

## **Monitoring of Flour Fortification: The Case of Indonesia**



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### **Abbreviations**

APTINDO	Indonesian Millers Association
BBIA	Center for Agro-Based Industry
Bea Cukai	Customs Office, Ministry of Finance
BPOM	National Agency for Drug and Food Control
Bupati	Regent or Mayor
CAB	Conformity Assessment Board
DHS	Demographic Health Survey
FAO FBS	United Nations Food and Agriculture Organization – Food Balance Sheet
NaFeEDTA	Sodium Iron Ethylenediaminetetraacetic Acid
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization of Standards
KAN	National Accreditation Committee
MOH	Ministry of Health
MOT	Ministry of Trade
MOI	Ministry of Industry
NTD	Neural Tube Defect
SME	Small and Medium Enterprise
SNI	Indonesian National Standards
WHO	World Health Organization

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### **I. Background**

Based on evidence of widespread micronutrient deficiencies and recognition of the increasing consumption of wheat flour products, in 1998 the Indonesian Ministry of Health issued a decree calling for the fortification of all wheat flour milled or imported into Indonesia. In 2001, a Decree of the Ministry of Industry and Trade on the *Compulsory Application of Indonesian National Standard (SNI) to Wheat Flour as Food Stuffs* laid the legal and regulatory foundation for national mandatory flour fortification. The SNI, updated in 2009,

<b>Table 1: Fortification Specifications</b>	
<b>Indonesian National Standard (SNI) 3751 2009</b>	
<b>Micronutrient</b>	<b>Added Quantity (mg/kg)</b>
Vitamin B1 (thiamin)	2.5
Vitamin B2 (riboflavin)	4
Vitamin B9 (folic acid)	2
Iron	50
Zinc	30

defines 16 required product quality parameters for wheat flour including 5 provisions mandating fortification with minimum levels of thiamin, riboflavin, folic acid, iron and zinc. The selection of micronutrients and required additional levels in the SNI (Table 1) emerged from an extensive consultative process including global and national experts representing government and private sector as well as international technical and development agencies.<sup>1</sup>

Key industry and government components for a successful flour fortification program in Indonesia are largely in place. The flour milling industry is comprised of large modern mills with the capacity to integrate fortification technology efficiently and effectively. Government agencies responsible for external monitoring are considered to have sufficient professional expertise, technical capacity and financial resources. The sections that follow, review Indonesia's internal and external monitoring processes to explore whether there is sufficient verification that the flour fortification program is operating as designed and optimized for public health impact.

### **II. Premix monitoring**

Indonesia does not produce its own vitamin and mineral premix. All premix is imported and monitoring of premix thus happens at import level (section IV).

### **III. Internal monitoring at production level**

Since 1971 when Indonesia's first flour mill was established, wheat flour consumption has increased more than 10-fold to more than 5.3 million metric tons annually.<sup>2</sup> Over the past 5 years alone, national wheat flour consumption rose more than 50%.<sup>3</sup> To satisfy increasing national demand, the domestic milling industry expanded to more than 20 mills with capacity of producing more than 20 MT wheat flour/day with another 4 being planned (as of March, 2013). All of Indonesia's mills are large, sophisticated operations which apply extensive internal quality controls throughout the milling process, including the fortification component. Reports by millers indicate a high level of systematic internal monitoring, stringent record keeping and other best practices include:

- Checking vitamin and mineral premix for formulation, quantity, packaging, Best Before Date and Certificate of Analysis;

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- Monitoring premix movement and stock levels;
- Calibration of dosing machine (microfeeder) to check premix addition rate;
- Testing the finished product using the iron spot test;
- Conducting and documenting quality processes;
- Sending finished product samples for third party verification.

Equally important, milling companies participate along with government agencies in the development of fortification related policies and are committed to and supportive of the mandatory national fortification program.

The regulatory documents reviewed did not identify any specific national requirements for internal monitoring at the mill. With no explicit legal requirements for internal quality assurance processes and related documentation, this function is left to individual private mills' internal policies, which are not routinely made public. A generally recognized best practice is for regulatory bodies to conduct a quality audit of processing operations.<sup>4</sup> However, with no required national norms as benchmarks against which to monitor internal fortification processes for compliance, regulators cannot perform an over-all quality audit and can only take a "snapshot" of quality by flour samples taken for laboratory analysis. While periodic sampling and analysis may be sufficient for enforcement, it does not achieve the key objective of having an independent external verification of fortification quality processes. Nevertheless, given millers' level of commitment to the fortification program and sophisticated operations, there is little reason to doubt that these internal systems work well to produce high quality fortified flour.

