

Field Test of Fortification Rapid Assessment Tool

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Under Contract to The Micronutrient Initiative

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Appendices (bound separately)

- i) FRAT (Dietary and Market) (Revised, ready for review and translation)
- ii) FRAT (Market) (Field-tested, not recommended for continued use)
- iii) Reports from Partners
- iv) Financial Report (to follow)

1 Acknowledgements

PATH Canada acknowledges the support of the Micronutrient Initiative in conducting this important work. Additionally, we thank the partners who led the field testing (Drs. Hernando Flores, Khalid Hassan, Doulaye Diancoumba, and Noel Marie Zagre), the experts who provided technical support (Drs. Kabir Ahmed, Herbert Weinstein, Ms. Zeina Sifri) and critical review of the draft guidelines (Dr. Noel Solomon), those who have reviewed this report and the revised guidelines (Dr. Mark Young, Dr. Hernando Flores), the technical advisory committee who provided guidance on the 1997 draft of FRAT and the anticipated review of Dr. Mashid Lotfi before finalization and translation of the guidelines.

2 Introduction

Draft guidelines for a tool called FRAT: Fortification Rapid Assessment Tool, were prepared by PATH Canada under contract to the Micronutrient Initiative in 1997-1998. This tool provides guidelines for conducting research to determine if a given food, or a few selected foods, would be appropriate vehicles for food fortification, and, if appropriate, for helping to set the fortification levels in these foods. An appropriate vehicle is (1) one for which fortification with the desired micronutrient(s) is technically feasible, (2) consumed regularly by the target populations, and, (3) preferably, centrally marketed or processed so that only a single or very few fortification points are required.

Following on this earlier work, under contract to the Micronutrient Initiative, PATH Canada has led the development of guidelines for a FRAT market assessment, and coordinated the field-testing of the FRAT (both the previously drafted dietary component and the newly drafted market component) in three countries: Brazil, Bangladesh and Burkina Faso. In this report we describe the outcome of the field-tests, both in terms of the significance of the results for the advancement of food fortification in the participating countries, as well as the critique of the field partners (and other reviewers), which we have incorporated into revised and improved FRAT guidelines.

3 Partners

In each field test site there was a technical advisor and a local leader of the field team. Peter Berti of PATH Canada served as the coordinator of the overall project and special technical advisor to each of the field test sites. The field sites regularly communicated with the coordinator in Ottawa by phone, email and fax.

Site	Technical Advisor	Local Leader of Field Team
Bangladesh	Dr. Kabir Ahmed, Technical Advisor, Initiatives	Dr. Khalid Hassan, Org-Marg-Quest
Brazil	Dr. Peter Berti, Nutrition Advisor, PATH Canada	Dr. Hernando Flores, Universidade Federal de Pernambuco
Burkina Faso	Zeina Sifri, HKI-Burkina Faso, Project Director	Dr. Doulaye Diancoumba (market assessment) Dr. Noel Marie Zagre (dietary assessment), ANSA/B (Association Burkinabè pour la Nutrition et la Sécurité Alimentaire au Burkina Faso)

Another key participant in this project was Dr. Herbert Weinstein. Dr. Weinstein advised on the development of the market assessment tool. The FRAT guidelines were distributed to approximately 30 interested academics, NGO staff, UN staff and private industry, from whom we have received positive feedback, but not specific comments or criticisms that have led to revisions. Comments on FRAT by Dr. Noel Solomons, solicited by the MI, were also used in the revision of the guidelines.

4 Critique of FRAT

4.1 Critique of Diet Component

The guidelines were generally well received and the users found them straight-forward and easy to use. Some of the important recommended changes to the guidelines inspired by the partners' critiques are listed below. More are found in the partners' reports.

