

COMBATING IRON DEFICIENCY

Evaluation Review Panel:

**Robert O. Nesheim, Ph.D., Nutrition Consultant
George A. Purvis, Ph.D., Gerber Products Company
Zak I. Sabry, Ph.D., University of California, Berkeley**

January 24, 1992

This evaluation was conducted for the Office of Nutrition, Bureau for Research and Development, Agency for International Development, under contract number PDC-5110-I-00-0070-00, Delivery Order No. 3, Project Number 93G-5115.

EVALUATION REVIEW OF AID OFFICE OF NUTRITION PROJECT ON COMBATING IRON DEFICIENCY

Executive Summary

Iron deficiency is the most prevalent nutrition problem in the world. Approximately 1.6 billion people suffer from it. In developing countries, two thirds of the women and children lack adequate supplies and stores of iron. And, the deficiency in half of these is so severe as to cause anemia. Even in the United States, Japan and Europe, the estimates show 10 to 20 percent of childbearing age women are anemic, with the incidence of anemia reaching epidemic proportions.

Iron deficiency anemia causes irreversible impairment of learning ability in children, reduces work productivity in adults, and diminishes the immune system, thus increasing the risk of infections. Iron deficiency anemia threatens the lives of women during pregnancy and increases the risk of infant mortality and morbidity. For all its devastating consequences, iron deficiency anemia symptoms are subtle and easy to overlook. They include pallor, fatigue and lethargy. This explains why iron deficiency anemia arouses such little action at the policy level.

Since the late seventies, the Agency for International Development (AID) has sponsored several pioneering programs to advance the frontier of knowledge about iron deficiency anemia. The program at the International Center for Control of Nutritional Anemia (ICNA) at the University of Kansas has been a leader in elucidating the conditions favorable to enhance iron absorption, developing effective new systems for delivering biologically available iron via support and fortification strategies, developing methods to evaluate iron status, and training personnel from developing countries in the skills to monitor and evaluate iron improvement programs. The program at Rutgers University is focusing on the technological aspects of enriching rice with iron without sacrificing color, flavor, texture and acceptability. The International Nutritional Anemia Consultative Group (INACG) at the

Nutrition Foundation, Inc. has been effective in heightening professionals' awareness about the iron deficiency problem, and communicating developments in this field of knowledge through international meetings and scientific reviews. All these programs have involved professionals from developing countries, bilateral and multilateral organizations, non-governmental organizations (NGOs), private voluntary organizations (PVOs), and food companies in the private sector.

This evaluation review (conducted November 18-20, 1991) has concluded that project activities were consistent with AID's objectives and that progress to date strongly warrants the continuation of support particularly in advocacy and field implementation if sufficient impact is to be made in combatting the iron deficiency problem.

The evaluation panel specifically recommended that:

- the project be strengthened and its impact enhanced given the potential of iron deficiency studies to provide a scientific, sociological and practical base for control of micronutrient deficiencies. Given the prevalence of iron deficiency anemia, efforts must be allocated via resources and mobilization of support from an international coalition;
- the project activities be oriented toward the support of field trials to have a direct impact on the iron deficiency problem by testing the iron delivery systems developed at ICCNA, evaluating fortification methods developed at Rutgers University, and utilizing skills in information dissemination and training;
- the existing activities be sustained as a valuable resource, with ICCNA and Rutgers University also emphasizing training of laboratory and field personnel to implement, monitor and evaluate field trials, and with INACG to establish a presence in interested developing countries;
- a component be added focusing on advocacy within and outside AID to support a major thrust to combat iron deficiency anemia by galvanizing efforts in other international agencies and in the food industry; and
- AID considers iron fortification of Title II commodities and blends using delivery systems developed at ICCNA and seek country-level approval for the use of iron EDTA through the Codex Alimentarius Commission to facilitate iron fortification in developing countries.

EVALUATION REVIEW OF AID OFFICE OF NUTRITION PROJECT ON COMBATING IRON DEFICIENCY

TABLE OF CONTENTS

Introduction	1
Program at the International Center for Control of Nutritional Anemia (ICCNA) at Kansas University Medical Center	2
Program at the Department of Food Science at Rutgers University	7
Program of the International Nutritional Anemia Consultative Group (INACG) at the Nutrition Foundation, Inc.	9
Salient Points Raised from Discussions with AID Staff	12
Comments on Issues Raised by Mr. Richard Seifman, Director, AID/R&D/N	13
Summary and Recommendations	15
Appendices	
● Evaluation Background Paper and Statement of Work	
● Evaluation Team Members' Background	

Introduction

Iron is the one micronutrient whose deficiency affects a large segment of the World population, in both developing and developed countries. One in five of the World population suffers from iron deficiency. Two thirds of the children and of the women of child bearing age lack adequate supplies and stores of iron; the deficiency in half of these being so severe as to cause anemia.

