# Good Manufacturing Practice in Brazilian wheat mills with particular reference to the flour fortification

# Boas Práticas de Fabricação em moinhos de trigo com particular referência à fortificação de farinhas

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**ABSTRACT**
Iron deficiency anemia (IDA) is a widespread nutritional disorder that affects a significant proportion of the Brazilian population. The obligatory fortification of wheat flour with iron and folic acid represents a strategy of the Brazilian Ministry of Health for combating IDA. However, several studies have reported the occurrence of iron in excessive concentrations and insufficient contents of folic acid in commercial flour samples. In the light of these information, a participatory observational study on the wheat flour production processes was undertaken in 11 major flour mills located in the São Paulo state, Brazil. This study aimed at writing a detailed good manufacturing practice (GMP) guidelines for the industrial sectors, including directives for standardized operational procedures (SOPs) on the flour fortification. The outcomes of this study are a GMP checklist and the recommended SOPs, which help to standardize the production processes in flour fortification, which currently is incongruous one, and also to facilitate the work of the government health inspectors.
**Keyword.** good manufacturing practice, standardized operational procedures, wheat flour fortification, iron deficiency.

**RESUMO**
Anemia por deficiência de ferro (ADF) é um distúrbio nutricional generalizado que afeta uma parcela significativa da população brasileira. A fortificação obrigatória das farinhas de trigo com ferro e ácido fólico representa uma estratégia do Ministério da Saúde para o combate à ADF. No entanto, há relatos que indicam a ocorrência de concentrações excessivas de ferro e quantidades insuficientes de ácido fólico em amostras comerciais de farinha de trigo. À luz destas informações, foi realizado este estudo observacional participativo nos processos de produção de farinha de trigo em 11 moinhos, localizados no estado de São Paulo, Brasil, para criar para este setor industrial, uma lista de verificação das Boas Práticas de Fabricação (BPF), incluindo-se diretrizes para os procedimentos operacionais padronizados (POPs) na fortificação de farinha. A implementação dessas ferramentas ajudam a padronizar os processos de produção, atualmente incongruentes na fortificação das farinhas, bem como facilitam o trabalho dos inspectores de saúde do governo.
**Palavras-chave.** boas práticas de fabricação, procedimentos operacionais padronizados, fortificação da farinha de trigo, deficiência de ferro.

## INTRODUCTION

Iron deficiency anemia (IDA) is one of the most important nutritional problems in Brazil since it affects a significant proportion of the population irrespective of economic class. Among the various measures introduced by the Brazilian Ministry of Health with the purpose of combating IDA has been the fortification of wheat and corn flour with iron and folic acid. In 2002, the National Sanitary Surveillance Agency (*Agência Nacional de Vigilância Sanitaria*; ANVISA), published a resolution determining the compulsory fortification of flour with iron (4.2 mg/100 g) and folic acid (150 µg/100 g)[1].

In 2005, Latorre surveyed the opinions and perceptions of managers in the wheat milling industry regarding the obligatory fortification of flour. The collective discourse revealed that the policy had received general approbation and was being implemented by the flour mills. However, according to this author, the legislation was considered authoritarian and had been applied without consultation with the industrial sector. Of particular concern were: (i) the tendency to overdose micronutrients in order to avoid technological issues, and (ii) the lack of availability of rapid analyses from laboratories[2]. Additionally, a report from the Sanitary Surveillance Center of the State of São Paulo, Brazil, has revealed that commercial samples of flour are often overdosed with iron and underdosed with folic acid[3].

In the light of this information, a participatory observational study of wheat flour production processes in 11 mills across the state of São Paulo was undertaken employing ethnographic method to observe the flour milling daily practices with the aim of verifying if this method is appropriate to elaborate good manufacturing practice (GMP) guidelines for the industrial sector including directives for standardized operational procedures (SOPs) in flour fortification and to investigate variations among protocols and controls used by different mills.

The Centers for Disease Control and Prevention[4] and the World Health Organization (WHO)[5], along with other acknowledged experts[6], consider the flour fortification strategy to be a centralized and managed public health program that includes the monitoring of industrial operations in order to guarantee the quality of the final product. Industrial practices in all flour-producing mills should comply fully with GMP guidelines, and such operations must be monitored if the health program is to be successful.

