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Research Article

Evaluation of Iron Concentrations in Enriched Wheat and Corn Flours Commercialized in Minas Gerais, Brazil: Compliance with Legislation and the Importance of Fortification Monitoring

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Abstract

In Brazil, the mandatory fortification of wheat and corn flours with iron and folic acid was established by Resolution RDC No. 344/2002 and updated by RDC No. 150/2017 and RDC No. 604/2022. This public health strategy, led by the Ministry of Health, aims to reduce neural tube defects and prevent iron-deficiency anemia. This study assessed iron concentrations in enriched wheat and corn flour samples commercially available in Minas Gerais, evaluating their compliance with current legislation and discussing the need for regulatory adjustments and ongoing monitoring. A total of 391 flour samples were analyzed, revealing that 29.9% were non-compliant with the legislation, which mandates an iron concentration between 4 mg and 9 mg/100g. The average iron content found was 6.31 mg/100g for wheat flour and 5.28 mg/100g for corn flour, with values ranging from 1.13 mg/100g to 31.80 mg/100g in wheat flour and from 0.71 mg/100g to 29.75 mg/100g in corn flour. The findings raise significant concerns about the efficacy and consistency of the fortification process. The non-compliance of nearly 30% of samples points to potential gaps in the fortification process and quality control during production and distribution. The wide variability in iron content suggests inconsistencies in fortification, leading to both under- and over-fortification. These discrepancies could undermine the public health objectives of the fortification program and pose health risks, including inadequate protection against anemia and potential harm from excessive iron intake. The study underscores the need for stricter enforcement of fortification guidelines and enhanced quality control measures across the food production chain. Regulatory authorities, such as ANVISA, should intensify monitoring to ensure compliance. Additionally, revisiting and refining current fortification policies may be necessary to address these issues. Continuous public health surveillance and research are essential to assess the long-term impacts of the fortification program and ensure its effectiveness.

Keywords: *Iron Fortification; Wheat and Corn Flour; Public Health; Neural Tube Defects; Iron-Deficiency Anemia; Compliance Monitoring*

Abbreviations

RDC: Resolução de Diretoria Colegiada (Board of Directors' Resolution); ANVISA: Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency); INCQS: National Institute for Quality Control in Health; LOQ: Limit of Quantification; LOD: Limit of Detection; CV: Coefficient of Variation; RSD: Relative Standard Deviation; PROGVISA: Food Quality Monitoring Program

Introduction

In recent years, Brazil has faced significant public health challenges related to nutritional deficiencies, particularly those affecting maternal and child health. Recognizing the urgent need to address these issues, the Brazilian government implemented a fortification program (2002) aimed at improving the nutritional quality of staple foods. This initiative primarily targets the prevention of neural tube defects, such as spina bifida, and iron-deficiency anemia, which have been prevalent health concerns in the country [1]. By mandating the addition of essential nutrients like folic acid and iron to widely consumed products such as flour, the program seeks to mitigate these deficiencies on a broad scale [2].

The purpose of this study is to evaluate the implementation and impact of Brazil's fortification program. Specifically, the study aims to assess the level of compliance with national fortification legislation, analyze the iron concentrations in commercially available flour, and determine the overall effectiveness of the fortification strategy in achieving its health objectives. By examining these factors, we seek to gain insights into the current state of fortification practices and their success in addressing the targeted nutritional deficiencies [3,4].

Recent initiatives in Brazil have increasingly focused on the fortification of staple foods to address widespread nutritional deficiencies, particularly among vulnerable populations such as children. As highlighted by Martins., *et al*. (2024) [5], the market-driven fortification of packaged foods with essential vitamins and minerals has become a significant strategy aimed at improving the nutritional intake of children in Brazil. This approach aligns with broader public health efforts, including the fortification of wheat and corn flours with iron, to combat iron deficiency anemia and other related health issues across the population. Understanding the effectiveness and compliance of these fortification strategies is crucial, as they play a vital role in ensuring that all segments of the population, including children and adults, receive adequate nutrients through their diet.

The significance of this study lies in its potential to influence public health policies and practices. Ensuring compliance with fortification laws is crucial for maximizing the program's benefits and ensuring that the target populations receive the necessary nutrients. Furthermore, understanding the effectiveness of the fortification strategy can guide future interventions and policy adjustments. The findings from this study will provide valuable information for policymakers, health professionals, and researchers, helping to refine the fortification program and improve public health outcomes in Brazil [6,7].

