

Fortification



Proceedings of the Research Forum on Vitamin A Fortification of Cooking Oil

Diagnostics, Lot Quality Assurance Sampling, Monitoring



May 3 2016
Astoria Plaza Hotel, Pasig City, Philippines

Nutrition Center of the Philippines

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Prepared by the Nutrition Center of the Philippines



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Background

The Nutrition Center of the Philippines (NCP; www.ncp.org.ph) has been working in the field of public health nutrition since 1974. The research of NCP contributed towards establishing the efficacy of fortification of flour and oil-based vehicles with vitamin A, and flour with Vitamin A and iron. The NCP works in four strategic program areas that contribute towards achieving nutrition security: 1) micronutrient deficiencies; 2) infant and young child nutrition; 3) communicable and non-communicable diseases; and 4) maternal and neonatal health. This forum supports our goal towards reducing micronutrient deficiencies.

The Philippine Food Fortification Law was enacted in 2000 and implemented in 2004. The National Nutrition Surveys conducted by FNRI-DOST before (2003) and after (2008) the start of implementation showed a marked reduction in Vitamin A deficiency and anemia with no change in the consumption patterns for meat, dairy or vegetables. In 2012, the Nutrition Center of the Philippines (NCP) was commissioned by the Department of Health National Nutrition Council to facilitate the Mandatory Food Fortification Review. This review was conducted as part of the Maternal and Young Child Nutrition Security Initiative in Asia (MYCNSIA). The review summarized many challenges facing mandatory food fortification. This research forum on Vitamin A Fortification of cooking oil addresses the challenge of maintaining an available supply of appropriately fortified oil.

The NCP focused on the fortification of oil with Vitamin A because of the threat that unregulated dip-out (takal) oil could adversely affect the gains made by the fortification program. NCP recognized that the fortification program needed a replicable methodology that describes the magnitude of the problem. This would require a well-characterized sampling methodology and reliable laboratory assays. Our first priority was therefore to document the diagnostic performance of available alternatives to high performance liquid chromatography (HPLC is the expensive and time-consuming gold standard). This was then followed by a study that modelled how lot quality assurance sampling (LQAS) can be used to measure availability as an objective and repeatable indicator of government performance in fortification.

This forum presents the evaluation of two diagnostic tests: a quantitative test made by Bioanalyt Inc GmbH and a semi-quantitative test developed by Bagco, Inc. Both methods use the Carr-Price reaction visualized in different ways. NCP then used one of the kits to describe the availability of fortified branded and unbranded oil in a province in the Philippines. This study utilized Lot Quality Assurance Sampling (LQAS), a methodology that allows efficient sampling to estimate quantifiable indicators. Finally, a presentation was made on a proposed monitoring mechanisms consolidating the previous work done in fortification through various donor-funded initiatives.

Opening the Forum

Dr. Juan Antonio Solon (President, NCP) welcomed the participants and thanked the different stakeholders for attending despite the relatively short notice given. Dr. Solon gave a brief overview of the rationale for focusing on Vitamin A fortification of oil and the partnerships that made the researches and the fora possible (see Background above).

Dr. Mary Christine Castro, the Executive Director of NCP, introduced and welcomed the participants. There was a total of 40 participants excluding the organizers and NCP staff. There were 14 representatives from government the Department of Health, the Department of Agriculture and the Department of Science and Technology. The Bureau of Customs (Department of Finance) and the Department of Trade and Industry were invited but did not send participants. There were 13 participants from the oil industry and 10 from suppliers. There were 6 representatives from the NGOs and academe.¹

The Forum Proper

To begin the program², Ms. Maria Lourdes Vega, Chief of the Nutrition Policy of the National Nutrition Council (NNC), set the scene by presenting a Policy Review on Vitamin A Fortification. As stated in the Food Fortification Law (Republic Act 8976), the NNC serves as the advisory body on food fortification. Ms. Vega presented the trends in the reduction of Vitamin A Deficiency, the salient points of the Philippine Food Fortification Law, the challenges highlighted by the review pertinent to fortification with Vitamin A and the challenges and recommendations made.

Briefly, NCP demonstrated that on average, the quantitative kit (iCheck Chroma) reads a slightly higher Vitamin A concentration compared to HPLC; the kit is more specific than it is sensitive, and the sensitivity can be improved by applying a correction factor. The semi-quantitative kit (Quick View) was found to be most suitable for identifying oil that met the 10 mg RE/kg or the 15 mg RE/kg threshold. The studies on LQAS showed that for the province examined, the unbranded dip-out oil sold in public markets were not fortified and the branded bottled oil was over-fortified. NCP also showed that pooled samples and individually tested samples arrived at a similar conclusion regarding the availability of fortified oil.

Mr. Hector Maglalang presented a possible monitoring system drawing on the findings of the research as well as the recommendations made from past fortification initiatives. The response from the FDA and PCA showed how the new laws strengthening the FDA and PCA's current mandate can help achieve better availability of fortified cooking oil. The local oil manufacturing industry reiterated their commitment to the program and their concerns about the unfair competitive advantage of non-compliant companies.

¹ See Annexes 1 and 2 for list of organizers, resource speakers and participants

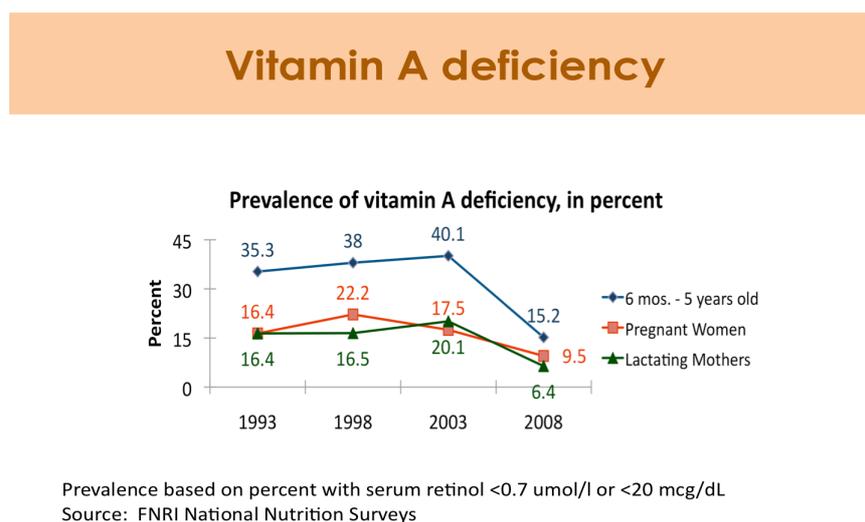
² See Annex 3 for Program Details

I. Policy Review on Vitamin A Fortification in Cooking Oil

Ms. Maria Lourdes Vega, Chief of the Nutrition Policy of the National Nutrition Council (NNC) presented the portion of the Mandatory Food Fortification Policy Review pertinent to Vitamin A Fortification on behalf of Assistant Secretary Maria Bernardita T. Flores (Executive Director IV, National Nutrition Council).

