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9. ABSTRACT

A joint discussion of various experiments in alleviating protein needs by "fortification." These trials included a Tunesian project adding lysine (a synthetic amino acid) to centrally milled wheat, a similar experiment in Thailand using rice, addition of synthetic amino acids and soy to corn in Guatemala, the testing of formulations and fortification of cassava in Brazil, and various projects in India including fortification of both atta and bread and the use of some new carriers to provide iron and vitamin A. The purposes of the workshop itself were: to exchange experiences, to consider modifications, to develop a fortification checklist, and to consider steps to move to full-scale implementation. This report includes summaries of and recommendations for each project, guidelines for field demonstration projects, and a discussion of implementing project results. There are no general summaries or recommendations.

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May 1972

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Washington, D.C. 20523

WORKSHOP ON FOOD FORTIFICATION

REPORTS

Vail, Colorado
May 2-4, 1972

Convened by

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Introduction

Adding vitamins and minerals to foods to improve their nutritive quality has been practiced to varying extents for many years, but the concept of going beyond this to alleviate protein needs by "fortification" has only recently emerged as a serious possibility. If successful, this approach could mean that in areas where fortification is undertaken many of the critical deficiencies could be met by a process which does not require changing food habits.

To test this concept in field settings AID has assisted the development of a series of pilot trials. In Tunisia, the synthetic amino acid, lysine, is being added to centrally milled wheat to improve its protein effectiveness. In Thailand, a similar trial is underway with rice. Improvement of corn through addition of synthetic amino acids and soy is about to begin in Guatemala. In Brazil, testing of formulations is nearing completion and the fortification of cassava is expected to commence shortly. In India, a number of activities are underway, or planned, including both fortification of atta and bread and the use of some new carriers for provision of iron and vitamin A.

The stage reached by these projects in 1972 suggested that it might be of benefit if those engaged on the projects could be brought together to discuss their activities. Key field personnel, both host country and U.S. nationals, were invited to a working meeting. Individuals with special expertise in various aspects

of fortification were also invited from universities, the private sector and government.

The purposes of the workshop were several:

To exchange experience: The projects all involve similar principles but in each case the application is different. It was felt that the personnel responsible for any given project would find it beneficial to obtain detailed knowledge of each of the other projects.

To consider modifications: From such a mutual interchange it appeared likely that some modifications in project design would emerge, and it seemed that this was the time for such modification--after initial experience had been gained but before the projects were completed.

To develop a fortification checklist: From a pooling of experience it was hoped that some general lessons could be derived which would be useful in the development of future projects. If possible, a checklist of such principles might then be developed.

To consider steps to move to full-scale implementation: Finally, it seemed important to consider what steps should be undertaken now or in the future to move from a trial to large scale implementation. What might be required to assure that host-country decision-makers become informed of these projects and seriously consider the implications of project findings for national programs?

The first half of the workshop was devoted to a discussion of each of the pilot projects. Project personnel described the activity, elaborating on a brief background paper distributed to the participants prior to the conference. Presentation was followed by discussion in which a number of points of view were brought to bear. On the one hand, there was concern with the question of what information should be provided by the projects to influence policy decisions. For example, should morbidity data be included as well as growth? Should psychological tests be included? How much attention should be given to developing information on costs of large-scale application?

Another type of question concerned design - e.g. what are the pre-requisites for a successful project; what type of dietary intake data is needed; what should be fortificant composition; what precautions are required to guard against toxic effects?

Finally, interrelated with consideration of what project components were most desirable was the question of what is actually feasible in a field situation. What types of information can reasonably be collected, and how?

Following these discussions, the workshop turned to another aspect of the problem: Beyond the execution of a successful pilot project how can one assure that the transition from trial to policy decision really occurs? A scheme of general action and communication flow was discussed together with various suggestions

on specific techniques for involving policy-makers. A critical issue in this discussion was what the role of the scientist-researcher should be. "Selling" or motivation of decision-makers is not supposed to be his area of expertise--or responsibility. But, it was argued, can he leave the application of his findings to a mystical "they" who will somehow convince the policy-makers, or must the project man, as the individual with the most complete understanding of the activity, also accept responsibility for laying the groundwork for the application phase of his work?

On the final day of the workshop, task groups for each project presented the implications of the preceding discussions for their activity. In addition, reports were made on a set of general guidelines for project development and on the question of moving from research and development to national action. The notes, as developed by these groups, are provided here. Preceding each of the project recommendations is a background summary of the activity which was distributed prior to the workshop.

MARTIN J. FORMAN
Director, Office of Nutrition
Technical Assistance Bureau

Drafted: George Kerr
Harvard

Fortification of Wheat - Tunisia

Under-nutrition is postulated to be the major cause of the short stature and maturational delay evident in the child population of many developing countries. Fortification of economically available cereal products with nutrients in which they are deficient has been shown to be of nutritional value in experimental animals and small groups of children. Whether such an approach is feasible or of significant nutritional value in large populations remains to be demonstrated.

The villages around Chott el Djerid, a large salt lake in southern Tunisia, were chosen to investigate the effect of supplementing wheat products with a variety of vitamins, iron, and lysine. Three racial or ethnic groups are found in the area: Arab, Berber, and Negro, each of which may have unique anthropometric features. The area is impoverished with a mean monthly family income equal to approximately 30-40 dollars. This obviously limits purchase of high quality protein foods. These villages border the Sahara Desert, and the rainfall of less than 100 millimeters per year is adequate only for the most limited local agricultural productivity. Harvesting of dates is the major occupation of most men, and provides most of the yearly income during a very short period of time. The infant mortality is estimated at about 20% of all live births, the majority of deaths occurring in the first month of life. Infants are generally breast-fed until about two years of age, thereafter they are fed the usual diet of adults.

Wheat is the main dietary staple in these villages, providing more than 60% of the daily caloric intake and over 70% of the daily protein intake according to data available at the start of the project. The majority of wheat products consumed are milled in northern Tunisia. All aspects involved in milling, distribution, and sale of wheat products are under governmental control.

After a preliminary survey and census of all villages in the area, containing a population of approximately 80,000 people, a group of 12 villages with a population of about 16,000 and a preschool child population of about 3,000 was divided into three study populations: These would receive (1) unsupplemented wheat products; (2) all wheat products supplemented with vitamins and iron; or (3) all wheat products supplemented with vitamins, iron, and lysine. Villages selected were chosen to meet the following criteria: (1) characteristic of the area and comparability to villages in the other study groups; (2) comparability of demographic, family

structure, racial and socio-economic criteria including the amount and source of income; (3) low-level of immigration or emigration; (4) comparability of racial backgrounds; (5) lack of local production of wheat; (6) accessibility by road but with limited contact with other commercial traffic; (7) absence of such extreme poverty that any effect of improved quality of food might be obscured by a lack of quantity on an economic basis, and finally (8) availability of all children in the study villages for serial evaluation.

The developmental processes of children are known to be sensitive to nutritional influences, and this study was designed to evaluate the effects of fortification of wheat products on development of preschool children whose nutritional intake is largely under parental control. Measures evaluated in all children at six-month intervals include standard anthropometric measures, bone maturation and linear growth, dental development, physical examination, hematologic status and a few urinary and serum measurements of nutritional status. Data on parental stature is collected in order to interpret the data derived from their children. In addition, a weekly census is conducted on births, deaths, and marriages in each village, and a detailed five-day dietary survey of food consumption of representative families is being performed. In order to maintain parental and child participation in the project, used clothing is distributed and an education-entertainment series of films is being introduced. All training of local personnel and all reliability trials are conducted in the pilot village representative of the area but not included in the study. A satisfactory format for a morbidity study has not yet been identified. Our major concerns to date have been in the area of quality control of personnel, of fortification processes and distribution of enriched products, of measuremental procedures, and of data analysis. Although it was originally intended to perform a survey of parasitic infestations, this has not been possible except on a sporadic basis.

The various fortification nutrients are sent by the manufacturers to Minneapolis and are premixed at the Pillsbury plant. The two types of premix - with and without lysine - are shipped to the study office in Tunis. Premixes are delivered to appropriate mills in Tunis where cereal products are fortified at pre-determined rates. Each fortification process is supervised by project personnel. After identifying bags of enriched products with colored strings, the products are shipped to warehouses from which they are purchased by storekeepers from the individual villages. These storekeepers are only allowed to purchase products marked with a particular colored string. They are not aware of the nutritional supplements contained in the bag, only that the string indicates improved quality.

The pre-fortification control data collected to date has identified significant shortness of stature in this child population by two years of age despite normal measurements at three and six months of age, a pattern and sequence of dental development which is generally comparable to those of accepted standards of reference, lack of classical signs of malnutrition, and significant reduction in hematologic status in a small population. In only 10% of the families does the per-capita food consumption meet the FAO recommendations.

All cereal products have been fortified since mid June of 1971. Although it is probably too early to detect any change as a result of this fortification program, it is hoped that the measures being followed will be adequately sensitive to detect changes in developmental velocity occurring over the next several years. The interpretation of such changes, their implication not only for the entire child community of Tunis, but most likely for much of the world, and methods by which such data can influence the governmental priorities for child care in Tunisia can not be anticipated at this time.

Task Group Recommendations for Project Modification - Wheat

Chairman: Boutourline
Secretary: Kerr
Members: Ard, Catoe, Hemaiden, Tesi, Rosenfield, Reed

General:

The stated primary purpose of the project is "...to conduct a rigorously planned and controlled test among a sufficiently large number of people living under natural conditions in order to demonstrate the nutritional benefits which can be derived from lysine fortification of wheat products."

It is felt that the primary goals and responsibilities of the project are being met in that the cohorts under study represent the most vulnerable section of the population, the measurements being made are objective, the data collected to date is extensive and is being efficiently analyzed.