The consequences of iron deficiency are so devastating as to cause irreversible impairment of learning ability in children, reduce work productivity in adults, and interfere with the immune system thus increasing the risk of contracting and dying of infection. Iron deficiency during pregnancy increases the risk of maternal mortality and prenatal and perinatal infant death. In those who survive, the infant is born with low iron stores that increase the risk of infant mortality, morbidity and irreversible learning disorders. The danger of iron deficiency is that although its consequences are serious, its symptoms are subtle and often go undiagnosed and arouse little action at the policy level.

Iron is found in many foods, and often the chemical analysis of diets give the impression of adequacy. However, only a minute fraction of the iron in most foods can be absorbed by the body. This low biological availability of naturally occurring iron in vegetable foods, combined with parasites that cause internal bleeding, deprive about a billion people, most of whom are women and children, of their chances for health, and mental and physical development.

The most common interventions have been the distribution of iron supplements to pregnant women and to infants and children, or the fortification of frequently consumed foods with an absorbable form of iron. Both approaches have proven effective in improving outcome of pregnancies, and the physical and mental development of children. Supplementation is useful in the short-term, and requires care with logistical and compliance problems to ensure targeting the vulnerable subjects. Food fortification, the more effective mode of intervention over the long-term, requires further technological development in the processing and formulation of foods to ensure the absorption of the added iron.

The AID project on combatting iron deficiency has addressed all the issues relevant to understanding the science and developing the technology needed to bear on this problem. Over the years, it has contributed significantly to the accumulated knowledge and experience in this field.

1

The AID project provides support to the following programs:

- The International Center for Control of Nutritional Anemia (ICCNA) at the Kansas University Medical Center in Kansas City, with Dr. James D. Cook, Principal Investigator. (AID/DAN-5115-A-00-7098-00)
- The Department of Food Science at Rutgers, The State University of New Jersey in New Brunswick, with Dr. Tung-Ching Lee, Principal Investigator. (Grant AID/DAN-5115-A-00-9089-00)
- The Secretariat of the International Nutritional Anemia Consultative Group (INACG) at the Nutrition Foundation, Inc. in Washington, D.C., with Dr. Suzanne Harris, Officer-In-Charge. (AID/DAN-5115-A-00-7114-00)

In addition, the Office of Nutrition staff work closely with those of other Offices and regional Bureaus to combat iron deficiency in developing countries.

The Panel evaluating the AID project reviewed reports on these activities over the past five years and met with investigators and staff of the involved institutions. On November 18, Dr. Nesheim met with Dr. Cook and his staff at Kansas University Medical Center and visited the facilities of ICCNA. On the same day, Dr. Purvis met with Dr. Lee and his staff at the Department of Food Science at Rutgers University. On the following day, Drs. Nesheim, Purvis and Sabry met with Dr. Suzanne Harris and her staff at the office of the Nutrition Foundation, Inc. in Washington, D.C. Also on that day and on the following day, all three members of the panel met with the Director of the Office of Nutrition, Mr. Richard Seifman, and other staff of the Office, Drs. Samuel Kahn, Susan Anthony, Eunyong Chung, and John Bauman. The panel members and Dr. Kahn also met with other AID officers including: Dr. Thomas Marchione of the Food and Humanitarian Assistance Bureau, Ms. Hope Sukin-Klauber, Health and Nutrition Adviser in the Africa Bureau, and Dr. Mary Ann Anderson of the Office of Health.

Program at the International Center for Control of Nutritional Anemia (ICCNA), Kansas University Medical Center

Dr. James D. Cook, Principal Investigator

In 1978, AID awarded the Kansas University Medical Center a three year contract to determine the biological availability of various

forms of iron, analyze diets consumed in developing countries, and devise strategies for iron fortification of foods. In 1982, AID and the University of Kansas concluded a cooperative agreement to establish an International Center for Control of Nutritional Anemia (ICCNA). The goals of the Center were to conduct relevant research on food fortification with iron, train overseas personnel, and provide technical advice to developing countries interested in establishing programs to combat nutritional anemia. An external review in 1985 concluded that the overall objective of the cooperative agreement had been accomplished, the program activities have been effective worldwide, and these activities should continue if a significant impact were to be made in combatting iron deficiency. The review recommended that food fortification with iron be undertaken in some developing countries and that longitudinal monitoring of outcome be included.

The cooperative agreement was extended after 1985 at six-month intervals, with modest additional funding, until 1987 when it was extended for a five-year term, though at a reduced scope of work. ICCNA continued to support overseas programs in their scientific development, training of personnel, provision of monoclonal antibodies for laboratory analysis, and evaluation of bioavailability results.

A 1988 review commended ICCNA for advancing the frontier of knowledge of iron bioavailability, and for contributing to the development of effective new systems for delivering biologically available iron via supplementation and fortification strategies. The reviewers recommended that field trials be conducted to allow the testing of these systems.