The National Nutrition Surveys conducted by the FNRI-DOST includes an assessment of Vitamin A Deficiency (VAD) based on serum retinol concentrations. The results of the past surveys up to 2008 show a decline in vitamin A deficiency in different age groups. The conclusion of the Review was that fortification (voluntary and mandatory) was the most plausible explanation of the decline in VAD. The results of the 2013 VAD data are still pending.

Figure 1. 2008 National Nutrition Survey Result for Vitamin A deficiency (NNC slide).



The Copenhagen Consensus Group cited micronutrient fortification as one of the interventions with a high benefit:cost ratio. Republic Act 8976 (Food Fortification Act of 2000) was enacted in 2000 and implemented in 2004. The law requires rice to be fortified with iron, sugar with Vitamin A, flour with Vitamin A and iron, and oil with Vitamin A. The law applies to all imported and locally processed foods for sale and distribution in the Philippines. The law also provides for voluntary fortification of processed foods.

Figure 2. The Copenhagen Consensus (NNC slide)

The Copenhagen Consensus: High Benefit Cost Ratio		
	Solution	Challenge
1	Micronutrient supplements for children (A & Zn)	Malnutrition
2	The Doha development agenda	Trade
3	Micronutrient fortification	Malnutrition
4	Expanded immunization coverage for children	Diseases
5	Biofortification	Malnutrition
6	Deworming, other nutrition programs in school	Malnutrition
7	Lowering the price of schooling	Education
8	Increase and improve girl's schooling	Women
9	Community-based nutrition programs	Malnutrition

The NNC may mandate other food items to be fortified, but it cannot delist items. The NNC is also mandated to conduct a periodic review of the micronutrients added to the food. The key findings from the policy review pertinent to Vitamin A in oil were summarized as follows : 1) Vitamin A in oil is more stable than Vitamin A in flour; 2) All 46 oil manufacturers are fortifying with Vitamin A but only 2 are within standards; 3) the difficulty of monitoring "dip-out" or "taka" oil and smuggled oil places compliant companies at a competitive disadvantage; and 4) the industry uses a rapid test kit to monitor the presence of Vitamin A. This needs government support in the validation and optimization of the assay.

The recommendations from the Review include :

1. Maintain current levels of fortification for vitamin A and iron
2. NNC as coordinating mechanism for interagency collaboration
3. Strengthen the capacity of regulatory agencies for monitoring
4. Establish a management information system for the Food Fortification Program
5. Design and implement incentive package for the compliant manufacturers
6. Hold periodic consultative meetings with the industry
7. Build and strengthen political will to implement the law

The next steps are to revive the Technical Working Group (TWG) on Food Fortification and to formulate the Food Fortification Strategic Plan for 2017 - 2022.

II. NCP Oil Fortification Studies: iCheck Validation Study

Objective: To assess the reliability of iCheck Chroma 3 to estimate retinyl palmitate and to classify coconut oil as appropriately fortified.

Methods

The test device (iCheck Chroma 3 ; Bioanalyt GmbH) which rapidly quantifies retinyl palmitate was tested against high-performance liquid chromatography (HPLC). Recovery, linearity and precision were measured at five target concentrations (5 to 25 mg Retinol Equivalents (RE)/kg). Agreement (Bland-Altman) was described and the diagnostic performance (sensitivity, specificity and predictive values) was calculated with HPLC as the gold standard. A sample size of 100 (allowing for outliers) was based on the formula for the upper and lower limits of agreement. This also allows an estimation of sensitivity and specificity of 85%, assuming a 50% prevalence and desired width of 0.1. The definition of appropriately fortified oil was based on the specifications of the Implementing Rules and Regulations for the Philippine Food Fortification Law (12 -23 mg RE/kg).

Results

Linearity ranged from 5 - 27.8 mg RE/kg and recovery was 84 - 130%. Precision ranged from 3.5% to 7.3% (intra-assay) and 1.3 to 14.7% (inter-assay). Mean difference was 1.9 mg RE / kg (SD 2.3; 95% CI -2.6,6.5) with iCheck reading higher than HPLC for majority of the samples. The specificity was 96% and the positive predictive value was 94%. Sensitivity improved from 62% to 83% after subtracting the mean difference from the portable device reading. The negative predictive value improved only slightly from 50% to 69%. The diagnostic performance is summarized in Table 1.

Conclusion

The portable iCheck Chroma 3 can be recommended for estimating vitamin A content in fortified coconut cooking oil in lieu of HPLC. It is best used to rule in (ie, accept) that the sample is within range because of its high specificity and positive predictive value.

Table 1. Summary of the Diagnostic Performance of iCheck Chroma 3 ¹

Parameter	Uncorrected	Corrected ²
	% (95% Confidence Interval)	% (95% Confidence Interval)
Sensitivity	62 (53, 72)	83 (76, 91)
Specificity	96 (93, 100)	96 (93, 100)
Positive predictive value	98 (95, 100)	98 (96, 100)
Negative predictive value	50 (40, 60)	69 (60, 78)

¹ Gold Standard was HPLC measuring 12 - 23 mg RE/kg (prevalence 72 % (63.2, 80.8));

² iCheck values were corrected by subtracting the mean difference from the actual reading.

Figure 3. iCheck Chroma 3



III. Quick View Validation Study

Objectives

To assess the validity of Quick View to estimate retinyl palmitate and to classify coconut oil as appropriately fortified or adequately fortified oil.

Methods

The Quick View Vitamin A Test Kit estimates vitamin A content in oil from 5-25 mg RE/kg (in increments of five) based on the Carr-Price reaction. High Performance Liquid Chromatography (HPLC) was the reference method. Linearity and agreement was described. Combinations of Quick View concentrations were used to predict the fortification status and minimum thresholds. A sample size of 100 allowed for the estimation of a specificity of 85%. Appropriately fortified oil was defined as oil that met the of the Philippine Food Fortification Law (12 -23 mg RE/kg). Adequately fortified oil was defined as oil with at least 12 mg RE/kg Vitamin A. Samples of branded coconut oil were purchased from retail stores in the Greater Manila Area and tested for Vitamin A using Quick View and HPLC.

