Monitoring of Flour Fortification: The Case of Chile

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Food Fortification Initiative
Enhancing Grains for Healthier Lives

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Abbreviations

ALIM	Asociación Latinoamericana de Industriales Molineros (Latin American Milling Association)
CoA	Certificate of Analysis
ESLAMO	Escuela Latinoamericana de Molinería (Latin American Milling School)
FAO	United Nations Food and Agriculture Organisation
INDUPAN	Asociación Gremial de los Industriales del Pan de Santiago (Industry Association of Breadmakers in Santiago)
ISP	Instituto de Salud Pública (The Public Health Institute)
SEREMIS	las Secretarías Regionales Ministeriales de Salud (Regional Offices of the Health Ministry)
SESMA	Servicio de Salud Metropolitano del Ambiente (Metropolitan Environmental Health Service)
WHO	World Health Organisation

I. Background

Responding to reports of micronutrient deficiency in adult males due to high alcohol intake, Chile began mandatory fortification of flour in 1951.[1] The market and industrial environment for flour fortification was favorable. Virtually universal and high flour consumption ~300 grams per capita per day is supplied by a centralized domestic industry comprised of 82 large-scale mills controlled by only 5 companies.[2] Before fortification began there was a long history of government monitoring of flour milling industry – and inspection and quality assurance of the flour fortification program was integrated into this over-all system. It is carried out in a systematic way with a planned budget with results that are reported annually. Most importantly, the results found by the monitoring system have led to institutional and legislative improvements in the flour fortification program.

II. Regulations

Chilean food law is founded under the Food Sanitary Law.[3] Mandatory flour fortification was developed in Article 350 published in 1951 and later amended in 1965, 2000 and 2010. Today, Chilean fortification regulations specify levels of 5 micronutrients in wheat flour, including iron and 4 B vitamins– defined as a minimum level for 4 micronutrients and expressed as a range for folic acid. Since intrinsic micronutrient content of wheat flour is not taken into account, added fortification levels may be lower than those specified in Article 350, but still comply with the mandatory requirements at the time of testing fortified flour.

Table 1: Micronutrient Content of Wheat Flour Required by Article 350 as of January 2010

Micronutrient	mg/kg
Thiamin	6.3
Riboflavin	1.3
Niacin	13
Iron (as ferrous sulfate or equivalent)	30
Folic acid	1.0 2.6

A key strength in the Chilean legal environment is that the Ministry of Health MOH is required to respond to individuals or organizations that may request changes to Article 350 and associated regulations and guidelines.[4] If initial technical evaluation suggests that reform is indicated, then MOH presents the issue to a multisectoral committee, which includes a range of stakeholders and experts as well as active participation of the milling industry. This is an institutionalized and active process typically requiring 1-2 years to achieve technical consensus, signature by the President and finally, publication. This process has been applied to the fortification program several times, including changes to the iron and folic acid requirements.

At the time of the initial national mandate for flour fortification in 1951, the only fortificant premix available in Chile included metallic iron, and consequently this iron compound was specified in the regulations. However, magnets at the mill, designed to remove contaminant metals, also removed the fortification iron. When this issue was clarified in 1965, the iron source was changed to ferrous sulfate, although the equivalent quantity of ferrous fumarate is also permitted.[5] This change addressed the technical issue at the mill but also, possibly inadvertently, specified a more bioavailable source of iron for the fortification program.

Responding to research demonstrating the impact of folic acid supplementation in reducing neural tube defects, this micronutrient was added to the required fortification profile in 2000, a few years after mandatory regulations were established in the United States of America and Canada. The

original requirement for folic acid in wheat flour was set at 2.0 – 2.4 mg/kg. In the following years, laboratories experienced difficulty in folic acid analysis, among the more difficult of the prescribed micronutrients to analyze. The folic acid failure rate was by far the highest of all micronutrients and had very little correlation with results for the other 4 nutrients in the premix. Regulations for the four other required micronutrients simply specify a minimum level as opposed to the narrow 0.4 mg/kg range specified for folic acid. Consequently, in March of 2010 the range for required folic acid was expanded to 1.0 – 2.6 mg/kg, to accommodate these technical difficulties.[1,3]

MOH, designated as the responsible agency for enforcement of the Food Sanitary Law, has developed technical guidelines designed to clarify how the law will be interpreted and implemented.[3,6] A key guideline states that if MOH determines the flour does not contain the required levels of any one of the micronutrients, then that flour is in non-compliance. Since the guidelines also define analytical protocols that exclude niacin, in fact, failure in any one of the remaining four micronutrients results represents non-compliance. Technical guidelines are also subject to review and amendment. For example, in response to questions about sampling operations, MOH amended procedural guidelines in 1999. A new set of revised draft guidelines were circulated for comment in 2011, including a new sampling protocol calling for mixing a composite sample from 8 individual samples.[7]

