CGIAR

RESEARCH PROGRAM ON Agriculture for Nutrition and Health

Submitted by IFPRI

PROPOSAL FOR PHASE II

2017–2022

SECTION 2

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CGIAR

Led by IFPRI

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SECTION 2.2
Flagship 2: Biofortification

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SECTION 2.2

SECTION 2: Flagship Program (FP2) on Biofortification

RATIONALE AND SCOPE

Micronutrient deficiency affects approximately 2 billion people globally. Children who are micronutrient deficient in early childhood are at a much higher risk of infections, and less able to recover than healthy children. It is estimated that 150 million years of healthy life were lost to poor nutrition in 2004—five times that lost to malaria (Department for International Development 2009).

A major cause of micronutrient deficiencies is poor-quality diets resulting in low intakes of key micronutrients. Vitamin A deficiency, which increases susceptibility to infection and can cause irreversible blindness, remains a significant public health challenge across Africa and Asia and in parts of South America. An estimated 33% of preschool-aged children (190 million) and 15% of pregnant women (19 million) do not have enough vitamin A in their daily diet (World Health Organization 2009). Iron deficiency, which causes anemia, lethargy, and reduced cognitive performance, affects about 25% of the world's population, most of them women and preschool-aged children. The proportion of developing-country populations at risk of inadequate zinc intake is estimated to be 25–33%. Zinc deficiency is associated with poor growth and impaired response to infection.

Biofortification uses plant breeding to improve the nutritional content of food crops. It addresses Sustainable Development Goal (SDG) 2, to end hunger, achieve food security and improved nutrition, and promote sustainable agriculture. By focusing on staple foods that poor people already eat, biofortification provides a comparatively inexpensive, cost-effective, sustainable, long-term means of delivering more micronutrients to the poor. Breeding staple crops for higher levels of vitamin A, zinc, and iron is technically feasible with conventional breeding. All biofortified crop varieties that have been released to date are competitive with or better than the best varieties farmers currently grow, in terms of productivity and other traits that farmers and consumers value.

The long-run solution to micronutrient deficiency is to improve the quality and diversity of diets. Improving dietary diversity is a complex and long-term undertaking that involves reshaping food systems. In the CGIAR Research Program (CRP) on Agriculture for Nutrition and Health (A4NH), FP2: Biofortification is undertaking this work. In the meantime, increasing the micronutrient content of staple commodities that the poor consume can reduce inadequate intakes and reducing micronutrient deficiency. Conventional approaches to tackling vitamin and nutrient deficiencies, like supplementation and fortification, require continual financial outlays, and there are challenges ensuring coverage, particularly in areas where services and markets are weak. Biofortification complements these approaches and is available to rural populations, and nutritionally vulnerable urban ones, who are difficult to reach through other nutrition interventions.

Even as evidence to biofortification grows, more research is needed to support scaling out and learning about delivery of biofortified crops through a systematic approach, especially to assess effectiveness and delivery at scale through markets, and to mainstream biofortification into crop improvement research, nutrition and agriculture policy, and partner activities.

Using a Theory of Change (ToC) for each country-crop combination, we identified evidence gaps and research questions relevant to delivery. In Phase II, strategic research will include impact assessments of delivery channels; efforts to better understand intrahousehold dynamics around adoption and consumption; and studies to identify mechanisms to maximize adoption and consumption of biofortified crops. As countries demand more biofortified crops, we need to better understand the nutritional impact and potential synergies of the biofortified "food basket" in which people consume a combination of biofortified crops. Partners are increasingly taking up and distributing biofortified crops, and it is important to assess the impact of these delivery efforts.

Determining the full impact at scale of biofortification can currently be estimated using ex ante models to simulate the impact of the intervention, and these suggest that biofortification is a cost-effective intervention, per World Bank standards. Effectiveness studies are planned for Phase II, to better understand the impact of biofortification and changes in the nutritional status of populations in real-world conditions.

HarvestPlus, which leads FP2, will strengthen its emphasis on mainstreaming biofortification into partners' crop development work and shift its long-term focus to scale up biofortification, retaining a focus on evidence, knowledge production and sharing, monitoring and evaluation, and technical assistance to assure impact at scale.

This FP builds on a strong history of strategic CGIAR crop breeding for important traits combined with nutrition evaluation to develop biofortified food crops, and is a logical extension of engagement with national implementing and enabling partners to extend these crops at scale. The clusters of activity (CoA) in this FP will build on previous research to mainstream biofortified traits into crop development research, while also focusing on learning about delivery in a contextually rich world of markets, farmer behaviors, and dietary practices. In Phase II, filling key evidence gaps and capturing lessons learned is critical, and will involve intensifying the work of promoting production and consumption in target countries as a "proof of concept" of the approach, analyzing the effectiveness of delivery mechanisms, and developing lessons for scaling up. This evidence will contribute to promoting an enabling environment for biofortification and developing tools to facilitate delivery by others.

OBJECTIVES AND TARGETS

FP2 addresses the problem of micronutrient deficiency due to inadequate dietary intake of micronutrients, contributing to the second system-level outcome (SLO2) on *improved food and nutrition security for health* through the intermediate development outcomes (IDOs) of *improved diets for poor and vulnerable people*, *increased productivity* (**Figure 2.2.1** and Performance Indicator Matrix-Table C) and all three cross-cutting IDOs. Improvements in productivity will also contribute to the SLO on *reduced poverty*.