Results

Linearity was defined by $y=0.9317 + 5.04x$; R^2 is 0.66. There was considerable overlap in the Quick View readings in the 10 - 20 mg RE/kg range. The mean difference between Quick View and HPLC was - 4.036 mg RE/kg with the difference becoming smaller with higher HPLC concentrations. The observed agreement was 64% and kappa = 0.22 ($p<0.01$). Quick View performs best when used to identify a minimum threshold of 10 mg RE/kg. For this threshold, sensitivity was 96% (95% CI 85,99) and specificity was 100 (69,100). For the minimum threshold 15 mg RE/kg, the sensitivity was 99 (95% CI 93,100) and specificity was 97% (95% CI 90,99). The 10 mg RE/kg threshold can be used by regulators and the 15 mg RE/kg can be used by producers. To identify appropriately fortified oil, there are wider trade-offs between sensitivity and specificity (Table 2). The overlap seen in the linearity suggests that there is still room to improve Quick View performance in the higher concentration ranges. The higher concentrations may be relevant to the Philippines and not in other countries.

Conclusion

The kit is best used to estimate minimum thresholds (adequately fortified) of vitamin A content in fortified coconut cooking oil.

Table 2. Summary of the Diagnostic Performance of Quick View

Estimated Concentration ¹ mg RE/kg	Quick View range ²	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value (95% CI)	Negative Predictive Value (95% CI)
≥ 10	10-25	96 (89,99)	100 (69,100)	100 (96, 100)	71 (42, 92)
≥ 15	10-25	99 (93,100)	81 (54,96)	97 (90, 99)	93 (66, 100)
12 - 23	15-20	65 (53, 76)	61 (41, 78)	81 (69, 90)	40 (26, 57)
12 - 23	10-15	64 (52, 75)	93 (76, 99)	96 (86, 99)	50 (36, 54)
12 - 23	10-20	90 (81, 96)	61 (41, 78)	86 (76, 93)	71 (49, 87)
12 - 23	5-15	69 (57, 80)	79 (59, 92)	89 (78, 96)	50 (35, 65)

¹ The Estimated Concentration is the HPLC reading against which Quick View readings were compared; ² The Quick View Range refers to the Quick View Color Scale Readings;

Figure 4. Quick View Vitamin A Test Kit



IV. LQAS of Vitamin A Fortified Cooking Oil in Negros Occidental

Objective:

To determine whether unbranded and branded cooking oil from public markets in Negros Occidental contain the appropriate Vitamin A levels using individual and pooled testing with iCheck and a lot quality assurance sampling methodology (LQAS).

Methods:

For this study, the supervision area, or 'lot', was defined as the province of Negros Occidental, covering 1 highly urbanized city and 6 inter-local health zones. 'Cases' in the lot consisted of the major and satellite public markets. Samples of cooking oil were taken from the randomly sampled 'cases'. Ten samples each of unbranded and branded cooking oil were purchased from 24 out of 87 randomly selected public markets in the province of Negros Occidental. The Vitamin A levels of these samples were determined individually using iCheck Chroma.

For the 'case' [market] to be acceptable, 9 out of the 10 cooking oil samples taken from that market should have Vitamin A levels within the legislated range of 12 - 23 mg RE/kg oil. For the 'lot' to be acceptable, at least 19 of the 24 markets sampled should pass the criteria for the 'case'.

Samples from each market were pooled and retested to compare if testing pooled samples would result in similar conclusions for the entire lot. This was done separately for unbranded and branded cooking oil.

Results:

Only 5% (12/240) of the unbranded oil samples had appropriate Vitamin A levels. Four in five samples (81%) were unfortified, 10% were inadequately fortified, and 3% were over-fortified with Vitamin A. On the other hand, all 240 branded oil samples had Vitamin A levels above the upper limit set by the implementing rules and regulations of Republic Act 8976 (Table 3).

'Case' criteria

None of the markets ('cases') had 90% of the samples with Vitamin A levels within the acceptable range. This was true for both branded and unbranded cooking oil.

'Lot' criteria

For both branded (0/24) and unbranded (0/24) oil, the criteria for acceptability of the lot was not met.

Pooled testing

2 out of 24 pooled samples of unbranded oil had Vitamin A levels within the acceptable range. For branded oil, 0 of the 24 pooled samples had acceptable Vitamin A levels. With pooled testing, the criteria for the acceptability of the lot was not met for both branded and unbranded cooking oil.

Conclusions:

Appropriately fortified oil is not available in Negros Occidental (81% of unbranded oil is not fortified, while 100% of branded oil is over-fortified).

Lot Quality Assurance Sampling using markets as sampling units can be used to estimate province level status. Pooled testing can reduce the number of tests required if there is > 80% homogeneity.

Table 3. Comparison of results of unpooled and pooled testing of unbranded and branded cooking oil.

	Unbranded		Branded	
	Unpooled	Pooled	Unpooled	Pooled
Markets sampled	24	24	24	24
Samples collected (#)	240	240	240	240
Samples tested (#)	240	24 pooled samples	240	24 pooled samples
Samples with correct VA level	12	2 (5 inadequate)	0	0
Markets with 90% appropriately fortified samples	0	2 (pools)	0	0
Decision Criteria	19 markets	19 pools	19 markets	19 pools
Conclusion for Supervision Area (LOT)	FAIL	FAIL	FAIL	FAIL

V. Proposed Monitoring System for the Use of iCheck Chroma and Quick View Vitamin A Test Kit

Mr. Hector Maglalang's presentation provided evidence-based recommendations on possible monitoring and evaluation of Vitamin A fortification of cooking oil and possible monitoring procedures with the use of the diagnostic tools for food control and program monitoring and evaluation. The framework for monitoring and evaluation of food fortification programs published by the WHO in 2006 was presented. This framework shows the aspects of food control for locally manufactured and imported products and program monitoring and evaluation. Examples of process indicators associated with performance of inputs, activities and outputs and effective indicators to measure the outcomes in the target population were given.

A scheme for internal monitoring was presented. This consisted of: 1) a certificate of analysis for every delivery of fortificant for producers and a product certificate of analysis for importers; 2) enforcement of proper handling and storage of fortificant; 3) appropriate use of mixing equipment; 4) routine conduct of fortification analysis in-house using iCheck Chroma or Quick View; 4) external monitoring once or twice a year using HPLC or iCheck Chroma; 5) Equipment calibration; 6) a system of recall, and 7) recording and documentation.

Previous efforts to strengthen external monitoring were presented. These include draft guidelines for licensing, plant inspection and surveillance for oil and flour developed with the Food and Drug Administration (FDA) in 2008-2010. Another relevant document was the draft guidelines for the Philippine Coconut Authority (PCA) for the monitoring of cooking oil refiners, importers, repackers and distributors. These were not implemented due to a lack of a Memorandum of Agreement between the FDA and the PCA that would provide for their responsibilities and coordination.

Two external monitoring schemes were presented. The first scheme was for the plant and warehouse of importers for FDA and PCA and the second was for the supply chain (repackers, distributors, and retailers) for FDA, PCA and Local Government Units (LGUs). The proposed scheme for the plant and the warehouse was tied to the renewal of the license to operate. This scheme includes: 1) determining the fortification levels ; 2) sampling from at least 2 brands of oil; 3) specific steps if the samples are below the minimum adequate level; and 4) specific steps if the samples have no Vitamin A. Failure to correct the problem particularly during the 3rd inspection will eventually cause a denial of application for the license to operate (LTO) and a cease and desist order (CDO) to discontinue production that may be lifted only after the company passes another round of FDA inspections.