This 1991 review is expected to address certain issues that are included under Article III of the Evaluation Background Paper and Statement of Work, presented in Appendix 1 of this report. The following summarizes the response to these issues:

- A. Is the project design consistent with the following objectives:**
- (a) expand the scope of knowledge regarding iron deficiency anemia and methods for its assessment and control;**
 - (b) develop and test intervention approaches;**
 - (c) disseminate new knowledge and experience relating to the control of iron deficiency anemia; and**
 - (d) encourage and assist countries to define and control the problems of iron deficiency anemia.**

With regard to the consistency of the project design with the objectives, there is ample evidence that the work at ICCNA has expanded the scope of knowledge in this field. Considerable progress has been made in developing and refining the use of

monoclonal antibodies in the assessment of iron status. With anemia in many areas having multiple causes, the value of a simple procedure to evaluate iron status is an important development and potentially can reduce the cost of laboratory evaluation several folds. Work on obtaining blood from a finger stick and developing a procedure for automating measures from a drop of blood on filter paper will further simplify and reduce the cost of the evaluation procedure.

The information generated from this program has been disseminated widely and effectively through participation in meetings and workshops, and in publications in the scientific literature. The ICCNA staff have been active in the training of personnel from developing countries. In addition, Dr. Cook has assisted in the development of test protocols and evaluation of projects in Egypt, Jamaica, Grenada, Tanzania, Ethiopia and Guatemala. He has been particularly helpful in encouraging and assisting these countries in determining the prevalence of iron deficiency and in designing systems for intervention.

B. Is the project making an impact consistent with the resources available: If so, has the rate of progress been satisfactory?

In the area of research and technical support, the program has made excellent progress. Its output has exceeded what could be expected from the level of the AID support. Dr. Cook has been very successful in securing additional resources for the program. Funding from the National Institutes of Health has provided the means for conducting the more basic research necessary for the development of the intervention technology for the AID program. In addition, there has been support from industry to augment the resources provided by AID. With this support from different sources, Dr. Cook has responded extensively to requests for training and technical assistance, which are necessary to the development of field intervention programs.

C. Within the constraints under which the project operates:
(a) are developing country needs being adequately responded to?
(b) has the balance between research and technical assistance provided to countries been sufficiently supporting of project objectives?

The ICCNA has responded to the needs of developing countries in dealing with iron deficiency. The level of this response has been well beyond the limited resources from the

cooperative agreement. It is clear that there is a great deal of leveraging of these resources through assistance from private industry, i.e. Nestle. While the rate of progress has been excellent in the laboratory phase, the limited funds available have not permitted a more aggressive approach to encourage the development of intervention programs.

D. Have AID resources been adequate to support the planned activities?

AID funds have been inadequate to support the full range of the planned activities. It is only because ICCNA secured other funding to support different parts of the research program that the project has been able to operate effectively.

E. Are there management issues or practices which may be adversely affecting progress of the project?

There do not appear to be any management issues of concern.

F. Is the interaction with other multilateral and bilateral donor agencies sufficiently active and effective?

Dr. Cook and other staff at the ICCNA have been interacting very effectively with other agencies, i.e. International Atomic Energy Agency (IAE), United Nations International Children and Education Fund (UNICEF), World Health Organization (WHO), World Bank, and Food and Agricultural Organization (FAO).

G. Is the interaction with the private sector sufficiently active and effective?

Dr. Cook has established effective working relationships with many organizations in the private sector, i.e. Nestle, Gerber, Roche.

H. How well has information been disseminated under the project?

Dr. Cook and others at ICCNA have been very aggressive in publishing research findings in scientific journals (between 1988 and 1991, Dr. Cook and his associates published 22 papers

in refereed journals and other scientific compendia), reporting at scientific meetings, attending workshops, and delivering lectures and seminars at academic institutions. In addition, they have collaborated closely with INACG in the dissemination of research findings in the professional and more popular literature.

I. Do the project achievements and potential appear to justify its continuation? Why?

The achievements under this project have been substantial. There continues to be a need to simplify iron status evaluation techniques, test biologically-available iron delivery systems for supplementation and fortification, and provide technical assistance to agencies and developing countries to implement iron fortification programs. Dr. Cook and the staff at ICCNA are an extremely important resource for assisting in the design and implementation of intervention programs.

J. Are the project's activities significant in combatting iron deficiency worldwide?

The AID project on Combatting Iron Deficiency has made a very significant contribution to the alleviation of this serious worldwide problem. The role of the ICCNA has been and continues to be fundamental. Through the program at ICCNA, several options have emerged for consideration as delivery vehicles for food fortification with available iron. The use of iron EDTA as a source appears to hold considerable promise in bypassing the effect of major absorption inhibitors found in many foods. Its use with such carriers as wheat, rice, salt, sugar and fish sauce needs to be tested both at the laboratory and field levels. Obtaining approval for the use of iron EDTA through regulatory agencies both nationally and internationally is an important step. This AID project is well designed and has achieved a great deal so far. Its continuation, whether as a highly visible project or within the scope of a micronutrient project, stands to pay dividends in alleviating the most serious world nutrition health problem.

Program at the Department of Food Science, Rutgers University

Dr. Tung-Ching Lee, Principal Investigator

This program was established in 1989 to develop an extrusion process for the fortification of rice, testing various forms of biologically available iron systems, and ensuring that the product will be acceptable for its color, flavor, and cooking quality. In a technological sense this is a difficult task. Rice is the only cereal in the world that is consumed as a whole kernel after cooking. Fortification requires milling the kernel, mixing in the iron compound, then extruding the mix back into the original kernel shape, without loss of color, flavor, or cooking quality.