During Phase II, this FP aims to:

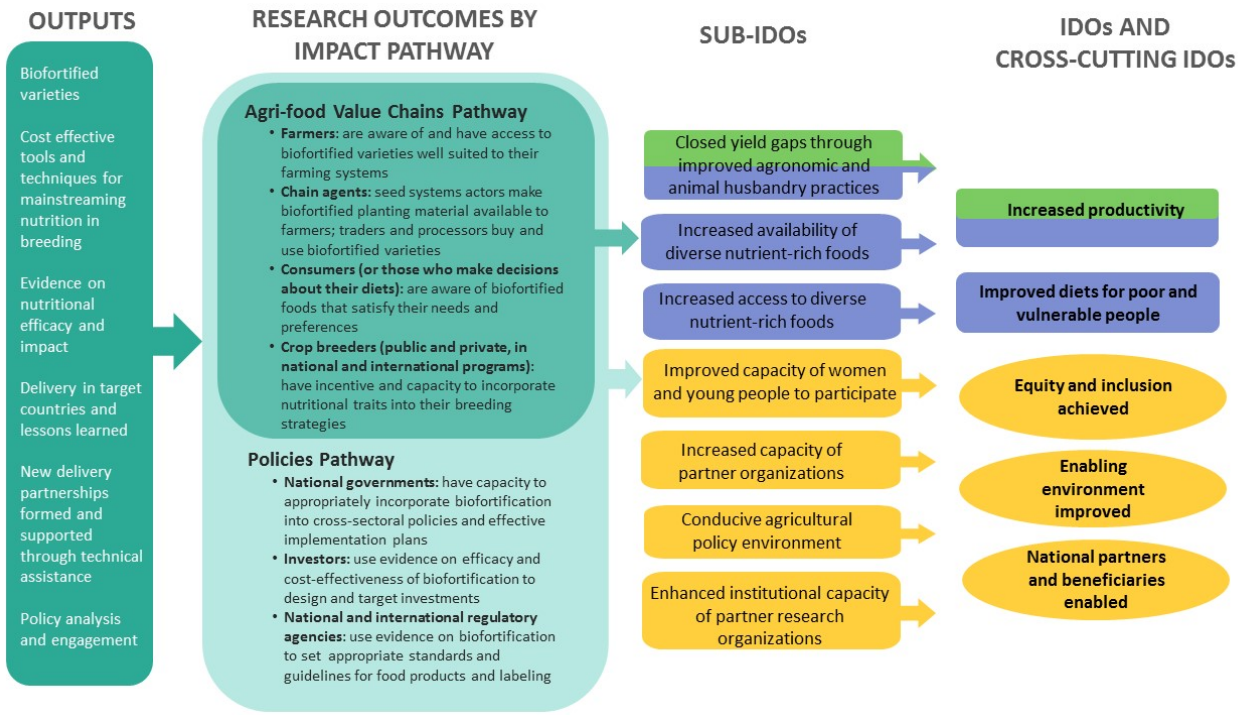
1. Assess the viability, cost-effectiveness, and impact of scaling up in the nine priority countries (Bangladesh, Democratic Republic of Congo (DRC), Ethiopia, India, Nigeria, Pakistan, Rwanda, Uganda, and Zambia) where HarvestPlus and national partners are taking the lead, in addition to those reached by partners working in other countries;
2. Develop and submit for national release biofortified varieties in target and expansion countries, while mainstreaming biofortification into CGIAR and national agricultural research system (NARS) breeding efforts; and
3. Provide evidence and analysis, and strengthen capacity and leadership to integrate biofortification into policy, program development, and implementation, to support the scaling up of biofortification.

By 2022, FP2 expects to have achieved the following (see Performance Indicator Matrix – Tables B and D for more):

- 20 million households will be growing and consuming biofortified crops (14 million reached directly by HarvestPlus and delivery partners [8.5 million in Africa and 5.5 million in Asia]; 6 million reached directly through partners and institutions);
- Varieties with the full target micronutrient content will be released in target countries and will be in release pipelines in partnership countries;
- Biofortified traits will increasingly be mainstreamed into CGIAR Centers' crop development work for target crops/agroecologies, annually increasing by 2.5% of breeding efforts
- Effectiveness evidence will be published for bean, wheat, and multi-crop system (orange sweet potato and bean) and will inform scaling efforts;

- Delivery lessons learned in target countries will be documented and applied in scaling up biofortification;
- Capacity will be built in at least 12 partner organizations to implement technically strong, cost-effective, and gender-sensitive programs that drive the uptake of biofortified crops;
- 20 countries with biofortified crops will be included in nationally or externally funded programs, with an array of public and/or private partners;
- Codex Alimentarius will adopt criteria for use of biofortification terms on food labels; and
- Biofortification will be included in national and regional policies, as well as WHO guidelines on micronutrient deficiencies.

FIGURE 1.2.1. IMPACT PATHWAYS FOR FP2: BIOFORTIFICATION



More specifically, FP2 will make contributions to two 2022 CGIAR targets: 20 million more farm households that have adopted biofortified varieties and 43.1 million more people, of which 50% are women, without deficiencies of one or more of the following essential micronutrients: iron, zinc, iodine, vitamin A, folate, and vitamin B12 (Performance Indicator Matrix – Table A).

Target Geographies

HarvestPlus's delivery science work focuses on the nine target countries (Bangladesh, DRC, Ethiopia, India, Nigeria, Pakistan, Rwanda, Uganda, and Zambia) where HarvestPlus and national partners are taking the lead. Target countries represent a variety of market environments for biofortified crops, from a primarily commercial private sector approach (India, Zambia), to various mixed public-private delivery systems (Bangladesh, Nigeria, Rwanda, Uganda), to primarily public or social marketing systems (DRC). HarvestPlus also works closely with government-sponsored biofortification programs in Brazil, China, and India. Through the HarvestPlus Latin American and Caribbean (LAC) program, led by EMBRAPA, HarvestPlus provides technical assistance and support to government-driven biofortification programs in Bolivia, Colombia, Guatemala, Haiti, Nicaragua, and Panama and is exploring efforts in several additional countries. Increasingly, HarvestPlus is seeking partners to take the lead in scaling up biofortification in partnership countries, a growing list that includes Ghana, Kenya, Malawi, Tanzania, and Zimbabwe, and is expected to

include several additional countries, such as Cambodia, Indonesia, Myanmar, Nepal, Sri Lanka, and Vietnam by the end of Phase II.