In working toward achievement of the goals of this project it is important to recognize the critical assistance and cooperation provided by Dr. Kallal, Director of the National Institute of Nutrition. As part of the execution of this project, we will continue to work with and train senior level Tunisians who can plan and implement nutrition programs. And since the Tunisian government has recently recognized the equivalency of U.S. degrees, Harvard plans to reintensify its efforts in this area.

We feel that a major achievement of this conference has been the recognition that a sequence of strategy options and methods for evaluating their potential must now be incorporated into our project in order to fully accomplish its original goals.

Recommendations

1. All cohorts currently under study are essential for the design and completion of the project. Each of the variables currently being measured are similarly essential to the interpretation of the total collected data.

2. Certain aspects of the study must be improved. The process of fortification of wheat in the mills, quantitative and qualitative control of the products, and accurate distribution of the products must be assured. Ideally these assurances will involve the recruitment, education and training of Tunisians.

3. We feel there is need to do a study of adolescents because this period of growth represents, together with the pre-school age, a period of life particularly vulnerable to the effects of malnutrition and, therefore, to the effects of fortification. Such a study would provide us with knowledge of the present pattern of growth from the first months of life through to maturity.

4. While we recognize the importance of nutritional correlates of maternal and neo-natal health, we have seen that a far more sophis-

ticated approach is being conducted in Guatemala, and a sharing of data, rather than duplication, may be of mutual benefit. Major logistic problems exist in initiating such a project in our study villages, and it could conceivably have an adverse effect on the current productivity of the project. We propose, however, to suggest that the National Institute of Nutrition of Tunisia explore the feasibility of such a study, ideally in concert with the Family Planning Program. Such a study would not be conducted in the villages which we have selected for intensive measurement, but would be undertaken in villages receiving fortification.

5. Studies of cost analyses, product acceptability and the feasibility of local lysine production are planned for a later date. We are, however, currently developing cost estimates based on present methodology and information. Such estimates will be updated at periodic intervals.

6. We feel that sufficient background data has been collected to initiate an education program directed at legislative and health care agencies in Tunisia. While it would be premature to assess in any refined sense the nutritional benefits of fortification before the research has been completed, considerable experience on the nature of the nutritional problems of Southern Tunisia and on the practical problems of carrying out wheat fortification procedures has been developed. It would, therefore, appear timely to begin

discussions with the Institute of Nutrition and other appropriate governmental agencies about the desirability and feasibility of conferences, workshops or similar activities addressing the long-range possibilities and implications of a national fortification program. Such conferences might take a wide variety of forms, ranging from medically oriented consideration of the nature and implications of growth retardation in Southern Tunisia to food industry consideration of the steps needed to introduce a wheat enrichment process. Nutrition policy-makers in Tunisia and similar countries might wish to learn more about the objectives and potential findings of this research project and related projects throughout the world as a basis for considering the additional types of information that they may need.

Drafted: Stanley Gershoff
Harvard

Fortification of Rice - Thailand

1. Project Objectives

A. To evaluate the health benefits to be derived from the fortification of rice in Thai villages with lysine and threonine plus some vitamins and iron or with a vitamin, iron mixture lacking amino acids.

B. To evaluate the health benefits of day care centers in Thai villages with or without the fortification programs.

2. Descriptions of Populations Receiving Fortification

Following a one year pilot study in four villages designed to work out methodology problems, 29 villages in the Chiang Mai area of Thailand were selected for a full field study of rice fortification. These villages have a total population of approximately 13,500 and 1,600 children between 6 months and 6 years of age.

The villages are similar in social structure and economic status and were selected because the villagers, their head men, and their millers indicated that they would be happy to cooperate in the study. The villages with one exception have only one rice mill apiece and are not conveniently close to what might be described as an urban shopping area.

The state of nutrition of the people of these villages is poor using a variety of clinical criteria. Rice is plentiful and provides approximately 80% of the calories consumed. There is some marasmus and kwashiorkor in the villages but acute protein or protein-calorie malnutrition is not common. Dietary and clinical surveys in this area of Thailand indicate that diets are very low in riboflavin and also poor in thiamin and vitamin A. Our own studies support this, and we are particularly aware of clinical signs compatible with riboflavin deficiency and with large numbers of cases of anemia both in the children and their mothers.

The villages have been divided into five groups whose preschool children appear similar physically according to our examinations.

Group 1 - Raw Controls, no treatment.

Group 2 - Placebo Controls, placebo fortification granules added to rice; day care centers provided.

Group 3 - Rice fortification grains containing thiamin, riboflavin, vitamin A, and iron; day care centers provided.

Group 4 - Rice fortification grains containing thiamin, riboflavin, vitamin A, iron, lysine, and threonine; day care centers provided.

Group 5 - Rice fortification grains used in group 4; day care centers not provided.

Concern over the acceptance of riboflavin because of its color caused us to leave it out of our original fortification mixtures. However, the large number of children with clinical signs compatible with riboflavin deficiency makes it necessary to add it to the fortification grains. Attitude surveys which we have recently conducted indicate that there will be little objection to the color of the granules containing riboflavin. It is expected that the vitamin will be fully introduced into the study in May 1972.

Although people of all ages will receive the rice fortification mixtures, current evaluation is limited to pre-school children and their mothers. As the study progresses we may study other groups in the population.

3. Fortification Mixture

The fortification mixtures used in this study are being added to rice in the form of a pellet which resembles rice. These rice fortification grains (RFG) are added at a 1% level to the rice as it pours out of the village mills. Low cost dispensers have been built by us and attached to each of the mills used in the study.

The nutrients in the fully fortified RFG consist of:

20% L lysine HCl
10% L threonine
0.05% thiamin (as thiamin naphthalene disulfonate)
0.6% riboflavin
0.7% vitamin A (At the time of manufacture 2370 IU of vitamin A in the form of an oil concentrate of vitamin A acetate is added to each gram of RFG. There is considerable loss of vitamin A activity during the processing of the RFG and some loss during storage. The data available indicate that storage of the RFG for 90 days at 30° C(86°F) would result in a combined loss from processing and storage of about 45%. Thus the RFG as used would contain about 1300 IU of vitamin A per gram).
0.2% Fe provided by 0.8% $FePO_4 .4H_2O$

4. Surveillance Procedures

It is obvious that it is essential to know whether or not the population being studied is consuming the RFG and whether the RFG is being added to the rice at the desired level. A variety of methods are being used to determine this.

A. All millers have been asked to keep records of the amounts of rice milled and for which households. We know how much RFG is used. Our calculations indicate that the RFG is being added at 1% $\pm$ 0.01 - 0.03%.

B. Our staff regularly checks the operation of the feeding device at the mills and whether the miller is using the RFG as planned.

C. After cooking, the RFG can be seen in the rice. This is true even before cooking when the RFG contains riboflavin. We are visually checking the rice brought to the day care centers by the pre-school children and spot checking in the homes for RFG.

D. As part of our system for collecting morbidity data, the mothers of all pre-school children in the study will be interviewed once every two weeks and will be asked if the family and her pre-school children are eating the RFG.

E. Occasionally, random samples of urine will be obtained from the pre-school children and examined for thiamin. In the pilot study we could see marked increases in urinary thiamin excretion in the children receiving the fortification mixtures.

5. Evaluation

Physical examinations of the subjects in this study are being conducted twice each year, during January-February and August. The winter examination is somewhat more complete in that it includes hand-wrist x-ray, fecal parasite, hemoglobin, and hematocrit examinations which are not done in the summer. Both examinations include the measurement of weight, height (reclining length), tricepts and subscapular skinfold thickness, head, chest, and arm circumferences, the taking of a clinical history, and a clinical examination.

In addition, morbidity records will be kept on each pre-school child every two weeks throughout the study. Attached are copies of the forms on which the data are kept and from which they can easily be transferred to IBM cards.

It is hoped that we shall be allowed to develop a capacity to measure the effects of this program on mental and motor development on the children in this study.

6. Special Problems

There have been no serious technical problems in this study. Those problems which have arisen have generally been the result of communication difficulties and delays.

7 and 8. Cost and Follow-on Application

The study which we are doing is designed to determine the benefits to be derived from a multifaceted rice fortification program and from village day care centers for pre-school children. Any program, no matter how small, costs money. We feel that the decision-makers in any country have the right to ask and the need to know what they can expect to get for their money if they adopt programs recommended by health planners. We hope that this study will provide some of the needed information.

The mechanics of rice fortification may be accomplished in a variety of ways and may vary from country to country and between urban and rural areas. The techniques we are using in our study were selected because they appeared likely to provide us with the data we wanted in as efficient a way as possible. We are not suggesting that if the results of this study support the concept of developing national rice fortification programs that our technique must be copied. It must be recognized that in an experiment it is necessary to reach essentially all of the people in the study group and that consequently the methods used may have to be considerably different than in large scale public programs where it is rare that the entire population can be included.