The Food Science Department at Rutgers University is extensive and well equipped to undertake the task. Dr. Lee has excellent evaluation and investigative equipment. The pilot facility is well equipped with numerous experimental extruders. The equipment they utilize for the rice investigation is a one inch single barrel batch extruder with varied temperature, pressure and die control. The equipment is excellent and well suited for scaling-up when the program is expanded. The evaluation equipment includes gas and liquid chromatography and spectrophotometric capabilities through several wavelength spectra.

The extrusion studies are at a critical point in progress. The basic investigation has been completed in several areas. The application and interpretation of the results will be possible from this juncture and hold considerable promise.

This program started in the later part of 1989 to provide a necessary technological input to the AID project on combatting iron deficiency. The initial emphasis is on developing a system for the fortification of rice with iron. So far, the program has proceeded on the right track and produced encouraging results. It holds the promise of being able to develop a suitable product that would be useful to many of the developing countries where rice is the staple item in the diet. The program certainly has generated an adequate impact, consistent with, or in excess of, the resources allocated to it. The program could benefit from a higher level of support and intensification of the rate of progress on rice and subsequently other cereals. This will be a necessary phase to field trials that, if successful, would be a strong motivation for developing countries to adopt fortification strategies.

The review of this program focused on its potential rather than on its achievements, since the program has been active for only a limited time. However, a number of points were raised in the course of this review that may be summarized as follows:

- **Iron Compounds:** The method for binary enrichment followed in this program holds a great deal of promise. It involves the production of an enriched mixture utilizing iron pyrophosphate as iron source in fortified simulated rice and mixing it with separate simulated rice containing disodium EDTA and/or ascorbic acid to enhance the bioavailability of the added iron. Iron pyrophosphate and disodium EDTA are not very soluble in water, thus they are stable in fortified simulated rice forms and do not affect the color, flavor, texture or acceptability of the final product.
- **Storage Studies:** Key storage studies are in progress at Nestle Research Center in Switzerland, for the evaluation of the product's shelf life. The iron forms and the binary enrichment are being evaluated, and so far show excellent stability after six months.
- **Cross Applicability:** Application of the technology to other cereal grains, such as wheat, corn and oat, is a logical extension of the experiments. Dr. Lee has adequate technological background to conduct these trial efficiently. Different extruder behavior would be anticipated, but the state of knowledge of fundamental technology would make cross application expedient.
- **Iron Absorption:** Product samples are being prepared for Dr. Cook at the ICCNA to evaluate the biological availability of the added iron systems.
- **Organoleptic Evaluation:** The color and texture problems encountered earlier in the experiments have been overcome. Visual inspection, confirmed by testing, indicated that differences in extruded particles are not significant from natural grains, which is a substantial accomplishment.
- **Dialysis Experiments:** The in vitro experiments with various iron forms demonstrate an elegant technique for the evaluation of the iron bioavailability in foods. If the dialysis results show good correlation with absorption studies, this would represent a significant contribution to the evaluation of food iron sources.

Program of the International Nutritional Anemia Consultative Group (INACG), Nutrition Foundation, Inc., Dr. Suzanne Harris, Officer-In-Charge

In 1977, the Nutrition Foundation, Inc. received a grant from AID to serve as Secretariat to the International Nutrition Anemia Consultative Group (INACG). This initial grant was renewed or amended at intervals of approximately one to two years until 1987, when a cooperative agreement for five years was signed.

INACG contributes to the alleviation of nutritional anemia worldwide through the dissemination of information on iron deficiency. It sponsors international meetings and scientific reviews, where issues related to the causes, treatment and prevention of anemia are analyzed, and position papers issued. These are crucial steps in increasing awareness, developing policies and formulating programs to deal with this serious nutritional health problem.

In the course of the present review, the following points may be made, particularly in response to the charge to the Panel, as listed under Article III of Appendix 1 of this report.

- A. Is the project design consistent with the following objectives:**
- (a) expand the scope of knowledge regarding iron deficiency anemia and methods for its assessment and control;**
 - (b) develop and test intervention approaches;**
 - (c) disseminate new knowledge and experience relating to the control of iron deficiency anemia; and**
 - (d) encourage and assist countries to define and control the problems of iron deficiency anemia.**

The INACG program of work over the years has contributed significantly to the dissemination of up-to-date information to professionals, scientists and program managers. It also provided a forum for international development specialists to communicate and exchange information about their experiences relating to the control of iron deficiency anemia. However, INACG has not created a constituency among policy makers. Also, the material generated has not helped senior public health officials develop an advocacy posture on the issue. The closest INACG came to moving in this direction was in the Action Plan put forward in the Group's XIIth meeting in December 1990. So far, little effort appears to have gone into packaging and promoting the plan. It would be beneficial to consider expanding the scope of INACG's activities to cover

greater interaction with interested AID missions, multilateral agencies and NGOs/PVOs.

B. Is the project making an impact consistent with the resources available: If so, has the rate of progress been satisfactory?