By 2030, HarvestPlus's aspirational goal is for 1 billion people to be regular consumers of biofortified staple foods. The roadmap to reaching 1 billion is still under development, and continues to be informed by lessons learned in target countries, detailed value chain analyses, and capacity assessment and strengthening of key actors, all of which will be a focus in the first years of Phase II. Key considerations for sustainability and scaling up are discussed in the next section.

IMPACT PATHWAY AND THEORY OF CHANGE

Available evidence and experience suggests that the goal of reaching 1 billion people by 2030 is audacious, but not impossible. To date, HarvestPlus has facilitated the release of biofortified varieties of six staple crops (vitamin A orange sweet potato, iron beans, vitamin A cassava, vitamin A maize, zinc rice, and zinc wheat), and several secondary staples (vitamin A banana/plantain[1], iron cowpea, zinc and iron lentils, iron and zinc potato, and iron and zinc sorghum). Biofortified varieties have now been released in 30 countries and are in multi-location testing in 42 countries. In 2015, biofortified planting materials reached more than 2 million farmers in HarvestPlus priority countries.

The pathway from research—through seed dissemination, adoption, and consumption—to improved diet and micronutrient status is long, complex, and context-specific. This FP has a good understanding of the pathway, specifically in contexts where delivery is taking place. In Phase I, we developed a series of country-by-crop-combination ToCs to identify key outcomes, underlying assumptions and risks for each, and availability of evidence to test them (Johnson, Guedenet, and Saltzman 2015). ToCs identify key areas for research in Phase II, guide country-level delivery and monitoring, and provide a framework for country-level and cross-country learning. ToCs inform scaling approaches in market environments, from the commercially oriented delivery of vitamin A maize in Zambia, to mixed public-private delivery models used in Nigeria and Rwanda. They help identify key areas for further research, like the role of youth in biofortification activities; gender-based differences in preferences and adoption; and unintended consequences of introducing biofortified crops.

Scaling and sustaining impact in target countries during delivery will require: (1) mainstreaming biofortification in agricultural research, together with crop CRPs; (2) learning from existing delivery efforts and developing operational partnerships in new countries; and (3) establishing a policy environment conducive to biofortified crops, in cooperation with the CRP on Policies, Institutions, and Markets (PIM). Based on lessons learned in the first years of delivery and potential risks identified by the ToCs, these activities are critical to attaining the 2022 and 2030 goals. They align with the three critical elements involved in scaling up biofortification: *supply* (agricultural research entities recognize high mineral and vitamin content as core plant breeding objectives), *demand* (consumers see the value of, and demand, high mineral and vitamin content in their staple foods), and *policy* (a wide range of public officials recognize the impact of biofortification to improve public health, and the high economic return to investments and commercial feasibility of biofortification). Scale in Phase II can be achieved only by working with other organizations and institutions to pilot, expand, and manage biofortification initiatives.

Investments in this FP have launched breeding pipelines in CGIAR Centers and NARS with biofortified varieties that are agronomically competitive, disease resistant, have preferred end-use qualities, and have full target levels of micronutrients. To sustain this investment, CGIAR Centers and NARS partners must mainstream biofortification, using micronutrient-dense materials throughout their breeding programs. In

[1] Provitamin A-rich banana varieties are naturally high in pVACs. They are being introduced from their center of origin in the Pacific to Eastern Africa.

2014, Director Generals (DGs) of CGIAR Centers made a commitment to mainstream biofortification, but this commitment requires concrete planning.

To support adoption in target countries and beyond, Phase II will focus on expanding knowledge in key areas, such as farmer and consumer acceptance, youth involvement, nutritional efficacy for a wider range of age and gender groups, and cost-effectiveness assessments (discussed further below). This evidence of lessons learned will be valuable, both to adjust delivery strategies for efficiency, and to help stakeholders decide whether and where to invest in biofortification. We will develop operational partnerships with development organizations interested in mainstreaming biofortified crops. In new partnership countries, we will facilitate multi-location testing by NARS and provide technical assistance and training for NARS. Once a crop is released, partners will take the lead in introducing and using the biofortified varieties.

Significant progress has already been made in mainstreaming biofortification into regional and national policies. At the Second International Conference on Nutrition (ICN2) in 2014, representatives from Bangladesh, Malawi, Nigeria, Pakistan, and Uganda highlighted the role of biofortification in their national strategies to end malnutrition by 2025. Panama and Colombia were among the first countries to include biofortification in their national food security plans. Since the 2nd Global Conference on Biofortification in 2014, biofortification has been included in national nutrition strategies in Nigeria, Rwanda, and Zambia. HarvestPlus is engaged with regional and global processes, like the African Union's Comprehensive Africa Agriculture Development Programme (CAADP) and the Scaling Up Nutrition (SUN) Movement, to ensure an enabling environment for biofortification. Efforts are underway to include biofortification in global standards and guidelines for food products and labeling, such as the Codex Alimentarius, the food standards-setting agency administered jointly by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) and recognized by the Sanitary and Phytosanitary Agreement (SPS) of the WTO as its reference organization. This work will be linked to work in A4NH's FP4: Supporting Policies, Programs and Enabling Action through Research (SPEAR).

SCIENCE QUALITY

In Phase I of A4NH, our research agenda focused on testing hypotheses to provide proof of concept that biofortification is feasible without affecting yield and other positive crop characteristics; that farmers would be willing to adopt, and consumers to consume, biofortified crops; and that consumption would lead to an improvement in the nutritional status of target populations. That evidence is now available for many crop, country, and nutrient combinations. Evidence of the effects of nutrition-sensitive agriculture on nutritional outcomes in real world conditions, however, is limited. The effectiveness of biofortified vitamin A–rich orange sweet potato for increasing maternal and child vitamin A intake and status has been demonstrated, but evidence of effectiveness is not yet available for other micronutrient and crop combinations.