III. Premix monitoring

The regulations state that the MOH shall issue a decree to "approve the guideline over the adequate technical parameters so that the vitamin premix composition for flours is uniform." However, this guideline, which might include a specific required formulation, has not been formally approved making it difficult for food control to ensure the premixes are actually uniform. Chilean regulations do require that the label on the fortificant premix package include the level of micronutrient per gram of premix - but does not stipulate a specific formulation for the premix. Interestingly, while formulation is not specified in the regulations, the dosage rate for fortification at the mill is stipulated at 200 grams per metric ton - which presumes a premix formulation to achieve the required levels in the wheat flour.[8] Ultimately, since premix composition is not stipulated in the law, it is not monitored by the MOH. Some, not all, wheat flour mills assure the quality of the premix they purchase based mainly on Certificates of Analysis from the premix suppliers, although in some cases the premix is sent for independent 3rd party analysis.[9]

The major quality assurance check for premix is left to the internal systems and "self-regulation" of the premix supplier. The major source of premix in Chile is Granotec, a sophisticated company with multi-national operations. Granotec has ISO 17025 status under Chilean accreditation and utilizes both internal and 3rd party independent laboratories for verification of quality.[10] Company protocols require strict and verifiable compliance with internal quality systems including: control intake of raw materials; verification of chemical characteristics, microbiological status and contaminants level; strict process control ensuring Good Manufacturing Practices (GMP), hygiene, equipment status, calibration of weighing equipment, waste disposal and finished product analysis; and issuance of Certificate of Analysis by a duly authorized and competent member of the staff.[11]

IV. Internal monitoring at production level

Chile's flour milling industry is large scale and centralized with 5 milling groups or companies operating 82 facilities (as of May 2013)– and 70% of all national flour consumption coming from 20 mills.[2] Communication channels are further centralized via two milling associations, one for the central and northern region of the country (Asociación de Molineros del Centro) and one for the southern region of the country (Asociación de Molineros del Sur).[11] The sophisticated business models, modern equipment and technical process expertise suggest strong internal monitoring systems. Moreover, Chile's legalistic business environment combined with robust external monitoring by MOH has resulted in mills adopting strong internal monitoring protocols. However, since national fortification regulations do not prescribe standard operating procedures (SOPs) specifying minimum levels of required internal monitoring that can be checked in an external quality audit by MOH Regional Offices, these cannot be officially verified or documented.

Despite the absence of a national standard for internal monitoring, the milling sector has strong quality control and assurance systems in place. Each mill or milling group has developed their own SOPs, to maintain and improve their internal quality systems. While milling companies understandably are reluctant to share internal protocols, all indications suggest the industry has instituted regular physical and visual control points including check weighing on the feeder, ensuring the feeder is charged and delivering the required quantity of premix, etc. and the results of checks on the fortification process are recorded. If MOH technical guidelines were amended to defined required benchmarks for internal monitoring, inspectors could check critical points, audit documentation and verify protocols are in place. This audit approach is generally considered to provide a superior picture of over-all quality than a single "snapshot" from a flour sample.[12]

VI. External monitoring at production and retail level

Parallel to Chile's decentralized government structure, food control activities are centrally designed, supervised and coordinated from the national level, but implemented by inspectors working for the Regional Offices of the MOH with support from the laboratories of the Institute of Public Health (ISP). The annual plans are disseminated to each region, whereupon each MOH Regional Office develops its own implementation plan, detailed down to the individual mill.

The food control activities for fortification focus on the point of production and on-site warehouses.[9] MOH Regional Offices are required to annually inspect each mill 4 times with all inspectors taking flour samples for laboratory analysis including the following range of flour quality parameters:[13]

- Moisture content
- Acidity expressed as sulfuric acid on a 14% moisture basis
- Ash content expressed on a 14% moisture basis
- Crude fiber expressed on a 14% moisture basis
- Nitrogen content expressed on a 14% moisture basis
- Thiamin, riboflavin, folic acid and iron content expressed in mg/kg

External monitoring relies almost completely on ensuring compliance at the mill level. There are no downstream commercial inspections at distribution, re-processing or retail levels. While monitoring

at the point of production minimizes the number of inspections and optimizes both MOH capacity and traceability of samples, some downstream monitoring might be considered – not as an enforcement or compliance mechanism but as a useful "double-check" especially for retention of labile vitamins.

All samples collected from mills are sent to a central laboratory, the National Reference Laboratory (NRL) at ISP. NRL analyzes each sample for required micronutrients, with the exception of niacin, and, reports back to the relevant inspector at the MOH Regional Office. Failure on any single micronutrient analysis is technically considered non-compliance -though MOH often use their discretion and only proceed with warnings and sanction if two or more micronutrients are found non-compliant. As warranted, MOH Regional Offices take steps stipulated by law including: advisory letter requesting appropriate attention, warning letter requiring appropriate attention within a prescribed number of days, and implementation of sanctions (typically a fine). Should the results of the analyses be deemed compliant then MOH takes no action and the mill is not advised of a satisfactory report.