PEDIATRIC CARD

CARD NO. [1] 1

NAME

VILLAGE

IDENTIFICATION NUMBER [2][3] VILLAGE [4][5][6] FAMILY [7] [8] CHILD

DATE OF EXAM [9][10] DAY [11][12] MONTH [13][14] YEAR

BIRTHDAY [15][16] DAY [17][18] MONTH [19][20] YEAR

SEX [21] MALE 0 FEMALE 1

SOURCE OF INFORMATION [22] MOTHER 0 OTHER 1

MOTHER NOW PREGNANT [23] NO 0 YES 1

BIRTH ORDER [24]

AGE OF MOTHER [25][26]

NUMBER OF PAST PREGNANCIES [27] LIVE BORN [28] STILL BORN [29] ABORTIONS

OF THE LIVE BORN [30] LIVING [31] DEAD

OF THOSE DYING [32] DIED<1 YR. [33] DIED>1 YR. [34] DIED 5 YR. OR OLDER

THIS CHILD PREMATURE [35] NO 0 YES 1

WALKED [36][37] MONTHS OF AGE

CURRENT MEDICAL HISTORY NO 0, YES 1

[38] DIARRHEA

[39] BLOODY STOOL

[40] MUCOUS STOOL

[41] CURRENT URI

[42] RECENT URI

[43] RECURRENT URI

[44] MEASLES

[45] CHICKEN POX

[46] _____

IMMUNIZATIONS NO 0, YES 1

[47] D [48] DPT [49] POLIO [50] SMALL POX

ANTHROPOMETRY

[51][52][53][54] LENGTH CM

[55][56][57] WEIGHT KG

[58][59][60] HEAD CIRC. CM

[61][62][63] CHEST CIRC. CM

[64][65][66] ARM CIRC. CM

TRICEPS [67][68] MM

SUBSCAP [69][70] MM

[71] EXAMINER'S NUMBER

BLOOD SAMPLE [72] NO 0 YES 1

STOOL EXAM [73] NO 0 YES 1

X-RAY [74] NO 0 YES 1

STUDY CODE [79][80]

END CARD 1

PEDIATRIC CARD SIDE 2

CARD NO. [1]

IDENTIFICATION NUMBER [2] [3] [4] [5] [6] [7] [8]
VILLAGE FAMILY CHILD

NO 0, YES 1

GENERAL IMPRESSION
- [9] APATHY
- [10] PALLOR
- [11] IRRITABILITY

HAIR
- [12] DRY, STARING
- [13] DYSPIGMENTATION
- [14] THIN
- [15] EASILY PLUCKABLE

EYES
- [16] CONJUNCTIVAL DRYNESS
- [17] CONJUNCTIVITIS
- [18] BITOT'S SPOTS
- [19] XEROPHTHALMIA
- [20] _____

LIPS
- [21] ANGULAR LESIONS
- [22] CHEILOSIS

GUMS
- [23] SWOLLEN RED PAPILLAE(DIFFUSE)
- [24] BLEEDING

TONGUE
- [25] FILIFORM PAPILLARY ATROPHY
  - [26] MILD [27] MOD. [28] SEV.
- [29] GLOSSITIS

GLANDS
- [30] THYROID ENLARGED

SKIN
- [31] INELASTIC
- [32] PETECHIAE
- [33] FOLLICULAR HYPERKERATOSIS
- [34] DERMATITIS WITH DESQUAMATION OR CRAZY PAVEMENT TYPE
- [35] NASOLABIAL SEBORRHEA

ABDOMEN
- [36] HEPATOMEGALY
- [37] SPLENOMEGALY
- [38] POT BELLY

LOWER EXTREMITIES
- [39] BILATERAL EDEMA
- [40] CALF TENDERNESS

SKELETAL
- [41] CRANIAL BOSSING
  - [42] FRONTAL [43] PARIETAL
- [44] CRANIOTABES
- [45] COSTOCHONDRAL BEADING
- [46] ENLARGED JOINTS
- [47] BONE TENDERNESS
- [48] MUSCLE WASTING
- [49] _____
- [50] _____

OTHER FINDINGS
- [51] _____
- [52] _____

CLINICAL IMPRESSIONS
- [53] MARASMUS
- [54] KWASHIORKOR
- [55] EXAMINER'S INITIALS

HEMOGLOBIN [56] [57] [58] GM/100 ML

HEMATOCRIT [59] [60] PER CENT

OSSIFICATION CENTERS [61] [62] NUMBER OBSERVED

BONE AGE [63] [64] MONTHS

PARASITOLOGY (NO 0, YES 1)
- [65] HOOKWORM
- [66] TAENIA
- [67] ASCARIS
- [68] E. HISTOLYTICA
- [69] ENTEROBIUS
- [70] TRICHURIS
- [71] OPISTHORCHIS
- [72] _____

STUDY CODE [79] [80]

END CARD 2

MORBIDITY RECORD

RICE FORTIFICATION PROJECT

1	2	3	4	5	6	7	8
Card No.							

Village _____

Name _____

Year 197_ Interval Dates		Days in Interval	Days of Illness in Interval											Days Absent from Center	
			Cold Bronchitis	Whooping Cough	Diarrhoea	Dysentery	Diphtheria	Encephalitis	Hemorrhagic Fever	Chicken Pox	Mumps	Measles	Others	Inc. Accident	
mo/d to	mo/d														
Jan 1	Jan 15														
Jan 16	Jan 31														
Feb 1	Feb 15														
Feb 16	Feb 28-29														
Mar 1	Mar 15														
Mar 16	Mar 31														
Quarterly Total		9	10	11	12	13	14	15	16	17	18	19	20	21	22

23 child uses centre (0, no) (1, yes)

24 child uses RFG (0, no) (1, yes)

Apr 1	Apr 15														
Apr 16	Apr 30														
May 1	May 15														
May 16	May 31														
Jun 1	Jun 15														
Jun 16	Jun 30														
Quarterly Total		25	26	27	28	29	30	31	32	33	34	35	36	37	38

39 child uses centre (0, no) (1, yes)

40 child uses RFG (0, no) (1, yes)

Task Group Recommendations for Project Modification - Rice

Chairman: Amorn
Secretary: Gershoff
Members: Uthai, Ueda

General:

This project seeks to assess the impact, acceptability and feasibility of improvement of rice through addition of a synthetic rice granule containing amino acids, vitamins and minerals. The project design calls for measurement of the impact of the fortification on pre-school children and their mothers. The test population includes both villages where children participate in day care centers and villages without such centers.

Below are listed the recommendations of the task group. The recommendations reflect discussions held concerning the project during the course of the workshop.

Recommendations:

1. Once every 15 days all new babies will be weighed and their reclining body lengths measured.

2. We feel that we should explore possibilities for evaluating the effects of our fortification program on other segments of the population than those being studied currently, particularly school age children and adults.

3. We have also decided to improve our system for evaluating the biological value of the ingredients of the fortification granules.

4. We would also welcome any suggestions as to how we can measure the economic effects of our program on village life.

5. It is our opinion that decision-makers in Thailand would be interested in learning whether this program has beneficial effects on mental and motor development. We would like AID to develop studies of the feasibility of our doing motor and mental tests on pre-school and school children under the conditions found in the Thai villages of our study.

6. We recommend that consideration be given to the holding of two workshops in Thailand for the purpose of disseminating knowledge on the project. One such meeting would be aimed at providing information to Thai decision-makers and others who would be involved in extension of the activity to the national or regional level. A second type of meeting would seek to acquaint personnel of other rice-eating countries with the potential and feasibility of the fortification approach.

Drafted: Leonardo Mata
INCAP

Fortification of Corn - Guatemala

1. Objectives.

The goals of the model are biologic, administrative and political. The biologic objective is to demonstrate a substantial improvement in the health of the inhabitants, particularly children, evidenced in a decrease of rates of infection and infectious diseases, improvement of nutrition, fetal and post-natal growth, and reduction of infant mortality.

The administrative goal is to show that corn fortification is economically feasible, susceptible of being surveyed and evaluated, and attractive to community participation.

The political goal is to demonstrate the feasibility of the nutritional intervention at the level of a community, region or country, before the authorities responsible for health planning.

2. Design of the study.

Two very similar highland Mayan Indian villages are being studied: Santa Maria Cauque, the Fortification Village, where corn will be enriched at the community level; Santo Domingo Xenacoj, the Control Village, where no fortification will be done.

The Fortification Village has 1500 inhabitants living under very low socio-economic conditions; and with a high prevalence of malnutrition, infectious disease and growth retardation. Extensive anthropometric, dietary, clinical and microbiologic investigations during the period 1964-1971 in the Fortification Village have revealed fetal and post-natal growth retardation, high prevalences of infectious disease and very deficient diets. To illustrate, the composition of the diet of children is shown in Table 1.

3. Formulation.

The formulation, developed by R. Bressani, Table 2, will be added in an 8% concentration by weight of dry corn, to "nixtamal" (corn cooked with lime). This mixture increases the protein content of corn to approximately 12%, and provides the limiting lysine, tryptophane, and the vitamins and iron deficient in the diet of the region.

Table 1

Average Daily Intake of 45 Children Studied From Birth to Age Three Years, Santa Maria Cauque, 1964-1970

Age, Months	Number	Calories	Total Protein*, g	Vitamin A Activity, mg
12	45, breast-fed	225	4.6	0.036
24	33, breast-fed	520	13.6	0.125
	12, weaned	614	17.2	0.164
36	11, breast-fed	830	23.7	0.141
	31, weaned	927	25.3	0.272
Recommended Allowance**	10 months	1100	20.0	0.600
	20 months	1250	25.0	
	30 months	1400	27.0	

* 80% or more from corn.

** INCAP, 1968

Table 2

Fortifying Mixture for Corn*

Ingredient	Composition of supplement, %	Content in 8% added to corn, g
Soybean flour	97.5000	7.800000
L-lysine HCl	1.5000	0.120000
Thiamin	0.0268	0.002144
Riboflavin	0.0162	0.001296
Niacinamide	0.1930	0.015440
Ferric orthophosphate	0.6000	0.048000
Vit. A 250-SD***	0.0313	0.002504
Corn starch	0.1327	0.010616
	100.0000	8.000000

* Developed by R. Bressani, unpublished data.

** Contains 28.17% Fe.

*** 75,000 mcg Retinol/g.

4. Monitoring of fortification

Quality control analysis of each lot of fortified mixture will be performed. A representative group of families will be surveyed every month to determine the content of lysine in "tortillas" (flat-cooked pancakes of nixtamal). Dietary studies and urine analyses will be conducted in pregnant women and children to determine dietary and nutritional changes.