Materials and Methods

Samples

Between May 2007 and November 2017, a total of 391 samples were analyzed by the Metallic Contaminants Laboratory - Sanitary Surveillance Division - Octávio Magalhães Institute - Ezequiel Dias Foundation. Of these, 305 samples were wheat flour and 86 were corn flour. The samples were collected from various commercial points across the State of Minas Gerais by municipal inspectors, in compliance with the Food Quality Monitoring Program, known as PROGVISA, which aims to ensure the nutritional quality of marketed products.

Analytical method

For iron analysis, the methodology used was that of the Adolfo Lutz Institute [8]. The standard curve was prepared using a 1000 mg/L iron solution (Merck) at concentrations of 1.00, 2.00, 5.00, 7.50, and 10.00 mg/L in an aqueous solution, acidified to 10% (v/v). The samples were weighed and placed in a muffle furnace (Vulcan, model 3-1750). After cooling, 1 ml of concentrated HNO_3 was added, and the samples were heated on a hot plate at 100°C until dry, then returned to the muffle furnace at 375°C for one hour. The resulting ash was dissolved in 10 mL of concentrated HCl, and the volume was adjusted to 100 mL with purified water in a volumetric flask using a Milli-Q system. The samples were then directly analyzed by flame atomic absorption spectrometry (Perkin Elmer, model Analyst 100), as recommended by the Adolfo Lutz Institute [8], using a wavelength of 248.3 nm and a slit width of 0.2 mm.

Validation of the analytical method

To ensure the reliability of the results, validation parameters were applied using samples spiked with the standard [9]. Precision and recovery were evaluated using ten independent samples. For the determination of the limit of quantification (LOQ) and limit of detection (LOD), samples without fortification were spiked with low levels of the standard, with the lowest concentration being 0.5 mg/100g.

Results and Discussion

Validation of the analytical method

The method was validated using a fortified sample at three concentration levels, covering the analytical curve range, with recovery tests, coefficient of variation, intermediate precision, and limit of quantification (LOQ) performed. For LOD determination, data from the low-level sample (0.5 mg/100g) were used:

- Recovery at medium range (5.0 mg/100g): 103.6%;
- Recovery at high range (21.1 mg/100g): 113.3%;
- Coefficient of Variation (CV): 16.9% at the low range (near LOQ); 1.6% at the medium range (5 mg/100g), and 5.0% at the high range (21.1 mg/100g);
- Intermediate precision was 5.2%;
- The calculated LOQ was 0.7 mg/100g.

Ten replicates of a retained sample from the FAPAS 1849 proficiency test with a nominal content of 26.4 mg/kg were analyzed, yielding the following results:

- Mean: 26.52 mg/kg.
- Standard deviation: 1.7 mg/kg.
- Average recovery: 100.4% (results ranging from 92.4% to 110%, with n = 7).

Participation in proficiency tests

The laboratory participated in a proficiency test promoted by the Swedish National Food Administration in 2004, presenting results of 99.4 mg/kg and a Z-score of 0.8. This proficiency test included 26 laboratories worldwide, with an overall mean of 87.1 mg/kg, a standard deviation of 15.0, and an estimated relative standard deviation (RSD) of 17.2%. In 2013, the National Institute for Quality Control in Health (INCQS) of the Oswaldo Cruz Foundation conducted a proficiency test for iron in flours using two samples. The laboratory demonstrated an accuracy of 99.87% and Z-scores of -0.4 and 0.6. In 2017, the LCM prepared a reproducibility study with the participation of six laboratories. LCM's results were satisfactory, with a Z-score of -0.30.

Analysis of wheat and corn flour samples

In compliance by Resolution RDC No. 344/2002 [10] and updated by RDC No. 150/2017 [11] and RDC No. 604/2022 [12], and in line with the Food Quality Monitoring Program (PROGVISA), the results obtained from the 391 wheat and corn flour samples, collected and analyzed between May 2007 and November 2017, are presented in table 1. Descriptive analysis showed that the average iron contents obtained were 6.31 mg/100g and 5.28 mg/100g for wheat and corn flours, respectively.

However, the samples showed highly variable results, as can be seen from the average minimum and maximum values and the average standard deviation (Table 1). In 2008, for example, the minimum and maximum iron concentration values obtained in wheat flour were 1.45 and 31.80 mg/100g, respectively. The largest variation in iron concentration in cornmeal occurred in 2014, with minimum and maximum values of 0.83 and 34.98 mg/100g, respectively.

