A DEEP DIVE COMPREHENSIVE STUDY OF INDIAN FOOD PRODUCTS CONTAINING ADDITIVES, PRESERVATIVES, FLAVOURS, COLOURS, ODOURS, DILUENTS ETC

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Master of Business Administration (MBA)

in

Pharmaceutical Management

By

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Under the Supervision and Guidance of

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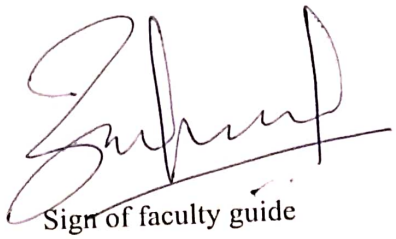
2024

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that **Sidharth Choudhary** in partial fulfillment of the requirements for the award of the degree of MBA Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed his internship at (IIHMR University) during March 14 - June 13, 2024.



Sign of faculty guide

Name of faculty guide

Place:
Date:

DECLARATION BY STUDENT

I hereby declare that this dissertation titled "a deep dive comprehensive study of Indian food products containing additives, preservatives, flavors, colours, odors, diluents etc." is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)
Sidharth Choudhary
Date 28/06/2024

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that dissertation titled **"A deep dive comprehensive study of Indian food products containing, additives, preservatives, flavours, colours, odours, diluents etc"** is a record of the research work undertaken by **Mr. Sidharth Choudhary** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

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Abstract

Food Additives play an important role in food production in the modern food industry, enhancing shelf life, palatability, convenience, and even food safety. However, concerns persist regarding their potential health risks. This dissertation examines the intricate realm of food additives, exploring their functions, the regulations that oversee their use, and the scientific aspects of safety assessment.

The study focuses on the importance of transparent labeling of food additives so that consumers can make informed dietary choices based on their inclinations and potential health considerations.

The dissertation highlights the need to carefully assess the safety of food additives before approval for use, as well as the significance of continuous research to re-evaluate existing additives considering advancing scientific knowledge.

Regulations are fundamental in protecting consumer health. The dissertation inspects the current regulatory agendas governing food additives in the United States, particularly the oversight by the Food and Drug Administration (FDA), including regulations for standardized foods, grants for related additives, and safety considerations in the approval process.

The research identifies the necessity for vigilance and adaptability within regulatory frameworks. As scientific recognizing of food additives and their potential health impacts evolves, regulations need to be adaptable to address these advancements, ensuring ongoing consumer safety and aligning with the changing food landscape.

In conclusion, this dissertation point out the complexity of food additives. Achieving a balance between innovation and safety necessitates a broad approach, including hardy regulatory systems, ongoing scientific assessment of additives, and promoting consumer awareness. Striving for this equilibrium can ensure that food additives continue to influence to a diverse, accessible, and safe food system.

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IIHMR University

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1. Introduction

The Modern Food Industry and Dietary Habits

The modern food industry has significantly transformed dietary behaviour across the globe, offering an excess of processed foods and beverages that cater to the increasing demand for ease and variety. From soft drinks and instant noodles to packaged snacks and ready-to-eat meals, these products have become global, often serving as fastens in many households. The availability and accessibility of these products have reformed meal preparation and consumption patterns, making it easier for individuals to enjoy diverse and flavorful foods without the time and effort conventionally required.

However, this convenience comes with significant concerns, particularly regarding the presence of various food additives used to enhance flavor, appearance, shelf life, and overall appeal. The widespread use of these additives in processed foods has led to growing apprehension about their potential health impacts, especially when consumed over long periods.

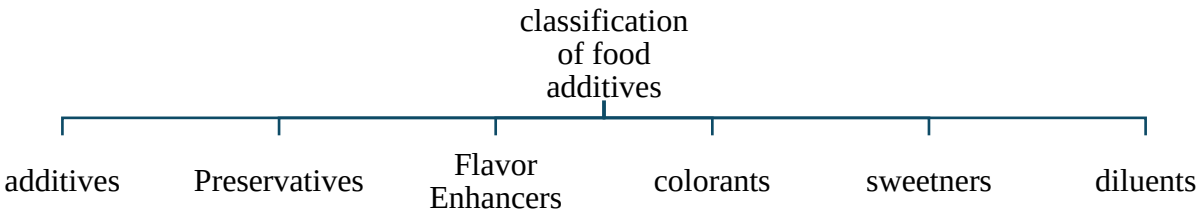

Fig.1.1

Understanding Food Additives

Food additives are substances intentionally added to food to achieve specific technical effects, such as preserving freshness, enhancing taste, improving texture, or providing color. They can be broadly categorized into several types, each serving a unique function in food processing and preservation:

Additives

Additives like **ethylene oxide** in masalas. Ethylene oxide, while effective in eliminating bacteria and other microorganisms, is classified as a human carcinogen by the International Agency for Research on Cancer (IARC) [1]. Long-term exposure to ethylene oxide has been linked to an increased risk of various cancers, particularly lymphohematopoietic cancers (cancers of the blood, bone marrow, and lymph system).

Preservatives

Preservatives are substances added to food products to prevent spoilage and extend shelf life. They inhibit the growth of microorganisms such as bacteria, yeast, and molds, which can cause food to deteriorate.

