Monitoring of Flour Fortification: The Case of South Africa

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Food Fortification Initiative
Enhancing Grains for Healthier Lives

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Abbreviations

BDSS	Birth Defects Surveillance System
CANSA	Cancer Association of South Africa
DBSA	Development Bank of Southern Africa
DFID	UK Department for International Development
DTI	Department of Trade and Industry (South Africa)
EHP's	Environmental Health Practitioners
FALS	Food Analysis Laboratory Services (Department of Health)
FAO	United Nations Food and Agriculture Organisation
FFFI	Flour Fortification Initiative
GAIN	Global Alliance for Improved Nutrition
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
HSRC	Human Sciences Research Council
INP	Integrated Nutrition Programme
INS	Integrated Nutrition Strategy
IU/g	International units per gram (3.33 IU = 1 µg Retinol or Retinol equivalent)
MI	Micronutrient Initiative
MoU	Memorandum of Understanding
MRC	Medical Research Council
MT	Metric ton
NCM	National Chamber of Milling
NFA	National Fortification Alliance
NFCS	National Food Consumption Survey
NPA	National Programme of Action for Children
NTD	Neural Tube Defects
RDA	Recommended Dietary Allowance
RE	Retinol Equivalent
SABS	South African Bureau of Standards
SAGIS	South African Grain Information Service
SAGL	Southern African Grain Laboratory
SANHANES-1	South African National Health and Nutrition Examination Survey
SARS	South African Revenue Service
SAVACG	South African Vitamin A Consultative Group
SOP	Standard Operating Procedure
UNCRC	United Nations Convention on the Rights of Children
UNICEF	United Nations International Children's Fund
USA	United States of America
USAID	United States Agency for International Development
WHO	World Health Organisation

I. Background

Confirming a range of earlier surveys and studies, The South African National Food Consumption Survey of 1999 (NFCS) found dietary intake of South African children deficient for a range of micronutrients.[1,2] The NFCS found that consumption of maize meal and wheat flour was high and widespread and more recent information indicates that South African population consumes approximately 167 grams of wheat flour and 284 grams of maize flour, per person per day;[3] 98% of wheat flour and 70% of maize meal consumption is processed at 66 mills. Recognizing this favourable market and industrial environment for wheat flour and maize meal fortification to deliver vitamins and minerals and provide added nutrition protection to consumers throughout the population, South Africa mandated fortification of white and brown bread flour and flour of the seventeen maize products in 2003.[4]

II. Regulations

Draft mandatory regulations published in October 2002 underwent a period of public comment including substantial discussion and debate, which resulted in extensive amendments, additions and deletions.[4] "R 504 Regulations relating to the fortification of certain foodstuffs" was published in April 2003 and later amended in "R 1206 Amendment of regulations relating to the fortification of certain foodstuffs" in 2008.[4,5] These regulations are very comprehensive, mandating required micronutrients, levels and compounds in wheat flour and maize meal and also specifying a required premix formulation, a regulated premix procurement process, mill record keeping practices and government inspection protocols. Penalties for non-compliance are not specified in the fortification regulations but are specified in the Food, Cosmetics and Disinfectants Act 54 of 1972.

This mandatory fortification framework emerged from an open and lengthy participatory process engaging a wide range of stakeholders who were empowered to assign individuals and/or organizations onto various working groups and technical committees. The multisectoral process was supported by a range of data gathering activities, including the National Food Consumption Survey, an extensive milling industry assessment, academic studies into micronutrient stability during storage and preparation, an expert position paper on optimal iron compounds, and considerable research and testing to establish consumer acceptability. The process was marked by debate and negotiation among stakeholders, some prioritizing optimal public health impact and others concerned with product change, cost and other factors relating to feasibility and sustainability of implementation. Ultimately, a consensus of stakeholders agreed on a fortification profile including 8 vitamins and minerals, more comprehensive than any other national mandatory program. Since intrinsic micronutrient content of maize meal and wheat flour is not identical, the required vitamin and mineral levels for maize meal and wheat flour are marginally different.

