other sources for project support and an explanation of budget variances. In addition, a series of templates for reporting performance against objectives and outcome indicators, activity monitoring against milestones as well as presentation and publication listings need to be filled out. All reports are

directed at the Management Team member responsible for the function covered by the project. Summarized feedback as well as critical cases are discussed with the Program Director and, if needed, brought to the attention of the PAC.

The Panel examined in greater detail project reporting in the case of two major HarvestPlus research partners, USDA Cornell and the University of Adelaide (breeding objectives). These HarvestPlus partners have received commissioned funding support over 3 to 4 years with rather flexible work programs under the topic "definition of breeding objectives". The projects have expanded their scope and received additional funding through contract amendments without, as far as the Panel could determine, a comprehensive evaluation of their research productivity. The Cooperation with the USDA Cornell and the Adelaide centers was based on 3 initial contracts (contract numbers 8003, 8004 and 8006). These contracts were amended multiple times each reflecting annual contracting, no-cost extensions or extensions of scope. As an example, the Panel presents contract 8003 amendment 4 in the Annex 11, together with a publication progress report. The Panel has not been able to fully ascertain the cost-effectiveness of these commissioned activities and based on the actual publication record there is some concern on the value of the output relative to the resources invested in these very large contracts.

The Panel finds that the Management Team has some rather natural limitations to its oversight over such large-scale project activities. Most of the major contractors are important and long-term partners of HarvestPlus, sometimes also rightly claiming co-ownership of the founding ideas of the Program, with a strong position within the program. The Management Team members charged with project monitoring may thus be placed in a difficult situation when a project underperforms. This is potentially more difficult in scientific areas beyond the direct expertise of Management Team member. There is also a high level of concentration of contracted funding, the top 5 centers get 55 %, and the top 10 are allocated 76 % of the consolidated budget. While only 5 % goes through competitive bidding mechanisms.

These considerations have led the Panel to recommend 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 because of the arguments presented above. A corresponding recommendation has been presented in the governance section of this report.

On the management level, the Panel is satisfied by the current reporting setup, since it concentrates progress information directly at the relevant management level. The Management Team members in charge for individual projects show a great deal of ownership. As far as the Panel could observe, and within the limitations outlined above, there is critical examination of project progress against agreed-upon objectives and milestones. This has in some cases even led to projects being terminated due to underperformance; it seems that the Management Team is showing the maximum independence that can be expected within the constraints mentioned above. Within the current setup, there is room for improvement potential such as e.g. making central expenditure information available in a timelier manner and to further require the consistent use of HarvestPlus contract templates for contractors and subcontractors. This has been identified previously¹⁸ and is currently being followed up by the host centers and the PAC Audit Committee.

¹⁸ "Report on an Audit of the HarvestPlus Challenge Program – IFPRI-Component", October 2006 and "Report on an Audit of the HarvestPlus Challenge Program – CIAT-Component", November 2006.

6 RESOURCE MOBILIZATION AND FINANCIAL HEALTH

6.1 Past Fund Raising Performance and Future Outlook

HarvestPlus has successfully raised funds in the past. Starting with World Bank seed funding of 3 million US\$ in 2003, the Gates Foundation, Danida, Sida and the Austrian Government joined in 2004. In 2005, USAID, DFID, ADB and the International Life Sciences Institute joined as donors.

With exception of the International Life Sciences Institute, all donors provided multi-year funding. In the case of the largest HarvestPlus donor, the Gates Foundation, funding was guaranteed for a 4 year period from 2004 to 2007.

The year 2008 will represent a crossroad for HarvestPlus in terms of funding because of two parallel effects.

Firstly, the Gates Foundation has not yet committed to the next 4 year funding package that had been under negotiation since the end of 2006. One reason for this is an internal restructuring at the Gates Foundation, leading to a transfer of the HarvestPlus account from the health sector into the agricultural sector. In early 2007 the Gates Foundation indicated that it required more time to make a decision on the new four year plan. In consequence, the idea of bridge funding for 2008, with a subsequent proposal for 2009-2012 funding was discussed. Currently, the Gates Foundation is preparing a detailed cost effectiveness assessment for the potential of HarvestPlus crops in various regions of the world. At the time this report was written, the assessment was in its pilot phase. Results are expected in November 2007. On the basis of that assessment, the Gates Foundation plans to decide on future funding.