## **IV. External monitoring at production and retail level**

The two primary entities tasked with external monitoring of the domestic food industry are the Ministry of Industry (MOI) and The National Agency for Drug and Food Control (BPOM). Control of vitamin and mineral premix and flour imports is conducted by Customs, under the Ministry of Finance (Bea Cukai), with support of BPOM. Under Indonesia's decentralized government structure, control of small and medium enterprises (SMEs) is at the discretion of local district government.

### **The Ministry of Industry (MOI)**

MOI is authorized to inspect mills for compliance with SNI through its administration of business license awards, which are renewed annually. To award or renew business licenses, MOI inspects food producers for compliance with a range of national regulations and standards, including fortification. MOI has a wide network of competent inspectors and houses the Center for Agro-Based Industry (BBIA) backed up with a network of 9 provincial laboratories and a central laboratory in Jakarta. These technical facilities are accredited by the National Accreditation Committee of Indonesia (KAN) and registered with the International Laboratory Accreditation Cooperation (ILAC) for the appropriate International Organization of Standards (ISO) benchmarks.

In practice, this business license review is carried out by designated third party Conformity Assessment Board (CAB), who work in conjunction with the KAN accredited laboratories. While a full audit covering

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all business and product requirements is conducted only every four years, the CABs conduct annual checks of compliance with the fortification SNI by taking a product sample for analysis. There are no sampling protocols, but generally a dozen bags are sampled from a packing line. The samples are then thoroughly mixed together and divided into three sub samples: one to be analyzed by the government laboratory, one for the miller and one retained on file in case of a dispute. However, these inspections are neither unannounced nor random. In fact, to conduct the required inspections it is a common practice for these third party inspectors to make appointments with millers - and the mill often provides inspectors with samples.

MOI is primarily mandated to promote industry investment and build industry capacity and perceives functions as a watchdog or inspection agency as secondary. Therefore, MOI conducts external monitoring as a collaborative and capacity building activity implemented in partnership with industry rather than as a more independent inspection and enforcement function. As a consequence, MOI is not, strictly speaking, conducting independent external monitoring.

### National Agency for Drug and Food Control (BPOM)

BPOM is an autonomous agency reporting directly to the President. In contrast to the MOI, BPOM is a pure enforcement agency. BPOM is mandated to register all commercial products sold in Indonesia and to inspect and enforce their compliance with national standards. Currently they monitor approximately 33,000 different registered products, which are checked by about 2,000 district inspectors, including 253 specialized in food safety and quality. Product analysis is via BPOM's central laboratory along with an accredited network of 31 provincial laboratories.

As is the case with most other registered food products, the primary focus for BPOM monitoring of flour fortification is at the retail or market level where flour is typically sold in 1-5 kg consumer packs. BPOM takes this responsibility seriously and designs an annual plan and budget for commercial monitoring of fortified flour. The agency developed a plan for *Intensified Control over National Fortification* (2014-2016) which includes improving competence of 70 food inspectors per year and taking as many as 3,100 samples of iodized salt and fortified wheat flour annually. However, this focus on the retail level does not reflect the realities of the flour market in Indonesia. Retail trade in flour represents about 65% of national flour consumption: about 10% are sold in 1-5 kilogram packs, and about 55% are sold in 25 kg bags mostly to small scale bakeries, and other food processing industries etc. Approximately 35% of the national flour supply is shipped in bulk tankers to large commercial food processing plants. As a result, one third of Indonesia's flour supply is not sold at the retail level and is consequently beyond the scope of BPOM's current inspection approach. Moreover, monitoring flour packs at the large number of retail stores across Indonesia's 34 provinces is a major task requiring a large number of samples and a high level of effort for inspection, administration and laboratory analysis. A more strategic focus at the mill would require fewer points of inspection at only 20-25 facilities, involve only the handful of provinces where major mills are located, and would cover a wider and more representative segment of national flour consumption.