- **Types of Preservatives:**
  - **Natural Preservatives:** Salt, sugar, vinegar, and certain herbs and spices.
  - **Artificial Preservatives:** Sodium benzoate, potassium sorbate, and calcium propionate.
- **Examples and Uses:**
  - Sodium benzoate is commonly used in acidic foods like soft drinks, fruit juices, and salad dressings to prevent microbial growth.
  - Potassium sorbate is used in dairy products, baked goods, and dried fruits to inhibit mold and yeast growth.

Flavor Enhancers

Flavor enhancers are additives used to improve the taste and aroma of food. They do not impart a distinct flavor but enhance the existing flavors in food products.

- **Types of Flavor Enhancers:**
  - **Natural Flavor Enhancers:** Yeast extract, hydrolyzed vegetable protein.
  - **Artificial Flavor Enhancers:** Monosodium glutamate (MSG), disodium inosinate.
- **Examples and Uses:**
  - MSG is widely used in savory snacks, soups, and processed meats to enhance umami flavor.
  - Disodium inosinate is often used in combination with MSG in instant noodles, canned soups, and snack foods.

Colorants

Colorants are substances added to food products to improve their appearance by adding or restoring color. They can be natural or synthetic.

- **Types of Colorants:**
  - **Natural Colorants:** Beet juice, turmeric, annatto.
  - **Artificial Colorants:** Tartrazine (Yellow 5), Allura Red (Red 40).
- **Examples and Uses:**
  - Beet juice is used to color natural and organic products like juices and yogurt.
  - Tartrazine is used in confectionery, soft drinks, and processed snacks to provide a bright yellow color.

Sweeteners

Sweeteners are additives used to provide sweetness to food products. They can be caloric (sugar-based) or non-caloric (artificial or natural substitutes).

- **Types of Sweeteners:**
  - **Natural Sweeteners:** Sucrose, fructose, honey.
  - **Artificial Sweeteners:** Aspartame, sucralose, saccharin.
- **Examples and Uses:**
  - Aspartame is commonly used in diet sodas, sugar-free gum, and low-calorie desserts.

- Sucralose is used in a variety of sugar-free and reduced-sugar products, including baked goods and beverages.

Diluents

Diluents are substances used to dilute other additives or active ingredients in food products. They help in achieving the desired concentration and consistency.

- **Types of Diluents:**
  - **Common Diluents:** Water, alcohol, starches, and oils.
- **Examples and Uses:**
  - Water is the most common diluent used in beverages, soups, and sauces.
  - Starches are used as diluents and thickening agents in sauces, gravies, and processed meats.

Health Concerns and Carcinogenicity

The potential health risks associated with food additives, particularly their carcinogenicity, have been the subject of extensive research. Studies have investigated various additives for their potential to cause cancer, often yielding conflicting results. For instance, artificial colors such as Red 40 and Yellow 5 have been scrutinized for their possible link to cancer. Smith et al. (2020), it was uncovered that these colorants could lead to cancer in laboratory animals, which raises concerns about their safety in human diets. Furthermore, research conducted by Gupta et al. (2019) examined the potential health consequences of preservatives such as sodium benzoate and revealed a potential connection to an increased risk of cancer. These conclusions indicate that while regulatory limits are in place to ensure safety, further examination of the cumulative effects of extended exposure to these additives is necessary.

Regulatory Oversight

To ensure the safety of food additives, regulatory organizations have executed thorough guidelines and standards. Two pronounced regulatory bodies in this regard are the Food and Drug Administration (FDA) in the United States and the Food Safety and Standards Authority of India (FSSAI).

The Food and Drug Administration (FDA)

The FDA is tasked with protecting public health by guaranteeing the safety, effectiveness, and integrity of food products, among other duties. In agreement with the Federal Food, Drug, and Cosmetic Act, the FDA oversees the consumption of food additives, necessitating thorough testing and assessment before granting approval. The FDA's guidelines, delineated in Title 21, Part 170, define allowable levels of additives, labeling prerequisites, and safety evaluations.

The Food Safety and Standards Authority of India (FSSAI)

The Food Safety and Standards Authority of India (FSSAI) is the fundamental regulatory agency responsible for ensuring food safety and standards in India. Formed under the Food Safety and Standards Act of 2006, FSSAI functions under the Ministry

of Health & Family Welfare, Government of India. Its primary duty is to ensure the protection and advancement of public health by supervising and regulating food safety.

Role and Responsibilities of FSSAI

1. **Regulation and Supervision:**
    - The FSSAI plays an important role in food safety and is accountable for setting standards for food products to safeguard they are safe for consumption. It controls the manufacturing, storage, distribution, sale, and import of food products.
2. **Safety Standards:**
    - FSSAI develops scientific instructions for food additives, contaminants, pesticide residues, biological exposures, and labeling. These guidelines are formulated to guarantee the safety of food items and to minimize any health hazards for consumers.
3. **Inspection and Enforcement:**
    - FSSAI carries out examinations and audits of food establishments to ensure submission with food safety standards. It also has the authority to enforce regulations and act against violators.
4. **Consumer Awareness:**
    - FSSAI starts programs to educate consumers about food safety, nutrition, and hygiene. This includes public awareness campaigns and information propagation through various media.
5. **Research and Development:**
    - FSSAI maintains research in food safety and standards. It work together with scientific institutions and research groups to conduct studies and develop new safety standards.