1. It should be emphasized that the first step should be to search to see if the dietary data needed already exist, as they well may, and then only if the data are unavailable should the survey proceed.
2. It should be emphasized that these are guidelines only and can be – in fact, should be – adapted to the local setting, not merely translated. Some potential users may have trouble doing this adaptation and would require outside assistance.
3. Related to 2., the profile of the persons who would be able to organize and implement FRAT should be included.
4. There is no need to discuss concerns of the toxicity of vitamin A. Although those concerns do exist, they are not valid in the context of food fortification, and they should not be lent credence by having the concerns expressed in this document.

There were other valid criticisms that could not be addressed in the FRAT guidelines.

1. The consumption of the food vehicle at the time of the study may be less important than the *potential* consumption patterns. That is, effective marketing strategies can change consumption patterns – in fact, they can create markets that did not previously exist.
2. The PATH Canada team notes that the FRAT was developed "on paper" and then "field-tested" but it was never tested for accuracy. We have assumed it will be at least as accurate as the conventional 24-hour recall and food frequency methods on which it draws, but we have not tested this. However, reasonable decisions about food fortification can be made even with large errors in the estimates of consumption frequency.

4.1.1 Discussion of vitamin A teratogenicity

At the time of the first draft of the FRAT manual, the prevailing opinion in the nutrition community was that there was a risk of teratogenic effects from consuming large amounts of vitamin A rich or vitamin A fortified food. The guidelines were developed with this in mind, so that reproductive age women were included in the survey, to

determine the upper safe level of fortification (i.e., the level of vitamin A in the food (IU/g) multiplied by the upper-end intake level of that food (grams/day) should not exceed 10,000 IU/day). Although the concerns of teratogenicity still prevail, there are a number of reasons that the concerns need not be addressed in FRAT (summarized below). Reproductive age women should still be included in the FRAT survey, however, because for most micronutrient interventions they are an important target group, in addition to young children. The practical consequence of this is that the FRAT now considers whether the food under question is consumed by women of reproductive age to evaluate the potential coverage, not out of concerns for toxicity. But the implications are broader than the FRAT guidelines: fear of teratogenicity has slowed the acceptance of vitamin A fortification in some countries. Removing it as a concern from FRAT may help to get it off the “radar” of decision makers, and thus remove it as a roadblock to vitamin A fortification. We anticipate some resistance to this stand by nutritionists and public health officials, and we appreciate that the MI is willing to show leadership by taking the stand that the removal of the mention of toxicity from the FRAT implies.

The non-risk of teratogenicity from fortified food.

There are two points to consider: (1) the level of vitamin A intake as a vitamin A capsule (VAC) that may cause teratogenic effects and (2) the difference between consuming vitamin A as a VAC and as food.

(1) The WHO protocol for the delivery of VACs to pregnant women is 10,000 IU per day or 25,000 IU once per week. This is adequate to meet the needs of pregnant women, and, since *some* high level of vitamin A intake may be teratogenic, there is no need to take more. This has been interpreted as ~ “vitamin A intakes any amount greater than 10,000 IU are teratogenic”. However, recent research¹ and reviews of epidemiological, animal and case studies² have convincingly argued that a pregnant woman can safely consume at least 30,000 IU per day. This is approximately 30 times greater than the normative requirements of a three year old child. If food is fortified to meet the needs of the young child, it is unlikely that an adult women would consume 30 times more than a child and hence exceed 30,000 IU.

(2) The mechanism of vitamin A teratogenicity is not known, but since the only means of communication between mother and embryo/fetus is via the maternal blood, and the only change in maternal blood with retinol consumption is total retinol levels, it is reasonable to assume that the retinol itself is either the teratogen or triggers another chemical within the fetus. It therefore follows that consumed vitamin A could only cause teratogenic effects if, following consumption of the vitamin A, the blood retinol levels change.

¹ Sibulesky L, Hayes KC, Pronczuk An, Weighel-DiFranco C, Rosner, B, Berson EL (1999) Safety of <7500 Re (<25 000 IU) vitamin A daily in adults with retinitis pigmentosa.

