

AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT DATA SHEET

1. TRANSACTION CODE

A = Add
 C = Change
 D = Delete

Amendment Number

4

DOCUMENT CODE

3

2. COUNTRY ENTITY

Inter-regional

3. PROJECT NUMBER

931-0045

4. BUREAU OFFICE

Science and Technology Bureau
Office of Nutrition

5. PROJECT TITLE (maximum 40 characters)

Vitamin A Deficiency
Nutrition: Program Support

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)

MM DD YY
09 30 88

7. ESTIMATED DATE OF OBLIGATION
(Under "B" below, enter 1, 2, 3, or 4)

A. Initial FY 74

B. Quarter

C. Final FY 87

8. COSTS (\$000 OR EQUIVALENT \$1 =)

A. FUNDING SOURCE	COSTS FY 84				LIFE OF PROJECT	
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	4.537		4.537	12.662		12.662
(Grant)	(4.537)	()	(4.537)	(12.662)	()	(12.662)
(Loan)	()	()	()	()	()	()
Other						
U.S.						
Host Country						
Other Donor(s)						
TOTALS	4.537		4.537			12.662

9. SCHEDULE OF AID FUNDING (\$000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH. CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1)	FN			4,162		4,818		8,980	
(2)	HE			375		3,307		3,682	
(3)									
(4)									
TOTALS				4,537		8,125		12,662	

10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)

11. SECONDARY PURPOSE CODE

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

A. Code

B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

To develop, implement and evaluate programs for the prevention and control of vitamin A deficiency in developing countries.

14. SCHEDULED EVALUATIONS

Interim MM YY MM YY Final MM YY
03 88

15. SOURCE/ORIGIN OF GOODS AND SERVICES

000 941 Local Other (Specify)

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a page PP Amendment)

This PDS amendment increases the life of project funding level from \$8,132,000 by \$4,530,000 to \$12,662.

17. APPROVED BY

Signature
J.S. Robins
Title Agency Director
for Food and Agriculture

Date Signed

MM DD YY
07 01 88

18. DATE DOCUMENT RECEIVED IN AID/V, OR FOR AID/V DOCUMENTS, DATE OF DISTRIBUTION

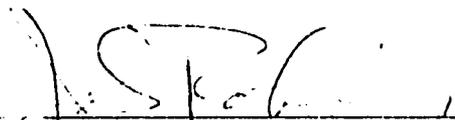
MM DD YY

PROJECT AUTHORIZATION

PART II

ENTITY: SCIENCE AND TECHNOLOGY BUREAU
PROJECT: VITAMIN A DEFICIENCY PROGRAM SUPPORT
PROJECT NUMBER: 931-0045

1. Pursuant to Section 103 of the Foreign Assistance Act of 1961, as amended, the Vitamin A Deficiency Program Support Project which is centrally funded was revised on June 29, 1982. That revision is hereby amended as follows:
 - (a). To increase the life-of-project cost from \$8,132,000 to \$12,662,000.
2. The project will be carried out in accordance with Project Paper revision 3, as amended.



J.S. Robins
Agency Director for Food and
Agriculture
Bureau for Science and Technology

Date: 7/1/85

Clearances:

S&T/N, M. J. Forman	_____	Date:	_____
S&T/N, N. Luykx	_____	Date:	_____
S&T/N, S. Mahone	_____	Date:	6/12/85
S&T/PO, G. Eaton	_____	Date:	7/1/85
S&T, D. Brennan	_____	Date:	_____

ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR
FOOD AND AGRICULTURE, BUREAU FOR SCIENCE AND TECHNOLOGY

From: William J. Forman

Problem: To authorize an increase in the authorized funding level of the S&T/N Project "Nutrition: Vitamin A Deficiency Program Support" (931-0045) from \$8.132 million to \$12.662 million and modification of the scope of work of this project as outlined below.

Background: The present authorized funding level for this project is not high enough to accommodate the funding proposed by A.I.D. for obligation during fiscal year 1985. The currently authorized funding level for this project is \$8.132 million. Obligations through fiscal year 1984 (\$4.537 million), plus the regular budget for fiscal year 1985 (\$0.450 million) total \$4.987 million. In addition to these amounts, A.I.D. has assigned \$3.5 million of the fiscal year 1985 Health/Child Survival and Nutrition funds from Section 103 (in support of the "Child Survival Action Program" (CSAP)) to S&T/N for additional vitamin A activities. This totals to \$8.487 million, which exceeds the currently authorized project funding level by \$355,000.

S&T/N is committed to use the CSAP funds to expand the scope of ongoing activities and initiate new activities under the project.