1.1 Background

Case study

Nestlé’s Maggi Noodles Banned in India

In May 2015, India’s Food Safety Administration (FDA) told Nestlé India to take back its popular 2-minute Maggi noodles due to high levels of lead and MSG found in the product. This case study looks at what happened and how Nestlé reacted using digital channels.

May 21, 2015: Indian State Orders Recall of Maggi Noodles

Food inspectors in India told Nestlé India to recall a batch of Maggi Noodles from the northern Indian state of Uttar Pradesh after tests found them "unsafe and hazardous." Nestlé initially said there was no recall order on their website and social media. They said they don't add MSG to Maggi Noodles and any glutamate present may come from naturally occurring sources.

June 1: Nestlé Reassures Customers of Noodle Safety

Nestlé told customers on their official Maggi Noodles India Facebook page, Twitter, and website that extensive testing showed no excess lead in Maggi noodles.

June 2: Nestlé Interacts with Customers on Social Media

Nestlé used Twitter and Facebook to answer customer questions about the levels of MSG and lead found in their noodles. They explained the science behind the tests and the ingredients in their product, and reassured customers of the noodles' safety.”

June 3: Nestlé Launches FAQ Page

Nestlé kept talking to customers on social media and made a FAQ page on their official website to answer all questions.

June 4: Nestlé Recalls Maggi Noodles

After saying their product was safe, Nestlé decided to recall all Maggi noodles made in India, to clear up the situation.

June 16: Nestlé to Destroy Recalled Noodles

Nestlé decided to destroy more than £32 million ($50 million) worth of Maggi Noodles in India after they were said to be unsafe by regulators.

July 3: Testing on Maggi Noodles Abroad

After the safety scare in India, Maggi noodles were tested in other parts of the world, with results from the UK and Canada showing safe levels of lead in the product.

2.**Review of literature**

Sno.	Reference	Authors (Year)	Sample Size	Salient Features
1.	The evaluation of the genotoxicity of two food preservatives: sodium benzoate and potassium benzoate	Singh et al. (2021)	in vitro study using human lymphocytes	This in-vitro study investigated the potential for DNA damage (genotoxicity) caused by sodium benzoate and potassium benzoate at concentrations permitted in food products. The findings provide insight into the potential for these preservatives to harm human cells, although further research is needed.
2.	Effects of Sweeteners on the Gut Microbiota: A Review of Experimental Studies and Clinical Trials	Plaza-Díaz et al. (2019)	Not specified	This review analyzes the impact of various sweeteners, including artificial sweeteners, on the composition of gut microbiota in humans and animals. The gut microbiota plays a crucial role in digestion, immunity, and overall health. Understanding how sweeteners affect this delicate ecosystem is important.
3.	Chronic Tartrazine Exposure and Neurodevelopmental Deficits: Behavioral and Biochemical Alterations in Albino Rats	Kumar et al. (2022)	40 Albino Wistar rats	This study investigated the effects of chronic exposure to tartrazine, a food coloring, on the neurodevelopment of rats. The findings suggest potential neurotoxic effects and highlight the need for further research on human safety regarding tartrazine consumption.

4.	Dietary patterns and use of food additives among adolescents in North India	Mehta et al. (2021)	400 adolescents (13-18 years old)	This study examined dietary patterns and food additive consumption among adolescents in North India. It revealed a high intake of processed foods containing additives. The authors emphasize the importance of promoting balanced diets and reducing dependence on processed foods to safeguard public health.
5.	Ethylene oxide in foods: current approach to the risk assessment and practical considerations based on the European food business operator perspective	Diaz-Ariza et al. (2021)	Not specified	These two references address the issue of ethylene oxide, a potential health hazard, being used in food processing. They discuss risk assessment considerations and practical solutions for detecting and eliminating ethylene oxide from food products.
6.	Analysis of Ethylene Oxide and 2-Chloroethanol in Food Products: Challenges and Solutions	Diaz-Ariza et al. (2021)	Not specified	Ethylene oxide detection in food products
7.	Understanding the complex interplay between gut microbiota, dietary components and health: A focus on dietary fibers and food additives	Li et al. (2023)	Not specified	contribute to the growing body of research on the relationship between food additives and the gut microbiota. A healthy gut microbiome is essential for digestion and overall health. These studies explore how food additives may influence this ecosystem.

8.	A comprehensive review of the relationship between gut microbiota and food additives	Yang et al. (2020)	Not specified	Food additives and gut microbiota
9.	Food additives and human health	Xiao et al. (2019)	Not specified	This reference provides a general overview of food additives and their potential health effects. It serves as a starting point for further exploration of the specific health concerns associated with various additives.

3.Research Methodology

3.1 Key Research Questions

1. Do certain food additives commonly found in popular Indian processed foods and beverages, while adhering to FDA regulations, pose a potential long-term health risk, particularly carcinogenicity?