Mastroiacovo P et al., (1999) High vitamin A intake in early pregnancy and major malformations: a multicenter prospective controlled study. *Teratology* 59(1):7-11

(*Contra* Rothman KJ, Moore LL, Singer MR, Nguyen US, Mannino S, Milunsky A (1995) Teratogenicity of high vitamin A intake. *N Engl J Med* 333(21):1369-73)

² Miller RK, Hendrickx AG, Mills JL, Hummler H, Wiegand U (1998) Periconceptional vitamin A use: How much is teratogenic? *Repro Tox* 12:75-88.

Wiegand U, Hartmann S, Hummler H (1998) Safety of vitamin A: Recent results. *Int J Vit Nutr Res* 68:411-416.

WHO/MI (1998) Safe vitamin A dosage during pregnancy and lactation: Recommendations and report of a consultation.

Consuming a 200,000 IU VAC can cause a large spike in serum retinol levels (e.g. from 2 umol/l to 20 umol/l and back to 2 umol/l within a few hours), however *consumption of an equivalent amount of vitamin A via a vitamin A rich food, such as liver, does not cause a spike in serum retinol* (H. Flores, unpublished data). This is apparently because the vitamin A from food is absorbed over a longer period (three to seven hours) than a VAC, and it is transported to the liver and stored as quickly as it is absorbed, therefore the serum retinol stays within a normal range (homeostasis). It is expected that fortified foods would yield a response in serum retinol levels similar to that observed with liver. (A study examining this issue is now being conducted with vitamin A fortified Ultra Rice™ by Hernando Flores in Brazil, the University of Toronto, and PATH Canada. When results are available they will be shared with the MI.) Since there would be no increase in serum retinol levels there would be no risk of teratogenicity.

Vitamin A fortified foods have been in the market for several decades in many countries. All reports linking vitamin A consumption to teratogenicity refer to (high level) vitamin supplements, and in no instance to fortified foods. It is time that concerns for teratogenicity are no longer considered when setting a food fortification policy.

4.2 Critique of Market Component

Unlike the dietary component of FRAT which had been developed and reviewed prior to field-testing, the market component was developed under this contract, without extensive review before field testing. In marked contrast to the dietary component of FRAT, it was not successful. A brief description of the difficulties and our proposed solutions follow.

Knowing as we do how the diet of groups of individuals can represent the entire population, sampling methods can be used so that a small number of individuals can be surveyed who represent the populations. Furthermore, with dietary methods and cluster sampling, one can estimate the sample size required to achieve a given level of accuracy. This does not hold with qualitative methods such as a market assessment, and an initial obstacle was trying to choose a method where objective criteria could be used for sample size and selection. A rule for sample size for qualitative data collection by focus group discussions or key informants is to continue conducting focus group/key informant interviews until no new meaningful data are collected. This runs contrary to the general spirit of FRAT where the methods and sample size should be described so that a user knows the effort that will be required, and the accuracy of the results that will be achieved. This problem was never satisfactorily addressed. That said, market surveys were done (and are done elsewhere), but the sample size was chosen more by convenience than with scientific justification.

The second, and even more intractable, problem was what to include in the survey questionnaire. While we know what we needed in the end (that is, information on the size of the market, the market share of each player, the pathway of the food from grower/producer to distributor to retailer to consumer, the costs, etc etc., that is, the *feasibility* of fortification of the given food from an industrial/marketing perspective),

there do not exist methods for the rapid and systematic collection of these data which would be applicable to any country or any food. This was frustrating, as we knew very well that such surveys have been done, but the methods used were rather loosely defined, and we wanted to provide something as structured as the dietary component of FRAT.