Phase II of A4NH offers a unique opportunity not only to develop effectiveness evidence for iron and zinc crops, but also to develop vital lessons on cost-effective delivery channels, public-private partnerships (PPPs), gendered effects of adoption and consumption decisions, and synergies of delivering and consuming multiple biofortified crops. Developing an understanding of the effects of nutrition-sensitive agriculture on livelihood and nutritional outcomes—across several countries, crops, and types of commercial and social marketing arrangements—will vastly deepen the body of knowledge on agriculture-nutrition linkages. In parallel with efforts to mainstream breeding for vitamin and mineral traits and provide evidence to support incorporation of biofortification into agriculture and nutrition policies and investments, the Phase II research will lay the foundation for global scaling of biofortified crops.

FP2 is committed to science quality and has a strong track record in developing a robust evidence base to support the biofortification concept (Bouis et al. 2013; Saltzman et al. 2013; Johnson, Guedenet, and Saltzman 2015). The success of the discovery phase of HarvestPlus (2003–2008) and the development phase (2009–2013) demonstrated that the team has the technical and institutional capacity to bring people

together across institutions, countries, and disciplines to forge partnerships and deliver high-quality technical outputs and immediate development outcomes.

Crop development research has not only produced new varieties of biofortified crops, but also contributed greatly to the field of knowledge, with findings about vitamin and mineral heritability in different crops, adaptation of rapid-throughput technologies to use in screening, and identification of new markers to use in marker-assisted selection. Vitamin and mineral traits can be effectively combined with other desirable agronomic traits, and all biofortified crop varieties that have been released to date are competitive with or better than the best varieties farmers currently grow. Effectiveness evidence is available for orange sweet potato (Hotz, Loechl, de Brauw, et al. 2012; Hotz, Loechl, Lubowa, et al. 2012). Nutritional efficacy has been demonstrated for vitamin A crops (maize (Gannon et al. 2014), cassava (Talsma et al. 2016)) and iron crops (bean (J. Haas et al., n.d.), pearl millet (Finkelstein et al. 2015), rice(J. D. Haas et al. 2005)), with zinc efficacy results expected in 2016. Research publications for 2014 provide insight into the depth and breadth of the HarvestPlus research program, which supports and informs delivery activities.

In addition to the ex post cost-effectiveness data that are available for vitamin A orange sweet potato, ex ante cost-effectiveness analyses (CEAs) have been carried out for other biofortified crops. These CEAs have long time horizons (about 30 years), as it takes time for the suitable biofortified varieties to become available and to be adopted and consumed on a large scale, and then for health benefits to materialize within the consuming population. The CEAs show that for all crop-country combinations, biofortification can be rated as very cost-effective. Moreover, biofortification is found to be more cost-effective than fortification for all crop-country-micronutrient combinations and more cost-effective than supplementation for all cases except one (Birol et al. 2014; Lividini and Fiedler 2015). The cost advantage of biofortification comes from the economies of scale (once a new crop has been developed, its benefits can be spread relatively cheaply over time and space) and its ability to reach a high number of rural farming households that produce and consume large amounts of staple food crops and whose members suffer from micronutrient deficiencies. A combination of biofortification, supplementation, and fortification may be best for achieving the desired objective—large-scale or targeted impact—in a cost-effective way.

In Phase II, research will build on Phase I evidence and focus on developing new evidence on speeding and scaling delivery, as well as unintended consequences that may result. A robust Monitoring, Learning, and Action (MLA) system is now in place in the HarvestPlus target countries, and analysis of the data collected through that system is expected to provide a great deal of insight into audiences reached through various delivery channels, including through informal diffusion and the seed market. Results will be used to inform and speed scaling strategies, particularly through a range of private-sector partnerships. Monitoring surveys will also provide information about the consumption of biofortified crops, particularly among the women and children for whom FP2 seeks to reduce micronutrient deficiency. To support scaling up of biofortification, the nutrition unit will place greater emphasis on knowledge translation for evidence sharing

Impact research will also generate new evidence, including results from effectiveness trials in at least two additional countries (zinc wheat in Pakistan and iron beans in Guatemala). Strategic research will provide insight into how gender influences decisions within households about producing and consuming biofortified crops, and into how the market can best support sustainable investment in developing biofortified seeds as well as promote awareness, access, and consumption of biofortified foods by target populations. Aiming to generate useful information for planning in this FP, as well as for external stakeholders, impact research will build on previous research to estimate the long-run impact and cost-effectiveness of biofortification across country-crop-micronutrient combinations, and compare the cost-effectiveness of biofortification to and in combination with other interventions in these countries.

LESSONS LEARNT AND UNINTENDED CONSEQUENCES

In Phase I, the research team built in mechanisms for ongoing learning, systemically gathering lessons through annual reporting and business planning cycles, which HarvestPlus reports through research

publications and an annually updated set of progress briefs. External evaluations, such as a 2012 evaluation by Abt Associates (Abt Associates Inc. 2012) and a Strategic Gender Assessment (SGA), completed in 2013-2014, have also provided strategic feedback that was used to improve FP performance during Phase I.

Lessons learned in Phase I help inform the Phase II research agenda. For example, lessons from countries with rapid expansion of biofortification, like Nigeria and Rwanda, can be applied to delivery strategies in later countries. As this FP achieved its projected outcomes in Phase I, it learned more about risks and gaps that can affect the impact of biofortification. Country- and crop-specific ToCs (Johnson, Guedenet, and Saltzman 2015) consolidated evidence that biofortification can work and helped identify gaps and potential unintended consequences to be addressed in Phase II. Remaining issues include managing identity preservation of biofortified seed and grain in the market, combating consumer perception that biofortified crops are genetically modified organisms (GMOs), and improving understanding of farmer and consumer behavior.