Nestel et al[6] proposed a GMP checklist for fortified flour based on the Codex Alimentarius[7] and the Food and Drug Administration (FDA) of the USA Health Department norms[8]. These authors emphasized that the FDA carries out routine inspections by specialist staff for each type of product. It is suggested that the Brazilian government should establish a similar procedure in order to monitor compliance with GMP by the flour milling industry, with particular reference to flour fortification.

In 1963, the World Health Organization and the Food and Health Organization (WHO/FAO) of the United Nations established the Codex Alimentarius Commission with the aim of coordinating international food standards, guidelines and codes of practice in order to protect the health of consumers and to ensure fair practices in international food trade[7]. Such codes are adopted by the World Trade Organization as references for all international trade in food products. Within these norms, the Hazard Analysis and Critical Control Point (HACCP) directives have been references for international food safety requirements since 1991.

In 1969, the Codex Alimentarius Commission published a manual entitled "*International Code of Recommended Practices – General Principles of Food Hygiene*" with the objective of providing guidance for the elaboration of codes needed in specific sectors of the food chain, processes or commodities in order to amplify the hygiene requirements that are fundamental to those areas[9]. This manual served as a benchmark for the creation of GMP norms and gave rise to a further publication entitled "*Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Human Food*"[10]. Both documents had international impact and influenced the development of generic and specific GMP norms.

In 1993, the Brazilian Ministry of Health published decree number 1428/MS[11] containing directives for the establishment of GMP in the food sector. This decree conferred practical and wide-ranging powers to food inspectors, and these were consolidated by further regulations including: (i) Decree SVS/MS no. 326, which approves the technical regulation of GMP to be implemented by food-producing companies[12], and (ii) Resolution RDC nº 275, which approves a GMP checklist for food-producing companies[13].

In addition to these fundamental regulations, particular categories of foods were regulated by specific GMPs and are subject to: (i) Resolution RDC nº 28, which describes basic GMP procedures and routine health inspections of companies that produce salt for human consumption[14], (ii) Law nº 6150, which regulates the obligatory supplementation of salt with iodine with the purpose of eradicating endemic goiter[15], (iii) Resolution RDC nº 23/2013, which specifies the minimum and maximum levels of iodine in salt destined for human consumption[16], (iv) Decree no. 2.362/GM, which restructures the National Program for Prevention and Control of Iodine Deficiency Illnesses[17], and (v) Decree no. 520/GM, which creates the Inter-institutional Commission for Prevention and Control of Iodine Deficiency Illnesses[18].

For the purpose of ensuring the quality of fortified flour according to the norms of the Brazilian authorities, it would be reasonable to adopt HACCP as a work tool and to employ SOP in the control of quality and dosage of micronutrients. In this case, it is essential to elaborate a GMP checklist including the SOP for the flour fortification with iron so that mills can construct their own detailed HACCP plans. Since the methods of production and control of fortified flour vary among the mills, it is clearly of the utmost importance to standardize these procedures in order to ensure quality and safety, as well as to facilitate the routine mill inspections by ANVISA. On this basis, the aims of the present study were: (i) to write a detailed GMP checklist to be used by the flour industry during the production of flour fortified with iron and folic acid, and (ii) to suggest SOP for all of the steps in the production process.

## MATERIAL AND METHODS

Details of the project were submitted to and approved by the Ethical Research Committee of the Faculdade de Ciências Farmacêuticas, Universidade de São Paulo (CEP nº 03/12022009). All procedures were performed in accordance with the Declaration of Helsinki and written permissions for carrying out interviews, discussions, observations and training of staff were obtained from the managers of the participating wheat milling industries and from the Centro de Vigilância Sanitária de São Paulo (CVS; Secretaria de Estado da Saúde, São Paulo, SP, Brazil). The anonymity of all mills involved and of individual participants was maintained rigorously throughout the study.

The participatory observational study described herein was conducted during 2007 and 2008, and involved 11 major wheat flour mills located across the state of São Paulo. In 2008, these mills were responsible for one third of all of the flour produced in Brazil.

The ethnographic study was executed in three stages. Firstly, a literature survey of scientific articles and government publications was carried out in order to draft a preliminary GMP checklist for the production of fortified flour. Prior to the inspection stage, 20 CVS health inspectors responsible for policing the selected mills were invited to participate in the planning of the project and to oversee the final GMP checklist. With the support and approval of CVS, the research coordinator organized and offered to the CVS inspectors' theoretical and practical training in the technology of wheat flour production and aspects of health legislation relating to GMP. At the inspection stage, the health inspectors were charged with visiting the 11 wheat mills three times according to a schedule arranged by the project coordinator. During the first inspection, which occurred prior to training, the health inspectors used the GMP checklist published in the annex to Resolution RDC nº 275 issued by ANVISA[13]. At the second visit, the health inspectors tested and modified (where necessary) the preliminary GMP checklist. Further checkpoints relating to the production and fortification of flour were then added to the preliminary GMP checklist, and this new draft was employed during the third visit of the inspectors. All stages of the study were closely supervised by the research coordinator.