The impact of INACG's activities is consistent with the resources provided from AID. In fact, it appears to exceed these resources to the extent that inputs from industry and other agencies complement the work done under the cooperative agreement.

C. Within the constraints under which the project operates:
(a) are developing country needs being adequately responded to?
(b) has the balance between research and technical assistance provided to countries been sufficiently supporting of project objectives?

There appear to be no doubt that the needs of developing countries have been responded to well, and to some extent this has been supportive of the project objectives, all within the constraints of the cooperative agreement with INACG. However, the gain to be realized from expanding the role of the Group to that of advocacy, rather than mere information dissemination, would strengthen the project and enhance its value to developing countries.

D. Have AID resources been adequate to support the planned activities?

The AID resources have been put to good use and adequately supported INACG's planned activities. But, that is mainly because these activities have been designed within the scope and the level of the resources.

E. Are there management issues or practices which may be adversely affecting progress of the project?

There appear to be no management issues or practices that would jeopardize the progress of the program. However, there appear to be missed opportunities, mainly because of limited resources and mandate.

- F. Is the interaction with other multilateral and bilateral donor agencies sufficiently active and effective? (refer to G below)**
- G. Is the interaction with the private sector sufficiently active and effective?**

The level of interaction with multilateral and bilateral agencies, as well as with the private sector is consistent with INACG's structure and mandate. This is clearly evident from the composition of INACG's Steering Committee and Task Forces; also the participants at its meetings. However, the benefits to be gained from expanding INACG's mandate and intensifying the level of interaction would enhance the impact of the project immensely. For example, there is a role for INACG to advocate the acceptance of iron EDTA for food fortification both by the Food and Drug Administration (FDA) and by the Codex Alimentarius Commission. This is a crucial step for AID missions and other international agencies to promote successfully the adoption of fortification strategies in developing countries. Iron EDTA is an inexpensive and effectively absorbable form of iron that has not been adopted by FDA nor by the Codex's Joint Expert Committee on Food Additives through benign neglect and failure to weigh the benefits of its use against perceived risks. INACG is uniquely suited to handle this issue.

- H. How well has information been disseminated under the project? (refer to J below)**
- I. Do the project achievements and potential appear to justify its continuation? Why? (refer to J below)**
- J. Are the project's activities significant in combatting iron deficiency worldwide?**

INACG has a long history in information dissemination by sponsoring scientific meetings and workshops and publishing study reviews, fact sheets and position papers. These activities are essential to the project, as they strengthen the impact and enhance the value of the sponsored programs at the ICCNA and Rutgers University as well as other institutions active in research and development related to iron deficiency. However, it would be advantageous to go beyond the present role of INACG and expand its scope to promote a positive image both at home and abroad. A national representation of INACG in interested countries, or the promotion of country level consultative groups with links to INACG would give the iron deficiency problem the visibility needed to trigger the formulation of policies and programs. This approach could beneficially be adopted not only in developing countries, but

also in developed countries, where the iron deficiency anemia prevalence is sufficient to warrant concern. It is estimated that in the U.S., Japan and Europe, between 10 and 20 percent of childbearing age women are anemic. This is at an epidemic level. Under the circumstances, there is an opportunity to learn from reverse transfer of technology and information.

Salient Points Raised from Discussions with AID Staff

- The link between hookworm and iron status has been well delineated in many publications. There is a considerable body of research on the relationship between iron status and malaria that needs to be articulated and disseminated. There is also recent research that suggests a relationship between iron and the onset of AIDS that needs to be assessed, followed up, and, when confirmed, disseminated. This information should have a strong impact on policy and program formulation in developing countries and needs to be communicated to AID missions, other bilateral donors, and multilateral agencies.
- AID has experimented with fortifying some of the PL-480 commodities sent to India, and found that iron resulted in substantial increase of birth weight. However, there has been no determined universal effort to adequately fortify all Title II foods. Where such fortification occurs, reduced-iron or iron fumarate is used. However, the bioavailability of these iron compounds is poor because of iron inhibitors present in many Title II commodities. This could be corrected since new technologies exist to enrich these commodities.
- It is commendable that efforts are focused on integrating control of iron deficiency into the activities of the MotherCare project. Analysis of the Integrated Child Development data set has shown a direct link between the nutrition of the mother and the health of the baby. The need exists for iron supplementation for the short-term, and fortification of suitable food carriers for the long-term effect.
- There does not appear to be a mechanism within AID to integrate the objectives of the project on combatting iron deficiency into the activities of relevant projects or programs of work in the regional bureaus. Yet, there was an expressed need for raising the awareness within AID of this very serious health problem, and ways to alleviate its magnitude and severity. This is an information dissemination issue that may best be handled through workshops and training

sessions. Suggestions were made in the course of the discussion for the need to prepare training packages to help grassroots AID and NGO workers integrate iron supplementation in their work, and proliferate this training through a training the trainer approach. There was also a suggestion for training packages aimed specifically at decision makers in the public sector, and at food producers and others in the private sector in developing countries.

Comments on Issues Raised by Mr. Richard Seifman, Director, AID/R&D/N

The first issue dealt with a balance of accomplishments among essential studies, field application/training, and advocacy.