HarvestPlus also developed lessons on engagement with the private sector. For example, in Zambia, a memorandum of understanding (MOU) between the Zambia Agriculture Research Institute (ZARI) and private seed companies licensed three released hybrids and allocated those hybrids to the seed companies; HarvestPlus was involved as ''interested party,'' but faced a challenge when initial seed production was lower than expected, setting back projected delivery targets. To address this issue, HarvestPlus recruited a Maize Seed System Specialist position for Africa south of the Sahara to assist with technical production issues and strengthened its contracts for seed production with seed companies. HarvestPlus also adjusted its growth projections based on feedback from seed companies. With a better understanding of how the private sector assesses and responds to market conditions, HarvestPlus is exploring different models of private sector engagement, as well as various incentive and risk mitigation tactics.

Partnerships are increasingly central to scaling up biofortified crops. Partnership activities in Phase I will inform efforts in Phase II, including addressing key capacity gaps. Identifying key allies and advocates in partnership organizations to help build trust with program staff was found to be essential to obtaining organization-wide buy in. Even as enthusiastic allies take up biofortification, challenges remain in standardizing systems for monitoring and reporting, which will continue to be a focus in Phase II.

Recognizing that a lack of expertise in gender-sensitive delivery strategies could result in unintended consequences for farmers adopting biofortified crops, HarvestPlus commissioned an external SGA to review and assess current programs, identify gaps in gender knowledge and implementation, and identify successful efforts that can be built upon or scaled up. Based on the SGA recommendations, HarvestPlus leadership endorsed an approach to promote the integration of gender-responsive programming into HarvestPlus's current work.

HarvestPlus undertook changes to organizational structure and staffing as the FP grew. For example, the Program Management Committee structure, which had grown to include more than 25 people, including all country managers and unit heads, was replaced by an Executive Committee, which includes the Director, Deputy Directors for Operations and Programs, and head of Strategic Alliances. Both the Deputy Director for Programs and head of Strategic Alliances positions were new in Phase I, developed on the recommendation of the 2012 external evaluation.

CLUSTERS OF ACTIVITY

FP2 is structured around three interacting CoAs, described below. Earlier phases of HarvestPlus focused on breeding and nutritional evaluation, bringing together scientific research evidence with an impact orientation. Through 2020, HarvestPlus is building on previous research to mainstream crop development (CoA1: Crop development mainstreaming and capacity building) while also focusing on delivery in a contextually rich world of markets, farmer behaviors, and dietary practices (CoA2: Delivery science and

developing lessons learned). Filling key evidence gaps and capturing lessons learned is of great strategic importance in this phase. This will involve intensifying work to promote production and consumption of crops in target countries as a "proof of concept" of the approach, analyzing the effectiveness of different delivery mechanisms, and developing lessons for scaling up. This evidence will contribute greatly to promoting an enabling environment for biofortification and developing tools to facilitate delivery by others (CoA3: Promoting an enabling environment).

The delivery phase offers an opportunity to learn about what works, what does not, and how delivery strategies can be refined to enhance impact. The biofortification research agenda builds on previous work with partners throughout CGIAR, including Centers that carry out crop development work and other A4NH FPs. In Phase II, in addition to collaborating with FP4: SPEAR around policy and the enabling environment at the national and international scales, we will collaborate with FP1: Food Systems for Healthier Diets and FP3: Food Safety to address research questions on production (e.g. aflatoxins), opportunities and risks associated with value addition (e.g. processing, storage), and reaching target consumers in specific crops and countries.

CoA1: Crop development mainstreaming and capacity building

Mainstreaming nutrition into breeding requires a two-pronged approach: (1) annually increasing the percentage of biofortified germplasm in Centers' breeding programs, which are then distributed to NARS for further adaptation and eventual release, and (2) developing methods to reduce costs of breeding for biofortified varieties (through marker-assisted selection and low-cost, high-throughput methods of measuring vitamin and mineral content). This FP also continues to lead training and capacity development with NARS for the development and eventual release of biofortified varieties. Mainstreaming biofortified traits into breeding parental lines is a strategy to ensure that as new climate-adaptive varieties are developed, they will also contain higher levels of micronutrients. During Phase II, we will work with CGIAR to realize its 2014 commitment to develop and implement a plan for mainstreaming.

The specific research questions that this CoA will address during Phase II include the following:

- Can HarvestPlus and its partners breed target levels of nutrients into staple crops adapted for an increasingly wide range of climatic conditions, without compromising other farmer-preferred traits and crop characteristics?
- What methods can reduce the cost and/or improve the efficiency of breeding for biofortified varieties?
- How can biofortified crops be mainstreamed in international and national breeding programs?

To accomplish this, researchers working on the crop development cluster will focus on the following primary activities:

1. Develop second and third waves of high-yielding, biofortified germplasm with higher nutrient content. These new lines will be distributed globally to NARS for further crossing, testing, and eventual release. Crop development activities will focus on Tier 1 biofortified staple crops (wheat, rice, maize, bean, cassava, and pearl millet), with some investment in secondary staples (banana/plantain, cowpea, lentil, potato, and sorghum).
2. Develop (i) cost-saving breeding methods, such as marker-assisted selection (identifying specific genes associated with high mineral and vitamin content); and (ii) improved low-cost, high-throughput methods for measuring the mineral and vitamin content in seeds (in collaboration with universities in Australia, Europe, and North America).
3. Negotiate with CGIAR Centers and national breeding programs the eventual inclusion of biofortified traits within regular breeding programs, independent of specific FP funding.

Outputs:

- Biofortified varieties; cost-effective tools and techniques for mainstreaming nutrition in breeding
- By 2017: Second-wave releases in all target countries; recommendations of molecular marker external review implemented
- By 2019: Third-wave releases in all target countries; multi-location testing of biofortified crops in 75 countries; application of molecular markers for rice, wheat, maize, and cassava
- By 2022: 2.5% annual increase in crop development efforts for target crop/ecologies that mainstream biofortified traits

Outcomes: Farmers will have access to biofortified varieties well suited to their farming systems; crop breeders will have the incentive and capacity to incorporate nutritional traits into their breeding strategies.