The model GMP checklist[13] employed by the health inspectors during the first visits to the mills contained general items relating to food production, such as industrial buildings and installations, aspects of hygiene associated with equipment, furniture and utensils, health status of the workers, hygienic conditions in the production line and transport of food materials, and legal documentation of the industrial procedures. A meeting, chaired by the research coordinator, was held during the first inspection of each mill at which the health inspectors and the managers and staff in charge of flour production/quality were present. The research coordinator attempted to reassure the mill personnel about the presence of the health inspectors by emphasizing the importance of IDA in Brazil and the value of the fortification strategy implemented by the government. The coordinator presented the hypothesis and objectives of the research project, and extensive discussions of the subject area were permitted before the actual inspection of the production line commenced. In this manner, considerable effort was devoted into making sure that an agreeable climate existed among the participating mill personnel in order to avoid distorted observations and results. At the request of the coordinator, the mill staff demonstrated the flour production line and explained each of the steps of the fortification process comprising the selection and control of the micronutrients, the technology of dosing and the quality control of the final product (Figure 1).

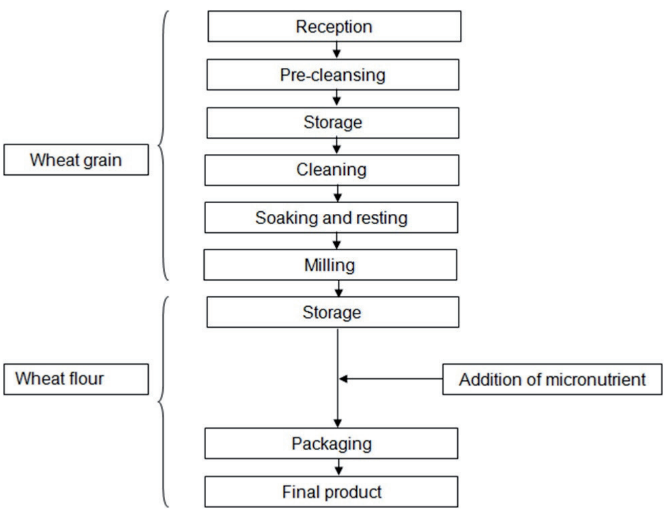


**Figure 1.** Simplified flow chart of the production of fortified wheat flour

The collected observations by the health inspectors gathered during the first and second visits to the mills were incorporated into the preliminary GMP checklist giving rise to a final checklist, which was presented in a tabulated form similar to that used by ANVISA to inspect other food areas. At the end of the project, the health inspectors produced a report on the final GMP checklist based on their experience in the field.

## RESULTS AND DISCUSSION

All of the GMP checkpoints of flour production in wheat mills were observed, from the reception of the raw material to the packaging of the final product. In this article, only GMP topics relevant to the production of fortified flour are presented and discussed. Table 1, represents the final version of the GMP checklist and the recommended SOPs only for the fortification of flour with iron and folic acid operation, constructed during the present study. Most of the CVS health inspectors considered that the final GMP checklist was appropriate since it contained a wide range of control items that allowed its application in mills with different characteristics.

Ethnography is defined as "the descriptive

**Table 1.** GMP checklist and SOP for the fortification of wheat flour with iron and folic acid

| **Identity of Mill** | | |
|---|---|---|
| Function: | | |
| CNPJ: | Phone: | Fax: |
| E-mail: | | |
| Address: | | |
| Town: | State: | |
| Post code: | | |
| Brands of flour produced: | Destination: | |
| | | |
| | | |
| Mean monthly flour milled (ton/ month): | ( ) Small scale mill (up to 300 ton/day)<br>( ) Medium scale mill (between 300 and 1000 ton/day)<br>( ) Large scale mill (more than 1000 ton/day) | |
| Mean monthly flour milled for bread making (ton/month): | | |
| Mean monthly flour milled for domestic use (ton/month): | | |
| Mean monthly flour milled for pasta making (ton/month): | | |