5. Evaluation.

The selection of the two villages, and the availability of a great amount of basal data, will permit several comparisons as illustrated in Table 3. The cohorts of pregnant women and babies could be compared: (a) in the Fortification versus Control Villages; (b) in the Fortification Village before and after the nutritional intervention; and (c) in the Fortification Village according to acceptance or rejection of the supplement. It is feasible that years after the commencement of the study, the Control Village could be initiated in a fortification program, thus producing a new type of experimental control.

6. Cost of fortification.

For the corn fortification model the mixture has been prepared utilizing ingredients of excellent and relatively expensive quality. However, the price of the first lot of fortifying mixture is of U.S. $0.26 per pound (transportation not included). Since the mixture will be added in an 8% concentration, the additional cost of corn will be U.S. $0.21 per pound of corn, that is, $0.21 per person per day. The fortification of corn at the community level in Santa Maria Cauque (1500 inhabitants) will cost U.S. $31.50 per day.

Approximately 2 million persons consume corn in Guatemala, representing $42,000 per day or $15.3 million per year, for fortification. Costs are significantly inflated because they are based on the price of a fortifying mixture produced in the United States, packaged at a relatively high cost.

One must keep in mind that estimated losses for protein of unfortified corn represents approximately U.S. $22 millions per year for Guatemala. It should be kept in mind also that soy beans can be grown and processed in Guatemala, mixing and packaging can be also locally done with considerable savings, particularly in transportation. Community participation will absorb most of the cost for logistics of implementation.

Table 3

COMPARISONS

FORTIFICATION VS CONTROL VILLAGE

A. Cohorts of children 1972 - 1976

a. fetal growth
b. post-natal growth
c. infant mortality

B. Cohorts of children 1964-1971 vs 1972-1976

a. fetal growth
b. post-natal growth
c. dietary intake
d. infant mortality
e. morbidity
f. *Shigella* infection

C. Cohorts 1964 - 1971 before and after fortification

a. post-natal growth
b. dietary intake

D. Cohorts 1972 - 1976, supplemented vs non supplemented

As in B.

However, the most significant economic impact of fortification cannot be at this moment evaluated because it relates to changes in the biological situation. A decrease in morbidity, a reduction of infant mortality, and an improvement of nutrition and fetal and post-natal growth, are, without question, the most important considerations in terms of the future of the society.

Task Group Recommendations for Project Modification - Corn

Chairman: Mata
Secretary: LaChance
Members: Bressani, Urrutia, Wilcke, Barreda

General:

The goals of the project are biologic, administrative and political. The biologic objective is to demonstrate a substantial improvement in the health of the inhabitants, particularly children, as evidenced in a decrease of rates of infection and infectious diseases, improvement of nutrition and fetal and post-natal growth, and reduction of infant mortality.

The administrative goal is to show that corn fortification is economically feasible, susceptible of being surveyed and evaluated, and attractive to community participation.

The political goal is to demonstrate the feasibility of the nutritional intervention at the level of a community, region or country, to the authorities responsible for health planning and policy making.

Recommendations:

1. We do not recommend changes in the parameters now being measured to permit the comparisons outlined in Table 3 of the background paper (preceding).

2. In order to optimize logistics (e.g., prevent unpredictable logistic interruptions) and reduce the long range cost of fortification, the fortification mixture should be prepared

in Guatemala. This would require a ribbon blender and a pellet machine. Local preparation would also permit examination of alternate modifications in the delivery system to anticipate emergencies, optimize technical considerations, decrease cost and anticipate expansion to broader segments of the population.

3. In addition to the existing dietary surveys of food intakes and calculated compositions, we propose the systematic random sampling of composites of the village dietaries. This is needed to quantify the nutrients present (and available) and their seasonal variations. The study must include the changes in protein quality, and the identification of micronutrients which may be limiting but have been unrecognized. It will also provide a basis for interpretations of improvements in diet through fortification.

4. We propose to add the measurement of selected biochemical and psychomotor parameters in the cohort of pregnant mothers and their children in both the control and fortification village. We have recently determined that blood samples could be obtained on an annual basis without adversely compromising the participation of the villagers. The following parameters are recommended: hemoglobin, hematocrit, iron binding capacity, albumin, vitamin A, urea and ratio of indispensable to dispensable amino acids and psychomotor development in infants. The systematic measurement of these parameters are fundamental for effective interpretations of the fortification effort.

5. In view of the favorable response to the AID sponsored conference on the Improvement of Corn held at INCAP in March 1972, we propose that a similar conference be held for decision makers and workers as soon as positive effects of the corn fortification intervention become evident, possibly two years hence.

Drafted: Marion Frazao
USAID Brazil

Fortification of Cassava - Brazil

BACKGROUND INFORMATION

Farinha de mandioca, or cassava flour, is one of the most widely-used basic commodities in Brazil, especially in rural areas and among those at the lower economic levels. Exact consumption is not known, as mandioca is often grown on the family food patch and consumed without entering production statistics, but Brazil is the world's largest producer, with an estimated 30 million tons of roots in 1970, of which around 10% is calculated for flour production. Mandioca flour is principally carbohydrate (around 83%), with only 1 - 2% protein. The major factors contributing to its widespread use, apart from traditionally acquired taste and ingrained habit of inclusion in the family diet, are:

1. Ease of cultivation: Mandioca will grow in very poor soil, without special agricultural techniques, with little water, and without fertilizer.

2. Freedom from infestation: Since its protein content is so low, it is unattractive to insects. It is also toxic to rodents.

3. Facility of storage: The roots may remain in the ground without spoilage almost indefinitely (up to 2 years) until needed.

4. Year-round availability: Although there are optimum periods for harvesting, nevertheless the roots can be dug up at other times so that as a foodstuff it is available all year.

5. Local and simple processing: Slightly more complicated than a backyard industry, mandioca processing is performed with the most primitive of equipment and can be carried out in a simple cooperative effort or exchange of services by any small group of people. Women and children can be used for the hand labor of peeling and cutting. There are, consequently, uncounted numbers of small industries scattered around the backlands, estimated by SUDENE at about 200,000, so that until recently the thought of fortifying the flour was untenable.

In the past decade or so, migration from unproductive or drought-ridden farmlands to the peripheries of urban centers where job opportunities might be greater has been marked. Thousands of farm families have left their land-to-mouth existence and entered the

commercial marketing system. On marginal incomes, they buy (1) what is familiar to them, and (2) what seems to be cheapest and most filling for the money. Mandioca flour is usually the product selected. This demand has led to the increasing commercialization of the product, sold in bulk in the street markets and more and more in paper or polyethylene bags in the supermarkets. Such large-scale commercialization has, fortunately, provided the needed intervention points where fortification may be undertaken.

PREVIOUS ATTEMPTS AT FORTIFICATION

In Brazil attempts were made at least as far back as the 50's to add protein to mandioca flour. These were unsuccessful due to the fact that the protein added (soy flour) imparted a bitter and unacceptable taste. However, within the past two or three years the first soy protein isolate plant in Latin America was set up in the south of Brazil and is producing commercially a product with 90% protein. Moreover, the Marine Research Institute in Rio de Janeiro achieved laboratory-scale production of a Fish Protein Concentrate, with a 80-88% protein level, which might also develop into an acceptable fortificant. Therefore, the idea of fortifying mandioca flour as one of the most appropriate vehicles for carrying more protein to needy Brazilians was resuscitated.

RATIONALE FOR DEVELOPINC THE FORTIFIED PRODUCT

Researchers and technicians in food fortification in Brazil had reached the following conclusions:

1. Since mandioca flour completely lacks protein, the addition of <u>any</u> protein would be beneficial and <u>any</u> amount would be better than the 1 - 2% it normally contains. (Dr. Aaron Altschul had stated, in Brazil, some time ago, that "the only protein that has nutritional value is that which reaches the stomach." Therefore, the first assumption was that whatever the protein added, and at whatever level, if the people ate it, it would be a nutritional improvement).

2. However, the Brazilian diet in general, based to a large extent on beans, was known to be short in methionine. Therefore the fortificant should either contain methionine itself, or methionine should be added to it. In other words, the fortified mandioca flour would be considered the vehicle for carrying methionine to the ration or diet, rather than a food to be fortified <u>per se</u>.

3. The selection of the fortificant to be used would depend on:

   a. Biological impact
   b. Availability within the country
   c. Taste acceptability
   d. Economic feasibility (comparative cost/benefit ratio)

To clarify this point: In the original fortificants check out, FPC was the best from the economic aspect, but was neither available within Brazil nor acceptable in taste; calcium caseinate was the most acceptable taste-wise, but would price the farinha out of the market; torula yeast was acceptable both taste-wise and economically, but was not available in Brazil; soy milk residue and dried whey were not in commercial production, and also had poor keeping qualities. The remaining possibility, soy protein isolate, was poor in methionine, and therefore methionine should be added. If this product were acceptable, it would be the one used initially in the market testing, but new possibilities and regional variations would continue to be studied.

OBJECTIVES

The objectives of the project are to get a fortified mandioca flour on the market in the Greater Rio area, to check its actual cost and acceptability; to utilize the market tests to prove to the Brazilian government and state and/or federal level that commercial marketing of a fortified flour is feasible; and to obtain government incentives to industry to produce this product on a larger scale. At the same time, this demonstration should also prove acceptability to public and private mass-feeding institutions and persuade them that they should support this, or similar fortified food efforts, by purchasing the products, thus providing base markets while the parallel commercial markets are being developed. Such market support would also contribute to a lowering of the price at which the product could be made available to consumers.

BIOLOGICAL IMPACT

Laboratory tests on small animals were undertaken at the School of Medicine in Ribeirao Preto, and Dr. Dutra de Oliveira will tell you about his findings at the workshop. Research on infants was also done by Dr. George Graham in Lima, Peru, and will also be done by Dr. Dutra and in Recife.