I. The new activities include the sponsorship of operational research studies in 3-4 countries to assess the reduction in morbidity and mortality in preschool age children receiving vitamin A supplementation. The National Institute of Nutrition of India (NIN) (which has an ongoing long-term collaborative research program with the National Eye Institute (NEI), U.S. National Institutes of Health), has offered to carry out such a study if A.I.D. is prepared to fund the required inputs of (1) technical assistance, (2) a minicomputer, and (3) supplies from the U.S. USAID/New Delhi concurs and has requested that S&T/N assume management and technical monitoring responsibilities for the study (New Delhi 6848, 3/20/85). It is proposed that this be done through a PASA with NEI, which would be funded under this project. NEI has a unique capability to provide technical assistance to NIN for the study within the framework of the existing collaborative research program.

A scientific oversight panel will be constituted to assure that there is adequate comparability between the impact assessment studies in the 3-4 countries. The panel would be asked to (a) review the various country study protocols to assure that the design of each country will permit technically and statistically valid conclusions, and that there is adequate standardization between

studies, (b) monitor the studies at about the mid-point of each to assure that there is conformance to the protocols, (c) review the final reports from each study, and (d) provide guidance to A.I.D. on the basis of the overall results. It is proposed that this panel be organized and funded through the National Academy of Sciences or a comparable institutional mechanism. Funds for this purpose would be made available through the existing cooperative agreement with the Johns Hopkins University International Center for Epidemiological and Preventive Ophthalmology (ICEPO).

II. Fortification of staple foods or condiments is a promising means of achieving widespread distribution of supplemental vitamin A at low cost and with minimal administrative requirements in some countries. Fortification as an intervention approach will be pursued in 4-5 countries under the expanded project through an established RSSA with the Office of International Cooperation and Development of U.S.D.A. This RSSA group has a particular capability in this area by virtue of historical involvement with the food technology groups in the countries being assisted by the project, previous experience in vitamin A fortification of weaning foods in several developing countries, and an established working relationship with the manufacturers of the vitamin A concentrates. These additional activities would be funded under the project.

III. In addition to the above described new activities, the increased funding level will permit S&T/N to underwrite a portion of the operational costs for expanded vitamin A interventions in Indonesia, the Philippines and Zambia.

The increased funding level would also permit a major expansion of nutrition education activities under the project, including support of vitamin A deficiency prevention and control programs in host countries through mass media messages and social marketing techniques. It is proposed that this technical assistance be provided through a sub-contract from ICEPO with Manoff International, a U.S. public relations firm with the most experience in the use of the mass media and educational techniques to promote improved nutrition in LDCs.

Recommendation: That you approve (A) an increase in the authorized level of funding for project 931-0045 from \$8.132 million by \$4.530 million to \$12.662 million within the authorized life of project through FY 1987; and (B) an expanded scope of work to provide that S&T/N establish a PASA with the National Eye Institute NIH/DHHS; amend a RSSA with the Office of International Cooperation and Development, USDA; establish a sub-contract through ICEPO with Manoff International; and through the National Academy of Sciences or a similar institutional arrangement, establish a scientific oversight panel for the series of vitamin A impact studies by signing the attached PAF, Part II.

Attachments:

1. Work scope, National Eye Institute PASA
2. Work scope, Office of International Cooperative and Development
RSSA
3. PDS and PAF, Part II.

Clearances:

S&T/N, S. Mahone

S. Mahone

Date:

1/11/57

S&T/N, N. Luykx

N. Luykx

Date:

10/21/56

S&T/PO, G. Eaton

G. Eaton

Date:

1/11/57



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 3, 1985

National Institutes of Health
Bethesda, Maryland 20205
Building : 31
Room : 6A03
(301) 496- 4583

Dr. John McKigney
Office of Nutrition
Bureau for Science & Technology
Agency for International Development
Department of State
Washington, DC 20523

Dear Dr. McKigney:

Enclosed is the proposal for a collaborative study to determine the impact of vitamin A supplementation on childhood morbidity and mortality in India. We anticipate that the study would require two years to complete. The work would be conducted as a joint venture between the National Eye Institute and appropriate institutions in India under the Indian Council of Medical Research. We assume you will use this draft as the basis for a formal agreement

Sincerely,

Edward H. McManus
Edward H. McManus
Deputy Director
National Eye Institute

Enclosure

NEI proposes to conduct a study in India of the impact of vitamin A supplementation on morbidity and mortality of children under 6 years of age living under conditions suspected to provide minimal or inadequate vitamin A intake.