Continue

Table 1. (Continued)

| **Items Associated with Flour Fortification** | | | **Yes** | **No** | **N/A** |
|---|---|---|---|---|---|
| Dosing equipment is readily accessible: | | | | | |
| Automatic linkage system stops the micronutrient feeders should the flour line stop, and vice versa: | | | | | |
| Micronutrient bins on the feeders are marked with minimum and maximum levels of the mix: | | | | | |
| Feeders are fitted with sensors or alarms to detect when the micronutrient mix is outside the required levels and requires correction or refilling: | | | | | |
| Load of micronutrient mix is within the minimum and maximum volumes of the feeders: | | | | | |
| Load of micronutrient mix exhibits arching-flow or funnel-flow patterns in the hopper: | | | | | |
| (  ) Screw-feeders<br>(  ) Other (specify): | Brand name and address of the feeder manufacturer(s): | | | | |
| Volume added by feeder is recorded: | | | | | |
| Frequency of measurement of volumes of flour and micronutrients is satisfactory (i.e. every 2 h or 4 times per shift): | | | | | |
| After analysis of micronutrient outflow, the volumes are corrected manually: | | | | | |
| After analysis of micronutrient outflow, the volumes added are adjusted automatically and electronically: | | | | | |
| Calibration curves exist for each micronutrient mix and their respective feeders in order to assist with the correction of volume errors: | | | | | |
| Producers of micronutrients have provided evidence of their compliance with GMP and appropriate validation of homogeneity of the formulation: | | | | | |
| After changes in the formulation of the micronutrient mix, the feeders are recalibrated to allow for alterations in the physicochemical characteristics (density, fluidity, concentration) of the new mix: | | | | | |
| Monitoring of the volumes of micronutrients and flour added is carried out by workers of proven competence: | | | | | |
| A record exists of the use of the mix, comparing the quantities of micronutrients used with those of flour produced in a determined time: | | | | | |
| Cleaning and removal of incrustations from the feeders is carried out periodically and each operation is recorded: | | | | | |
| Type of iron used:<br>[ ] dehydrated (dry) ferrous sulfate<br>[ ] ferrous fumarate<br>[ ] reduced iron<br>[ ] electrolytic iron<br>[ ] sodium iron EDTA<br>[ ] iron bis-glycine chelate | Type of flour:<br>( ) bread-making<br>( ) domestic use<br>( ) pasta / biscuits<br>( ) other industrial uses | Name of micronutrient provider: | | | |
| The micronutrient dosing points are currently located at: | | | | | |
| The micronutrient dosing points are situated sufficiently far from the packaging module to allow good homogenization: | | | | | |
| Tests have been conducted using different micronutrient dosing points and the results have been recorded: | | | | | |
| The stock of micronutrient is adequate and located close to the dosing point: | | | | | |
| The micronutrients are stored appropriately in the raw materials depository: | | | | | |

Continue

Table 1. (Continued)

| **Quality Control of the Final Product** | Yes | No | N/A |
|---|---|---|---|
| Semi-quantitative measurements (color tests) of iron in the final fortified product are performed and recorded: | | | |
| All actions to correct iron concentration in the final product are recorded: | | | |
| Reports are available of all analyses carried out in recent months by a validated laboratory showing iron and folic acid concentrations in all lines, especially those destined for bread-making flour: | | | |

| **Labels** | Yes | No | N/A |
|---|---|---|---|
| Show the name of the vendor and information relating to fortification: | | | |
| Show essential nutritional information – e.g. 1/2 cup = household measure = 50 g flour provides 2,1 g iron (15% daily value) and 75 µg folic acid (31% daily value): | | | |

| **Documentation** | Yes | No | N/A |
|---|---|---|---|
| GMP manual available for reference: | | | |
| Operations are carried out in accordance with the GMP manual: | | | |
| Official receipts of purchase of micronutrients are available and relevant reports from a validated laboratory are provided by the producer verifying the levels of iron and folic acid for each lot: | | | |
| Reports available from a validated laboratory verifying the levels of iron and folic acid: | | | |
| Reports available from a validated laboratory verifying granulometry (Tyler mesh 325) of reduced, electrolytic or carbonyl iron in the micronutrient mix: | | | |
| Laboratory report available verifying humidity of the stored micronutrient mix: | | | |
| Reports available from a validated laboratory verifying the levels of iron and folic acid in the flour or final products (mixtures for bread making): | | | |
| Existence, compliance and record of SOP for flour fortification with iron and folic acid: | | | |