At this stage of progress in the project, a balance among these components has not been achieved, nor should it be expected. These components must evolve in sequence. The essential studies that would identify the suitable food carriers, the form of iron to be used, and the fortification process had not been conducted ten years ago. The information base available today was generated mainly as a result of this AID project and work undertaken by the food industry often in collaboration with this project. So, there has been considerable and satisfactory progress in the scientific and technological development of this field.

Field application/training had to await sufficient accumulation of knowledge on the basis of which projects could be developed. So far, field studies have progressed on a limited scale and in step with scientific and technological advancements. At present, large scale trials are needed, and are, indeed, feasible with the availability of supporting educational and training material.

Advocacy is the unfortunate void in achieving the desired balance among the stated components at present. A conscious and concerted effort must be made to develop a constituency and an advocacy base to improve iron status in many countries.

Therefore, it has been necessary to do good research to provide a basis for fortification and the technical assistance required for program implementation. The planned intervention trials in Tanzania, Indonesia and Grenada will add to the database to encourage other programs. Now, a major thrust of the project must be focused on advocacy.

The second issue addressed whether the iron project could have progressed without AID involvement, and whether it could now be designed with less AID input.

It is hard to imagine that the frontier of knowledge on iron status assessment and improvement could have advanced to the present level without the AID project. Dr. Cook's contribution to the field has been fundamental to this development. AID's support was essential to ensure the initiation of the studies, and has allowed emphasis on the utilization of knowledge from the applied research.

The heightened awareness of the iron deficiency problem worldwide could not have reached the present level without the efforts of INACG and the support it received from AID. An objective 'third party' was essential to provide a credible forum for industry, regulatory agencies, academia and advocacy groups to communicate. INACG, with the support of AID, provided such a forum.

If the project were to be re-designed with less AID input, an effort will have to be made to interest an organization that is concerned with the health and socio-economic development of Third World countries to undertake some of the project's components. It may be possible to interest other bilateral or multilateral donors and organizations to undertake such a task. In this case, AID should keep enough involvement to share in the success that will grow out of its investment to date.

It should be stated that it would be highly undesirable and counter-productive for AID to dissociate itself from such serious an issue. AID has contributed enormously towards the solution of the problem and has access to technological resources like no other organization. AID exercises considerable influence and prestige that should be brought to bear with governments of developing countries, bilateral and multilateral organizations, NGOs/PVOs, and the food industry.

The third issue sought to identify the gains and losses that may result from the private sector buying into the iron project.

The private sector has been involved, and has contributed to the project over the years. Collaboration from industry, i.e. Nestle with the ICCNA and the International Life Sciences Institute (ILSI) with INACG, has contributed significantly to the success of the project. There is a great deal to be gained from the continuation of such inputs where coincidence of interest and complementarity of expertise exist. However, a lot of time and effort could be lost were we to search and seek interested private sector groups. In

the developing countries, this is particularly difficult. Many of the countries that have severe iron deficiency problem do not have a well developed food industry. In fact, much of the food that is consumed in major amounts is locally processed at the village or even family level. Finding a private sector group or individual company that would benefit directly in many cases is very difficult. Perhaps one way to overcome this difficulty is to encourage partnerships between the private sector and donor agencies.

Summary and Recommendations

The evaluation of the project and the many activities generated within it revealed impressive achievements that would not have been possible without AID's initiatives as far back as the late seventies. Expenditures on programs at the ICCNA, Rutgers University and INACG have leveraged AID with funds and resources to achieve the project stated goals.

The activity at the ICCNA has advanced the frontier of knowledge of iron bioavailability, and has contributed to the development of effective new systems for delivering biologically available iron via supplementation and fortification strategies. Of these, iron fortification of foods is the more effective approach. The use of iron EDTA as an iron source holds considerable promise in bypassing the effect of major absorption inhibitors found in many foods.

The activity at Rutgers University has made significant progress to date in dealing with the difficult technological problems in the iron fortification of rice. The technology, if proven successful, should be applicable to other foods and benefit from the scientific resources of the ICCNA.

The activity at INACG has played a major role in heightening professionals' awareness of the iron deficiency problem via international meetings and scientific reviews. The structure of INACG, with its Steering Committee and many Task Forces, has been effective in involving bilateral and multilateral organizations, and the food industry. However, their role in influencing policy makers and advocating for fortification programs has been limited.