TECHNOLOGICAL PROBLEMS

Technological problems regarding the method and level of mixing also arose which will be described by Miss Maria José Paes Leme of the Institute of Agricultural and Food Technology in Rio.

INTEREST BY THE GOVERNMENT

Unfortunately, government interest in food fortification has not been demonstrated as yet in Brazil. The recent lifting of one of the taxes which falls on foods was designed to control inflation rather than for nutritional reasons. There is very little coordinated effort as regards improvement of food quality. Although there is a National Food Commission (and it is the counterpart through which AID works), it has neither the staff nor budgetary support for any real action. At the state level, here and there a spark of interest in improving nutritional levels appears, but only the most developed state (Sao Paulo) has made any progress towards formulating a nutrition policy or implementing a real program with nutritional objectives (other than school feeding, which is going well in practically all states).

INTEREST BY THE PRIVATE SECTOR

Initial contacts with industrial leaders indicated enthusiastic support of the idea of fortifying mandioca flour. Therefore, based on the premise that the private sector would probably take the lead rather than the government, the fortification project in Brazil began somewhat "hind-side-to" and from its starting point in the middle went backwards to obtain the necessary clinical studies and laboratory tests to validate the selection of the most appropriate fortificant, and forwards to obtain the collaboration for market-testing from the country's largest mandioca flour packaging firm and from two major supermarket chains.

PRESENT STATUS

Taste tests on the theoretically "final" product were run just last week by International Flavors and Fragrances which is collaborating gratuitously in the project. Depending on the results, the current product may be the one to be test marketed within the forthcoming two or three months.

COMMENTS

Since mandioca flour is used by the entire family, starting as a formula "thickener" for small babies, it was decided that no specific target groups would be determined. By the same token, since the test-marketing is to be done within an urban area, it is almost impossible to make a nutritional evaluation. The success of the project will depend on its commercial feasibility, and if purchases are repeated, it will be assumed that the consumers are benefitting nutritionally. Monitoring to see that fortification is

added at proper levels will be practically impossible if the project becomes nation-wide, as surveillance of food quality is practically non-existent. However, preliminary efforts are already being initiated by Brazilian counterparts to make fortification of mandioca flour compulsory; pressure will be exerted by the various organizations producing possible fortificants as well as by those interested in improving the nutritional level of the people, and there is a legal precedent in the iodization of salt.

FUTURE PLANS

Investigations are already underway in the area of Recife in the Northeast of Brazil and in the Campos area of the State of Rio de Janeiro regarding possible intervention points for mounting similar projects in other locations. In the area of Ourinhos, State of Sao Paulo, the largest cooperative of mandioca products for export, COPEM, has also ben contacted and has declared an interest in entering the fortified mandioca flour field if the Rio experiments are successful. The Rio reprocessing/packaging industry, GRANFINO, which will do the preliminary test-marketing has declared that if the results are positive, they will convert one or two of their suppliers in the south (as they are reprocessors and not manufacturers of the flour) to pre-mix within their own sales framework. Everything, of course, depends on obtaining an acceptable product, tastewise, utilizing soy protein isolate with methionine. We hope to have an answer within a very short time, perhaps even before the termination of this meeting.

Traditional procedure for making mandioca flour

("farinha" de mandioca)

The manufacture of mandioca flour may be divided into two categories: (1) when prepared by small rural processors, and (2) when processed in medium or large scale plants. In the first case it is an emprical method, based on rudimentary equipment. In the second case, where a high quality product is desired, not only installation and proper machinery are required, but also some degree of technical knowledge. In a factory, the process is as follows: the roots are taken to the plant directly from the field and immediately utilized. Delay will greatly depreciate the product, as it is well known that mandioca, once dug from the soil, deteriorates rapidly.

Washing and peeling

As soon as possible after the roots reach the plant, they are washed and peeled. This process is carried out in washing/peeling cylinders of different sizes, according to the plant's capacity. The roots are deposited in the cylinders and submitted to a continuous jet of water, which removes the earth and debris adhering to them. The rotation and friction cause the loosening of the peel, which is carried away by the water. In small home industries this is usually accomplished manually.

Grating

As soon as it has been washed and peeled, the mandioca must be grated. The graters are wooden or stainless steel plates, with steel or iron teeth parallel to the main axle. These are true disintegrators which produce a fine and uniform mass, often eliminating the necessity for final grinding.

Pressing

This is done in order to eliminate a great part of the water that accompanies the mass. In the factories it is performed by means of hydraulic presses of great capacity and high pressure. A good pressing will bring, as a consequence, a more rapid and economical drying.

Disintegration

The mass comes from the presses in the form of blocks of packed consistency. The moisture at this point is 40-50%. After being broken up, the mass passes through vibratory sieves where peels, chips, and other rough residues are separated.

Drying and/or toasting

This is the process that requires the most care, so that a good-looking product may be obtained. The drying is carried out in cylindrical driers of iron or steel plates of one to two meters in diameter. Heating may be by wood or oil. The flour is dried and toasted on the surface of the oven, where it is moved mechanically by means of some rotary blades or brushes put into action through a central axle. The flour comes out automatically through an outlet. There are also horizontal driers in which the unilateral heating produces a temperature gradient. Propulsion of the flour through these driers moves it from the last hot zone to the hotter one by means of brushes in helicoidal arrangement (endless screw). The flour may also be submitted to sieving and grinding, so that the larger grains may be eliminated or reduced in size: the resulting flour is classified as coarse, medium and fine. It should contain a minimum of 74% of starch and its moisture should be around 12%.

Packaging

Packaging is done in cotton sacks for distribution in bulk, or in paper or polyethylene packages for direct sales to the consumer.

Fortification

Fortification involves all these steps plus protein addition, which is done immediately after the disintegraion of the mass that comes from the presses. At this moment the right amount of protein concentrate must be mixed to the "farinha", so that it will adhere to it in the oven.

MANDIOCA FORTIFICATION - TECHNOLOGICAL ASPECTS

The experiments on cassava fortification with different protein concentrates carried out at the CTAA (Center for Agricultural and Food Technology) in Rio de Janeiro during the last two years may be summarized in two categories:

1. Dry mixtures - This approach involves a simple dry mixture of both ingredients (protein and concentrate and mandioca flour). Due to the extreme difference of textures, these two ingredients do not adhere, and become completely separated after packaging. The method was rejected.

2. Wet mixtures - This method consists of making the mixture during the usual process of preparing the "farinha", i.e. putting the protein powder into the wet "farinha", and afterwards drying it. There are two principal reasons for doing this:

   a. The very fine particles of protein powder can in this way be adhered to the farinha particles.

   b. It is a cheap method, as it includes only one more step in the traditional process.

TRADITIONAL PROCESS	FORTIFICATION
Washing and peeling	Washing and peeling
Grating	Grating
Pressing	Pressing
Disintegration	Disintegration
----------	Protein addition
Drying	Drying
Packaging	Packaging

This has been considered the best method, at least up to the point we have now reached.

In this study we have tried two different procedures for the same method (wet mixture).

1. Pre-mix i.e., high protein level mixtures to be diluted subsequently with common "farinha", already prepared. This method is used for preparation of fortified mandioca flour at reprocessing but not manufacturing centers.

2. Direct mixtures i.e., "farinha" prepared with protein at level ready for sale. (See tables). Both were made, with Soy Protein Isolate (SPI) with 0.75% methionine.

Theoretical calculations on which test mixtures were based

(using Soy Protein Isolate - SPE - at 90% protein content plus 0.75% methionine)

SPI 90%	Wet Farinha	Yield	Gr. of Prot.	Gr. of Meth.
1 gr added to	100 gr	60 gr	0.90	0.0075

PRE-MIX

Identification	Prot. % on ration SPI	SPI Added	Wet Farinha	Yield	Gr. of Prot.	Gr. Meth.
PM A	26.0%	391 gr	1,700 gr	1,350	351.9 gr	2.9325
PM B	41.4%	782 gr	1,700 gr	1,700	703.8 gr	5.8650

DILUTION FOR PRE-MIX

PM A	PROT. LEVEL %	METHIONINE LEVEL
Dilution 1:7	3.75	0.0271
Dilution 1:3	7.5	0.0543

PM B	PROT. LEVEL %	METHIONINE LEVEL
Dilution 1:15	2.5	0.0216
Dilution 1:7	5.1	0.0431

DIRECT MIXTURES

Identification	Prot. % on ration SPI	SPI Added	Wet Farinha	Yield	Gr. of Prot.	Gr. Meth.
D 25	3%	60 gr	3,000	1,800	54 gr	0.4500
D 50	5.2%	104 gr	3,000	1,800	93.6 gr	0.8500

ANALYSIS (% in final product)

%	Control	Direct Mix			Pre-mix		
		D 25	D 50	PM A 1:7	PM A 1:3	PM B 1:15	PM B 1:7
Protein		4.39	-	5.29	7.42	-	-
Acidity	1.0	0.6	0.4	1.0	0.4	1.0	1.0
Moisture	12.58	7.4	6.28	12.26	11.72	12.41	12.87
Ash	0.81	0.66	0.54	1.02	0.78	0.82	0.92

Task Group Recommendations for Project Modification - Cassava

Chairman: Frazao
Members: Dutra, Leme, Crowley

General:

The mandioca fortification project was started in Brazil as an effort of Brazilians and personnel of USAID to try to bring together and coordinate what was already being done in improving the nutritional value of mandioca flour in various regions of the country, based on the fact that it is one of the most widely utilized basic commodities.

Three national meetings were held between October of 1970 and March of 1972 with the presence of government, industry and university people involved. It appeared evident that it would be possible to take several measures towards fortification. The following conclusions were reached:

1) There were sources of protein within the country which could be utilized for mandioca fortification.
2) Their nutritional impact was tested in the laboratory.
3) There was sufficient technological expertise available in the country to develop an appropriate and acceptable fortified product.
4) There was a possibility of market-testing, through collaboration by industry and by two major supermarket chains.
5) There should be an economic study undertaken to determine the feasibility of fortification.