The purposes of the study will be to test the following hypotheses:

1. Mortality of children under 6 years of age is reduced by at least 25% by providing a high dose of vitamin A (200,000 IU) at periodic intervals.
2. Morbidity of children under 6 years of age from diarrheal and respiratory diseases is reduced by supplementation with vitamin A at periodic intervals.

The study will be conducted in collaboration with investigators at the National Institute of Nutrition, Hyderabad, India with the concurrence of the Indian Council of Medical Research (ICMR). Design, implementation and evaluation of the study will be the responsibility of the Indian and NEI collaborators. In so far as feasible and appropriate, the design will replicate similar studies planned for other countries sponsored by the Office of Nutrition. The existing advisory panel of the NEI-NIN collaborative Clinical Research Center for Nutritional Blindness, augmented by ad hoc appointees as deemed appropriate and necessary, will provide on-going oversight to the project.

The project will be conducted in areas that have not yet been covered by the vitamin A distribution program of India. A sufficient number of children will be identified to participate in the study from treatment and control villages to provide the statistical power needed to test the hypotheses within a two year time period in the field.

The dollar costs for the study is anticipated to be approximately \$100,000 for the two year period. The costs of implementation not requiring dollars will be provided in rupees through the ICMR. The estimated dollar expenditures include the following:

Travel Indian investigators to U.S. for consultation		
2 individuals for 14 days annually		15,400
Travel U.S. investigators to India for consultation, attendance advisory committee meetings and data monitoring: 4 individuals for 14 days annually		
		27,600
Minicomputer and necessary software for field entry of data and processing:		
		7,000
Forms and Supplies for field studies:		
		5,000
Supplies and chemicals for laboratory analyses at 15,000 annually:		
		30,000
Salary NEI coordinator	10% annually	10,000
secretarial	10% annually	5,000
		<u>5,000</u>
		\$100,000

Reporting Requirements

- A. NEI will, within 30 days after the completion of each fiscal year quarter, submit to S&T/N a brief quarterly narrative report of activities carried out under this agreement.
- B. NEI will submit quarterly expenditure vouchers to FM/PAD, A.I.D. with an information copy to S&T/N.
- C. NEI will provide A.I.D. special reports as may be deemed necessary for purposes of Child Survival Action Program reporting procedures required by the U.S. Congress or for the A.I.D. scientific oversight panel for the vitamin A impact studies.
- D. Ten copies of a final report will be submitted to S&T/N upon completion of the study, and not later than 90 days after the project assistance completion date.
- E. All technical reports shall include a title page showing (a) the title of the report, (b) the PASA number and (c) appropriate wording to indicate that the report is being submitted to the Office of Nutrition, U.S. Agency for International Development.

FORTIFICATION OF FOOD WITH VITAMIN A

SCOPE OF WORK AND BUDGET

THE PROBLEM

Vitamin A deficiency is a widespread nutritional problem in many third world countries. Severe vitamin A deficiency causes blindness in 500,000 young children annually. Of perhaps greater significance, recent studies in Indonesia indicate that even mild to moderate vitamin A deficiency leads to a 3-4 fold increase in morbidity and mortality among preschool children. Therefore the consequences of vitamin A deficiency are extremely serious and it has become clear that the problem should be addressed vigorously.

FOOD FORTIFICATION

Over the past decade pilot programs have demonstrated that distribution of vitamin A supplements and foods fortified with vitamin A can alleviate vitamin A deficiency. Therefore, AID in collaboration with various cooperating organizations, is preparing to launch a major program to attack vitamin A deficiency using supplementation and fortification interventions. The project described in this paper relates to vitamin A fortification interventions and deals specifically with technologies required to implement vitamin A fortification programs in LDCs.

Food fortification with vitamin A has been practiced extensively in both developed and developing countries for several decades. Basic food commodities such as wheat flour, fats and oils, and milk powder have been routinely fortified using well-established technologies. Breakfast cereals, infant foods and weaning supplements have also been fortified using simple, easily practiced technologies. In addition, special methods have been developed to fortify food

items such as sugar and tea and methods to fortify condiments such as salt and monosodium glutamate (MSG) have been explored. However, available technologies for fortification are not always applicable in LDC settings because (1) the foods consumed by most of the people are frequently not those for which technologies have been developed, or (2) the LDC food processing methods or food consumption patterns are of a type that precludes use of existing technology. In order to practice fortification in these situations, new approaches must be developed either to adapt existing technologies to the small-scale systems used in the countries (such as that for fats and oils and cereal flours) or to generate new technologies applicable to the special foods used widely in the countries (such as crushed salt, crude sugar, MSG, etc.).

The purpose of this project is to identify and develop methods of fortification which can be used in vitamin A intervention programs and to transfer the technologies to LDCs where the methods will be applied.