Secondly, several "traditional" HarvestPlus donors such as the World Bank, USAID, and Danida may reduce their commitments to HarvestPlus for 2008. The reasons for this differ by donor, for example.

- The World Bank may split its total Challenge Program allocation amongst a growing number of Challenge Programs in 2008 or 2009 while at the same time focusing primarily on kicking off new Challenge Programs.
- USAID currently funds HarvestPlus from two sectors: the agricultural and the nutrition sector. In interactions of the Panel with USAID it was indicated that, while funding from the agricultural sector is assumed to remain stable, funding from the nutrition sector is likely to decline, due to the perceived long time to impact for biofortification compared to other fortification methods. This is not considered to be in line with current priority setting in the nutrition sector of USAID.

The fact that the Gates Foundation and some other traditional HarvestPlus donors are reviewing their funding puts HarvestPlus in a situation marked by some uncertainty. While HarvestPlus management and the PAC are reasonably confident of receiving funds as planned, based on positive signals e.g. from the Gates Foundation, a series of measures have been planned to mitigate financial risk.

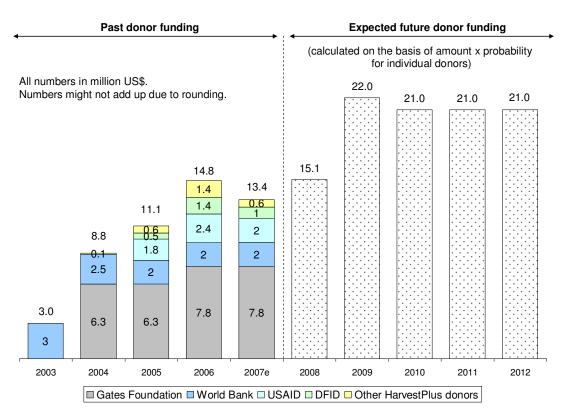
Firstly, HarvestPlus has launched a new fundraising effort, focusing on European bilateral and multilateral donors. The HarvestPlus director has visited several European donors and research proposals will be submitted to the 7th European Union Framework Program.

Secondly, HarvestPlus has adapted its work plans for 2008, adjusting them to the level of expected funding for 2008.

Finally, in its last session, the PAC has decided to develop a contingency plan in order to be prepared for a situation where expected major funding would not materialize.

The overall past and expected future sources of funding are depicted in the table below. For the purpose of extrapolating future funding, the HarvestPlus management has been asked to estimate potential funding levels for each donor, and then to discount them with the perceived probability for obtaining commitment for these funds. This implies that, in the case all funding materialized entirely, considerably higher funding levels would be obtained (e.g. 40 million US\$ in 2009). However, in order to avoid interference with ongoing donor communication, the Panel has decided not to show expectations for individual donors but rather the sum of expected future donor funding for 2008 to 2012 below. The actual donor funding for 2003 to 2007 are based on the HarvestPlus Strategic Plan 2008-2012.

Figure 6.1. Past and future donor funding



The Panel finds that the high level of past commitment – and the prospect of further increased future funding – represents a laudable achievement and confirms the actuality and relevance of the HarvestPlus mission.

In the same instance, the dependence on the Gates Foundation as dominant donor also poses the largest funding-related risk for HarvestPlus.

In the past (2003-2007), the Gates Foundation has provided over half (55%) of HarvestPlus funding and in future plans this share is expected to grow, while total funding from other donors (existing and new, with similar contributions) is expected to be stable.

In this situation, the Panel finds it crucial that HarvestPlus safeguards and strengthens its independence with respect to individual donors in several aspects.