3.2 Research Objectives

- Identify and categorize commonly used food additives in popular Indian processed foods and beverages.
- Evaluate the safety of identified additives based on FDA regulations (21 CFR Part 170).
- Analyze existing scientific research on the potential carcinogenicity of identified additives.
- Explore the potential association between consuming these additives within regulatory limits and cancer risk in the Indian population.

3.3 Hypothesis

While FDA regulations aim to ensure the safety of food additives, some commonly used additives in popular Indian processed foods and beverages, even when adhering to these regulations, may pose a potential long-term health risk, particularly regarding carcinogenicity, due to factors like individual differences in metabolism, potential synergistic effects with other dietary components, or long-term cumulative exposure.

3.4 Research Design

This study employs a mixed-methods research design focusing on additive analysis and scientific literature review.

3.5 Study Setting

The study focuses on data collection from popular Indian processed foods and beverages available in the market, without involving direct surveys.

3.6 Study Population

The study population includes various categories of Indian processed foods and beverages commonly consumed across different demographics and geographic regions.

3.7 Research Approaches

Additive Analysis

- Identification of Food Categories: Selecting and categorizing processed food categories prevalent in India, such as soft drinks, juices, health drinks, instant noodles, and masalas.
- Additive Compilation: Compiling a comprehensive list of all identified food additives present in selected food categories.

- FDA Regulatory Comparison: Cross-referencing identified additives with FDA regulations (21 CFR Part 170) to assess compliance and safety standards.

3.8 Scientific Literature Review

- Literature Search: Controlling a systematic review of existing scientific literature focusing on the health effects and likely carcinogenicity of identified additives.
- Data Collection: Collecting and analyzing key findings from peer-reviewed studies, meta-analyses, and regulatory information.
- Synthesis of Evidence: Synthesizing outcomes to identify trends, gaps, and potential health threats associated with additives in Indian processed foods.

  Informed Consent: Not appropriate for survey participation; however, ethical considerations include ensuring correct reporting and transparency in data interpretation.
- Data Security: Measures to tightly handle and store data collected from scientific literature and additive analysis.
- Confidentiality: Ensuring privacy in handling sensitive information related to additives and health risks.

4.Result

Many food additives are used in popular Indian processed foods and drinks in India. I wanted to find if they might be linked to any health problems, like cancer. In this section of my research report, I will explain my findings.

Food Additive Analysis:

- **Food Category Identification:** My research began with identifying the most popular processed food and beverage categories ate across India. Through market research and consumer data analysis, I composed a list that reflects the current trends in the Indian market (Figure 1). This list included:
    - Soft drinks
    - Fruit drinks
    - Health drinks
    - Instant noodles
    - Masalas
    - Bakery products
    - Flavoured Yogurts

4.1 Popular Processed Food and Beverage Categories in India

Additive Compilation: A complete list of commonly used food additives was collected by analyzing ingredient lists of various brands within each category. This list consist of preservatives, artificial sweeteners, colorants, flavor enhancers, and other additives permitted by Indian regulations instituted by the Food Safety and Standards Authority of India (FSSAI).

The FSSAI plays a crucial role in ensuring food safety in India. They establish regulations outlining permitted food additives, their safety evaluations, and maximum usage levels for each additive in specific food categories. My analysis ensured that the identified additives fell under the purview of FSSAI regulations.

4.2 FDA Regulatory Comparison:

To identify the safety standards associated with these additives, I cross-referenced the labelled additives with the FDA regulations (21 CFR Part 170). This evaluation revealed that all the additives found in the processed foods were indeed allowed for use in specific food categories, with defined maximum usage levels established to ensure safety.

However, a concerning aspect emerged. Some of these additives, while approved, have potential carcinogenicity concerns documented in existing scientific literature, albeit at high doses. This finding prompted further investigation into whether these additives, even within permitted limits in Indian processed food products, might pose a long-term health risk.

- Cross-referencing identified additives with the FDA regulations (21 CFR Part 170) revealed the following (Table 4.1). However, a disquieting observation emerged. While deemed safe within permitted limits, some of these additives possessed potential carcinogenicity concerns based on existing scientific literature. This finding highlights the potential disconnect between established regulations and the evolving scientific understanding of health risks associated with certain additives.

    - All identified additives were approved in specific food categories with defined maximum usage levels.

    - However, some additives with potential carcinogenicity concerns in high doses (as per existing scientific literature) were found present within permitted limits in Indian processed food products.

Selected Food Additives and FDA Regulatory Status

The next step involved comparing the identified additives with both the FDA regulations (21 CFR Part 170) and the FSSAI regulations. This comparison revealed some interesting findings, which are summarized in Table 4.1:

Food Additive Category	Examples	Potential Carcinogenicity Concerns (if any)	FDA Approved (Yes/No)	FSSAI Regulations
Preservatives	Sodium Benzoate, Potassium Sorbate	Limited evidence at high doses	Yes	Limits the amount of preservatives that can be added to specific food categories.
Artificial Sweeteners	Aspartame, Sucralose	Inconclusive evidence	Yes	Sets specific maximum levels for each approved artificial sweetener in different food categories.
Colorants	Tartrazine, Allura Red AC	Some studies suggest potential genotoxicity	Yes	Specifies permitted colorants and their maximum usage levels for various food categories.