The evaluation of the project identified many opportunities that would enhance the project's impact enormously. These are reflected in the following recommendations:

- The project should be strengthened and its impact enhanced. Iron deficiency studies have the potential to form the pillar for studies of micronutrient deficiencies. Iron malnutrition is the most studied, best understood and most frequently acknowledged of micronutrient deficiencies; therefore, iron deficiency studies provide a scientific, sociological and practical base for control of many micronutrient deficiencies. Given the grave consequences and the prevalence of iron deficiency, priority to combatting iron deficiency anemia has to be given in the allocation of resources and mobilization of support from a very broad international coalition. AID with its resources and international prestige has a responsibility to spearhead such an effort.
- The project needs an advocacy component to reach the decision makers within AID Headquarters and its missions in developing countries. AID commitment to solving the problem of iron deficiency anemia in the world would galvanize efforts in other international agencies and in the food industry, and would mobilize their many resources. Advocacy activities are crucial at this stage to enhance the impact of the project and put to full use its many technological achievements.
- AID should promote and support field trials like those planned in Grenada, Indonesia and Tanzania. This will afford the project the opportunity to test the usefulness and applicability of the iron delivery systems developed at the ICCNA, and to evaluate the acceptability of fortification methods developed at Rutgers University. Field trials will also make use of skills in information dissemination and development of training material by INACG. All the technological achievements of the project are of value only to the extent that they may be used in developing countries to alleviate the iron deficiency problem.
- The project's current programs represent a very valuable resource. The momentum they provided should not be lost. They should be sustained. Their activities, however, will need to reflect a strong orientation to planning, implementation, monitoring and evaluation of field operations. ICCNA and Rutgers University may emphasize training of laboratory and field personnel to implement, monitor and evaluate field trials. INACG may need to establish presence in some interested developing countries or help them develop their own national consultative groups.
- AID should review iron fortification of Title II commodities and blends, using biologically available forms of iron, such as the iron delivery systems developed and tested at ICCNA. In Title II commodities and blends fortification programs, the most contemporary information should be applied relative to iron compounds, process technology, and interacting nutrients.

- AID should first seek country-level approval for the use of iron EDTA. This should lead to Codex Alimentarius Commission approval that in turn should facilitate iron fortification of foods in developing countries. This form of iron has proven most efficient and least expensive in many fortification systems.

Appendix 1

Evaluation Background Paper and Statement of Work

BACKGROUND

This project serves as the Office of Nutrition's mechanism for assisting developing countries in combatting iron deficiency anemia. The project channels scientific, technical and planning expertise to host country institutions and A.I.D. field staff through cooperative agreements/contracts with the Kansas University Medical Center (KUMC), the Nutrition Foundation (NF), Rutgers University (RU), and John Snow, Inc. (Mothercare S&T/H project activity).

The current project was instituted in FY 1987, as a follow-on to a previous activity. Both KUMC and NF had been supported under the previous initial activity.

KUMC, under which the International Center for the Control of Nutritional Anemias (ICCNA) was established, functions as the scientific and technical resource for this project. The current cooperative agreement with ICCNA/KUMC focuses on: (a) refinement of methods to assess iron nutriture; (b) studies of iron bioavailability in humans; and (c) overseas technical assistance and the development of field intervention strategies.

The International Nutritional Anemia Consultative Group (INACG) is administered under a cooperative agreement with the Nutrition Foundation. The purpose of INACG is to guide international activities aimed at reducing nutritional anemia in the world. The group offers consultation and guidance to various operating and donor agencies who are seeking to reduce iron deficiency and other nutritionally preventable anemia. In fulfilling this mandate, INACG sponsors scientific reviews and convenes task force groups to analyze issues related to etiology, treatment and prevention of nutritional anemias.

Iron currently used in fortifying commercially available rice is not well absorbed. The Cooperative Agreement with Rutgers University is to develop a cost-effective bioavailable iron fortified rice. If accomplished, rice would become a vehicle for delivering this important micronutrient iron to a large segment of the world population which depends on rice as a principal diet food staple (e.g. Southeast Asia).

Office of Nutrition funds have been added to the Office of Health's MotherCare project. This activity is contracted with the John Snow, Inc. MotherCare focuses on the health of women during pregnancy and the perinatal period. The Office of Nutrition funding supplements the MotherCare project to support activities on iron supplementation to pregnant women.

A cooperative agreement is to be executed in FY 91 with the Caribbean Food and Nutrition Institute (CFNI), Kingston, Jamaica. CFNI is a field unit of the Pan American Health Organization (PAHO), Washington, DC. This new activity will support the initiation of a country-wide iron fortification of wheat flour in Grenada, West Indies.

The project has developed new and improved methods for the assessment of iron status. These methods have improved the accuracy and precision of iron assessment in shorter time, employing only microquantities of sample and at less cost. New systems of supplementation and fortification for the delivery of bioavailable iron to populations have been developed and have field tested or are poised for field use. Country strategies for combatting iron deficiency anemia have been formulated. The project has expanded the sum of applied knowledge which can be used as an attack in worldwide iron deficiency. In addition, the preparation and documentation of information such as state-of-the-art monographs, technical abstracts, guideline reports have been universally accepted as basic reference documents on iron deficiency anemia.

External reviews of the predecessor iron project were conducted in 1988, 1985 and 1980. The current review is being conducted at the point of termination of the iron project, increased interest in micronutrients, and the design of a new micronutrient project. Lessons learned from the project and recommendations from the evaluation will be factored into the design of the new micronutrient project.