- Financial independence. Obviously, the first HarvestPlus priority must be to secure sufficient overall funding levels to allow for successful program implementation. However, a secondary goal should be a balanced donor mix, with no single donor dominating the HarvestPlus funding exclusively. Such an approach would minimize financial risks such as changing donor priorities, as well as render the program more independent in pursuing its original goals. The Panel would like to point out, however, that the donor mix is a second priority and should not interfere with overall fundraising for the program. Other global programs have, e.g., fared well while being almost exclusively dependent on one donor.
- Management resource allocation. The HarvestPlus Management Team needs to balance its
 allocation of time and effort to different donors. The Gates Foundation, for example, currently
 pilots a large-scale review of HarvestPlus that will also require considerable investment of
 HarvestPlus management resources. While without doubt important, this should, in turn, not
 lead to neglecting information needs of other existing or potentially new donors.
- Program strategy. Different donors have different philosophies regarding their influence on
 the strategy of programs funded by them. Some donors, such as DFID, have refrained from
 interfering with HarvestPlus strategy at all. Others expect that some strategic requirements
 are to be incorporated into program strategy. The Panel finds that, as for the points above, a
 delicate balance is needed between safeguarding the original program goals on the one hand
 while accommodating value-adding donor input on the other hand.

Safeguarding the program's independence along these lines is a delicate and difficult process, marked by trade-off decisions that require a high degree of self-reflection both in the PAC and in the HarvestPlus Management Team.

The Panel has observed a deep level of understanding of the above mentioned issues in both the PAC and the Management Team. The Panel finds that HarvestPlus has managed this difficult situation well.

The measures taken by the Management Team in terms of responding to requirements of major donors as well as the fundraising efforts undertaken by the director in securing new funding seem appropriate and balanced.

The PAC has proven to safeguard key strategic elements of the HarvestPlus approach, e.g. the finite lifetime of about 15 years of the Challenge Program during the last PAC meeting.

The Panel encourages the PAC and the Management Team to continue and further intensify efforts to securing a sufficient and sufficiently balanced program funding making strategic use of its management resources and to safeguard the overall program strategy.

6.2 Performance against Budget

HarvestPlus has reached – and exceeded – its revenue budget targets.

The original proposal (August 21, 2002) proposed a total budget for the first 4 years (2003-2007) of operation of 46 million US\$.

Including the inception year 2003, HarvestPlus revenue will reach about 52 million US\$19 at year end 2007, if all pledged donor commitments materialize.

In terms of budgeted and actual expenditures, HarvestPlus has a policy in place (as part of the Cooperative Research Agreement) that allows for contracting research only under the condition that necessary funds are available. In addition, project contracts contain a clause that allows for project termination if pledged donor funding does not materialize. On the basis of these provisions, HarvestPlus is effectively shielded against overspending its budget through contracted research. Past and planned budgeted expenditures are summarized in table 6.2.²⁰

Figure 6.2 Past and planned budgeted expenditures

	Budgeted					Proposed			
Activity	2003-2004 Actual	2005 Actual	2006 Actual	2007 Estimated	Total 2003 – 2007	2008	2009	2010	Total 2008- 2010
Crop Breeding & Reg Coll	4.842	5.944	6.098	5.644	22,528	6.124	6.369	6.624	19,117
Beans	415	326	352	325	1,418	417	434	451	1,302
Cassava	575	516	490	375	1,956	581	605	629	1,815
Maize	543	581	697	660	2,481	758	788	820	2,366
Rice	476	473	474	400	1,823	728	757	787	2,272
Wheat	462	484	641	546	2,133	735	765	796	2,296
Sweet Potato	422	371	495	420	1,708	587	610	634	1,831
Phase 2 Crops	1.000	800	902	877	3,579	1062	1104	1148	3,314
Tech Asst+Reg Coll+Coord	628	1,605	1.441	1,270	4,944	1256	1306	1358	3,920
Other Restricted	321	788	606	771	2,486				
Nutritional Genomics	1,129	919	1,515	895	4,458	1,566	1,629	1,694	4,889
Human Nutrition	1.343	1,886	2.627	1,991	7,847	2.492	2.592	2.696	7.780
Food Science and Nutrition	350	1,046	1.801	1,261	4,458	1.600	1.664	1.731	4,995
Breeding Objectives	993	840	826	730	3,389	892	928	965	2,785
Impact and Policy Analysis	1,303	908	1,342	977	4,530	1,338	1,392	1,448	4,178
Reaching & Engaging End- Users	57	236	2,178	2,951	5,422	3,213	3,342	3,476	10,031
Communications	360	266	275	293	1,194	302	314	326	942
					1,101				
Management and Coordination	2,206	1,045	1,417	1,293	5,963	1,358	1,412	1,468	4,238
Total Expenditures	11.241	11,204	15,452	14.045	51,941	16.394	17.050	17,732	51,176