N/A – not applicable

Table 1. (continued)

**SOP for Wheat Flour Fortification**

The wheat milling industry should describe how the fortification technology functions (volumetrically or gravimetrically) and should make available standard procedures for:

- the maintenance of dosing equipment, with details explaining how to deal with the problems most frequently encountered;
- the measurement of outflows of flour and micronutrients during production, and the recording of this information;
- the calculation of micronutrient dose employing spreadsheets that are easily interpreted by the workers;
- refilling feeders with micronutrients and recording the time intervals;
- the provision by the micronutrient producer of reports of analyses of iron and folic acid levels carried out by validated laboratory;
- the provision of reports of analyses of iron and folic acid levels in the micronutrient mix carried out using validated methods in a qualified laboratory chosen by the mill;
- the provision of reports of analyses of iron and folic acid levels in flour and mixtures for bread making carried by a validated laboratory at the time intervals specified in the following section.

**Sampling, qualification of analytical laboratories, presentation of analytical reports, and frequency of analysis of iron and folic acid levels in flours and bread-making mixes**

The sample should be composed of the production lots from one day and should be collected in the packaging area from a determined production line. Mills should elaborate specific sampling plans for their production lines. The health authority may establish a different sampling routine according to the GMP in place at the mill.

Analytical reports should identify the lots of flour or fortified products, the date of production, the name of the micronutrient mix and the lots used in that sample.

The analytical laboratories must apply appropriate Good Practice and employ trained analysts, validated analytical methods and proficiency tests for iron and folic acid analysis.

**Small scale mill (up to 300 ton/day):**

Analyze 1 flour sample per month and alternate the various production lines (if more than one exists) each month.

**Medium scale mill (between 300 and 1000 ton/day) and large scale mill (more than 1000 ton/day):**

Analyze 1 flour sample per month for each 300 ton milled/day and alternate the various production lines each month.

**CONCLUSIONS**

Place, date and signature of auditors.

term for the cultural material of a particular people"[19] and is based on a few key informers selected for their competence and logical views regarding the study culture, rather than on a representative sample group[20]. The method of participative observation for the accession of field data is critical in ethnological research since it involves the establishment of relationships with a particular community. The researcher collects data by participating in the daily life of the group or organization under study, and by observing people and situations and interpreting the behavior observed. This technique brings the researcher closer to the native language of the social group under study and allows him/her to understand their culture intuitively and to speak with confidence about the significance of the observed data. Occasionally, field circumstances may allow a number of similar events to be observed or similar questions to be put to a number people in a systematic approach, thereby yielding data with a quasi-statistical foundation and providing conclusions regarding frequency or distribution[21].

The present study revealed that the participating mills had already implemented some form of GMP and employed many of the controls reported in the literature and outlined in the present paper. Furthermore, the managerial staff demonstrated significant involvement in the elaboration of the GMP checklist and interest in the results obtained.

The GMP checklist for flour fortification developed by our research team includes items extracted from the scientific literature and governmental health legislation documents, as well as from the reports on the observations performed in the milling industries. Information concerning critical control points and the use of inspection checklists for the flour fortification process were available in the literature and included aspects such as the quality and storage of micronutrients, the frequency (once per shift) of verification of feeder dosages, the frequency (daily) of product sampling for micronutrient analysis, and the maintenance of records of all procedures, problems encountered and proposed corrective actions[6]. Some authors have suggested GMP inspections by health authorities every three to six months[5].

In agreement with MI[22], and Brasil[23], Buzzo et al[24] one of the key items included in the GMP checklist related to the dosage and control of micronutrients. Considerable variation was observed between the mills regarding the micronutrient dosing systems employed, and this reflected the concern of the company with respect to flour quality and the level of investment made. A few companies had installed automatic dosing systems with electronically adjusted rates, although the majority relied on mechanical and less precise systems that generally lacked warnings about potential faults and procedures for troubleshooting.

Perhaps unsurprisingly, inspection of company records revealed a wide variation in the concentration of micronutrients in the flour samples analyzed. Such discrepancies may be attributed to the lack of adequate maintenance of equipment, particularly of non-automated dosing systems, which is essential for system reliability and safety. The point at which micronutrients were added to the flour within the production line was also found to constitute an important checkpoint. For example, a mechanical dosing device could be incorrectly positioned such that the mix of micronutrients and flour was uneven, giving rise to a product that was non-homogenous in terms of hygroscopicity, fluidity and particle size. With automated dosing systems, micronutrients and flour were typically homogenized effectively with only small variations being detected between four consecutive samples. Automated systems were of the continuous, gravimetric and electronic type, or of the batch type with a gravimetric feeder and a Y-shaped mixer that provided good homogenization. In some of the mills inspected, the feeders were difficult to reach since they were located at the top of a long or difficult stairway.