Product	No. of Samples Analyzed	Average Concentration (mg/100g)	Average Standard Deviation (mg/100g)	Average Minimum Value (mg/100g)	Average Maximum Value (mg/100g)
Wheat flour	305	6.31	2.8	1.99	13.63
Corn flour	86	5.28	4.46	1.41	21.00

Table 1: *Descriptive analysis of the iron content results in wheat and corn flour samples.*

Given the high variability in iron levels observed and considering that food fortification programs must also address other health-related aspects, and that Ordinance 31/1998 [13] establishes that the nutrient added to food must be at a concentration that does not result in insignificant or excessive intake, a recommendation to the competent authorities for the establishment of a maximum limit became essential [11,12].

The observed variation in iron concentration in the analyzed samples is likely due to the difficulties faced by mills in adapting the fortification procedure. One of the main factors contributing to this variability is related to the adjustment of the flow rate for the addition and homogenization of micronutrient mixtures [14,15], which requires corrective measures.

According to the results in table 2, of the 391 samples analyzed, 70.1% comply with the 2002 legislation [10] and are therefore considered satisfactory, as they presented a minimum iron content of 4.2 mg/100g. However, when the samples are analyzed according to the 2022 legislation [12], only 62.4% comply with the regulation, which establishes a concentration range of 4.0 to 9.0 mg of iron. This suggests that the fortification process used by industries has flaws, as evidenced by the decrease in the percentage of samples in compliance with the current legislation.

Year	2007	2008	2009	2010	2013	2014	2015	2016	2017
No. of samples analyzed	69	37	60	38	42	45	40	34	26
Compliance with Regulation 344/2002	57	29	49	32	23	30	21	19	14
%	82,6	78,4	81,7	84,2	54,8	66,7	52,5	55,9	53,8
Compliance with Regulation 604/2022	48	22	45	32	22	26	19	18	12
%	69,6	59,5	75,0	84,2	52,4	57,8	47,5	52,9	46,1

Table 2: *Number of samples analyzed per year and compliance with regulations 344/2002 [10] and 604/2022 [12].*

To find feasible solutions for improving the quality of fortified products, the Interinstitutional Committee for supplementation, monitoring, and evaluation of wheat and corn flour fortification actions and their by-products proposed in 2011 [11], a joint action between the Brazilian Wheat Industry Association and the mills to address production process failures. Another issue requiring attention was that about 70% of companies in recent years used reduced iron in food fortification due to its lower cost compared to other forms, as revealed by a survey by the Brazilian Wheat Industry Association and data published in the report of the Working Group created by Anvisa in 2012 [16], to revise RDC No. 344/2002 [10]. Although economically more viable, reduced iron has low bioavailability, negatively impacting the fortification program's results [11].

Thus, on April 13, 2017, Anvisa issued RDC No. 150 [11], which revoked RDC 344/2002 [10]. The new regulation aimed to adjust the fortification limits for flours, establishing the minimum and maximum iron levels to be added and specifying which iron compounds would be permitted. It was agreed that only ferrous sulfate, ferrous fumarate, and their encapsulated forms could be used, considering their bioavailability. This new RDC will come into effect after two years.

Analyzing the results (Table 3), we observe that 37.6% of the analyzed samples do not fall within the iron concentration range established by RDC No. 150/2017 [11], which prompts reflection on the relevance of the legislation. The regulation aims to prevent excessive iron exposure, avoiding the onset of diseases caused by increased oxidative processes [17] common in reactions involving the mineral, and also ensures that products contain the minimum stipulated iron values.

Product	No. of Samples Analyzed	Satisfactory	Unsatisfactory
Wheat flour	305	213 (69,8%)	92 (30,1%)
Corn flour	86	31 (36%)	55 (64%)
Total	391	244 (62,4%)	147 (37,6%)

Table 3: *Percentage of satisfactory and unsatisfactory samples according to RDC 150/2017 [11].*

Thus, the present study highlights the importance of maintaining monitoring programs not only in Minas Gerais (BRAZIL) but throughout the country, as a tool to guide producers to comply with the legislation and as a means of inspecting and controlling food products consumed by the population.

Compliance with legislation and the importance of fortification monitoring

Ensuring compliance with fortification legislation is crucial for public health, particularly in addressing micronutrient deficiencies. Iron fortification of staple foods, such as wheat flour and cornmeal, has been a key strategy to combat iron deficiency anemia, which remains a significant public health concern globally. However, the effectiveness of these fortification programs relies heavily on consistent monitoring and adherence to established guidelines.

Recent studies emphasize that irregularities in fortification levels can diminish the intended health benefits, potentially leading to either insufficient or excessive iron intake among the population. For example, research by Manzoor., *et al*. [18] highlights that inadequate control in fortification processes can result in significant variations in nutrient content, which may not meet the recommended dietary allowances (RDAs) set by health authorities.