The proposed scheme for the supply chain includes : 1) analysis of samples from the distribution chain; 2) a brand-specific regional sampling plan ; 3) on-site testing using the test kits presented; 4) samples outside the standards will trigger communication to

the company for corrective action; 5) samples without Vitamin A will result in a report of a violation and plant inspection.

The proposed scheme for program monitoring focuses on household consumption to be measured using the National Nutrition Surveys conducted by the Food and Nutrition Research Institute (FNRI) every five years. Testing of oil used in the household can be done using various testing methods that were presented.

It was concluded that the Vitamin A test kits may have various uses in program monitoring and evaluation from internal monitoring, external and commercial monitoring as well as program monitoring. The kits can also be used for advocacy purposes by different stakeholders to promote the oil fortification with Vitamin A program for the control of Vitamin A deficiency.

Response from Food and Drug Administration (FDA)

As a response from the FDA, Dr. Maria Victoria Pinion, Officer in Charge of the Product Research and Standards Division (Center for Food Regulation and Research, FDA) commented on the presentations, FDA's organizational structures and programs relevant to food fortification, and how the research could potentially impact policy.

Oil fortification studies done by the Nutrition Center of the Philippines, namely the iCheck Validation Study and the Quick View Validation Study, were very relevant in monitoring regulatory compliance on oil fortification. Likewise, the two presentations supporting the two oil fortification studies, the LQAS of Vitamin A in Negros Occidental and Proposed Monitoring System for the Use of iCheck Chroma and Quick View Vitamin A Test Kit were very timely as the Food and Drug Administration is currently strengthening the FDA post market monitoring system and implementing a comprehensive monitoring program pursuant to Republic Act 9711³.

FDA's new organizational structure has just been approved by the Department of Budget and Management. Thus, this new organizational structure leads to the creation of four centers⁴. Dr. Pinion cited that before, as mentioned by Mr. Hector Maglalang, many documents have been prepared for external monitoring dating back to the year 2000. At that time, the FDA (then BFAD⁵) regulated health products (i.e. drugs, food and cosmetics) are under one office head. Now FDA has a center for food office that will handle, among other food concerns, the implementation of the regulatory component of oil fortification. The other components of the food fortification program such as promotion and advocacy are being handled by the DOH – Health Promotion and Communication Service (HPCS) and program management by the DOH-NNC.

As for the regulatory component, the studies presented in this forum are very timely in strengthening the FDA's annual product monitoring specifically for all processed food. In terms of oil fortification, the FDA is coordinating with concerned agencies such as the Philippine Coconut Authority in terms of standards for the level of fortificant in cooking oil for product registration as stated in RA 8976.

Dr. Pinion said that for this year, cooking oil as covered by RA 8976 is among the priorities for annual product monitoring under the post marketing surveillance (PMS) system of the Center for Food Regulation and Research (CFRR) in coordination with the office of Field Regulatory Operations (FRO) and its Regional Field Offices (RFOs). FDA will

³ RA 9711. Food and Drug Administration Act of 2009.

⁴ The Center for Drug Regulation and Research; The Center for Food Regulation and Research; The Center for Cosmetics Regulation and Research; The Center for Device Regulation, Radiation Health and Research

⁵ Bureau of Food and Drug

run after the products in the market for intensive monitoring checking for sustained compliance.

Under the new FDA structure, five clusters have been created (North Luzon, South Luzon, Visayas, Mindanao West and Mindanao East). These clusters will work for the inspection and monitoring of products in the market. Dr. Pinion also added that FDA in the past had a different system of monitoring, covering all health products and no specific monitoring tool for food alone. At present, external monitoring or specific product monitoring for each Center is currently being strengthened. FDA regional clusters will continuously conduct spot monitoring and annual product monitoring.

According to Dr. Pinion, scientific studies will be useful in crafting policies for both program management and regulatory component of oil fortification, i.e., dealing with (a) quality and safety to address Vitamin A deficiency and food safety for public health and (b) regulatory compliance to standards for economic health.

She said there are no objections regarding the use of test kits in accordance with RA 8976 e.g. the Quick View and the iCheck Chroma, since the law does not specify any limitation as to what type of test kit to be used in monitoring products in the market. However, a confirmatory test must be done in the laboratory through titration system. Presently, FDA is using High Performance Liquid Chromatography (HPLC) in the laboratory. Dr. Pinion said that as presented by the researchers although Quick View results showed good linearity with HPLC yet it reduces the ability to differentiate ranges of concentration, it is best used to estimate threshold of Vitamin A content in fortified cooking oil. Currently, the FDA has the Quick View test kit as an aid in speedy analysis. This test kit, being semi-quantitative, was also said to be quite subjective since it might depend on the visual acuity of the tester. However, this test kit is being used and helps FDA to determine if further confirmatory tests are needed.

On the other hand, the portable iCheck Chroma as presented seems interesting in terms of the data being shown that linearity is good and is said to be reading higher Vitamin A content specifically in fortified cooking oil. FDA has not yet tried using iCheck to date.

In agreement with the recommendation to pursue the use of test kits for purposes of monitoring in the market, a policy just needs to be issued to support its use especially in the regions and local government.

With regard to the Lot Quality Assurance Sampling of branded cooking oils and takal oils done in Negros Occidental, FDA noted the findings of the study and will act on the concerns following due process. FDA is addressing similar concerns and is working on a comprehensive program in coordination with the LGU having mandate in RA 10611⁶ to monitor products for safety and quality in its territorial jurisdiction. The FDA is creating a product recall committee to deal with similar concerns. The Food Safety Act is the linking framework for FDA and LGU to coordinate. The LGU could issue local ordinance

⁶ RA 10611. Food Safety Act of 2013.

supporting the Food Safety Act. This Act gives LGU mandate on food safety on top of Sanitation Code.

The FDA will be developing easy-to-use information education and communication (IEC) materials on food safety for the local government to serve as reference e.g. how much additives are to be put in a processed food product like oil, addressing food safety concerns in the country.

With respect to the takal oil and other processed foods, FDA is coordinating with the LGUs through the RFOs in product monitoring especially the micro-enterprises complying with the rules since business cannot be stopped. Micro-enterprises are supported in coordination with the DTI. There is an issued policy on this regarding DTI Negosyo Centers and Local Government Units (LGUs).

Dr. Pinion added that compliance to labeling is also another concern in takal oil. If the product has no label, it is difficult to trace the source. Apart from quality assurance, another issue is safety because not all plastic materials or packaging materials can contain the oil. Guidelines on packaging materials upon issuance will be disseminated with regional inspectors to guide them in monitoring.