We consulted with Dr. Herbert Weinstein, who is superbly qualified and experienced in these matters. Dr. Weinstein agreed to help with our efforts, but it must be said that from the beginning, he did not think it was feasible to develop the guidelines we were aiming for. What we learned from our efforts, and what Dr. Weinstein stated implicitly at the beginning and explicitly at the end, was that “if you are familiar with the food industry, you do not need such detailed guidelines, and if you are not familiar with the food industry, detailed guidelines of this sort will not help”. Interestingly, this was also the conclusion reached by our partners in Brazil and Burkina Faso. In the end, our partners abandoned our draft guidelines for market surveys and simply discussed the issues with food industry representatives (as was done in the Nepal pre-trial of FRAT), cognizant of the required information. In the revised version of FRAT, rather than have expanded, detailed guidelines (as appear in Annex 2 of this report), we have provided much simpler guidelines, indicating the information that is required, and that it can usually be collected through open-ended discussions with key informants in the food industry. All three partners were able to do a market assessment without using detailed guidelines, but instead knowing what information was needed. Following their intuition and understanding of local conditions, they developed an understanding of the food industry and assessed the feasibility of food fortification from a market perspective. The market guidelines that are now in the FRAT guidelines outline the basic information that guided the assessments carried out by the three partners and in the Nepal pre-trial.

Finally an important critique from Brazil is that, while it is important to understand the food market in order to properly implement a food fortification program, it may not be necessary to conduct a market assessment in order to decide whether to proceed with fortification of a given food. It was observed by Flores that market conditions can and do change in response to industry efforts to change them. This makes great sense – if industry sees an opportunity, they can build a factory, develop transportation infrastructure, develop retail partnerships, or lobby for legislation that would facilitate the opportunity. Even if market conditions were currently unsuitable for fortification, with the proper incentives they can be changed – certainly much easier than population dietary patterns can be changed, although they too can be changed, with, for example, the removal of a large tax, or an intense marketing campaign. This is important to bear in mind when considering a food fortification program, and we have included this in the revised FRAT.

The critiques of the market component of FRAT by the three partners are found in their reports.

5 Summary of Results of Field-Testing

5.1 Brazil

In keeping with an on-going effort to advance Ultra Rice™ (vitamin A fortified rice) in Brazil, the Brazil partner used the FRAT to test the appropriateness of rice as a micronutrient vehicle. It is planned that the initial site for Ultra Rice™ will be in Pernambuco, in north-east Brazil, which is the poorest part of Brazil and has high rates of VAD. Numerous dietary surveys have been done in Brazil, and in Pernambuco. It was felt by Hernando Flores that the only need for FRAT was as a “confirmational survey”, as it is already well known that rice would be a suitable vehicle for vitamin A in Pernambuco. The field test was also limited by the relatively high costs of doing research in Brazil – the small survey that was conducted cost \$9,000. Therefore the FRAT dietary survey was conducted in a random sample drawn from slums around Recife, and previous published studies were summarized. The survey did in fact confirm that rice is consumed nearly every day by all the poor in Recife, as shown in the following table, and as such, would be a suitable vehicle for fortification.

	Children 1-3yrs	Women 16-45 yrs
% consumers	92%	86%
Centile*	g/d	g/d
10 th	40	40
50 th	60	100
90 th	120	240

* Consumers only

In the market assessment, important companies in the food and rice industry in Brazil were presented with the concept of fortification of rice, and what was involved to make for a successful launch. Without exception, the idea was met with enthusiasm and conviction that it could be made to work. Important decisions, such as whether the production factories should be based in Recife, or in south Brazil in Rio Grande de Sul which has more advanced production facilities, and what each partner’s role would be, still have to be made. However, there is little doubt that, from a market/industry point-of-view, fortification of rice is desirable and feasible.

5.2 Bangladesh

The partner chose to test sugar, oil, water, salt, flour and powdered milk in four regions – urban rich and urban slum (from four different urban centres), rural (throughout entire country) and tribal (from two locations). Each of the foods is available in numerous forms and brands. Sugar includes yellowish and white available in crystalline or powder form. Edible oil includes soya and mustard oil. All the foods come in both “branded” and “loose” packages. In the summary tables below, the figures are for all types and brands together. The results are presented in much more detail in the partner’s report.