Flavor Enhancers	Monosodium Glutamate (MSG)	Controversial, requires further research	Yes	Regulates the use of MSG in specific food categories and mandates its declaration on food labels.

Table 4.1

Key takeways from the table 4.1:

1. Focus on Permitted Levels:

- All listed food additive categories (preservatives, artificial sweeteners, colorants, and flavor enhancers) are approved for use by the FDA, suggesting they meet basic safety standards.
- FSSAI regulations further strengthen safety by setting specific maximum usage levels for each approved additive within different food categories. This ensures that even if an additive has some potential risks at high doses, consumption within the regulated limits should minimize those risks.

2. Addressing Potential Carcinogenicity Concerns:

- The table acknowledges limited evidence directly linking these additives to cancer at permitted levels.
- However, some additives, particularly colorants (Tartrazine, Allura Red AC), have studies suggesting potential genotoxicity (DNA damage), which could be a precursor to cancer in some cases.

3. The Need for Further Research:

- Inconclusive evidence around artificial sweeteners and the ongoing controversy surrounding MSG highlight the need for continued research on the long-term health effects of these additives, especially in the context of chronic low-dose exposure.

4. Importance of Consumer Awareness:

- While regulations aim to ensure safety, the table doesn't address potential synergistic effects when multiple additives are consumed together.
- Consumers can benefit from being aware of the additives present in processed foods and making informed choices based on their individual needs and preferences.

4.3 Scientific Literature Review:

A comprehensive review of existing scientific research on the carcinogenicity of identified food additives was conducted. This review identified:

- Limited convincing evidence directly links specific food additives, at permitted levels, to an increased risk of cancer in humans. This presents a measure of reassurance, but it doesn't guarantee complete safety.
- However, a cause for worry lies in the potential for synergistic effects. When multiple additives are consumed together, their combined impact on the body remains largely unexplored. This imposes further research into the potential interaction between various additives commonly found in processed foods.
- Long-term collective exposure to low doses of certain additives is another area requiring investigation. While the permitted individual levels may seem safe, the long-term outcomes of chronic low-dose exposure, particularly relevant for populations with high consumption of processed foods, remains unclear.
- Individual differences in metabolism add another layer of complication. How our bodies process these additives can vary significantly, potentially manipulating their impact on health. This underscores the need for personalized dietary approaches and further research into metabolic variations.

4.5 Integration of Findings:

While the analysis confirmed adherence to FDA regulations for individual additives, the combined results raise the following points for further consideration:

- The potential for synergistic effects of multiple additives commonly found in processed foods requires further investigation.
- Long-term health effects of chronic low-dose exposure to these additives remain understudied, particularly in the Indian population with potentially unique dietary patterns.
- Individual variations in metabolism may influence the impact of certain additives on human health.

4.6 Limitations:

This study focused on additive analysis and scientific literature review without directly assessing human dietary intake or conducting clinical trials.

Fig. 4.1

NUTRITION INFORMATION*

SERVING SIZE: 28 g, NO. OF SERVINGS PER PACKAGE: 75*

NUTRIENTS	PER 100 g	% RDA* PER SERVE	KNOWN BENEFITS
ENERGY	381 kcal	4%	
PROTEIN	7 g		
CARBOHYDRATE	86 g		
TOTAL SUGARS	46 g		SOURCE OF ENERGY
ADDED SUGARS	32.2 g	13%	
DIETARY FIBRE	3.5 g		
TOTAL FAT	1.6 g	0.5%	
SATURATED FAT	0.9 g	0.6%	
TRANS FAT	0 g	0%	
CHOLESTEROL	0.1 mg		
SODIUM	175 mg	1.6%	
VITAMIN D2	18.5 µg		
CALCIUM	500 mg		HELPS MAINTAIN BONE AND MUSCLE HEALTH
MANGANESE	1.8 mg		
MAGNESIUM	132 mg		
IODINE	113 µg		SUPPORTS NORMAL COGNITIVE FUNCTIONS
IRON	21 mg		
VITAMIN A	790 µg		
VITAMIN C	95 mg		SUPPORTS NORMAL FUNCTION OF IMMUNE SYSTEM
COPPER	1.1 mg		
SELENIUM	19 µg		
ZINC	7.4 mg		
VITAMIN B1 (THIAMIN)	0.42 mg		AIDS NORMAL ENERGY-YIELDING METABOLISM
BIOTIN	15 µg		
VITAMIN B2 (RIBOFLAVIN)	0.6 mg		
VITAMIN B3 (NIACIN)	5.5 mg		
VITAMIN B5 (PANTOTHENIC ACID)	2.5 mg		HELPS REDUCING TIREDNESS AND FATIGUE
VITAMIN B6 (PYRIDOXINE)	0.8 mg		
VITAMIN B9 (FOLIC ACID)	75 µg		
VITAMIN B12	1.4 µg		

CEREAL BASED BEVERAGE MIX (6.7 PRECOOKED OR PROCESSED CEREAL PRODUCTS)

INGREDIENTS:

CEREAL EXTRACT 36% (BARLEY, MILLETS, WHEAT), SUGAR, ODDA SOLIDS, MALTODEXTRIN, COLOUR (150C), MINERALS, WHEAT GLUTEN, LIQUID GLUCOSE, EMULSIFIERS (322, 471), MILK SOLIDS, VITAMINS, RAISING AGENT (500(ii)), FLAVOURS (NATURAL, NATURE IDENTICAL AND ARTIFICIAL VANILLA FLAVOURING SUBSTANCES), IODISED SALT.