The FDA will review the annual product monitoring program in coordination with the RFOs. Dr. Pinion said that the proposed use of Quick View Vitamin A Test Kit and iCheck Chroma may be acceptable on the basis of coherence with the prevailing FDA regulations and could be used as a basis in policy direction.

Response from Philippine Coconut Authority (PCA)

As a response from the Philippine Coconut Authority (PCA), Ms. Josephine Nieva (OIC, Food Product Development Division) gave brief information on what the PCA has done with regards to Food Fortification. In compliance with the Food Fortification Law and in support to the NCP and FDA-DOH programs, PCA has conducted surveillance and monitoring activities for Vitamin A fortification in cooking oil, specifically coconut and palm oils, which are the products under the mandate of PCA and identified as one of the staple food products.

The monitoring activities started with the enforcement of the law. These were done initially by the PCA representatives, the Coconut Production and Regulation Officers (CPOs) from the regions. Oil refineries in the regions were visited and Vitamin A determination was conducted using the Quick View test kit.

Based on the results of the monitoring, Vitamin A fortification of cooking oil was to be improving in terms of compliance with the fortification standards set under the law, with an increase of cooking oil samples being fortified from 8% in 2006 to 40% in 2007 and 56% in 2008.

The most recent monitoring activity was in 2013 done in two batches. As mentioned earlier, initially, monitoring was conducted on site in the refineries. In the recent monitoring, cooking oil samples of different brands were collected by the PCA Market Department from the supermarkets in Metro Manila and nearby places, and tested using the Quick View test kit in the PCA laboratory. Results showed that out of the 49 samples that were collected and tested, 42 samples (86%) were fortified with a range of 10-25 ppm and 7 samples were not. Most of these unfortified samples were imported cooking oil and some were declared fortified with Vitamin A.

Another batch was done in Region IV where 21 samples were gathered, also from the supermarkets. Out of the 21 samples, 18 samples (86%) were found to be fortified with Vitamin A and 14% were unfortified.

The monitoring done by the PCA, according to Ms. Nieva, was only for branded cooking oils and a considerable volume of unbranded oil is available and sold in the wet/public markets by the takal system. With this system, she said that to ensure compliance to the requirement of fortification of cooking oil in the supply chain, PCA should also look at those unbranded products and would also conduct monitoring and inspection of warehouses of importers, traders, distributors and repackers particularly of takal oil because problems could arise from these unbranded oil products.

According to her, the two kits presented are very timely in the monitoring activities being done by the PCA, since the analysis fee of using HPLC is very expensive and it was good to know that the two kits have been validated using the standard method with HPLC as the reference method. She added that validation is very important to determine the efficiency of the test kits.

Moreover, in the implementation of the law, the Food Fortification Law, and in support of the DOH programs through FDA, PCA is very willing to be involved and to join in the activities concerning food fortification. Especially it is recommended that imported cooking oils have certification attached that it is fortified and the Vitamin A level included in its label. It is also important to conduct random sampling for Vitamin A determination on all imported cooking oil to ensure that products to be consumed contain the required essential micronutrients.

Another guideline, in addition to the one submitted to Mr. Hector Maglalang which has not been implemented yet is to require the oil refineries/manufacturers with certification for Vitamin A fortification on their application for the renewal of their registration.

Open Forum

The open forum was moderated by Dr. Solon. Some of the participants gave comments and asked questions regarding the studies being presented.

1. Ms Remedios Baclig
Technical Consultant on Food
Oleo Fats, Inc.

Ms. Baclig commented that most of the tests presented are on vitamin A content of oil in the bottle. A question was raised by her if how does a person consume the oil. She said that the person doesn't drink it and it is being consumed by cooking it through different methods like sauteing and frying. She shared some food for thought, if it's being tried to see whether vitamin A is retained in cooking oil after cooking it, because the oil after being cooked would be the end-product and that's how the customers are going to be able to take in the vitamin A. She said that it's not going to be in the bottle of oil with vitamin A.

Another thought being shared by Ms. Baclig was that the final target of the fortification are the poor classes of people, because for those who can afford they will get supplements of vitamin A instead of getting it from oil. And most of the poor classes cannot afford to buy the branded oils so they opt to buy takal oils. She said that the results being presented showed that the takal oils did not contain vitamin A and she was questioning the effect of the proof.

Dr. Solon answered that the stability of vitamin A oil is outside the scope of the forum so there is no data shown today. However, there are already studies that show how a specific overage fortification level at production reduces in time with processing, storage, distribution and finally the cooking. The data is well-established and the fortification program is now beyond the stability phase of the the fortification program since it cannot be started if there's no stability data present. Supporting data will be included in the proceedings to be provided. Note: Please see the response of Dr. Barba and Dr. Saises below.

With the second question raised regarding the takal oils, Dr. Solon said that was really the problem because the masses do not have access due to unavailability of fortified oil. This is what Negros Occidental would like to address. We need to determine why this is happening, and ensure that people who are bringing in unfortified oil and selling it will be compelled to comply. At the end of the day, it's just about the money and the cost of being regulated will become more expensive, compelling industry to follow the law.

Dr. Solon mentioned that part of the NCP agenda is to show that availability data from markets (not just at the manufacturing plant or households) can be utilized by the fortification program. When shown repeatedly that availability is poor, it is hoped that the government will evolve to get their acts together. FDA has shown what they are doing; PCA has shown their willingness but there are also other players like for example

the Bureau of Customs. Dr. Solon said that they want to repeat the availability data frequently enough to show that either something is happening or nothing is happening. Equity (reaching the poorest) is such an issue, and equity cannot be obtained if there is no availability. So availability data is needed to actually make sense of the household coverage data that will be obtained in future studies.

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2. Mr. Mamerto N. Bernardo
AVP Sales & Marketing
CIIF Oil Mills Group (Minola)

Mr. Mamerto Bernardo commented on the study done in Negros Occidental showing that all branded cooking oils is over fortified. He said that they are a bit confused because they know that the stability of vitamin A is decreasing and considering that most of the branded cooking oils are coming from Manila shipped to Negros Occidental, stay on the warehouse for distribution then the level of vitamin A will decrease yet the study showed that oils are over fortified.

He gave emphasis that 90% of the takal oil failed to comply, now knowing that from the presentation that the Baguio Oil, Marca Leon, Minola's consumer pack is probably 10-12% already which means the goal is basically to sustain the level of those that are decreasing. Then it's about time that the FDA together with the Bureau of Customs to police intensively the takal oils.

Unfortunately, only coconut branded players are fortifying and complying with the law. But they who are complying with the law turn out to be the ones being intensively monitored by government agencies. This issue being raised is said to be in conflict with NCP objectives and with the law because large portion in the market are not complying.