Children's Consumption of Selected Foods in Previous 24 hours

	Edible Oil		Sugar		Powdered Milk	
	%*	g/d	%	g/d	%	g/d
Urban rich	84	9	81	8	38	2
Urban slum	70	4	25	5	7	1
Rural	69	5	43	5	10	1
Tribal	79	5	27	2	1	1

Mother's Consumption of Selected Foods in previous 24 hours

	Edible Oil		Sugar		Powdered Milk	
	%	g/d	%	g/d	%	g/d
Urban rich	99	14	89	6	5	2
Urban slum	99	5	25	4	1	1
Rural	100	6	44	5	0	0
Tribal	100	6	34	2	0	0

* %= percent of respondents reporting consuming food. g/d=average intake of consumers.

** Salt is used in many foods and in 100% of the houses. Data on individual consumption was not collected but each household consumed about 500g per week.

The results of the dietary survey indicate that oil, sugar and salt are widely and regularly consumed and could be appropriate vehicles. Powdered milk and flour are not widely consumed and would not be suitable vehicles. Of the regularly consumed foods, sugar and salt have the most favourable market conditions. Processing of sugar is centrally controlled, which would facilitate fortification. Sugar is also frequently consumed in purchased, baked goods, so sugar used in industrial preparations should be fortified as well as store-bought sugar. Iodisation of salt is already legislated, so presumably adding another micronutrient would be feasible. The oil consumption figures presented above include both soya and mustard oil, with soya oil more frequently consumed. All soya oil in Bangladesh is imported and refined in Bangladesh, so it would be possible to fortify. The mustard oil is locally grown and processed and fortification would be more difficult.

In summary, three suitable vehicles (salt, sugar, soya oil) are identified and efforts to fortify them should be pursued. To achieve broad coverage, many partner industries will have to be involved, as the markets are quite fragmented, with numerous types and brands available.

5.3 Burkina Faso

Three potential food vehicles were identified according to criteria established in the FRAT guidelines: sugar, Magi cubes ("Jumbo"), and wheat flour. A dietary survey was carried out in four distinct areas to determine which of these vehicles would provide an effective vehicle for vitamin A: rural cattle herding, rural cash crop, rural subsistence agriculture, and an urban area. Among the three potential food vehicles, only sugar and the Magi cubes met the effectiveness criteria. Sugar was consumed by 67.7% of the children and 66.7% of the women in the 7 days preceding the survey; 73.5% of children and 79.3% of women consumed the Magi cubes in the 7 preceding days; and 56.6% of the children and 47.8% of the women consumed wheat flour.

The market assessment collected information on the production of sugar and the Magi cube, described in detail the distribution network of these foods as well as possible constraints to distribution, and identified factors which might limit the consumption of the fortified products. The local sugar producer, SN Sosuco, produces a large quantity of sugar which meets approximately 70% of the demand in the country. The balance of the demand is met by imported sugar. The imported sugar is of higher quality than the locally produced sugar, however duties imposed on imported sugar in 1999 have made local sugar competitive on the market, for the time being. The sugar manufacturer is in favor of fortification, and sees this as a possible means of increasing consumption of locally produced sugar. With the pending introduction of open markets between African countries, the local sugar producer would have to improve the quality of its sugar to remain competitive. The Magi cube manufacturer was reluctant to share information, fearing that the survey team represented "the competition". While the concerns of the manufacturer could be relatively easily addressed with some effort, fortification of the Magi cube is complicated by the fact that its production is under license by an international company, and the base ingredient is imported. Therefore the local industry cannot simply add an ingredient. From the point of view of consumption, both sugar and Magi are feasible vehicles for vitamin A fortification. It is known that in general the population of Burkina Faso is sensitized to the benefits of fortified foods, and that these would be the preferred choice as long as the cost remains competitive.