Study by Cardoso., *et al*. [19] aimed to describe the prevalence and predictors of childhood anemia in an Amazonian population-based birth cohort. The research estimated the prevalence of maternal anemia at childbirth and in their children at one, two, and five years of age. Additionally, ferritin, soluble transferrin receptor, and C-reactive protein concentrations were measured in mothers at childbirth and in their children at ages one and two to estimate the prevalence of iron deficiency and its contribution to anemia, adjusting for potential confounders using Poisson regression analysis. Results showed that maternal anemia, iron deficiency, and iron-deficiency anemia were present at childbirth. At one year of age, a significant proportion of the children were anemic, iron deficient, or had iron-deficiency anemia. These rates decreased at two years of age, and by five years of age, only a small percentage were anemic. Iron deficiency and consumption of ultra-processed foods were significant contributors to anemia at one year, after adjusting for maternal education. At two years, anemia was significantly associated with maternal anemia at childbirth, malaria since birth, and iron deficiency, after adjusting for child age and family wealth index. The findings highlight that anemia remains highly prevalent during pregnancy and early childhood in the Amazon. Public health policies should address iron deficiency, consumption of ultra-processed foods, maternal anemia, and malaria to prevent and treat anemia in Amazonian children.

Moreover, a study by Olson and colleagues [20] points out that effective monitoring and enforcement of fortification standards are essential for maintaining public trust in these programs. They argue that robust monitoring systems not only ensure compliance but also provide valuable data for assessing the impact of fortification on public health outcomes. This is particularly relevant in regions like Minas Gerais, where ongoing surveillance of food fortification is necessary to adjust strategies and address any discrepancies in nutrient levels.

In addition, the role of government agencies and public health institutions in maintaining these monitoring programs cannot be overstated. They play a critical role in ensuring that fortification policies are uniformly implemented across different regions, thereby reducing disparities in nutrient intake and contributing to the overall effectiveness of public health interventions.

The evidence suggests that continuous monitoring of fortified foods is essential not only for legal compliance but also for optimizing public health benefits. Therefore, maintaining and enhancing food monitoring programs, particularly in regions with diverse food production and consumption patterns, remains a priority for ensuring the success of fortification initiatives and improving population health.

The wide variation in iron content in the samples analyzed from 2007 to 2017 (0.90 to 31.80 mg/100g for wheat flour and 0.60 to 34.98 mg/100g for cornmeal) highlights the lack of adequate control in the iron fortification process. Of the 391 samples analyzed, 37.6% were found to be non-compliant with the current legislation (4.0 to 9.0 mg/100g of iron). When considering the previous legislation, which is still in effect and establishes a minimum concentration of 4.2 mg/100g of iron, only 29.9% of the samples were non-compliant. This difference in percentages underscores the critical importance of effective inspection, which promotes the standardization of fortification across the country. The situation justifies the importance of maintaining food monitoring programs in the state of Minas Gerais, not only as a strategy for verifying compliance with legislation but also as a guide for reflecting on and evaluating the impact on the population and potential changes.

Additionally, understanding the effectiveness of the fortification strategy can guide future interventions and policy adjustments. Possible future interventions could include:

1. **Enhanced quality control**: Implementing more rigorous quality control measures throughout the production and distribution processes to ensure consistent fortification levels in food products.
2. **Regular monitoring and evaluation**: Increasing the frequency and scope of monitoring and evaluation efforts to better assess the impact of fortification programs and ensure compliance with established standards.
3. **Public awareness campaigns**: Conducting public awareness campaigns to educate consumers about the importance of fortified foods and how to identify compliant products.
4. **Policy refinement**: Revisiting and refining fortification policies to address any identified gaps or inconsistencies, and adjusting nutrient levels as needed based on updated research and public health data.

5. **Support for affected populations**: Providing additional support and targeted interventions for vulnerable populations who may not benefit adequately from current fortification efforts, such as low-income or remote communities.
6. **Research and innovation**: Investing in research and innovation to explore new fortification techniques and formulations that could improve nutrient bioavailability and overall effectiveness.

By implementing these interventions, policymakers can enhance the effectiveness of fortification programs and better address nutritional deficiencies across the population.

Conclusion

The significant variation in iron content among the samples analyzed from 2007 to 2017 highlights the inadequacy of control in the iron fortification process. Many samples were found to be non-compliant with current regulations, and this issue persists even when considering previous regulations. This variation underscores the critical need for effective oversight to ensure consistent fortification practices across the country. The situation emphasizes the importance of maintaining food monitoring programs in Minas Gerais, not only as a means of verifying regulatory compliance but also as a tool for assessing public health impact and guiding potential improvements.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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