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3. Dr. Corazon Barba
Nutrition Consultant
UN World Food Programme

Dr. Barba thanked NCP for giving evidence particularly for the takal oil thinking that this topic has to be addressed considering that other people have said this takal oil has been used by the poorer sector of the community. Dr. Barba reacted on the comment given by the participant from the oil industry and said that it is true that oil is used for cooking, therefore there are changes and cited that there are literature not only in the Philippines but in other countries that looked into the different changes and the different temperature. Dr. Barba added that if the smoking point is high, just like when sauteing, a lot of things will be disintegrated but the retention is still high.

Dr. Barba also shared a study done by the Food and Nutrition Research Institute. This study showed the vitamin A supplementation program in the Philippines wherein the

Department of Health spends a lot and invest to make sure that every child is getting two vitamin A supplements in April and October. However, these studies done at FNRI have shown that serum retinol is not maintained within the six months.

4. Ms. Ella Saises
Senior Science Research Specialist
DOST-FNRI

Ms. Saises mentioned that she was a member of the team that studied oil fortification with support from PCHRD and the San Pablo Manufacturing Corporation. The studies look into the fortification of vitamin A. According to Ms. Saises, San Pablo Manufacturing Corporation is the first to study fortification of vitamin A.

She added that aside from fortifying the oil, they also have a small study on the retention of vitamin A in cooked food. She said that they have experiments on fried fish and that they have already completed the studies on how much vitamin A are retained in cooked fish. They compared it with the controlled set-ups, and it showed that there is substantial amount of vitamin A retained in the fish.

They also conducted the study with other products like fried kamote, fried banana, and other baking products; and the experiments showed that there is substantial retention of vitamin A.

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5. Ms. Yvonne Agustin
Executive Director
United Coconut Association of the Philippines

Ms. Agustin said that they have more problems with the takal oil; thus she suggested that we concentrate more on the monitoring of the takal oil, because we are sure that the producers and the manufacturers are always complying with the requirements of the other oil products. She also added that it seems that the takal oil and the imported oils are the problem, because these are not fortified. She cited an example, and told that for the palm oil, we are working with 500 thousand tons, but we are only using a little of these thousands of tons.

6. Mr. Renato O. Gamboa
Executive Vice President and General Manager
International Oil Factory (Baguio Oil)

Mr. Gamboa mentioned that they're from the industry. He said that the Quick View test kit was actually made after the food fortification law for their branded oils because there

is a requirement that oils should be fortified. So they used it to know whether it is fortified or not. They collaborated with Dr. Aloysius Baes of the USAID-MOST (Micronutrient Operational Strategies and Technologies) Project initially for the development of the test kit. Unfortunately, Dr. Baes passed away without fully developing it. So it was their head Chemist (now 97 years old) who improved and developed it. The aim was to have a cheaper method than the HPLC. They did discover that it is so easy, and it's something that is really cheap. As a matter of fact, the Quick View test kit, admittedly being qualitative is really good for monitoring for government agencies, but the problem is the cost and organization which FDA and PCA have mentioned.

But at least on their part, as far as monitoring is concerned, the cost of the Quick View, even the Chroma can be lowered down depending on the use of economies of scale. A Chroma would cost 500 per test, versus 2,400 for the HPLC. For the Quick View, you can even have ¼ of the 50% of the Chroma cost, or even 25% of the Chroma cost depending on distribution and economies of scale.

He said that the purpose of letting you know all these, is to show that it is really available for qualitative tests, and it can help monitor. He said that the we (oil manufacturers) are all being monitored for compliance and for takal oil there's none. So, when you have this kind of cheap kit, you can go down to the basic rules of it by going to the plants. As what Mr. Maglalang said, the monitoring agencies can go through FDA with their annual reports, and they can inspect the plants if they are fortified or not with this kind of kit. For the takal oil, you can also go to the retail and from there you can source. For an example, importation, importations are not cleared unless you have an LTO. Why not make it a point to make to test whether those importations are fortified or not, before they are given to the customs for release. There are so many ways, but we have to put our acts together. This forum allowed for the presentation of different ways of monitoring at lowest possible costs.

7. Mr. Nestor M. Latay
National Sales & Distribution Manager
Limketkai Manufacturing Corporation (Marca Leon)

Mr. Latay said it will be hard for our government agencies to control takal oils. The first reason is that they don't issue receipts to the retailers; some of them use the papers of cigarettes (palara) for receipts, so how can we chase after these retailers if we don't have proof? For those who are compliant, like the oil companies, they issue a sales invoice and pay VAT. Those who are in the (public) market, they don't really care. Unless you're competitors (other oil companies), they don't pay VAT.

Only 15% of the market composed of the branded players are competing for compliance; and the remaining 85% are those who are not compliant, and who don't compete are enjoying the market fare. One time, he had a discussion with the DTI,

because they want to make prices low. But he personally raised the question of how we can police these takal suppliers? First, they are paying VAT, while the takal suppliers are not. That is already 25% advantage. Second, they maintain their product's quality standards; as compared to these takal supplies whose products have moisture, because of the process, they combine water and oil. And just by looking at that, he admitted that he already lost a lot by the takal suppliers' cheap costing. He added that these are the reasons why they can only find their bottles in the public market; but these bottles do not contain their products, but those of the takal suppliers and other businessmen.

Closing Remarks

Ms. Vega reiterated her appreciation for the initiative of NCP in conducting the studies being presented and knowing that these studies have no funding. The studies presented addresses the concerns being expressed. Positive responses were heard from FDA, that things needed to be done are completed and that they are ready to do business.

Ms Vega noted that we are more hopeful that we will get better in monitoring and regulation and it will not just be on cooking oil, but also on items covered by the mandatory fortification as well as salt iodization. By breaking down issues and problems, we are able to sustain whatever has been achieved and food fortification would be a good sustaining strategy.

The response from industry and their concerns were noted and will not be forgotten. The problem of compliant companies being sanctioned although they are compliant with the law and non-compliant companies are not sanctioned. This issue will fall on regulation. We hope to see licenses not being issued, registrations not being approved as evidence for being suspended if tests are being done in the market and if results show that fortification is not done, otherwise the law would have no meaning. Aside from regulation is promotion which the government needs to do, like promoting fortified foods and a lot of things have to be done along that line. These thing have been done in the past years, we just need to revisit and put our acts together.

Ms. Vega is grateful for everyone for not giving up and for continuing to find better ways to do things. She mentioned the continuing work being done by the FDA and PCA. She recognizes the changes in the industry now that there is coconut and palm oil and these things would be considered in regulation. She relayed the continuing commitment of NNC to work and consider the concerns of different stakeholders so they will be able to put their acts together and assume that everyone is with them in this endeavor.