Being not unusual for programs that depend on donor contributions, HarvestPlus budgets are adjusted year by year.

6.3 Financial Health

Financial transactions of HarvestPlus, inflows and outflows of funds, are processed through the accounting and internal control systems of CIAT and IFPRI. The two centers prepare an annual supplemental schedule to their audited financial statements showing sources and application of

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¹⁹ Including other income (mainly interest) of about 1.3 million US\$.

²⁰ HarvestPlus Medium Term Plan 2008-2010.

funding on a cash receipts and disbursements basis. For the 4 initial HarvestPlus years, overall cash has evolved as shown in table 6.1.²¹

Table 6.1 Cash evolution

In million US\$	Year end 2003	Year end 2004	Year end 2005	Year end 2006
Cash receipts	10.1	4.0	15.6	12.6
cumulated	10.1	14.1	29.8	42.3
Disbursements	2.0	7.8	9.5	12.6
cumulated	2.0	9.9	19.3	32.0
Cumulated	8.1	4.1	10.4	10.4
undisbursed cash ²²	(1.458 days)	(198)	(401)	(300)

The high amounts of cash held on behalf of the Challenge Program at year ends 2005 and 2006 reflect the program's policy of only awarding project contracts when funds are secured.

The CGIAR indicators for financial health cannot be directly applied to Challenge Programs. Most of the CGIAR standard financial performance indicators are determined from the balance sheet of individual centers. These ratios cannot be directly applied to the HarvestPlus as there is no HarvestPlus balance sheet. In a strict CGIAR accounting sense, HarvestPlus itself is a restricted program and as such cannot generate unrestricted net assets. Unrestricted Net Assets are generated by unrestricted funding surpluses.

The undisbursed cash shown in the table above may however be used as a proxy for the short-term liquidity financial indicator. As can be seen, HarvestPlus has held 10.4 million US\$ in cash at year ends 2005 and 2006. For year end 2007, on the basis of the budgeted revenues and expenses, a similar cash level of about 10.2 million US\$ (or 264 days)²³ can be expected.

Since most of these funds are already committed to projects, this indicator does not provide information about the "unallocated cash reserve", i.e. the amount of unallocated, uncommitted and unbudgeted funds that are still free for use within program purposes.

The HarvestPlus Audit Committee estimates that at year end 2006, the size of such an unallocated cash reserve is at about 3 million US\$ or 87 days^{24.}

It is expected that this reserve will be drawn further down in 2007, reaching the level of total accumulated interest of ca. 0.75 million US\$ or 20 days²⁵ in year end 2007.

²¹ Numbers might not add up due to rounding.

²² Number of days calculated on basis of total expenditures of that same year and 365 days per year.

²³ Budgeted revenues and expenditures for 2007 are 13.9 and 14.0 million US\$ (Strategic Plan 2008-2010). Using these values as proxies for expected cash receipts and disbursements in 2007, the cumulated undisbursed cash will be 10.2 million US\$ at year end 2007 (differences due to rounding).

²⁴ Based on actual disbursements of 12.6 million US\$ in 2006.

 $^{^{\}rm 25}$ Based on budgeted expenditures of 14 million US\$ in 2007.

The decrease is a consequence of reaching the end of HarvestPlus' first program phase. In accounting terms, most HarvestPlus donor funds are restricted in the sense that they have to be spent for program purposes in the timeframe negotiated with the donor, i.e. in the respective program phase.