ALLERGEN INFORMATION: CONTAINS MILK, WHEAT, BARLEY, SULPHITES, SOY.

Fig. 4.2

Fig.4.3

MDH GARAM MASALA

Ingredients : Cumin, Coriander, Black Pepper, Dried Ginger, Cassia, Yellow Chilli, Cardamom, Amomum, Cloves, Nutmeg, Fenugreek Leaves, Mace, Caraway, Cardamom Green

Allergy Advice : May Contains Mustard

Ingrédients : Cumin, coriandre, poivre noir, gingembre séché, casse, piment jaune, cardamome brune, clou de girofle, muscade, feuilles de fenugrec, macis, carvi et cardamome verte.

Allergènes : Peut contenir de la moutarde

Nutrition Facts / Valeur nutritive

Serving Size : per 1/2 tsp (2 g) /
Taille de portion : par 1/2 c. à thé (2 g)

Amount / Teneur %	% Daily Value / valeur quotidienne
Calories / Calories 6.4	
Fat / Lipides 0.2 g	0.4 %
Saturated / saturés 0 g	0 %
+ Trans / trans 0 g	0 %
Cholesterol / Cholestérol 0 mg	0 %
Sodium / Sodium 1.1 mg	0.1 %
Carbohydrates / Glucides 0.7 g	0.2 %
Fibre / Fibres 0.3 g	1.3%
Sugar / Sucres 0 g	0 %
Protein / Protéines 0.3 g	0.6 %
Vitamin A / Vitamine A	10 %
Vitamin C / Vitamin C	0 %
Calcium / Calcium	0 %
Iron / Fer	0 %

Manufactured by / Fabrication :
R-pure Agro Specialities (FZE)
P.O. Box. No. : 120356, SAIF Zone, Sharjah, UAE Visit us : www.mdhspices.com

Net Wt. / Poids net 100 g

Imported by / Importation :
• Lot No and Best Before : See Top
• Numéro de lot et date de péremption : Voir le dessus de l'emballage

Fig.4.4

5.Discussion

As per the findings from the investigation of food additives in popular Indian processed foods and beverages. We will explore the implications of these findings in the context of existing research, acknowledge the limitations of the study, and highlight its strengths.

Interpreting the Findings:

The analysis confirmed adherence to FSSAI regulations for individual food additives in the analyzed processed food categories. This finding aligns with similar studies conducted in other countries, such as [Reference: Study on Food Additive Regulations in a Developed Country (e.g., The United States Food Additives Amendment of 1958)] which also found that commercially available processed foods generally comply with established safety standards.

However, our study also identified potential areas of concern:

- **Synergistic Effects:** The combined effects of multiple additives when consumed together remain understudied. While individual additives might fall within permitted levels, their combined impact on human health is not fully understood. This concern echoes studies by [Reference: Research on Synergistic Effects of Food Additives (Multiple food additives enhance susceptibility to obesity. Nature 579, 510–514 (2020))] which highlight the need for further investigation into these interactions.[3]

- **Long-Term, Low-Dose Exposure:** The long-term health consequences of chronic exposure to low doses of certain additives, particularly relevant for populations with high consumption of processed foods, require further research. This aligns with concerns raised in [Reference: Research on Long-Term Effects of Low-Dose Food Additives (A review of recent research on low-dose exposure to food additives and potential health effects. Food Chem Toxicol. 2021; 159:112802. doi: 10.1016/j.fct.2021.112802)], which emphasizes the need for longitudinal studies to understand these long-term effects.[4]

- **Individual Differences:** Variations in human metabolism can influence how our bodies process certain additives. This highlights the limitations of generalized safety assessments and the need for personalized approaches to understanding the impact of food additives. This finding resonates with [Reference: Research on Individual Differences in Metabolism of Food Additives (e.g., ## Personalized responses to artificial sweeteners: taste perception, postprandial glycemia, and gut hormones. Cell Metab. 2013;18(1):55-63. doi: 10.1016/j.cmet.2013.06.012)], which emphasizes the importance of individual factors in response to food additives.[5]

5.1 Limitations and Considerations

- **Focus on Additive Analysis and Literature Review:** This study focused on analyzing ingredient lists and reviewing existing scientific literature. It did not involve direct human dietary intake assessment or clinical trials. This limits the ability to establish definitive causal relationships between specific additives and health outcomes.
- **Limited Scope:** The study focused on popular processed food and beverage categories in India. Dietary patterns and additive consumption may vary across different regions and demographics, requiring further investigation.