Annexes

Annex 1. List of Resource Persons and NCP Secretariat

Name	Agency/Institution	Designation
Juan Antonio A. Solon, MD	Nutrition Center of the Philippines	President
Mary Christine R. Castro, MD	Nutrition Center of the Philippines	Executive Director
Maria Lourdes A. Vega	National Nutrition Council	Chief, Nutrition Policy and Planning Division
Cherry C. Maramag, RND, MSc.	Children International	Monitoring, Evaluation and Learning Coordinator
Hector C. Maglalang		Food Fortification Consultant
Dr. Maria Victoria D. Pinion	Food and Drug Administration	OIC, Product Research and Standards Division
Josephine T. Nieva	Philippine Coconut Authority	OIC, Food Product Development Division
Nikki Fatima A. Caisip	Nutrition Center of the Philippines	Research and Programs Unit Assistant
Rose Ann I. Marquez	Nutrition Center of the Philippines	Administrative Assistant
Gereck J. Asendido	Nutrition Center of the Philippines	System Administrator

Annex 2. List of Participants

Government Agencies

Name	Agency/Institution	Designation
Maria Lourdes A. Vega	National Nutrition Council	Chief, Nutrition Policy and Planning Division
Julze Alejandre	National Nutrition Council	Nutrition Officer
Edzell Arcinue	National Nutrition Council	Nutrition Officer
Luz B. Tagunicar, RND, MPH	DOH – Family Health Office	Supervising Health Program Officer
Enrique A. Tayag, MD	DOH - BLHSD	Director IV
Luz Brenda P. Balibrea	Philippine Coconut Authority	Chief, Trade Information & Relations Division
Josephine T. Nieva	Philippine Coconut Authority	OIC, Food Product Development Division
Aileen A. Belen	Philippine Coconut Authority	Technical Staff, Research and Development Bureau
Rina Angeles	Philippine Coconut Authority	Trade Industry Development Specialist II
Rosemarie Dumag	DOST-FNRI	Supervising Science Research Specialist
Ella Saises	DOST-FNRI	Senior Science Research Specialist
Cecilia S. Acuin	DOST-FNRI	CSRS
Marina Vargas	DOST-FNRI	Senior SRS
Dr. Maria Victoria D. Pinion	FDA-CFRR	OIC, Product Research and Standards Division

 Oil Industry

Name	Agency/Institution	Designation
Mamerto N. Bernardo	CIIF Oil Mills Group (Minola)	AVP Sales and Marketing
Renato O. Gamboa	International Oil Factory (Baguio Oil)	Executive Vice President and General Manager
Emelita Magsino	International Oil Factory (Baguio Oil)	
Nestor M. Latay	Limketkai Manufacturing Corporation (Marca Leon)	National Sales and Distribution Manager
Charmaine Almonte	Limketkai Manufacturing Corporation (Marca Leon)	QA Supervisor
Jeremiah Jhocson	Nutri-Asia Group (Golden Fiesta)	Brand Manager, Cooking Oils
Naomi J. Lambus	Magnolia, Inc (Magnolia Nutri-Oil)	Product Development Head
Ma. Josefina L. Pascasio	Magnolia, Inc (Magnolia Nutri-Oil)	Product Development Specialist
Remedios Baclig	Oleo Fats, Inc.	Technical Consultant on Food
Marijoy B. Balancio	Agana Circle Enterprises, Inc.	QA/R&D Head
Leila C. Frades	Malabon Soap and Oil Industrial Co., Inc	QA
Antonio Agus		

 Other Agencies

Name	Agency/Institution	Designation
Dr. Corazon Barba	UN World Food Programme	Nutrition Consultant
Yvonne T. V. Agustin	United Coconut Association of the Philippines	Executive Director
Vermelyn Ortiz-Evangelista	Philippine Coconut Research and Development Foundation	Technical Supervisor
Marie Geraldine N. Liboro	CODHEND-University of the East	Chair, Nutrition and Dietetics Department
Ma. Lindsay J. Alvarez	CODHEND-Centro Escolar University	Faculty Member, Nutrition and Dietetics Department
Ma. Socorro Ignacio	UP-CPH/PAN	Associate Professor
Richard Dandan	DSM Nutritional Products Philippines, Inc.	Manager, Human Nutrition and Health
Candie Gagpanan	DSM Nutritional Products Philippines, Inc.	Account Manager
Lie Chico	BASF Philippines, Inc.	Head, Corporate Affairs
Dr. Patrick Talavera	BASF Philippines, Inc.	Senior Manager, Nutrition and Health Business Unit
Candice Lazo Bautista	BASF Philippines, Inc.	Business Manager, Human Nutrition
Felix Co	Vitachem Industries	President and General Manager
James Acuna	Connell Bros. Company Pilipinas, Inc.	Sales Executive
Polly Anna Caragan	Connell Bros. Company Pilipinas, Inc.	Sales Manager
Marichu L. Chan	TFE Sales Marketing Corp.	Sales Manager, Pharmaceutical Division
Henzel Lizardo	TFE Sales Marketing Corp.	
Christine Ymata	GreenPower Industries Co.	

Annex 3. Program

- 1:00 - 1:30 PM Registration
- 1:30 - 1:35 PM Welcoming Remarks
Juan Antonio A. Solon, MD PhD
President, Nutrition Center of the Philippines
- 1:35 - 1:40 PM Introduction of Participants
- 1:40 - 1:55 PM Policy Review on Vitamin A Fortification
Maria Lourdes A. Vega
Chief, Nutrition Policy and Planning Division
National Nutrition Council
- 1:55 - 2:15 PM NCP Oil Fortification Studies: iCheck validation Study
Juan Antonio A. Solon, MD PhD
- 2:15 - 2:35 PM Quick View Validation Study
Cherry C. Maramag, RND, MSc.
Project Leader, NCP Oil Fortification Studies
- 2:35 - 2:55 PM LQAS of Vitamin A in Negros Occidental
Mary Christine R. Castro, MD
Executive Director, Nutrition Center of the Philippines
- 2:55 - 3:15 PM Proposed Monitoring System for the Use of iCheck Chroma and Quick View Vitamin A Test Kit
Hector C. Maglalang
Food Fortification Consultant
- 3:15 - 3:20 PM Response from Food and Drug Administration
Dr. Maria Victoria D. Pinion
OIC, Product Research and Standards Division
Center for Food Regulation and Research
- 3:20 - 3:25 PM Response from Philippine Coconut Authority
Ramon L. Rivera
OIC - Deputy Administrator, Research & Development Bureau
Given by Ms. Josephine Nieva (OIC, Food Product Development Division)
- 3:25 - 3:40 PM Open Forum
Moderator: Juan Antonio A. Solon, MD PhD
President, Nutrition Center of the Philippines
- 3:40 - 3:45 PM Synthesis
Juan Antonio A. Solon, MD PhD
President, Nutrition Center of the Philippines
- 3:45 - 4:00 PM Closing Remarks
Maria Lourdes A. Vega
Chief, Nutrition Policy and Planning Division
National Nutrition Council
- 4:00 - 5:00 PM PM Snack