The Panel endorses a recent recommendation of the PAC that HarvestPlus keep an uncommitted cash reserve that allows to cover unexpected program expenditures and covers the management and governance costs for a reasonable time. The minimum level of such a cash reserve is to be calculated to cover a contingency scenario that would allow an orderly wind-down of HarvestPlus activities in the event of significant and unfavorable changes in donor funding.

It should be kept in mind, however, that HarvestPlus is a program with a finite lifetime. Such a reserve would therefore remain limited and should be used for program purposes at the end of the last HarvestPlus phase.

In its last meeting, the PAC has discussed the necessity to analyze the necessary size of such an unallocated cash reserve. Results are expected before year end 2007.

The program efficiency (indirect cost ratio) can be approximated by the transaction cost ratio, defined as management and administration disbursements divided by research-related disbursements, based on the information available in the supplemental schedule to the financial reports of CIAT and IFPRI.

Table 6.2. Transaction cost ratio

In million US\$	Year end 2004 (including 2003)	Year end 2005	Year end 2006
Disbursements for research	6.92	7.53	10.80
Disbursements for program management and administration	2.95	1.95	1.82
Transaction cost ratio*	43%	26%	17%

The non-research related disbursements include some²⁶ disbursements for the Management Team, for HarvestPlus governance, for HarvestPlus communication, as well as a 4% administrative fee paid to CIAT and IFPRI for financial management of research funds²⁷.

Research related disbursements include all contracted research at CIAT, IFPRI and all other HarvestPlus research partners and include indirect cost²⁸.

With the above definition, the transaction cost ration for HarvestPlus dropped from a high initial value (43%) in 2003/2004 to 26% in 2005 and ultimately to 17% in 2006.

The Panel generally finds that the 2006 level of expenditures for management, governance and administration is adequate.

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²⁶ E.g. most functional coordinators are project-financed.

²⁷ The administrative fee is not charged on research funds of CIAT and IFPRI.

²⁸ E.g. for 2006, audited indirect cost rates were 15.08% for IFPRI and 19.65% for CIAT.

As pointed out previously, the Management Team is operating at capacity limits while showing high performance. The management also seems to show a high degree of cost sensitivity. The Program Director, for example, travels in economy class even on intercontinental flights. 10 out of 12 PAC respondents (83%) in the survey done for this report are "highly satisfied" with the administrative efficiency of the Management Team. The Panel finds that either reducing size or cost per employee (salary levels) significantly would most probably lead to a loss in overall performance that would outbalance the cost savings significantly.

Concerning governance costs, the Panel is of the opinion that the current PAC meeting frequency of two in-person meetings per year constitutes one of the reasons for HarvestPlus' strong governance performance. HarvestPlus management has stressed the importance of the strong guidance through the PAC in its day to day business. The size of the PAC might be reduced slightly, but the Panel is of the opinion that a "Steering Group of no more than 7 members", as originally proposed by the CGIAR²⁹ would not allow for the representation of the spectrum of expertise needed in the current setup. The obvious alternative would be a small Executive Steering Committee or Board that could draw on experience from expert and/or stakeholder groups. The Panel is however of the opinion that the present HarvestPlus setup represents the more cost-efficient alternative.

The administration fee level of 4% is a CGIAR standard and has been audited in 2006. This fee is applied to research-related expenditures only and CIAT and IFPRI research remains excluded. This arrangement seems reasonable to the Panel.

The last transaction costs cost driver, communication, has not been analyzed in detail by the Panel. The overall communication ansatz and strategy seem appropriate. HarvestPlus target groups have been identified and are addressed. As a general rule, a stronger focus on targeting messages at well-defined target group segments may increase communication efficiency further.

The Panel endorses the recent PAC recommendation that HarvestPlus defines and builds up an adequate unallocated cash reserve. The minimum requirements for this reserve would be defined by a contingency scenario that would allow for the eventual orderly conclusion of HarvestPlus program activities. If no contingency arises the funds would enter the final year budget.

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²⁹ See "Guidelines for the Governance and Management of Challenge Programs" in CGIAR Reform Program 2001, CGIAR Secretariat, April 25, 2002.