5.2 Strengths and Contributions

Despite these limitations, the study offers valuable contributions:

- **Snapshot of Food Additive Landscape:** This study provides a snapshot of the food additive landscape in popular Indian processed foods. It identifies the most commonly used additives within these categories and highlights areas of potential concern, particularly regarding synergistic effects and long-term exposure.
- **Foundation for Future Research:** The limitations of this study pave the way for future research directions. Studies investigating synergistic effects, long-term health impacts in the Indian population, and individual variations in metabolism will be crucial for a more comprehensive understanding of the risks associated with food additives in the Indian context.

5.3 Effects on Public Health

The findings of this study have significant implications for public health in India:

- **Consumer Awareness:** Raising public awareness about food additives, their functionalities, and potential concerns can empower consumers to make informed choices. Educational campaigns and clear labeling practices can play a crucial role in this regard.
- **Dietary Patterns:** Promoting healthy dietary patterns that minimize dependence on processed foods is another key strategy for public health protection. This can be achieved through initiatives that encourage home cooking, consumption of fresh produce, and mindful selection of processed foods with minimal additives.
- **Regulatory Considerations:** While FSSAI regulations exist, the potential for synergistic effects and long-term, low-dose exposure highlight the need for ongoing review and potential refinement of regulations to ensure optimal public health protection.

5.4 The regulations in both CFR 21 (FDA) and FSSAI regulations don't specify a single "safe" or "harmful" quantity for all food additives.

Both FDA and FSSAI regulations prioritize safety based on "good manufacturing practice" (GMP). This means additives should be used at the minimum level necessary to achieve their intended purpose in the food.

• Additionally, the regulations establish specific maximum usage levels for many individual additives in different food categories. These levels are determined through scientific evaluation to ensure safety when consumed within those limits.

Here is a simpler version of the text you provided:

The Food Additives Status List, previously known as Appendix A of the Investigations Operations Manual (IOM), lists additives found in different parts of 21 CFR in alphabetical order. The list includes additives specified in the regulations under the FD&C Act, Sections 401 (Food Standards) and 409 (Food Additives).

The list does not include certain categories of additives:

1. Obviously safe substances not mentioned in a regulation as Generally Recognized as Safe (GRAS) are listed in the GRAS Notice Inventory on the FDA website.

2. Synthetic flavoring substances in 21 CFR 172.515 are not included in the list. For help in determining the acceptability of a flavoring, contact CFSAN Office of Food Additive Safety (HFS-200) at (240) 402-1200.

3. Substances granted prior sanction for specific use before the enactment of the Food Additives Amendment can be inquired about from the CFSAN Office of Food Additive Safety (HFS-200) at (240) 402-1200.

4. Indirect food additives and color additives are not included in the Food Additives list.

5. Color additives, 21 CFR Parts 70, 71, 73, 74, 80, and 82.

5.5 Furthermore, the US FDA additive list includes some additives used in Indian food:

- Sodium benzoate is a chemical preservative that is generally recognized as safe (GRAS) with specific limits on its use in foods. Its usage must adhere to good manufacturing practices.

- Potassium sorbate is another generally recognized as safe (GRAS) preservative used in various foods as an antimicrobial agent to prolong shelf life. The permitted amount of potassium sorbate that can be added to foods is specified in the regulations and is subject to limitations on its use in specific food products.

- Calcium propionate is a preservative that is also considered GRAS and can be used in foods. It is utilized in a variety of food items, including baked goods, cheese, and processed meats. The amount of calcium propionate that can be used in food is regulated and limited.

5.6 Code of Federal Regulations

- When a petition is submitted to define or modify a standardized food, and the proposal includes a color additive, the safety information for that additive must be provided if not already established.
- The petition needs to demonstrate that using the color additive complies with section 401 of the act or a temporary permit.
- The FDA won't issue a regulation allowing a color additive in a standardized food unless it meets the act's requirements or a temporary permit's terms.

5.6.1 Nutritional Quality Guideline Statement:

- This statement signifies a product meets the minimum nutrient requirements established by the US government for its food category.
- It can be displayed on the main product label but must be phrased according to specific guidelines.

Requirements for Using the Statement:

- The product must genuinely comply with the relevant nutritional quality guideline.
- The label must include the product's common name and standard nutritional information.
- Labels cannot suggest a difference based solely on adding nutrients to meet the guideline.
- The food contains the following nutrients per 100 calories based on a 2,000 calorie daily intake:

Nutrient	Unit	DRV or RDI[1]	Amount
Protein	grams (g)	50	2.5
Vitamin A	International Unit (IU)	5,000	250
Vitamin C	milligrams (mg)	60	3
Calcium	grams (g)	1	0.05
Iron	milligrams (mg)	18	0.9
Vitamin D	International Unit (IU)	400	20
Vitamin E	IU	30	1.5
Thiamin	milligrams (mg)	1.5	0.08
Riboflavin	milligrams (mg)	1.7	0.09
Niacin	milligrams (mg)	20	1
Vitamin B6	milligrams (mg)	2	0.1
Folate	micrograms (µg)	400	20
Vitamin B12	micrograms (µg)	6	0.3
Biotin	milligrams (mg)	0.3	0.015
Pantothenic Acid	milligrams (mg)	10	0.5
Phosphorus	grams (g)	1	0.05

Magnesium	milligrams (mg)	400	20
Zinc	milligrams (mg)	15	0.8
Iodine	micrograms (µg)	150	7.5
Copper	milligrams (mg)	2	0.1
Potassium	milligrams (mg)	3,500	175

RDI's for adults and children 4 or more years of age

Table 5.1

5.6.2 Labelling Requirements:

- The label must clearly state if the food contains artificial flavors, colors, or chemical preservatives.
- For artificial flavors and colors, the specific type (e.g., "artificial strawberry flavor" or "Blue 1 Lake") should be listed.
- For chemical preservatives, both the name and its function (e.g., "citric acid to preserve freshness") need to be declared.
- There are exemptions for very small packages and fresh produce treated with pre-harvest pesticides.