At the third national meeting, technicians from African and Asian Cassava-consuming nations also attended under AID sponsorship to exchange information and technologies.

Recommendations

Considering the experience already acquired within Brazil in Mandioca fortification and the additional insights acquired during the current meeting, it is recommended that:

1) Market-testing of a soy-protein isolate fortified product should proceed as soon as possible without considering the addition of methionine at this time.
2) Research should be continued on the addition of methionine, as well as on other possible fortificants which may be developed, and also on the addition of Vitamin A and iron.
3) The objective of the market-testing is to demonstrate to the decision-makers that fortification of this staple commodity is feasible (later assessment of the market tests should indicate the target groups being reached). Successful marketing of the fortified product would indicate that the consumers were receiving the benefits of the added nutrients, which have already been proven in the laboratory.
4) After the optimum product is determined, monitoring and evaluation mechanisms should be established. It is not expected that protein impact will always be evident, but vitamin or mineral levels could be determined which would indicate that the fortified product was of value; the quanti-

tative data obtained might be valuable in motivating the decision-makers to support the fortification principle. It is suggested that possible field trials be carried out in the Northeast of Brazil.

5) A method of improving the administration of the project and obtaining functional support should be sought.

NOTE: A considerable number of technological recommendations came out of individual meetings with technicians from other countries: (Need for triangular taste-testing, storage and transportation tests for stability, temperature control tests, possible utilization of soy flour instead of soy isolate, possible use of methionine hydroxy analogue, etc.). These will be further investigated in Brazil.

Drafted: Charles Puttkammer
USAID India

Fortification of Salt with Iron - India

The dream of an ambitious fortificationist in India would be to have every few grams of salt contain enough protein (or amino acids), calories, vitamins and minerals to compensate for every nutrition deficiency commonly found in Indian diets. Salt is the only item consumed by all Indians every day which can be reached reasonably easily at a point in the production-distribution-consumption cycle.

Obviously, the dream must be tailored to reality if the utilization of salt as a carrier is to have any practical validity at all. Because of factors of bulk, cost, nutrient stability and salt acceptability, only one or possibly two needed nutrients could ever be added to the 2.5 million tons of salt the Indian people consume annually. Tests have actually been made of lysine and vitamin A in salt but both cost and technical factors quickly discouraged the effort.

USAID and the Government of India's Department of Food have grown more and more confident that the 70 to 80% of India's total edible salt production produced by a mere 200 large salt factories can be fortified with enough iron to substantially remove anemia as a health problem. If nutritionally desirable, calcium could also be added, albeit after a different set of technical problems were solved. The purpose of this paper is to give an updated report on the progress of iron fortification since the project was first begun during the Alan Berg and Jim Levinson days in India back in 1968.

WHY CONCENTRATE ON IRON?

Faulty statistics can justify very illogical plans. It is always risky in India to trust your best projections about the extent of any specific nutrient deficiency. But by all accounts - including those of experienced field observers - iron deficiency anemia is an extremely serious problem in India. Estimates of the percentages of different population groups suffering from frank anemia vary widely. Apparently, women in their child bearing years are more likely than not to be anemic and the situation is almost as bad for growing children.

While no one can project accurately the toll widespread anemia has on the nation's productivity and its health care costs, the cost must be very high. It is much easier to calculate the cost of adding iron to salt at the rate of 500 ppm which would provide

an adult with about 40 percent of his daily requirement. For an iron compound containing 20% Fe, about 0.25% of the total salt would have to be iron compound. If the iron compound cost Rs. 10 per kilo or $1.33, the total cost including equipment and mixing costs for the 2,000,000 tons annually would be only about $8 million annually. Surely, that is a bargain when $8 million would only buy a 100 gram daily food supplement for less than one percent of the Indian children less than six years of age.

GETTING AN EVEN IRON DISTRIBUTION

Three years ago there was some hope that small quantities of iron could be evenly mixed in salt by adding the iron to the brine as the salt crystalized. It was hoped many salt crystals would capture particles of iron and that these fortified crystals would become mixed during harvest and handling with those crystals not enclosing iron.

But trials at the Central Salt and Marine Chemicals Research Institute quickly revealed the mix-in-the-brine, capture-in-the crystal method to be impractical. Our attention shifted to finding a dry mixing method that would be simple and accurate. Fortunately, we had the services of a multi-talented Indian salt consultant named M. M. Gurunath. Gurunath knows more about salt production methods in India - and about the mannerisms of her salt producers - than any man in the whole nation. We feel this does as much as anything could to guarantee that what is proven valid during mixing trials can be replicated on a large scale.

We are almost at the dry mixing trial stage now. Equipment is being assembled and it will be tested during June and July. All of the equipment is being secured indigenously. Mr. Gurunath has insisted that simplicity and ruggedness be the standard rather than sophistication and elegance - for instance mild steel rather than stainless steel is to be used whenever possible.

It is impossible to tell now how well each component in the dry mixing operation will work. There is a salt grinder, a batch mixer, a feeder, a ribbon conveyor with a heating element for drying and a screw blender. No doubt tests will indicate equipment faults to be corrected. Mr. Gurunath feels the salt moisture level will be particularly crucial to the iron dispersion and its adherence to the crystals. He believes the moisture level will have to come down to about 3% from the 6 to 8% commonly found in harvested salt.

We think we will have the talent necessary to make the most of the June-July tests. Besides Mr. Gurunath, his son, Venkatesh, will be on hand. Venkatesh followed his 1971 masters in chemical engineering degree from Northwestern with six months of field work experience with the Hardy Salt Company in Michigan. In addition to the two Gurunaths, we are bringing to India as a consultant for six weeks an American, Horace Diamond, who has recently retired after a career in drymixing micro nutrients into salt. They will do the tests at a salt factory north of Madras. The capacity of a mixing line would be about ten tons and hour, 100 tons a day and 20,000 tons for an average 200 day operating year. At this rate something like 250 separate mixing units costing about $20,000 each would be ample to cover the 200 salt factories which produce more than 70% or 2,000,000 tons of India's total requirement for edible use.

PROBLEMS

Of all the problems which have occurred in implementing this pioneering iron fortification program, by far the most persistent has been the selection of an iron salt. On the surface the selection should be quite easy - a salt is selected which has the best combination of three features: high bioavailability, low cost, and minimal interference with consumer acceptability. Any one of these standards can eliminate a particular iron compound from consideration. For instance, ferrous sulphate is cheap and scores excellently in bioavailability. But even a few hundred ppm turns salt deeply yellow. Or sodium ferric pyrophosphate is reasonably cheap, consumer acceptable and virtually non absorbable from intestines.

I wish we could report an answer to this problem. We think now ferrous citrate may be the best overall compound. James Fritz of the FDA believes ferric pyrophosphate would do a good job. Perhaps encapsulated micro grains of ferrous sulphate might work although our trials with a sample were not successful.

Assuming the major tasks of selecting a good iron compound and working out a good dry mixing method are accomplished, there are some additional problems to overcome. One would be acceptability of the smaller grained salt crystals. Mr. Gurunath believes this would not be a lasting difficulty, but it is true that Indians traditionally think larger crystals are their chief protection against adulteration. At this time between 15 and 20% of the salt issued for edible use is finely ground and hence suitable for iron fortification. But fortunately, finely ground salt does benefit from the reputation of being the salt the better off folks use.

A potential problem would be paying for the fortification. Calculating liberally for equipment depreciation and extra labor and energy costs as well as the iron compound, the extra cost per ton of salt would be about 30 rupees or $4. While this approximates the production cost of the ton of salt itself, it adds nothing to the distribution costs of salt. Thus a consumer would pay only 3 paise (.03 of a rupee) per kilo, or 10% more for fortified salt than he now pays for unfortified salt. His total cost per year assuming consumption of 15 grams per day would only be 16 paise which is 2.2¢. Surely it would be wise not to try to extract this small extra sum from the consumer directly. Instead it would make sense to give cooperating producers a full rebate for all their fortification costs - perhaps a 110% rebate would be even more effective. The cost to the nation for 2,000,000 tons would be only Rs. 60,000,000 or $8,000,000.

EVALUATING RESULTS

We have never assumed that once an iron compound was selected and a dry mixing method fixed that a national salt fortification scheme would automatically follow. The lesser part of the scaling up task will involve motivating the doers--the salt producers, the government planners and finance officials, the salt inspection laboratories. The more difficult task will be to introduce fortified salt to the public at an appropriate rate. Some public rejection must be expected. It will be vital for a careful analysis to be made of initial reactions in a small number of test villages and urban areas so that necessary corrections can be made.

At first, we feel the crucial variable to be most concerned about is public acceptance of iron fortified salt. Later, the nutritional effect can be evaluated. Distribution would be confined to a village or two in different sections of the country so as to see if the iron had any peculiar effect on foods popular in them. Home science colleges might be asked to undertake this work. Later, the All India Institute of Medical Sciences would be requested to make a study of the nutritional benefits accruing from iron fortified salt. It almost goes without saying that before even a limited test distribution begins, the medical safety of iron fortified salt will have to be approved by the Indian health authorities.

SUMMARY AND CONCLUSIONS

In the vast and varied subcontinent the large majority live in villages. They are poor and they live a life that is still largely traditional. The need for nutritional improvement by fortification is great but the practical scope for it is limited. The only

carrier for fortification guaranteed to reach this population which can be fortified at some point in the production-distribution-consumption cycle, is salt. But salt can not carry most needed nutrients. We believe it can carry iron. Fortified salt has the potential to supplement the iron intake of 70 to 80% of the population by 40% at a cost of only about 2¢ per person per year or less than $10 million for the Indian nation. Considering the widespread iron deficiency anemia which is believed to exist, this would be a very low price to pay.