Table 1: South African fortification profile including micronutrient compound specification and level[4]

Micronutrient	Compound specification	Level in wheat flour (mg/kg)	Level in maize meal (mg/kg)
Vitamin A	Palmitate, protected, stabilized; activity 75,000 mcg/Retinol Equivalent/g	1.79	2.09
Thiamin	Mononitrate; activity 78% minimum	1.94	2.19
Riboflavin	Riboflavin	1.78	1.69
Niacin	Nicotinamide/niacinamide	23.68	25.0
Pyridoxine	Hydrochloride; activity 81% minimum	2.63	3.13
Folic acid	Activity 90.5% minimum	1.43	2.0

Table 1: South African fortification profile including micronutrient compound specification and level[4]			
Micronutrient	Compound specification	Level in wheat flour (mg/kg)	Level in maize meal (mg/kg)
Iron	Electrolytic; activity 98% minimum <45 microns particle size	35.0	35.0
Zinc	Oxide; activity 80% minimum	15.0	15.0

The nutrient standards were based on relatively detailed consumption data, the latest available information on retention and bioavailability of the various fortificant compounds, projections for average proportion of World Health Organization Recommended Nutrient Intakes (WHO RNI) delivered to various risk groups as well as comparisons to national cereal fortification standards from other countries. However, stakeholders recognized that nutrition and food science continues to develop and agreed that based on results of program monitoring this fortification profile, as well as other components of the regulations would be reviewed. R 504 was published well before the *WHO/FAO Recommendations for Fortification of Wheat and Maize Flours* in 2009 and the levels are marginally lower for vitamin A and substantially lower for iron, folic acid and zinc.[6] A process to reform the regulations to address this new information and other lessons learned is currently ongoing and described in Section 8.

South Africa's Department of Health (DOH) is responsible for inspection and monitoring of fortification compliance, with key responsibilities falling to the Directorate of Food Control (DFC) with the support of the Food Analysis Laboratory Services (FALS) and the Directorate of Nutrition (DN). However, in the Republic of South Africa's (RSA) decentralized governmental structure, while national directorates are authorized to issue guidelines and coordinate, actual implementation is by provincial and district governments, that ultimately direct and finance inspection activities of the country's 2,500 Environment Health Practitioners (EHP). DFC can only guide or request rather than mandate monitoring activities.

As a result of a major training and communications program that accompanied the publication of the fortification standards, EHPs are fully conversant with the rationale of fortification and trained in monitoring protocols. However, fortification is a small component of EHPs' portfolio of responsibilities, which covers a wide range of environmental and food safety issues. Since wheat flour or maize meal that does not comply with fortification regulations remains safe to consume, district authorities do not consider sub-standard flour or maize to be an urgent threat to public health. Consequently, in the context of "competing priorities," food fortification is usually not considered a priority activity. The decentralized government structure and a natural bias by local authorities to focus on inspection activities in areas that represent the most immediate threats, represent some major weaknesses in monitoring the fortification program.

III. Premix monitoring

Premix control is recognized as a critical control point monitored by DOH. National regulations specify a required formulation for the fortification premix as well as prescribe that millers can only purchase premix from suppliers included in an official register maintained by DOH.[4] Since the premix formulation is prescribed by law, the indicated addition rate at the mill is also on the premix

container. While millers can vary the addition rate based on their own requirements, requirements for the finished flour or meal remain the same.

The main point of control for fortificant premix is the requirement for supplier registration. To qualify for selling premix into the South African market, fortificant suppliers are mandated to register annually with DOH and submit to a process which requires providing a Certificate of Analysis for each batch of premix; conducting stability tests for vitamin A; and undergoing an external audit by a DOH appointed auditor every 6 months. All of these requirements must be met and verified before the supplier can be registered. The authorized premix supplier list is available on the DFC website and millers are responsible for purchasing only from those firms that are currently listed.[7]

Based on a Memorandum of Understanding (MOU) with the DOH, the external audit of premix suppliers is implemented by the South African Bureau of Standards (SABS). The audit protocol is based largely on Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practice (GMP) and requires the premix supplier to inform the auditor of the source of the vitamin A and iron being used; provide evidence that vitamin A stability meets Department of Health specifications;[8] and present monthly records of premix sold, including the purchaser. The SABS also takes random samples of premix for verification at the SABS laboratory, a facility with ISO 17025 accreditation for vitamin and mineral analysis. Upon completion of the audit, a confidential report is issued to DOH for inclusion in the official supplier registry. Other than the approved list of suppliers, there is no public record of the audit contents, and therefore other government agencies, industry, NGO, consumer groups or other independent experts are not able to analyze the data for quality assurance trends and challenges. SABS supplier audits represent the major point of premix monitoring, with very little downstream monitoring of stocks held by supplier agents or millers.