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### **MOI and BPOM Approach to Laboratory Analysis**

Establishing compliance with any SNI in Indonesia requires full analysis of every quality parameter in the SNI. This means verifying conformity of fortified flour requires analysis of all 16 parameters included in the SNI, including separate analyses for each of the five required micronutrients. This comprehensive approach, requiring a separate analysis for each micronutrient burdens laboratory capacity and strains limited resources. More important, it is widely recognized that analytical error in finished product micronutrient analysis is high, particularly for vitamins added at very low levels, 2-4 mg/kg, like folic acid, thiamin and riboflavin. Testing for one or two micronutrients added at higher levels, as markers for adequacy, could lower the over-all analytical burden as well as provide adequate data on fortification quality.

Limited laboratory records made available by MOI and BPOM indicate failure for at least one of the five required vitamins and minerals may be as high as 20%. However, these records do not clarify whether these failures are likely due to substandard premix, industry non-compliance, variability in the laboratory analysis or some other parameter. Nevertheless, once made aware of these high failure rates, industry responded by increasing the premix dosage, in some cases to 180% of the indicated rate. Given this concern with compliance and positive reaction to external monitoring data, deliberate under-dosing at the mill seems unlikely.

In general, MOI and BPOM's external monitoring strategy appears to be very reliant on taking samples for laboratory analysis, with its considerable expense as well as unavoidably high variability and margin of error. A generally regarded best practice is for sampling and laboratory analysis to be used as a second line of inspection, as back-up or verification for a quality audit of over-all fortification quality processes.<sup>5</sup> A quality audit is a check made by inspectors to confirm that agreed upon requirements for the fortification process along with supporting documentation are in place; i.e. frequency of checks on the microfeeder, rapid test results, external verification of micronutrient levels, evidence that internal audits are conducted, action taken if problems are discovered. However, enabling an external quality audit by public agencies means mandating compulsory requirements for mill quality processes and associated documentation as benchmarks against which regulators can measure performance or compliance.

### **Local Governments: Monitoring foods made with flour**

More than half of flour utilization in Indonesia is by thousands of small and medium enterprises (SMEs) involved in producing and selling fresh noodles, baked goods and other ready to eat foods. Within Indonesia's decentralized governing structure, Regulation No 28/ 1994 delegates authority for inspection and monitoring of SMEs to district government (Regent/Mayor or Bupati) to inspect and, if necessary, close down businesses that do not comply with foods safety, quality and business requirements. However, in practice, district governments have little awareness of the importance of food fortification and limited capacity for inspection and analysis of fortified products – and many

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competing priorities. Given the large scale, centralized organization of the flour market, monitoring at the point of milling or import may be a more cost-efficient and effective option to control a much higher supply of fortified flour in the country.

### **V. Import monitoring: Vitamin & mineral premix and flour**

The Customs Office within the Ministry of Finance (Bea Cukai) is authorized to perform import monitoring of both vitamin & mineral premix as well as imported flour, usually coordinated with BPOM.

#### **Premix**

All vitamin & mineral premix used in the flour fortification program is imported – there is no local production. Bea Cukai conducts paper verification of all premix shipments via a required Certificate of Analysis and BPOM is authorized to take random samples for chemical analysis. There is potential for MOI to support the control of imported premix as carried out by Bea Cukai and BPOM, since MOI is authorized to take premix samples from mill inventory and send them to one of BBIA's laboratories for analysis as part of its external monitoring functions. However there is little evidence of laboratory analysis being carried out on premix on a comprehensive and consistent basis by either BPOM at the port of entry or MOI during mill inspections. Therefore, it appears that premix monitoring by public agencies relies totally on Certificate of Analysis and related paperwork. Nevertheless, while there is no legal or regulatory restriction on premix suppliers, Indonesia's mills are known to purchase fortificant from reputable global suppliers, suggesting high and consistent premix quality. In addition, individual mills support government external control with their own internal quality systems and periodically send premix samples to third party laboratories for verification.