Implementation of the project has almost reached the stage of a full scale test of dry mixing procedures. We have been continually frustrated in the selection of an iron salt which is low in cost, high in bioavailability and does not affect the taste or appearance of the salt. With luck these and other problems should be solved and test distributions be undertaken within a year. If no serious new difficulties are revealed, all India usage of fortified salt could be a reality five or ten years from now.

The great protein-calorie debate has made accomplishment of worthwhile fortification projects more difficult because it has diverted attention away from projects which answer part of the problem though not the total problem of undernutrition. Part of the answer lies in Aaron Altschul's plea for considering nutrition as an integrated system in which a low cost improvement in one area frees resources for application in another area. Certainly removing a large part of the incidence of anemia is not a complete answer to nutritional problems in India. But it is something which appears to be doable. Those of us who have worked in the field for a while can not help but be partisans for doable projects which have the potential for making a worthwhile nutritional impact.

Task Group Recommendations for Project Modification - Salt and Tea

Chairman: Puttkammer
Members: Adkins, Weil

General:

Two new approaches are being considered in India for alleviation of vitamins and mineral deficiencies. Iron would be added to salt and vitamin A to tea. Both commodities have the advantage of being centrally processed but consumed in rural as well as urban areas. The problem of identifying an iron compound that has high bioavailability but does not discolor salt has not yet been completely solved. Dry mixing trials are, however, scheduled for this summer. The technical problems in adding vitamin A to tea have largely been worked out, although a final decision to proceed with trials has not yet been made.

Taking into account the workshop discussion of these pilot trials, the task group for these activities makes the following recommendations:

Recommendations:

Salt (fortification with iron):

1. There is a danger that fortified salt, if it becomes popularly known to have nutritional value, might be fed by some over zealous mothers to infants in quantities which would be toxic. It is recommended that those responsible for this activity be alerted to this possible danger before proceeding with a national program.

2. In refining project plans and setting iron supplement levels, the degree of iron deficiency of the target group (older children and adults) should be taken into account, together with the adequacy of the supplement to meet this deficiency,.

3. Once the fortification is begun on a larger scale, a monitoring system should be established to check consumption patterns and to evaluate effects on body iron.

Tea (fortification with vitamin A)

1. Care should be taken to assure that the level of vitamin A added is adequate for alleviation of the deficiencies of the target group - older children and adults.

2. A monitoring system should be instituted to test the nutritional impact of vitamin A fortified tea. This could be done in conjunction with launching of a national program.

Guidelines for Field Demonstration Projects

Chairman: Hornstein
Members: Chopra, Borenstein, Dragastin, Jansen, Wooden, Graham

General

The experiences of those participating in the fortification field studies discussed in this workshop have served as a base for the compilation of a "check list" to be considered in designing similar studies involving other foods.

In developing this check list, it became apparent that it is imperative in designing a project to clearly enunciate the study "rationale" in order to develop the proper methodology for carrying out the project. Both aspects (rationale and methodology) are considered in the suggested protocol for the design of a fortification trial.

I. Rationale for Proposed Fortification Field Study

A. Identify and define the nutritional problem.

B. Review alternate approaches to solving the stated problem. Estimate, to a first approximation, the potential costs of each approach.

   1. Review previous experiences in attempting to solve similar problems.

   2. Justify fortification approach.

C. Relate proposed effort to national objectives and priorities.

D. Relate proposed effort to other ongoing nutrition activities in country.

II. Project Goals

These must be precisely defined. Depending on the project rationale, one or more goals may be pursued. Examples are cited below.

A. To demonstrate ability to reach defined target group (s).

B. To demonstrate nutritional value of a given fortification program.

C. To determine logistic feasibility.

D. To determine marketability of products, etc.

III. Local Initiative and Leadership

A. A prerequisite (but not a guarantee) for attaing project goals is to enlist the participation of local investigators at the working level, and if possible, at the planning level.

B. The active interest of government officials in the project is desirable - their approval of the project is essential.

C. Rapport with the local scientific community is desirable.

D. If the field study is intended to lead to implementation of a fortification project within the country, then:

1. The involvement of the national scientific community is essential.

2. Communication of progress, plans, etc., to appropriate government individuals and bodies is a prerequisite for enlisting government support.

IV. Methods of Procedure

A. Obtain data on food consumption patterns. If data is not available from previous surveys, initiate food consumption surveys.

B. Decide on food(s) to be fortified: Justify choice.

C. Decide on fortification mixture: Justify choice.

D. Decide on project site: Justify choice.

E. Technology

1. Point of intervention in processing system must be selected.
2. Acceptability of fortified product must be determined.
3. Stability of fortified product must be determined.
4. Food safety from microbiological and compositional viewpoint must be determined.
5. Packaging, if needed, must be designed.
6. Distribution system must be developed or existing systems adapted to needs.
7. Quality control procedures must be established.

F. Duration and timetable of project must be established.

G. Staff - Define expertise needed to carry out project.

H. Project cost must be estimated. Catagories to be considered should include:

1. Personnel
2. Consultants
3. Equipment
4. Supplies
5. Building alterations
6. Travel - foreign
   - local
7. Publication costs
8. All other
9. Overhead

I. Evaluation:

Depending on specific goal(s), the paramterters to be measured in order to determine if goal has been achieved must be defined in detail. This is the key to a successful project. Statistical design, sampling procedure and plans for analysis must be spelled out. A system for ongoing evaluation of project must be incorporated in project design.

V. Communication and Motivation

A. Ongoing

1. As meaningful results become available, share with local scientific and government community, e.g. conferences, meetings, relevant visitors, etc.

2. Assure early publication of meaningful results in scientific journals.

B. Final

1. Final report(s) in appropriate scientific journals, meeting(s).

2. Final report to be made available to government bodies in country's own lanuage.

VI. Implementation of Results

To translate results of field study into a national program, it is essential to have government and industry support. For suggestions on accomplishing this see "Thoughts on a Model of the Decision-Making Process" page 52.

A. Estimate cost of implementing fortification project nationwide.

B. See "Thoughts on a Model of the Decision-Making Process."

Implementing Project Results - General Discussion

The workshop devoted a general session to the question of moving from a pilot trial to implementation of full scale fortification. In the course of this session, two general principles emerged. First, a strategy should be developed to promote movement to a national policy. A government decision-making apparatus is a complicated entity involving many levels, and sometimes also includes state and local organizations. In addition, the private sector may also play a part in influencing the adoption or execution of a program. Accordingly, neither getting the ear of one influential person nor simply submitting the research results to the appropriate officials will necessarily be sufficient. Rather, a series of planned steps addressed to the various links in the decision-making chain is required.

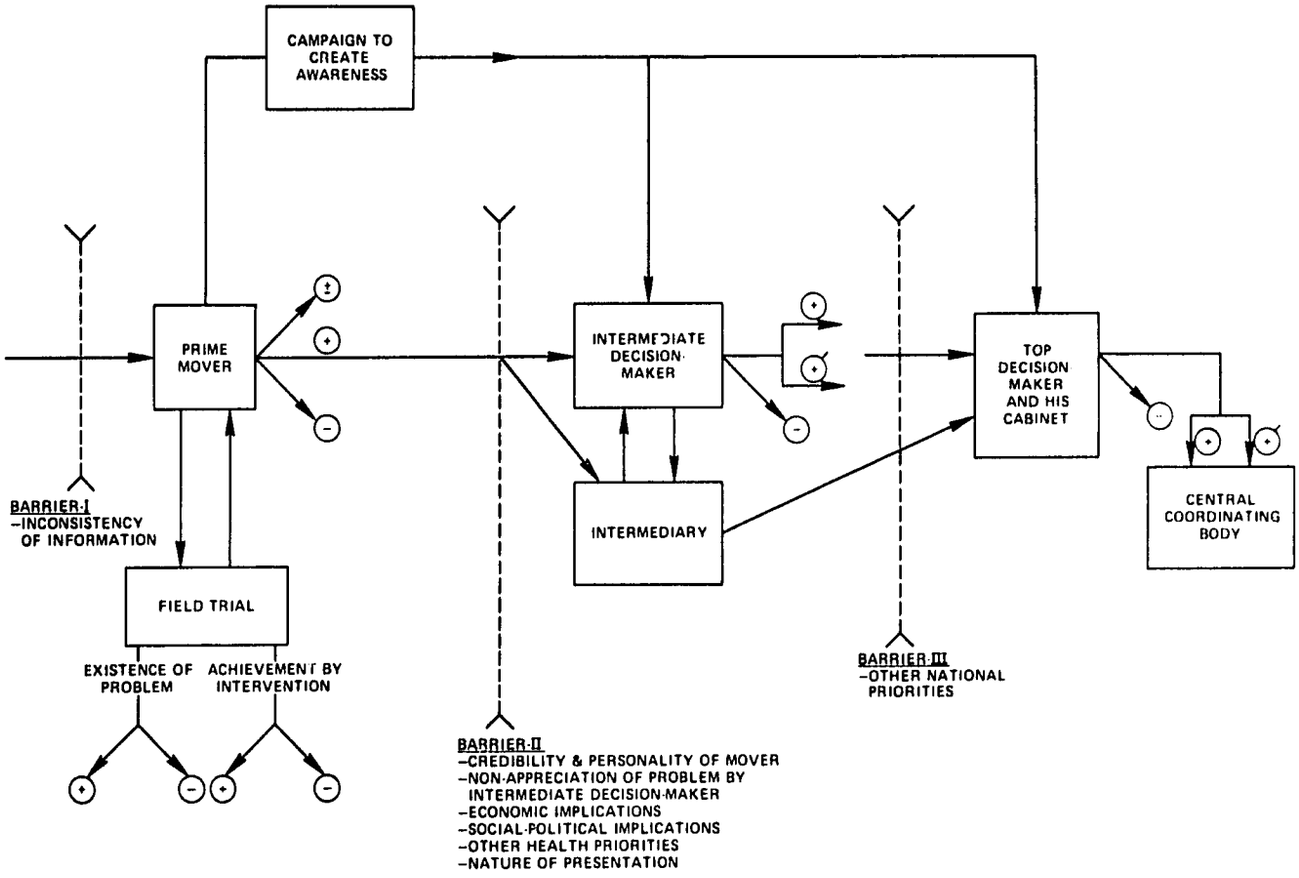
Second, this motivation task cannot be left to the future or to some undefined person or group to perform. Rather the man responsible for the pilot phase of the work must also take at least partial responsibility for getting the policy-maker to consider his findings. For it is the project man that has the greatest understanding of the activity, and it is also during the testing phase that the involvement of the decision-maker must be initiated. At the same time, the research man may not be able to do the whole job, but may need to also work with others who can provide additional perspectives.