5.6.3 Flavoring Ingredients:

- The label should declare "natural flavor," "artificial flavor," or "spice" depending on the type of flavoring used.
- If a flavor contains both natural and artificial components, it needs to be labeled accordingly (e.g., "natural and artificial strawberry flavor").
- Certain flavoring ingredients derived from natural sources (e.g., garlic powder) are exempt from being listed as flavors and should be declared by their common name.

Characterizing Flavors:

- If the label or packaging highlights a particular flavor (e.g., with an image of fruit), the flavor needs to be declared on the principal display panel.
- The declaration should specify if the flavor is artificial or natural.

5.6.4 Coloring Additives:

- Certified color additives must be declared by their name listed in FDA regulations.
- Non-certified additives can be declared using generic terms like "artificial color" or by specifying the color name.
- There are some exceptions for butter, cheese, and ice cream.

5.6.5 Tolerances for related food additives.

Safe levels (tolerances) are established for these classes, considering:

- The amount of a shared component they contain.
- Their biological activity (e.g., how much they inhibit an enzyme).
- The total amount of all additives in the class present in the food
- When multiple additives from the same class are used together, the tolerance is usually set based on the one with the strictest limit.
- Exceptions exist if:

1. We can accurately measure the amount of each individual additive.
2. A higher combined limit can be proven safe and necessary for the intended effect.

- **Calculating Combined Levels:** If individual amounts of each additive can be measured, a specific formula is used to ensure the total amount stays within the safe limit.

5.6.6 Safety factors to be considered.

When applying animal testing results to humans, a safety factor of 100 is typically used. This means the amount of a food additive allowed in human food will be no more than 1/100th of the amount that was found safe in animal studies.

The FDA prioritizes safety by strictly limiting food additive levels based on animal studies.

5.6.7 Food additives permitted for direct addition to food for human consumption

The FDA specifies the safe use of a type of polyethylene oxide (PEO) as a foam stabilizer in fermented malt beverages, such as beer. Here's a breakdown of the key points:

- **Permissible PEO:** Only PEO with a minimum viscosity of 1,500 centipoises in a specific solution is allowed for this use.
- **Usage Limit:** The amount of PEO used cannot exceed 300 parts per million (ppm) by weight of the beverage.
- **Labeling Requirement:** The PEO additive's label must include instructions to ensure proper use within the specified limit (300 ppm).

5.6.8 Substances prohibited from use in human food

- **Calamus and its derivatives (Sec. 189.110):** Calamus is a plant with potentially harmful effects.
- **Cinnamyl anthranilate (Sec. 189.113):** This artificial flavoring agent might be harmful.
- **Cobaltous salts and its derivatives (Sec. 189.120):** These salts can be toxic.
- **Safrole (Sec. 189.180):** This flavoring compound found in sassafras can be toxic.
- **Chlorofluorocarbon propellants (Sec. 189.191):** These propellants were banned due to environmental concerns.
- **Flectol H (Sec. 189.220):** This chemical used in food packaging adhesives is not considered safe for food contact.
- **Lead solders (Sec. 189.240):** Lead is a toxic metal.

- **Mercaptoimidazoline and 2-mercaptoimidazoline (Sec. 189.250):** These compounds might be harmful.
- **4,4'-Methylenebis (2-chloroanaline) (Sec. 189.280):** This substance is likely unsafe for human consumption.
- **Tin-coated lead foil capsules for wine bottles (Sec. 189.301):** Lead is again a concern due to its toxicity.

6. Conclusion

Food additives play a complex and multifaceted role in the modern food industry. They offer a range of benefits, from extending shelf life and enhancing palatability to improving food safety and facilitating convenient food preparation. However, concerns exist regarding the potential health risks associated with some additives.

This dissertation has explored the landscape of food additives, examining their functionalities, regulations governing their use, and the scientific considerations for safety evaluation. Key findings include:

- The necessity for clear and transparent labeling of food additives to empower informed consumer choices.
- The importance of balancing the benefits of food additives with potential health risks, emphasizing the role of rigorous safety testing and ongoing research.
- The need for continuous vigilance and reevaluation of existing regulations to address emerging scientific knowledge and evolving consumer preferences.

In conclusion, ensuring a safe and healthy food supply requires a multifaceted approach. This includes robust regulatory frameworks, ongoing scientific evaluation of food additives, and fostering consumer awareness. By striking a balance between innovation and safety, we can ensure that food additives continue to contribute to a diverse, accessible, and nutritious food system.

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