CoA2: Delivery science and developing lessons learned

In this CoA, operational partnerships are developed for countries where biofortified crops are released, and a wide variety of partners are sought, including private seed companies, international NGOs, multilateral institutions, food processing companies, and national governments. Important research questions remain about which approaches work best to reach target beneficiaries (within farm households), how gender influences consumption and production decisions within households, and how the market can best support, not only sustainable investment in developing biofortified seeds, but also awareness, access, and consumption of biofortified foods by target beneficiaries. The nine target countries offer a rich source of information about how to effectively deliver biofortified crops, and allow for comparisons between countries to understand how delivery modalities can vary across market environments.

Where full-target varieties are available, rigorous impact evaluations will measure impacts on outcome variables, such as micronutrient intake and nutritional status of target beneficiaries. These efforts will be complemented by targeted research in key areas, such as gender, markets, and technology adoption specifically designed to answer important questions about the FP2 ToC, and about potential for scaling up biofortification and other agricultural interventions.

The specific research questions that this CoA will address during Phase II include:

- What drives uptake of biofortified crops in target countries? What is the role of research tools, evidence, and ex ante cost analysis in increasing investment and scaling? What are the determinants of farmer and consumer acceptance of biofortified varieties?
- Will biofortified crops improve nutritional status for infants, prior to conception through infancy, and how do multiple biofortified crops improve nutritional status?
- Which delivery models are most cost-effective, including for reaching women, in different market environments?
- What is the impact of biofortification on key outcome variables (adoption, diffusion, micronutrient intake, and deficiency status, all disaggregated by sex) under non-controlled conditions?
- What guidelines for approaches and processes can be replicated by stakeholders who are interested in scaling up biofortification in other countries or environments?

To accomplish this, researchers working on the delivery science cluster will focus on the following primary activities:

1. Assess scalability of biofortification through direct intervention in target countries, developing lessons learned about delivery modalities, consumer acceptance, and private sector engagement. Identify the factors that drive farmer and consumer acceptance and behavior change, including differences by age, gender, and other relevant social variables.
2. Conduct nutritional efficacy trials for a wider range of age groups (including infants); for a longer time frame (for example, prior to conception through infancy); and combining multiple biofortified

crops with different nutrients (for example, high-iron and high-zinc pearl millet combined with orange sweet potato).
3. Implement ex ante and ex post cost-effectiveness assessments, and expand ex ante cost-effectiveness analysis to include food-basket approaches.
4. Conduct impact assessment studies in target countries, and implement at least two effectiveness studies (iron beans, Guatemala; zinc wheat, Pakistan).
5. Combine short-term monitoring with medium-term progress indicators to track adoption by farmers, as well as to estimate consumption and public health impacts.

Outputs:

- Evidence on nutritional efficacy and impact; delivery in target countries and lessons learned
- By 2017: Bioavailability and efficacy evidence published for zinc rice; zinc wheat effectiveness trial initiated in Pakistan; ex ante analysis for more countries and food-basket approach; impact assessment surveys completed in at least three countries (Nigeria – cassava, Rwanda – beans, Zambia – maize); monitoring and forecasting models validated for country-crop combinations
- By 2019: Efficacy evidence published for multiple biofortified crops in a single study; effectiveness trial for Guatemala completed
- By 2022: Assessment of the efficacy of multiple biofortified crops in culturally accepted combinations for women of child-bearing age and for children 6–24 months of age; zinc wheat and iron bean effectiveness study results published

Outcomes: Farmers will be aware of and have access to biofortified varieties well suited to their farming systems; agents will incorporate biofortified planting materials and crops into their value chains; consumers will be aware of biofortified varieties that satisfy their needs; evidence on cost-effectiveness, nutritional efficacy, and consumer acceptance will be used by implementers in the design and implementation of investments in biofortification.

CoA3: Promoting an enabling environment

In Phase II, this FP will undertake a broad agenda of developing regulatory standards, partnerships, and policy analysis and tools to support a policy environment conducive to a broad range of nutrition interventions, including scaling up biofortified crops. This engagement, and the translation of efficacy and effectiveness evidence to be understood as relevant by policymakers and regulators, must continue in order to sustain the momentum for biofortification. Recently, HarvestPlus has increased its efforts to convene other actors around biofortification, including at the 2nd Global Conference on Biofortification in 2014. The Global Panel on Agriculture and Food Systems for Nutrition released a policy brief in early 2015 reviewing the evidence on biofortification and recommending that policymakers take steps to scale up biofortified crops.

HarvestPlus will continue to develop tools, like the Biofortification Prioritization Index (BPI), to help partners identify high-potential country-crop combinations for expansion, as well as implementing and evaluating biofortification projects (Asare-Marfo et al. 2013). Policy research will help identify the best mix of nutrition interventions for specific country contexts, considering the contributions of complementary interventions to addressing micronutrient deficient populations, and disseminate evidence through decision support systems like ReSAKSS. HarvestPlus LAC is demonstrating the importance of linking government-supported biofortification programs together across countries, and with CIAT and other CGIAR Centers working in LAC, producing lessons that can be applied elsewhere as biofortification scales up. Many activities in this area will have significant synergies with FP4: SPEAR.

A primary international standards vehicle is the Codex Alimentarius, the food standards-setting agency administered jointly by the WHO and FAO and recognized by the SPS of the WTO as its reference organization. Recognition and standardization of biofortification requires consensus from the 184 member governments of the Codex Alimentarius. In close cooperation with IFPRI, which has been accorded observer

status within Codex, HarvestPlus is working with the Codex Committee on Nutrition and Foods of Special Dietary Use (CCNFSDU) to develop an internationally accepted definition of biofortification. Without an internationally accepted definition, national governments are unable to include biofortification in national legislation and cannot set regulations and related policies specific to biofortified foods. This is an impediment to harmonization and international trade.