ARTICLE I - TITLE

A. Project No. 936-5115, Combatting Iron Deficiency

B. Contractors/Grantees:

Kansas University Medical Center
39th & Rainbow Boulevard
Kansas City, Kansas 66103
CA #: DAN-5115-A-00-7908-00
Contact: Dr. James D. Cook

The Nutrition Foundation
1126 Sixteenth Street, NW
Washington, DC 20036
CA #: DAN-5115-A-00-7114-00
Contact: Dr. Suzanne Harris

Rutgers University
Dept. of Food Science, Cook College
New Brunswick, NJ 08903-0231
CA #: DAN-5115-A-00-9089-00
Contact: Dr. T.C. Lee

John Snow, Inc.
1616 N. Fort Myer Drive
Arlington, VA 22209
Contract #: DPE-5966-2-00-8083
Contact: Dr. M. Koblinski

Caribbean Food and Nutrition Institute (CFNI)
Pan American Health Organization (PAHO)
Kingston, Jamaica, W.I.
CA #: (TBD)
Contact: Dr. W.K. Simmons

ARTICLE II - OBJECTIVE

- A. To evaluate the activities carried out under the current cooperative agreements and contract in order to assess:
- (1) compliance with the objectives of each cooperative agreement;
 - (2) project progress and accomplishments to date: technical assistance, research, dissemination of information; and
 - (3) gaps in project activities.

- B. To advise S&T/N as to future project directions in the context of past and current project activities and in light of recent global interest regarding micronutrient malnutrition.

ARTICLE III - STATEMENT OF WORK

The evaluation team will address the following issues:

- A. Is the project design consistent with the following objectives.
- (a) expand the scope of knowledge regarding iron deficiency anemia and methods for its assessment and control;
 - (b) develop and test intervention approaches;
 - (c) disseminate new knowledge and experience relating to the control of iron deficiency anemia; and
 - (d) encourage and assist countries to define and control the problems of iron deficiency anemia.
- B. Is the project making an impact consistent with the resources available? If so, has the rate of progress been satisfactory?
- C. Within the constraints under which the project operates:
- (a) are developing country needs being adequately responded to?
 - (b) has the balance between research and technical assistance provided to countries been sufficiently supporting of project objectives?
- D. Have AID resources been adequate to support the planned activities?
- E. Are there management issues or practices which may be adversely affecting progress of the project?
- F. Is the interaction with other multilateral and bilateral donor agencies sufficiently active and effective?
- G. Is the interaction with the private sector sufficiently active and effective?
- H. How well has information been disseminated under the project?
- I. Do the project achievements and potential appear to justify its continuation? Why?
- J. Are the project's activities significant in combatting iron deficiency worldwide?

ARTICLE IV - METHODS & PROCEDURES

The evaluators will complete the following activities in the general sequence of the listing below:

- A. Review project documents:
 - (a) cooperative agreements and contracts;
 - (b) report of previous project evaluation;
 - (c) project reports;
 - (d) INACG reports;
 - (e) other publications; and
 - (f) project funding history.
- B. Conduct interviews with relevant staff in AID/Washington, Nutrition Foundation, Kansas University Medical Center (to be conducted in Kansas), Rutgers University (to be conducted in New Jersey) and John Snow, Inc. (MotherCare).
- C. Prepare and submit an evaluation report in draft form.
- D. Discuss the evaluation findings and recommendations with AID, Office of Nutrition, and with cooperative agreement principal investigators prior to finalizing evaluation report.

Appendix 2

Evaluation Team Members' Background

Dr. Robert O. Nesheim, a nutrition scientist, was Senior Vice President for Science and Technology and President of the Advanced Health Care Division of Avadyne, Inc. (1983 to 1991), Monterey, California. From 1969 to 1983, Dr. Nesheim was with the Quaker Oats Company (Chicago, Illinois) where he served as Vice President for Science and Technology and Vice President for Research and Development. At the University of Illinois (Urbana), Dr. Nesheim headed the Department of Animal Sciences (1964 to 1967). The author of many academic publications, Dr. Nesheim has contributed his expertise to numerous scientific organizations, including the National Academy of Sciences' Food and Nutrition Board. Dr. Nesheim currently chairs the Board's Committee on Military Nutrition Research.

Dr. George A. Purvis, a nutrition and food scientist, has been with Gerber Products Company (Fremont, Michigan) since 1963 where he is Vice President for Scientific Affairs. Dr. Purvis' duties include serving as scientific policy representative to scientific organizations, professional societies, governments and trade associations. He is a trustee of the International Life Sciences Institute/Nutrition Foundation, has served in numerous scientific committees, including several of the National Academy of Sciences, and has published extensively, particularly on infant nutrition.

Dr. Zak I. Sabry, a nutrition scientist and food technologist, has had a distinguished career in academia, the international civil service, and the private sector. Dr. Sabry is currently Professor of Nutrition at the School of Public Health, University of California, Berkeley. Previously he held professorships at the Universities of Toronto (1964-1972) and Guelph (1976 to 1979) in Canada. Dr. Sabry was President of Nutrition Research Consultants, Ltd. from 1972 to 1976. He served as Director of the Food Policy and Nutrition Division of the United Nations's Food and Agriculture Organization (FAO) in Rome from 1979 to 1984. Dr. Sabry is a frequent consultant to FAO, the World Bank, and AID.