It was suggested by Dr. Amorn Nondasuta that the process of motivation should be broken up into its component parts and that it should be possible to develop a checklist of actions and conditions necessary for bringing about the final policy decision. This approach is described in the next paper.

As an important component within a general approach, the participants also discussed specific actions that might be undertaken to acquaint policy-makers and other potential users with the projects. Some of the techniques considered were:

1. Organizing an in-country workshop for government leaders, industry personnel, members of the scientific community and others who might play a part in the eventual implementation decision. The objective would be to deepen understanding of the project and to bring these individuals in on the ground floor before the trial was completed.
2. Arranging site visits for particular individuals or groups. It was noted that one such group could be the faculty and students of the national medical school who could be influential in subsequent policy discussion.
3. Holding a workshop for the decision-making personnel of other countries where similar conditions exist and the same staple is used.

A MODEL OF COMMUNICATION AND DECISION–MAKING IN A NUTRITION INTERVENTION PROGRAM



Implementing Project Results - Thoughts on a Model of the Decision-making Process - Amorn Nondasuta

The diagram (fold out opposite page) attempts to present in schematic form the process required for bringing about a policy decision or "motivating" a government.

I. The Principals

The individuals or groups which participate in this process are as follows:

- The Prime Mover(s): He may be alone or associated with a group. He may be a scientist or very closely associated with a scientist. Ordinarily, he would be a top level government official, probably with the ministry of health, or a well-recognized academician.
- The Intermediate Decision-maker(s): He has the authority to decide among health-related options. This may be one person or a committee.
- The Intermediary(ies): He has the prestige and influence to communicate unofficially with the Intermediate and the Top Decision-makers.
- The Top Decision-maker: He is usually the head of the government or one to whom the head of government has delegated broad authority. His responsibility is beyond health alone.

II. The Channel of Communication

The initial step is for a communication to reach the Prime Mover describing the opportunity for fortification.

The Prime Mover evaluates the communication, makes a decision on holding a field trial, and develops two kinds of information. First he confirms the existence of the problem of malnutrition and defines it more clearly. Second he determines the limit that he can achieve by specific intervention.

Throughout the field trial he creates awareness of the problem and what he is trying to do, principally directed at the Intermediate and Top Decision-makers.

At an appropriate stage of the field trial, he will get either an equivocal (±) result, a negative (-) result or a positive result (+), and he makes his decision. If his decision is positive (+), he communicates this decision to the Intermediate Decision-maker.

If the Intermediate Decision-maker approves, he may accept the recommendations unchanged (+), or he may modify it (+✓, and provide his recommendations to the Top Decision-maker.

If the Top Decision-maker approves, he may implement the recommendation as received (+) or modify it (+✓. He then examines the appropriate organization to implement the program. Usually when the program is multidisciplinary in nature, a Central Coordinating Body, such as a Food & Nutrition Committee is needed, or one may already exist in the establishment under the Intermediate Decision-maker.

The Top Decision-maker establishes a policy, asks The Coordinating Body to formulate a plan, and assigns the execution of the plan to appropriate agencies.

III. The Barriers

There is a barrier (I) which stands before the Prime Mover as he acquires the initial information on which he will base his decision as to whether or not to hold a field trial. The critical component of this barrier is the inconsistency of information on the problem and the potential of intervention. If the information is grossly inconsistent, or if there is an insufficient consensus to satisfy himself, he will take no action. If the information is sufficient to warrant further examination, but insufficient to recommend a policy decision, he may opt for a field trial in order to gather more information as a basis for policy. Even if the information is completely satisfactory and adequate for policy decision, he still may opt for a field trial for the purpose of improving his chances of convincing the Intermediate and Top Decision-makers.

There is another barrier (II) which stands between the Prime Mover on one side and the Intermediate Decision-maker or Intermediary on the other. This barrier will have to be considered in the design of the Field Trial. It consists of the following: 1. credibility of the Prime Mover and his personality; 2. non-appreciation of the problem by the Intermediate Decision-maker; 3. economic implications; 4. social-political implications; 5. other health priorities; 6. nature of presentation.

There is still another barrier (III) which stands between the Intermediate and Top Decision-makers. In addition to health priorities, the Top Decision-maker will have to choose between

these and other national priorities. At this point, the political and economic implications are most important.

IV. Application of cheme

As an example of how to treat this scheme, we shall consider the issue of rice fortification in Thailand.

A. Achievements to date:

1. Passed Barrier - I
2. The Prime Mover was identified.
3. The Prime Mover decided to set up a Field Trial.
4. The Field Trial was designed and put into operation.
5. The program was designed in such a way that the community would be able to participate to overcome social aspects of Barrier II (via establishment of a day-care center system and village communication networks).
6. As part of campaign to create awareness in the Intermediate and Top Decision-makers, reports and personal contacts were made.
7. Awareness was created in the medical community.

B. Present considerations: (1) Strengthening of the experimental design; (2) decision that channel of the Intermediate Decision-maker is adequate, although other channel through the Intermediary has also been opened.

C. Future Consideration: When there are indications that the field trial is going in a positive direction, data on economic and administrative feasibility if operated on a large scale will be sought.

Annex - I

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Annex - II

AGENDA

Workshop ground rules, objectives, etc. will be presented briefly at dinner on Monday evening May 1st.

Tuesday - May 2nd

The following day and a half will be devoted to an in depth discussion of each fortification activity. A 30 to 40 minute summary of each project (along the lines of project descriptions prepared and distributed prior to the workshop) will be followed by floor discussion.

Three sets of issues will be considered. First - practical aspects of implementation. For example: best intervention points; types of personnel and expertise required; best surveillance procedures; types of fortification mixtures and concentration needed to yield meaningful results. Second - evaluation. For example: will present evaluation measures be sufficiently meaningful to policy-makers? Should any other measures be added and are there any additional groups which should be considered for measurement? Third - cost and application. Based on project experience, what would be costs per person if fortification were conducted on a regional or national scale? Are there any bottlenecks to large scale fortification, such as availability of fortificants or special concerns of policy-makers, which must be dealt with in order to move to full scale fortification?

(Persons listed as making presentations will call on other project personnel as appropriate.)

	A.M. - Chairman Altschul
9:00 - 10:30	Wheat - Stare
10:30 - 10:50	Coffee break
10:50 - 12:00	Floor discussion continued
12:00 - 1:30	Lunch
	P.M. - Chairman Hornstein
1:30 - 3:15	Rice - Amorn, Gershoff
3:15 - 3:35	Coffee break
3:35 - 5:20	Corn - Mata

Friday - May 5th

8:00 a.m.	Bus departs for Denver

- -

Note re Task Groups

All workshop participants will be asked to take part in task groups. The functions of these groups are described below. (Proposed membership list is attached to this agenda.)

A. Workshop implications for each project: The personnel directly involved in each project will be asked to consider whether, on the basis of the workshop experiences, any alterations should be made in their projects. Each group will present any such findings for general dis-discussion on Thursday, May 4th. In the case of India a more general presentation of reflections applicable to country fortification activities might be made, as more than a single project is involved.

B. General lessons from workshop: In the course of the conference a report will be developed that reflects the general insights gained as a result of the workshop. The report will take up factors pertaining to pilot project design; for example, best intervention points, expertise and personnel required, surveillance procedures, selection of target group, selection of fortificant, evaluation measures, etc. The object will be to summarize lessons emerging and serve as a guide for improving ongoing projects and for development of new fortification activities.

Thursday - May 4th

9:00 - 10:40	Meetings of task groups (See note on task groups following page)
10:40 - 11:00	Coffee break
	Project Discussion - Chairman: Forman Spokesman for each project presents workshop implications for each project (10-15 minutes) followed by floor discussion.
11:00 - 12:00	Wheat
12:00 - 1:30	Lunch
1:30 - 2:30	Rice
2:30 - 3:30	Corn
3:30 - 3:50	Coffee break
3:50 - 4:50	Cassava
4:50 - 5:45	India activities

8:00 - 9:30	General Reports - Chairman: Forman Report of task group for project design and report on session "Motivating Governments and Consumers."

Wednesday - May 3rd

Project discussion continued	Chairman: Jansen
9:00 - 10:45	Cassava - Frazao, Leme, Dutra
10:45 - 11:05	Coffee break
11:05 - 12:45	Atta, Salt, Modern Bread - Puttkammer
12:45	Lunch

Afternoon - Free

7:30 - 9:30	Motivating Governments and Consumers

Chairman: (to be designated)

Panelists: Altschul, Amorn, Forman

Steps which should be taken now to promote interest of key host government personnel in ongoing projects. Steps which should be taken as project nears completion. Other steps, external to project activity per se, required to motivate policy makers and to motivate consumers for full-scale fortification