The specific research questions that this CoA will address during Phase II include the following:

- What are the barriers and constraints to creating cross-sectoral policy and institutional environments that better support the inclusion of biofortified crops in agriculture, nutrition, and development policies and programs?
- What standards, guidelines, and recommendations for biofortified foods and regulations are internationally accepted, supported by evidence, and can be taken up by Codex Alimentarius and national governments?
- What can be learned from countries that are successfully incorporating biofortification into their policies and programs (including Brazil and others in LAC)?

To accomplish this, researchers working on the enabling environment cluster will focus on the following primary activities:

1. Seek inclusion of biofortification in strategies, policies, and programs on global, regional, and national levels through multilateral and regional organizations. This will include the CAADP and SUN policies, as well as other collaborative bodies, in coordination with CoA3: Capacity, Collaboration, Convening (3C) in A4NH FP4: SPEAR
2. Engage in developing biofortification standards and regulations through formal global normative, regulatory, and donor agencies and global technical, scientific, and implementing agencies, including: (i) develop a definition and standards for biofortification within the Codex Alimentarius and (ii) establish links to national nutrition policies to share standards, guidelines, and recommendations developed by international bodies
3. Evaluate and synthesize knowledge and lessons learned in HarvestPlus LAC countries
4. Identify and develop tools to help partners implement and evaluate biofortification projects, including biofortification priority indices at the subnational level

Output:

- By 2017: 3rd Global Conference on Biofortification, including dissemination of evidence and lessons learned
- By 2019: Tools to assess the cost-effectiveness of different portfolios of complementary interventions to address micronutrient deficiency, including biofortification; national and international standards and guidelines on biofortification
- By 2022: Synthesis of lessons learned from countries incorporating biofortification into their policies and programs; Building country capacity to develop and monitor national standards on biofortification

Outcomes: National governments will have the capacity to incorporate biofortification into cross-sectoral policies and implementation plans; national and international regulatory agencies will use the evidence on biofortification to set appropriate standards and guidelines for food products and labeling. Standards for biofortified foods are developed and approved by Codex Alimentarius and biofortification is included in WHO guidelines on micronutrient deficiencies.

PARTNERSHIPS

As HarvestPlus seeks to mainstream and scale up biofortification, its types of partnerships will expand from predominantly academic institutions, CGIAR Centers, and NARS, to new types of partners throughout to achieve SLOs 1 and 2. This FP will develop a wide range of international public goods at each step of the

impact pathway, from discovery to development to delivery. Lessons learned on partnerships in different countries will inform partnership strategies for scaling in Phase II. Learning from PPPs, in particular, may offer new approaches that can be used throughout CGIAR.

Scaling will require building new and expanding existing partnerships, maintaining engagement, and increasing partner capacity. Earlier phases of HarvestPlus focused on building an evidence base for biofortified crops, working with research partners to initiate studies on agronomic characteristics, nutritional efficacy, and consumer acceptance, investing specifically in upgrading equipment and training technical staff in 22 labs.

As HarvestPlus shifted into delivery, it launched delivery partnerships with private seed companies, local and international NGOs, government extension programs, and school feeding programs. In Phase I, this F2 developed capacity in more 100 delivery partners, trained thousands of extension staff on agronomic practices and nutrition messages for biofortification, and developed technical packages for partners to use in delivery programming. Through these experiences, the FP learned to effectively engage different types of partners, find mutually beneficial areas for collaboration, and maintain momentum in partnerships. We also learned about the challenges of coordinating, influencing, and gathering data from partners with different priorities and systems,

In Phase II, this FP will add new and diverse partners, including private food companies and retailers, UN agencies, regional organizations, and innovative financing mechanisms and development banks. A focus in Phase II is building capacity for evidence sharing and policymaking at national and regional levels, including through the SUN platform and CAADP nutrition initiatives. Upstream partners include private sector seed and food companies, from small start-up companies to large multinationals. Involving private sector seed companies to develop and test biofortified varieties shortens the time to market and lays the groundwork for the proof-of-concept stage. Food companies test biofortified crops for use in processed foods, evaluating mineral and vitamin retention for different types of processing.

Many different types of partners are involved in proof of concept work, including private seed companies, international NGOs, and multilateral agencies. In countries with robust private seed systems that reach smallholder farmers, private seed companies are a natural partner, which is particularly advantageous in crops where hybrid seeds predominate (e.g. Seed Co. in Zambia (hybrid maize) and Nirmal Seeds in India (hybrid pearl millet) and where seed companies operate regionally). An MOU was developed with World Vision to introduce biofortified crops into its agricultural programs, which are then linked to its health and nutrition programs. The World Food Programme's (WFP) Purchase for Progress program is very interested in local purchasing of biofortified crops, and partnerships are being developed in several countries. In Rwanda, local bean production is purchased and stored in WFP warehouses for later emergencies.

As this FP scales up biofortification, it will expand its delivery partnerships and pursue different ways of working with a wide variety of partners, including FAO, WHO, World Bank, the International Fund for Agriculture Development (IFAD), WFP, Africa Union, CAADP, and the SUN Movement.

CLIMATE CHANGE

Biofortified crops can contribute to improve the resilience of farmers and rural communities to climatic changes and weather extremes by improving the quality of diets (at no extra cost to the consumer), and thus their nutritional status. Other things being equal, projections indicate that food price levels will rise and that prices will be more variable, due to climate change. Biofortified staples ensure that farmers and their families can access essential micronutrients, even if rising food prices reduce their access to more micronutrient-dense non-staples.

Climate change may have an impact on the nutritional quality of the crop itself. While rising carbon dioxide (CO_2) levels may accelerate plant growth initially, some studies suggest that the nutrient content of crops is likely to decline, especially as plants adapt to higher atmospheric CO_2 levels. One review found a decline in micronutrient content. Overall, the evidence on effects of climate change on nutritional quality is mixed; other climate-related factors may influence nutrient density in the opposite direction. Further research is needed, as there is variability in how plants will respond to the different effects of climate change. Biofortification could offer a solution in those instances where crop nutritional quality will decline.