PROJECT DESIGN

While the particular countries where fortification programs will be developed through the new AID initiative have not yet been selected, it is anticipated that Indonesia, The Philippines, and Malawi will be included. In Indonesia and The Philippines, the governments have concluded that the problem of vitamin A deficiency is serious and wish to consider intervention programs which include fortification of MSG. In Malawi, the government has observed extreme vitamin A deficiency in certain areas of the country and is considering possibilities for fortifying salt to alleviate the deficiency.

Although fortification of MSG and salt have been studied, fully satisfactory technologies are not yet available for either product. In the case of MSG, it is possible to fortify small crystals of MSG simply by mixing dry vitamin A powders with MSG or by preparing special vitamin A premixes using techniques developed in the past by USDA contractors. However, fortification of coarse crystals of MSG, which is a widely used form in both Indonesia and the Philippines, cannot be carried out with this technique because the vitamin A separated physically during handling causing excessive non-uniformity of composition. Furthermore, because vitamin A powders are yellow, white products such as MSG, tends to be discolored by fortification. Discoloration is intensified when the vitamin A segregates forming yellow pockets or areas of high vitamin A concentration and the fortified MSG is noticeably different than the unfortified product, thereby creating a problem of acceptability among consumers and/or producers.

In the case of salt fortification, similar problems prevail. Furthermore, in LDCs table salt often contains iron and other impurities which tend to cause rapid loss of vitamin A potency. Therefore fortification of salt in Malawi is expected to require special techniques to promote vitamin A stability as well as prevent segregation and discoloration.

Several possibilities exist for overcoming the problems. The problem of segregation might be overcome through use of a special premix in which particles of vitamin A are bound to some of the MSG or salt to form large agglomerates or glued to the surface of larger particles of the MSG or salt. Alternatively, the vitamin A might be applied to the MSG or salt as a liquid which adheres to the surface and therefore will not segregate. The color problem might be solved by

masking the vitamin A by coating it with fine particles of the MSG or salt or possibly "painting" the vitamin A with a whitener. (A "white" vitamin A product was recently produced experimentally by The Coating Place, a USDA contractor, by applying titanium dioxide in a vehicle of hydroxypropyl cellulose to the surface of vitamin A particles in a fluidized bed.) Deterioration of vitamin A in salt might be prevented through protective coatings on the vitamin A.

While these techniques appear to have potential, proof of their utility must be established experimentally. The methods must be tested and evidence of the physical and chemical stability, etc. determined through laboratory and field evaluations. Also the costs and the practicality of using the methods under LDC conditions must be assessed and the technology transferred to organizations which will use it.

If for any reason technologies for fortification of products other than or in addition to salt and MSG are required, this project will endeavour to identify, develop, and transfer those technologies in place of or in addition to the ones outlined above. Activities of this type might include development and transfer of fortification technologies for rice in Bangladesh, wheat flour in Sri Lanka, or tea in Northern India or Pakistan.

PROJECT OUTPUTS

The outputs of the project will be procedures for fortifying food products with beneficial levels of vitamin A which will have been tested and shown to be technically suitable for use in LDCs. At the end of the project, know-how concerning application of the technology will have been provided to personnel in the LDCs and, in situations where required, pilot-scale fortification equipment will have been provided and personnel trained in its operation. (Note: This project has

not been funded to furnish equipment, materials, training, and associated inputs necessary to implement national or other large-scale fortification programs; these inputs will be furnished through other projects, such as AID grant or loan projects or through this project if amended to provide additional funds).

PROJECT INPUTS

The project will take place over a two year period beginning July 1, 1985.

Total costs of the project to the USG will be \$250,000. Funding will be made available from AID to USDA through a Resource Support Service Agreement (RSSA).

Anticipated expenditures by USDA are itemized in Appendix A.

Paul R. Crowley
May 28, 1985

APPENDIX B

Proposed Functional Budget - July 1, 1985 through June 30, 1987

<u>Item</u>	<u>Total</u>
<u>Personnel</u>	
Professionals	\$54,811
Benefits	11,894
Technician	28,660
Benefits	7,340
Hourly	<u>5,000</u>
Total	\$107,705
<u>Equipment</u>	59,000
<u>Materials & Supplies</u>	13,000
<u>Communications</u>	2,000
<u>Computer</u>	1,250
<u>Contracts and Consultants</u>	25,000
<u>Travel and Per diem</u>	
Foreign	16,000
Domestic	<u>2,000</u>
Total	\$18,000
Direct Cost	\$225,955
Indirect Cost	<u>40,153</u>
Total Cost	\$266,108