Results of monitoring activities are published annually and disaggregated by region, and compliance by micronutrient. Performance of individual mills is not part of this public record. These national reports suggest significant improvements in fortification quality from 2008-2011.[14-18] NRL analyzed 243 flour samples in 2008, finding 73.6% met the thiamin regulation, 65.2% met the riboflavin regulation, 47% met the iron regulation and 10.2% met the folic acid requirement (note that these results for folic acid include samples taken before March 2010 when the required specified range was widened). Only 1-2% of samples met the legal requirements for all four micronutrients. Two years later, NRL reported that of 212 samples, 61% passed for all required micronutrients. MOH understands that monitoring results need to be interpreted with caution because legal requirements are strict and inflexible while laboratory vitamin analysis is characterized by large margins of error.

Generally, the food control system is well planned, financed and implemented and resourced. However, there are several potential weak points or loopholes. While MOH Regional Offices are required to take samples four times a year from each mill, not all regions meet these requirements. For example, national MOH records from 2008 and 2011 indicate 200-250 samples annually, suggesting an average of 2-3 inspections across 82 known mills. Moreover, a 2008 report found no complete census of mills, suggesting coverage of the food control system may not reach all mills.[14] Nevertheless, given the centralization of the milling industry in large players, these unknown mills are unlikely to account for a significant share of national consumption.

A more significant challenge is laboratory capacity. Whilst each MOH Regional Office has its own laboratory facilities, these are not equipped to analyze for micronutrients. Consequently, the NRL has been appointed as the responsible analytical laboratory. While the most competent available national laboratory, the NRL food analysis laboratory does not have ISO 17025 status (as of July 2013). Nevertheless, results of NRL analysis are considered final - even if a disputing analysis comes from a 3rd party laboratory certified with ISO 17025 status in vitamin and mineral analysis.

Given the high capacity and solid commitment of the national milling industry, even the improved 39% non-compliance rate in 2011 (see above) seems high. Under-dosing at the mill is an unlikely

explanation given the results of NRL folic acid analysis for 2008, which found 75 of the 76 failures reflected levels exceeding the maximum range. More likely explanations might include very high overages of folic acid in the premix from the supplier or analytical error at the laboratory than any deliberate act or unintentional oversight at the mill. Approved guidelines specifying premix formulation, together with strict monitoring of the supply, may address the first possibility. MOH is currently conducting extensive research into the folic acid analysis methodology. However, most methodologies for folic acid analysis are known to have a relatively high margin of error of ~20%, as opposed to ~10% for iron or less for other micronutrients. Given the uncertain nature of chemical food analysis, relying only on spot samples rather than overall quality mill audits, may result in a high rate of "non-compliance" even though mill processes may be of high quality and their flour adequately fortified.[12] Based on experience and best practice, a quality audit verifies whether systems are in place that will most likely result in the production of well fortified flour.

VII. Import level

Monitoring of fortified flour at import level is not necessary as the volume of flour imported into Chile is insignificant.

VIII. Household monitoring and impact evaluation

Currently available national data show low and decreasing micronutrient deficiency in Chile. Additionally, results from the 2003 National Health Survey found the prevalence of anemia among women is 5.1%.[19] With no older national survey as a baseline, it is difficult to totally attribute this low prevalence to iron fortification of wheat flour. However, a historical review of many data points over 25 years tracing the prevalence of anemia across children, adolescent girls and women of childbearing age found a steady and consistent decline.[1] While no information on anemia was gathered in the more recent 2009-2010 National Health Survey, folate deficiency among older adults, a key risk group, was 0.6%.[20]

Perhaps the most robust indication of program effectiveness comes from detailed records of nine maternity hospitals. These records, representing ~25% of national births in Chile, indicate significantly reduced incidence of neural tube defects. After the implementation of the folic acid mandate in 2000, these hospitals recorded a steady decrease in neural tube defects from 18.6 per ten thousand births in 1999 (the year before folic acid was introduced into the flour supply) declining to 8.39 per ten thousand in 2009.[21] Despite covering 25% of births, the MOH cautions against extrapolation of the data of the hospital study to a national basis.[4]

IX. Summary and discussion

Chile's wheat flour fortification program is systematically and extensively monitored at mill level with the results of this external monitoring published annually. Some problems appear to exist with premix monitoring, regularly implementing the required number of annual mill inspections, and laboratory capacity and analysis. However, these issues are being addressed. The regulatory environment has an institutionalized reform process and changes are in process. These adjustments indicate a key strength of the Chilean program, namely a regular and transparent mechanism to enable the program to change in response to evidence.

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