Breeding for nutrient traits is and must be strongly linked to breeding for adaptation to climate change. Increasingly, FP2 must consider other programmatic adaptations that might be required due to changing climatic conditions. Less predictable weather patterns may affect farmers' varietal preference in ways that are not yet known. Inconsistent weather can affect seed production, and as this FP scales up its partnership in seed production, it will consider measures to mitigate the risks posed by climate change.

GENDER

FP2 will specifically promote gender equality by identifying how biofortification can be effective in targeting the nutritional status of women and children, by targeting interventions and gathering evidence on the impact of different approaches to scaling up biofortified crops.

The independent SGA will help ensure this FP reaches its goal to improve micronutrient intakes for 20 million households by 2020. As delivery scales up, FP2 will be more systematic in understanding how gender dynamics can affect the adoption and consumption of biofortified crops. It is clear that men and women engage differently with new crop varieties and the path from adoption to consumption is not always direct. We are beginning to understand the full implications of how specific activities may affect men and women differently, and the best pathways through which to achieve equitable access to biofortified crops and foods.

The SGA highlighted the importance of deepening understanding of gender dynamics for delivery issues, including household decisionmaking processes. FP2 will identify practical examples where unintended gender consequences may negatively affect program impact. A version of the Women's Empowerment in Agriculture Index (WEAI) is included in impact assessment and effectiveness studies to investigate the role of gender in adoption of biofortified varieties and the impact of varietal adoption on various women's outcomes (e.g. iron intake, time allocation, and income).

We are working to understand the gendered dynamics of delivering biofortified crops through research. Country teams are thinking critically about how to better reach target consumers: micronutrient-deficient women and children. We are asking whether men and women access biofortified planting materials differently and what the implications of any difference may be. A gender advisor to coordinate gender activities and conduct gender analysis for specific situations will be recruited in Phase II.

CAPACITY DEVELOPMENT

Phase II will continue to emphasize and invest in capacity building in NARS and national research partners and in training at existing labs, in addition to expanding lab support to the LAC region. The ToCs for target countries (Johnson, Guedenet, and Saltzman 2015) identify capacity gaps in the seed value chain as a potential bottleneck for biofortification. This FP supports increasing public and private sector capacity to deliver biofortified seeds. The FP assesses the seed and grain value chains for each crop-country context and develops a delivery strategy. Our approach is determined by the normal operation channels for a particular crop in a given country or subregion; private sector partners are preferred when a developed market exists, but in less-developed markets, value chain activities may be supported by government, NARS, or civil society partners. In some countries, we provide technical assistance to NARS to increase seed production. In others, like Uganda, we support strong PPPs for maintaining production and supply of clean

planting materials so they are easily accessible to farmers. In selected countries, coordination with IFPRI country programs will be used to identify opportunities to increase the capacity for the priority setting process in the NARS and develop seed policy capacity to speed up the process of seed multiplication.

In contrast to earlier phases of HarvestPlus, which focused on building capacity to support the research agenda, development of expertise is now shifting to support the mainstreaming and scaling up objectives. Staff in target countries and regional teams support capacity development in seed systems, marketing, nutrition, monitoring and evaluation, and policy in country offices and with national delivery partners. New and strengthened partnerships, both public and private, will be critical to achieving capacity at national and global levels to scale biofortification.

INTELLECTUAL ASSETS AND OPEN ACCESS MANAGEMENT

In Phase II, researchers from FP: Biofortification will contribute a number of intellectual assets, such as genetic characterization of staple crops and underutilized plant genetic resources; improved biofortified varieties suitable to a broad range of target environments; decisionmaking tools; and evidence, including cost-effective analysis and impact evaluations.

Intellectual assets will be designed with CGIAR open access (OA) and open data principles in mind. For example, researchers will make their raw data available to other researchers through their Center-specified platform in a timely manner. For IFPRI, from which all nutrition and impact data in this FP is generated, this platform is Dataverse. Tools to support improved decisionmaking developed by this FP will follow OA and open data principles, minimizing the hurdles to scaling out. More details are on both open access and intellectual assets are included in Annexes 3.8 and 3.9, respectively.

FP MANAGEMENT

The current HarvestPlus director, Howdy Bouis, will soon be retiring, and recruitment is underway for his replacement, who will begin by the 3rd quarter of 2016. FP2 links with crop breeding programs of the agri-food system CRPs (AFS-CRPs)/Centers through a coordinated and well-managed program unit. Day-to-day management decisions are determined through a consultative process within the Executive Committee, composed of the Director, Deputy Director of Operations (Wolfgang Pfeiffer), Deputy Director of Programs (Ina Schonberg), and Head of Strategic Alliances (Thom Sprenger). CVs are in Annex 3.7.

Management tasks include six broad mandates:

- **A.** Provide strategic planning and managerial direction to program initiatives, in consultation with IFPRI and CIAT management and the Program Advisory Committee.
- **B.** Provide appropriate leadership, oversight, and support to country programs and supporting technical and administrative functions/units.
- **C.** Mobilize sufficient resources to meet project and organizational objectives.
- **D.** Plan, track, and manage financial resources effectively.
- **E.** Perform administrative and coordination functions in a timely and effective fashion.
- **F.** Facilitate knowledge sharing within the project, through intranet and other information technologies.

These activities have important synergies. For example, documenting progress in target countries will assist in partnership activities. Success in breeding varieties is also required for rapid scale-up. Monitoring, evaluation, and learning will inform planning and implementation inside and outside of HarvestPlus. Close coordination across organizational functions is critical to achieve the ambitious outcomes of FP2 and A4NH. Using lessons from the first half of Phase II, we may seek alternative arrangements for working with partners, who will increasingly scale biofortified crops independent of HarvestPlus. Discussions of the types of institutional arrangements needed to support this work are already underway.

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