IV. Internal monitoring at production level

Some internal monitoring norms have been established. Annexure 1 of the mandatory regulations specifies internal requirements to be met by the milling industry.[4] The South African milling industry is sophisticated and institutes a great deal of self-regulation – and the trade association, National Chamber of Milling (NCM), via its technical committee offers a powerful forum for cooperatively addressing production, quality and regulatory issues. The NCM provides a monitoring template that can be adopted or adapted by each mill. Most of RSA's mills are sophisticated operations where quality assurance is taken seriously. Internal monitoring systems go well beyond the quality control processes outlined in the regulations. However, there are a large (but unknown) number of small millers in South Africa, especially maize millers, and it is generally agreed that there is a high level of non-compliance amongst this segment of the industry. However, all of the main industry players – and the smaller millers who have joined the NCM – have adequate equipment and capacity to fortify and many International Standards Organization (ISO) management systems in place.

For various reasons the milling industry is reluctant to discuss the details of their internal processes, or make records available for public disclosure. Consequently, the details of internal quality assurance and quality control protocols are not known. Most millers control the fortification process with a minimum of a daily physical check of the quantity of premix delivered, check on premix usage, a visual check that the microfeeder is functioning twice per shift, and rapid chemical test every two

hours. While not prescribed, industry makes use of the iron spot test for the rapid chemical test.[9] Mills periodically send composite samples from inventory, as well as grab samples of their competitors' products, for analysis at the Southern African Grain Laboratory (SAGL).[10]

It appears that each mill, or at least each milling group, has its own Standard Operating Procedures (SOPs) and that summary reports are collated on a periodic basis within a mill and/or a group. At one time, these data were occasionally collated by the NCM, but this activity is now prohibited by a ruling of the RSA Competitions Commission, to prevent appearance of collusion between the milling groups. An audit of these presumably robust internal mill records could be a powerful tool in external quality monitoring. However, while R 504 as amended requires records be kept, there is no requirement that they be supplied to regulators. Consequently, while quality audits, mainly via checking required internal documentation, is generally considered a superior and more cost effective approach to external checks on mill quality, EHPs activities are limited to taking samples for compliance analysis.[4]

V. External monitoring at production and retail level

DFS routinely plans integrated bi-annual national surveys for a range of foods and beverages to check compliance with national standards for mycotoxins, aflatoxin, patulin and other substances; maximum residue limits for pesticides and veterinary drugs; colorants, preservatives and other additives; contaminants like heavy metals, melamine; and nutritional parameters such as food fortification. Within the context of these surveys, EHPs are authorized to enter the mill to take samples for analysis. The 2008 amendment to R 504 established the mill (the point of fortification) as the legal site of inspection for compliance with fortification standards. This approach minimizes the number of inspection sites (and related costs) and optimizes traceability, communication, corrective action and enforcement.

With relative centralization of the South African milling industry, two annual inspections at 66 mills suggest 132 mill visits and associated samples for analysis. With 2,500 local EHPs, who have been trained in fortification inspection, and are already collecting an estimated 10-12 thousand samples generated by these bi-annual surveys, mill monitoring seems imminently feasible. However, while the DFC designs national plans, implementation is based on the priorities and capacities of provincial and local government officials. Even though fortification may be included in national sampling plans, with competing priorities and low awareness among decision makers at the local level, twice annual inspection of all mills is rare, although some provinces are more active than others.

When samples are collected, based on a specific protocol issued by DFC, EHPs send samples to FALS laboratories in Cape Town and Pretoria. The regulations specify that these laboratories analyze vitamin A along with either riboflavin or niacin as markers of adequate fortification. Using "marker micronutrients" rather than testing for each required vitamin and mineral, requires fewer laboratory analysis and therefore is a more affordable approach of verifying compliance. This reduces the burden of analyzing all 8 prescribed micronutrients, and avoids the ambiguity of 8 results– many reflecting complex testing protocols and large margins of error. Nevertheless, FALS is resource depleted. Only one of the two laboratories has the capacity to perform micronutrient analysis. Although this laboratory contains all the required equipment, it is understaffed and turn around

time is lengthy. This reportedly frustrates EHPs who originally collected the samples, and tends to lower the number of samples authorized by local authorities and collected by EHPs in the next sampling run.