#### **Flour**

BPOM and Bea Cukai have significant capacity at major ports throughout Indonesia to control compliance of imported flour with the SNI. However, even in large ports where there is strong presence of BPOM and Bea Cukai, testing of flour imports is not routine, systematic or comprehensive. Competition between domestic mills and imported flour is intense and during some periods of time, imports have gained as much as 18% market share.<sup>3</sup> Since then, a range of government policies including legal action against importers for “dumping” flour onto the Indonesian market, have resulted in a decline of imports to a 4% share of the national market. Nevertheless, the competition and concern with imports continue and this remains a fluid environment. Moreover, the existence of many small ports scattered among Indonesia's many islands suggests that control of flour imports may be a weak link in the regulatory infrastructure. While premix usually arrives at the large national ports, the dispersed smaller ports with no regulatory presence or capacity offer limitless opportunities for smuggling unfortified flour – a point often raised by domestic millers.<sup>6</sup> While large food processors are supplied with fortified flour by large domestic mills, it is possible that illegally imported flour supplies reach some of Indonesia's food processing SMEs, representing a significant share of over-all national flour consumption.

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This situation may have been exacerbated by a Ministerial Decree<sup>7</sup> of 2011 aiming to clarify some technical aspects of the SNI, which may have inadvertently created a loophole for imported non-fortified flour destined for non-food industries to leak into the local market for human consumption. Previous to 2011, trade in non-fortified flour was strictly controlled requiring special exemption requested by the producer on a case-by-case basis. However, the Decree of 2011 created a separate category for non-food use flour that need not conform to the SNI. This decree provided no guidance on how to distinguish between food use and non-food use flour and did not require any specific procedures for exemption. Milling executives believe imports of flour claiming non-food use are higher than is warranted by local market conditions – and both Ministry of Trade and Ministry of Industry are concerned about imported non-fortified flour entering the food chain.<sup>6</sup> Although the trend in imports has declined since 2011, as the current portfolio of protective trade policies expires in the coming year, imports of flour not intended for food use should be carefully monitored.

### **VI. Household monitoring and impact evaluation**

In Indonesia, there is no ongoing household monitoring or official household survey defining levels of individual flour consumption. However, a number of sub-regional and national consumption surveys, as well as supply-side analysis based on industry data, roughly suggest daily flour intakes average 70-80 grams among regular consumers.

Similarly, there is no documentation of program benefits via biological survey which presents a potential threat to the sustainability of the program. Ultimately, sustainability will be founded on clear evidence of impact on public health, including reduction in prevalence of iron-deficiency anemia and iron deficiency and incidence of neural tube defects (NTDs).

### **VII. Summary and discussion**

There is widespread agreement among stakeholders that Indonesian millers have largely complied with the fortification requirements of the SNI and that for more than a decade Indonesian consumers have benefited from the added micronutrients supplied by noodles, bread and other products made with fortified wheat flour.

Despite the adequate capacity of both flour mills and government regulatory agencies, there are some opportunities to increase the level of confidence in the operation and quality of the flour fortification program:

- Most inspection activities occur at the retail level. A more effective use of resources would include a greater focus on control at the mill, the point of import and large commercial food processors. These more centralized points of control can be inspected more cost-effectively, capture a larger and more representative proportion of flour production and consumption, and minimize the often difficult and time consuming task of tracing the flour to its source for enforcement and corrective action.

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- Most mill inspections are neither random nor unannounced but made by appointment. While there is no evidence that this hampers the process, it casts doubt on the independence and objectivity of the external monitoring and veracity of the results. To improve confidence, these activities should be random, unannounced and in general work to be independent, objective and non-biased.
- A quality audit at the mill, using sampling and analysis as verification is generally considered a best practice for external monitoring.<sup>5</sup> Enabling quality audits of the fortification system will require government and industry to agree on establishing national milling norms that can be checked by external inspectors.
- The results of monitoring activities by both MOI and BPOM are not in the public domain, are not routinely reported back to industry, and appear not to be shared between the two entities and other fortification stakeholders. A broader sharing of information would result in resource efficiencies and tighter food control. With multiple stakeholders reviewing the information, the database could be analyzed from a range of perspectives and yield important program quality information.
- The greatest hypothetical weakness in the capacity of BPOM and MOI to monitor flour fortification is the potential flow or leakage of non-fortified imported flour – either illegally imported or officially destined for non-food industries. Systems to strengthen import monitoring to reduce potential for smuggling imported flour and close loopholes to prevent leakage of non-fortified flour from industry should be explored.
- Without updating the SNI in conformance with the fortification levels and compounds and levels recommended by WHO, there is reason to believe that even if the program is being implemented properly, public health impact may not be optimal.
- While mandatory flour fortification *implies* that all food processors are required to use only fortified flour, standards for flour products such as bread, pasta, biscuits, and fresh or instant noodles do not specifically require fortified flour in the recipe or reflect the use of fortified flour in their individual product standards. While this does not represent a major threat to compliance among Indonesia's large and sophisticated processors, this opens the door to the many smaller and largely uninspected home industries producing fresh noodles and other flour products to utilize non-fortified flour officially destined for non-food industries. A requirement to use only fortified flour provides a technically simple and efficient way for district level food control personnel to inspect SMEs for compliance with fortification - namely checking flour labels during inspections of the SME. While there are steep challenges to local enforcement, a reform of the different product-specific SNIs to specify use of fortified flour as an ingredient could be considered.