Concerning the variability in the level of investment in modern process systems for flour fortification, it is worthwhile emphasizing a key characteristic of the Brazilian wheat industry. Until 1990, the buying and selling wheat was under the government control (subsidized by the government). Thus, the industry has had only two decades to adjust to the free competitive global market. Moreover, Brazil depends to a large extent on imported wheat since national production is insufficient to meet the qualitative and quantitative needs of the country. Therefore, the price of wheat flour in Brazil is very much dependent on the fluctuations of the international commodity market.

The origin of the micronutrients employed in flour fortification exerts a considerable influence on the quality of the final product. Numerous factors must be taken into account when appointing a micronutrient supplier, amongst which are: the type and granulometric characteristics of the iron, the quality of the formulation, the quality and hygroscopicity of the iron carriers and the quality of the laboratory analysis to ensure appropriate iron formulations. Low quality formulations of micronutrients were encountered during the inspections, especially with respect to the granulometry of the iron particles, the fluidity and balance of the formulation, and the questionable quality of some analytical reports, which appeared to contain non-reproducible results.

The frequency of product sampling and the techniques employed in collecting samples differed from one company to another. Since laboratory analyses increase the costs of the milling operation, the number of analytical procedures performed is often insignificant in terms of the total volume of flour produced. The final GMP checklist proposes a standardized sampling procedure based on the daily production of flour, and requires the mill to provide monthly reports containing the results of iron and folic acid analyses for each 300 ton lot of flour produced each day. The classification of the scale of the mill, which determines the sampling routine, was observed during the field project and the frequency of sampling suggested takes into account the analytical costs. Improving GMP would remove the necessity for excessive product analyses.

In this context, the GMP checklist for the salt industry published in the annex to Resolution RDC no. 28 issued by[14] includes the minimum obligatory controls for salt iodination, such as the quality and storage of the micronutrient, preparation and addition of the iodine solution, control of the solutions and feeder addition rates, the point of application of iodine during the salt production process, the responsibilities of the workers, salt sampling for analysis of iodine in the final product and the complete records of the whole process (log book).

However, information relating to the flour fortification with iron and folic acid, as presented in the present study, is scarce. Lopes, Franco[25] monitored GMP in three wheat mills at the grain milling stage, and noted the effects on the microbiological quality of the final product. Frequent cleaning of equipment and the use of bleach with 100 ppm of free chlorine improved the quality of the process and of the product. In the present study, controls to improve the quality of flour fortification were incorporated.

Additionally, Tavolaro et al[26], used Resolution RDC nº 275 issued by ANVISA[13] to evaluate hygienic practices in the milking of goats in three farms located in the State of São Paulo. The authors interviewed the dairy workers before and after they had received instruction on operational hygiene and subsequently analyzed the collective discourses. In this case, however, training in hygienic practices did not give rise to changes in the routine procedures carried out by the workers.

## CONCLUSION

Quality control of fortified flour is fundamental if the governmental strategy is to produce a positive and permanent impact on the prevalence of IDA in the Brazilian population. The ethnographic method employed in observing the daily practices of flour milling was appropriate since it allowed the collection of a considerable amount of information regarding the routine work in the mills, including the performance, protocols, conduct, language and technology employed by the personnel. Furthermore, it was possible to confirm that the protocols and controls employed in the industry varied considerably from one mill to another. The investigation resulted in a GMP checklist and a recommended SOP that is specific for the flour fortification industry. This GMP checklist will not only help to standardize the currently incongruent production processes but will also facilitate the work of government health inspectors. Since the GMP checklist developed by our research team derived from observations at dissimilar settings, it will be readily adaptable for use in the majority of flour mills in Brazil. However, it is important that the GMP checklist be submitted to critical analysis by ANVISA in order to validate its extensive application. Finally, the results and the experience accumulated in the National Program for Prevention and Control of Iodine Deficiency Illnesses should inspire the creation of a similar program for the prevention of IDA, since the GMP checklist for flour fortification presented herein is similar to that issued by ANVISA[14] for salt fortification.

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