The food control system relies heavily on the results of these spot samples as opposed to a quality audit. A quality audit is a check made by inspectors to verify that the agreed upon requirements for the fortification process and supporting documentation is in place i.e. frequency of checks on the feeder, rapid test results, external verification of micronutrient levels, evidence that internal audits are conducted, action taken if problems are discovered. Although quality auditing is an approach used in premix control, auditing the fortification process at the mill, which is generally considered a more efficient external quality check than periodic spot samples, is not conducted by EHPS.[11] Another key weakness is that FALS communication to EHPs is not usually copied to DFS. Consequently, there is no national database for number of samples taken, analyzed, or the results. Moreover, data forwarded to DOH is considered confidential and not in the public domain where independent experts might be enabled to analyze data, identify emerging trends and needs, and when necessary advocate for improved performance and reform.

A key critique of the food control system comes from large milling companies, who support mandatory fortification and stringent enforcement as a way to ensure a "level playing field." Millers know that inspection is sporadic at their facilities and suspect the inspections at most smaller and less visible milling facilities are rare or non-existent. Ultimately, South African mills are fortifying not because of stringent food control or possible legal penalties, but because they have been involved in the process and support fortification regulations, and as large commercial operations the business liability of non-compliance is steep. Therefore, it is in their own interest to assure compliance.

Since R 504 as amended in 2008 specifies the mill as the only legal point of food control, there is little government monitoring at the commercial level.[12] While these downstream points of monitoring are of limited benefit from an enforcement perspective, this can be a critical point to monitor effectiveness of the fortification program. Periodic small-scale sampling at the retail level yields information on retention of labile vitamins through the distribution chain including vitamin A, folic acid and other B vitamins.

Since there is no specific mandate for government agencies to monitor the retail marketplace, the function falls to interested NGOs and academic researchers. In 2011 Yusufali et al. reported on the vitamin content of packaged wheat flour and maize meal at retail stores in several provinces.[13] The sampling frame emphasized rural areas and packs from smaller mills. Even though samples from larger milling groups were taken only if other options from smaller mills were not in stock, approximately 80% of the samples were collected from the larger milling groups - indicating the level of penetration these companies have into the rural marketplace. Laboratory analysis indicated that only ~70% of samples complied with the minimum vitamin A content as specified in the regulations. The authors concluded that for failing samples, vitamin A stability could be a "significant contributory factor" and also suggested "insufficient addition of premix is likely to be a more significant cause of low fortification levels."[14] There is currently an assessment to determine whether a change in microfeeder equipment might help address issues raised by the study.

VI. Import monitoring

Volume of imported flour into the Republic of South Africa is considered insignificant.

VII. Household monitoring and impact evaluation

To assess whether the fortification program was achieving its public health objectives, a baseline survey was conducted by the University of Stellenbosch: the National Food Consumption Survey 2005 (NFCS 2005).[15] However, since this survey was conducted after fortified wheat flour and maize meal had been on the market for more than 2 years, it provided little information on baseline micronutrient status and in fact was used as interim follow-up data. Compared to a previous survey in 1994, the 2005 survey indicated that national iron and vitamin A status had declined. In light of the results for iron and vitamin A status, many stakeholders questioned the adequacy of the levels and technical specifications in the fortification program. On the other hand, evaluation of the folic acid component of the fortification program suggests important benefits. NFCS 2005 was linked to DOH's sentinel Birth Defects Surveillance System (BDSS) which found significant decreases in the rate of folic-acid-associated neural tube defects in the years after fortification had been implemented.[16,17]

The publication of the South African National Health and Nutrition Examination Survey (SANHANES-1) in 2013, a survey which included >25,000 individuals and >8,000 blood specimens, painted a different picture. Relative to the findings of 2005 NFCS eight years earlier, SANHANES indicated prevalence of anemia among children <5 years of age decreased by 63%, iron deficiency anemia by 83% and vitamin A deficiency by 63%.

The study also found that in women of reproductive age, anaemia declined from the NFCS level of 29.4% to 23.1%; and iron-deficiency anaemia from 10.5% to 9.7%.[18-20] While the rate of anemia and vitamin A deficiency among children are still classified as major public health threats based on WHO thresholds, these findings represent significant improvements. However, since SANHANES-1 was not designed specifically to measure the impact of fortification, the extent to which these improvements are attributable to the program remains unclear.

VIII. Summary and discussion

Since the promulgation of mandatory standards in 2003 and amendments in 2008, lessons from implementation experience as well as the mixed results of two national micronutrient surveys suggest a number of issues that may require regulatory reform. Based on the same open, multisectoral and participatory process established during the development of original regulations more than a decade ago, a number of issues are now under discussion and study.