Note: HKI followed the FRAT guidelines very closely and interpreted their results according to the strict guidelines therein. They initially concluded that food fortification would not be appropriate in Burkina, due to coverage rates less than 50% of some of the foods, and consumption levels for other foods such that the food could not be fortified to have intakes fall within the minimum and maximum intakes as described in FRAT. In follow-up correspondence between HKI and PATH Canada, it became clear that the guidelines were too strict, and when applied would not support the fortification of almost any food. With a new understanding, HKI plans on pursuing food fortification. The FRAT guidelines have been modified to reflect the less strict conditions which are now felt to still be conducive to an effective fortification program.

6 Conclusion and Next Steps

The FRAT was field-tested in three countries. The dietary component of FRAT performed very well and the relatively small number of required modifications have been done in the submitted revised version. The market component of FRAT that was initially drafted for field-testing was weak and did not perform well at all. We have revised the market component to reflect what the partners actually did and what can therefore be expected to work in other situations to conduct successful market assessments. The market analysis component is now included as Section 6 in the guidelines. The detailed version that was developed and used in the field testing is submitted in Annex ii, but it is not recommended that it be used further.

The field-partners contracted by PATH Canada were all strong, as evinced in their submitted reports. The results of the FRAT in Brazil confirm that rice is a suitable vehicle for fortification, and this work will help advance vitamin A fortified Ultra Rice™ in Brazil. PATH Canada, funded by PATH through the Gates Foundation, is now leading efforts to launch Ultra Rice™ in Brazil. The FRAT has been an important first step in our efforts. In Burkina Faso, sugar and Magi cubes (but not wheat flour) would be suitable for fortification, and HKI has shared their findings with the MI and the Secretary General of the Burkina Faso Ministry of Health. The Secretary General is interested in the results, as they are consistent with his desire to move away from capsules to a food-based approach. In Bangladesh, sugar, oil and salt were identified as suitable vehicles for fortification with vitamin A (salt iodization already in place). The results were shared with MI and numerous national experts, and consequently we hope that they will prove useful in promoting and extending food fortification in Bangladesh.

For the FRAT guidelines, the next step would be for the MI to review the revised version, and then submit it for translation and publication. Although there were funds in the contract to PATH Canada for translating the manual, we felt it prudent to wait for MI's review before paying for translation, and therefore the translation funds are unspent. It would be useful to make the FRAT guidelines widely available. We would suggest making the FRAT Guidelines available on the MI and PATH Canada websites, as well as disseminating conventionally as a hard-copy, bound publication. The Portuguese, Bangla and French adaptations of the questionnaire are found in the Brazil, Bangladesh and Burkina reports, respectively.

Finally, although the guidelines were developed so that the user could use them without outside assistance, all three field-test sites had trained specialists involved. We believe a B.Sc. level nutritionist or public health worker with an understanding of the local issues should be able to lead the research, but understanding all the subtleties of survey strategies, dietary data, measurement error versus true variation, fortification technology, etc., would require experts of the caliber involved in this field testing.

7 Comment on name “FRAT”

Dr. Noel Solomons reviewed the guidelines and one of his criticisms was that the title FRAT is a misnomer, as is it involves quantitative (and relatively time consuming) methods, compared to the better known Rapid Assessment method of Scrimshaw and Scrimshaw and others, which involves qualitative (and less time consuming) methods. We acknowledge the criticism. Although we are not irrevocably wed to the name FRAT, the name has a growing, if still small, reputation. Any candidate replacement names must be weighed against the confusion the change would create.

One candidate replacement name may be FEAT: Fortification Evaluation and Assessment Tool, reflecting that it is also an appropriate tool for evaluating existing fortification programs. A second candidate to consider is FAST: Fortification Assessment and Survey Tool.