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There is every indication that the national program is delivering high quality fortified flour to Indonesian consumers and that this will provide some level of population benefit. However, the lack of documentation of program benefits via biological survey presents a potential threat to the sustainability of the program. Ultimately, sustainability will be founded on clear evidence of impact on public health, including reduction in prevalence of iron-deficiency anemia and iron deficiency and incidence of neural tube defects. In February 2008, in response to lobbying by flour importers claiming that fortification represents a barrier to trade and that limiting flour imports was driving up the over-all domestic price of flour products, MOI revoked the mandatory SNI. Intensive advocacy by the flour industry along with prominent national nutritionists succeeded in reversing this decision and the SNI was reinstated 6 months later – along with calls for better monitoring data and demonstrations of impact. The incident highlighted continuing opposition to mandatory fortification by powerful constituencies as well as the diminishing awareness, understanding and support of fortification among key government stakeholders. As a result of strong and timely advocacy, the 2008 threat was averted. But these challenges to fortification will emerge again. Without clear documentation of public health benefits, it may be increasingly difficult for supporters of fortification to mount a strong response.

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### Annex 1. SNI Technical Specifications

The fortification profile applied in the SNI was developed in 1998 with close collaboration of international experts and reflected the best food science and nutrition knowledge at that time. Science and program experience continues to develop, and in 2009, based on a review of the most recent nutrition and food science, the World Health Organization (WHO) published recommendations for wheat flour fortification defining compounds and addition levels for 5 micronutrients based on average daily individual flour consumption, ranging from less than 75 grams per day to over 300 grams per day.<sup>8</sup> In Indonesia, there is no ongoing household monitoring or official household survey defining levels of individual flour consumption. However, a number of sub-regional and national consumption surveys, as well as supply-side analysis based on industry data, roughly suggest daily flour intakes average 70-80 grams among regular consumers, straddling the two lower consumption categories used in the WHO guidelines.<sup>3</sup> A reform of the SNI is currently being discussed which might increase levels of fortification in-line with WHO recommendations.

Table: Comparing Compounds and Addition Levels Specified in WHO Recommendations versus Wheat Flour SNI				
	Compound	Addition Level (mg/kg)		
		<75 g/day	75-149 g/day	Current SNI
Iron	NaFeEDTA	40	40	50 not specified
	Ferrous Sulfate	60	60	
	Ferrous Fumarate	60	60	
	Electrolytic Iron	Not recommended		
Folic Acid		5	2.6	2
Zinc	Zinc Oxide	95	55	30
Vitamin B12		0.04	0.02	0

While mandatory flour fortification *implies* that all food processors are required to use only fortified flour, standards for flour products such as bread, pasta, biscuits, and fresh or instant noodles do not specifically require fortified flour in the recipe or reflect the use of fortified flour in their individual product standards. While this does not represent a major threat to compliance among Indonesia's large and sophisticated processors, this opens the door to the many smaller and largely uninspected home industries producing fresh noodles and other flour products to utilize non-fortified flour officially destined for non-food industries. A requirement to use only fortified flour provides a technically simple and efficient way for district level food control personnel to inspect SMEs for compliance with fortification - namely checking flour labels during inspections of the SME. While there are steep challenges to local enforcement, a reform of the different product-specific SNIs to specify use of fortified flour as an ingredient should be considered.