Iron Choice

Table 2: South African Fortification profile compared to WHO recommendations for consumption of wheat flour and maize meal (combined) of 150-299 grams per capita per day

Micronutrient	Compound	Fortification Profile in R 504[4]		WHO recommendations[6]
		Wheat flour (mg/kg)	Maize meal (mg/kg)	mg/kg
Vitamin A	Activity 75,000 mcg/RE/g	1.79	2.09	1.5
Folic acid	Activity 90.5% minimum	1.43	2.0	1.3
Zinc	Oxide	15.0	15.0	40
Iron	Electrolytic iron	35.0	35.0	60
Iron	Ferrous Fumarate/Sulfate	Not specified	Not specified	30
Iron	NaFeEDTA	Not specified	Not specified	20

The decision to specify 35 mg/kg iron as electrolytic iron was based on product and consumer trials showing no negative impact of product quality as well as consultation with one of the world's foremost experts on iron nutrition, Professor Patrick Macphail, who presented a position paper to the DOH supporting the choice of electrolytic iron.[21] However, recommendations from WHO indicate that for average consumption of 150-299 grams per day, as is the case for the combination of flour and maize meal in South Africa, the likelihood of significant public health impact requires 60 mg/kg iron as electrolytic iron.[6] Other, more bioavailable compounds are indicated at lower levels, such as 20mg/kg for NaFeEDTA and 30 mg/kg for ferrous fumarate and sulphate. Discussions among government, industry and other stakeholders in 2012 led to an agreement that amending regulations to specify 20 mg/kg from NaFeEDTA, as recommended by WHO and shown in Table 2 above, would offer optimal likelihood of positive nutrition impact while not causing sensory change. Trials are currently underway to confirm that this change will not affect consumer acceptance within the South African context.

Vitamin A Stability

With the suggested decline in vitamin A status of children found in the NFCS 2005, some stakeholders questioned the stability of vitamin A in the original premix as a possible explanation for this lack of impact. Consequently, the 2008 amendments to the fortification regulations made key changes in the requirements for premix suppliers to register with DOH. For inclusion in the approved premix registry, suppliers are now required to undergo two annual quality audits during which samples are to be taken. However, the result of this sampling and audit process is held confidential between the DOH and the premix suppliers. Consequently, data on vitamin A content and stability in the premix not in the public domain where it can be analyzed by independent experts. Other approaches to assuring optimal stability of vitamin A and sufficient levels of vitamin A at the consumer level are under discussion.

Cake Flour Exemption

The original fortification regulations exclude cake flour, a low extraction more refined wheat flour, which was believed to represent a small market share and not consumed by the lower income consumer segments. The original rationale for exemption of cake flour was to lower the capital requirements and recurring cost burden on the milling industry. However, current estimates suggest the cake flour share of the flour market has increased dramatically from 10-15% in 2002 to 40-50%

in 2013.[22] Moreover, there are reports that cake flour is increasingly used in foods purchased by low income consumers. The milling industry is cautious about including cake flour in the fortification mandate citing concerns over potential for adverse sensory changes as well as the capital investment required to procure additional microfeeders necessary to fortify the cake flour lines at the mill. Nevertheless, a consensus of stakeholders is moving towards recommending that cake flour be added to the list of food vehicles that must be fortified.

Bread and bakeries

The regulations do not specifically require the use of fortified flour in all bread, but only stipulate that the logo and any associated claims on packaging and advertising may not be used unless the bread contains >90% fortified wheat flour. As many of the small bakeries in South Africa use a mixture of cake and bread flour and market with no packaging (and associated opportunity to make claims on a label), the fortification program may be losing a portion of the bread market as a delivery vehicle. The South African Chamber of Baking noted that in 2003 major plant bakeries accounted for 50% of bread production with the remaining half produced by possibly more than 5,000 bakery outlets (an estimated 600 bakeries in supermarket, 250 franchise bakeries and 3,000-4,500 small independent bakeries and in-store café bakeries).[23] While revoking the exemption on cake flour may have some impact on these bakers, amending regulations to require the use of fortified flour in all bread, whether packaged or not, may be helpful in closing this potential loophole.

Based on a participatory process including stakeholders from government, industry, academia and other sectors, South Africa's fortification program provides a solid legislative foundation for what appeared to be a strong food control system. However, the system appears not to have taken into account the true technical and administrative burden of food fortification monitoring. Therefore, fortification monitoring was not adequately prioritized and resourced to provide adequate oversight and enforcement. Currently, an ongoing process of communication between all stakeholders is exploring ways and means to address these challenges, reform the regulations and strengthen the monitoring system in order to optimize and sustain the national fortification program in South Africa.

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