Mary Christine R. Castro, MD
Master of Ceremonies

Annex 4. Proposed Monitoring System for the Use of iCheck Chroma and Quick View Vitamin A Test Kit by H. Maglalang

Proposed Monitoring System for the Use of iCheck Chroma and Quickview Vitamin A Test Kit

By
Hector C. Maglalang
Food Fortification Consultant
Presented during the
Research Forum on Vitamin A Fortification of Cooking Oil
3 May 2016
Astoria Plaza Hotel, Ortigas Center, Pasig City

Objectives

- To provide evidence-based recommendations on possible monitoring and evaluation of vitamin A fortification of cooking oil as provided in RA 8976 with the objective of controlling Vitamin A deficiency thru the use of the diagnostic tools presented during this forum
- Provide possible monitoring procedures with the use of the diagnostic tools for food control (internal, external, market surveillance) and program monitoring and evaluation (household consumption and promotions)

Framework for Monitoring and Evaluating Food Fortification Programs (WHO, 2006)



Types of Indicators for FF Monitoring and Evaluation

- 1. Process indicators are associated with the performance of inputs, activities, and outputs—for example, proof of commitment to carry out the programs (DOH and other agencies), provision of products and services, and their coverage (or market penetration in business terms)—product quality (internal and external monitoring) and accessibility of it by the target population (commercial/market monitoring), and materials and actions aimed to raise awareness, educate, or transfer information (social marketing and promotions).**
- 2. Effectiveness indicators measure the diffusion and quality of outcomes in the target population, such as changes in behavior, consumption of foods and additional intake of micronutrients, and biochemical, physiological, and functional parameters (Nutrition Surveys).**

Internal QA System for Oil Fortification

- With Certificate of Analysis for every delivery of Vitamin A fortificant (1 million IU/gm or 1.7 million IU/gm) for Producers and product CA for importers
- Proper handling and storage of fortificant (cool dry place)
- Equipment used is appropriate, mixing time observed
- Routine conduct of fortification analysis thru in – house (iCheck Chroma or QuickView test kit usually every batch or tank) and external (HPLC or iChrome once or twice a year per type of oil)
- Equipment calibration (RPM)
- Recall system
- Recording and Documentation

Basis for External Monitoring

Draft Guidelines developed with FDA 2009 – 2010
BUREAU CIRCULAR NO. _____

TO : ALL CENTERS FOR HEALTH DEVELOPMENT
DIRECTORS AND SECRETARY OF HEALTH – ARMM

ATTENTION : FOOD AND DRUG REGULATORY OFFICERS

SUBJECT : GUIDELINES FOR LICENSING AND CONDUCT OF
PLANT INSPECTION AND BAKERY/MARKET SURVEILLANCE OF
LOCALLY PRODUCED WHEAT FLOUR AND COOKING OIL FOR
COMPLIANCE TO REPUBLIC ACT NO. 8976

Basis for External Monitoring

Draft Guidelines for PCA based on the FDA Guidelines 2008 – 2010

MEMORANDUM NO. _____

TO : ALL REGIONAL MANAGERS

ATTENTION : COCONUT PRODUCTION AND REGULATION OFFICERS (CPRO)

SUBJECT : GUIDELINES FOR THE CONDUCT OF MONITORING OF COOKING OIL REFINERS, IMPORTERS, REPACKERS AND DISTRIBUTORS OF COOKING OIL FOR COMPLIANCE TO REPUBLIC ACT NO. 8976.

External Monitoring (FDA/PCA – Plant/Warehouse)

- For renewal of license during plant/warehouse inspection
- Determine fortification level based on records
- Conduct sampling from at least 2 brands of oil
- For each brand collect 100 ml from each of 5 packs of the same brand of oil picked at random. Test each pack using vitamin A test kit. If samples are negative give show cause order. If possible test all brands using the test kit.
- If samples are positive or negative, mix the samples, label and send to FDA for laboratory testing.
- If samples are below standard, inform company to adjust fortification levels and conduct follow-up inspection 1 month from release of results. If 2nd inspection shows adjustment of the company to the proper fortification level then its LTO is renewed.

External Monitoring (FDA/PCA – Plant/Warehouse)

- If the results are negative, the company will be issued a report of violation and the company is required to submit action plan to address the deficiency.
- If during 2nd inspection using the procedure same as above and the company implements plan and passes the testing requirements, an LTO will be renewed.
- In case, during the 2nd inspection FDA still notes deficiencies, the company will be given another chance to address the problems.
- In case after the 3rd inspection, deficiencies still exists without justifiable cause, the FDA will issue a denial of LTO application and will issue a cease and desist order to the company. The CDO will be lifted only after the company passes another round of FDA inspections.

External Monitoring (FDA/PCA/LGU – Market Monitoring)

- For market monitoring, FDA and PCA will collect samples from repackers, distributors and retailers.
- FDA and PCA to devise sampling plan per region based on the company marketing and distribution plan from the plant inspection.
- For the sampling plan, FDA and PCA should be able to collect market samples for each brand of the company
- Samples collected can be tested at the site using the test kit.
- If samples are above or below the required fortification level, FDA and PCA will inform the company for corrective action.
- If samples are negative, FDA will issue a report of violation and conduct plant inspection as reported earlier.

Program Monitoring (Household Consumption)

- DOST-FNRI conducts National Nutrition Surveys every 5 years
- The surveys include food consumption surveys to include determining nutrient intake including vitamin A.
- Testing of oil used in the household can be done using various testing methods presented to determine oil intake as well as vitamin A intake due to fortified oil.
- In addition, the test kit can be used for program promotion by oil companies, fortificant suppliers, government and LGUs among others

Conclusions and Recommendations

- The vitamin A test kits presented in this forum was shown to have various uses as part of the monitoring and evaluation of vitamin A fortification of cooking oil as follows:
 - Internal monitoring and QC by companies and importers
 - External monitoring by regulating agencies by FDA, PCA and LGUs and other agencies
 - Program monitoring as part of food consumption surveys
 - Program promotion by oil companies, fortificant suppliers, government and LGUs among others

Annex 5. Selected References

This annex contains selected references relevant to :

- 1) Stability of Vitamin A in oil [1,2];
 - 2) Efficacy and Effectiveness of Vitamin A in oil and margarine [3–7];
 - 3) Diagnostics [8–10];
 - 4) Program Effectiveness [11–13];
 - 5) Oil Quality [14–16];
 - 6) Good Practices in Regulatory Monitoring [16];
 - 7) Lot Quality Assurance Sampling [17–19]
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