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Safety and effectiveness of synthetic food preservatives in India: Toxicological implications and regulatory challenges

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ABSTRACT

The paper deals with the classification, industrial uses, permissible limits and toxicological effects of important food preservatives in Indian context highlighting sodium benzoate, sodium nitrite and sulphur dioxide. The study uses regulatory information from the Food Safety and Standards Authority of India (FSSAI), the Codex Alimentarius Commission and peer-reviewed literature to explore three surveillance-based case studies. Results show that, although preservatives have important antibacterial properties, some commodity chains are still dangerous to public health because of enforcement lapses and excesses. The recommendations are based on evidence.

Keywords: Food preservatives, sodium benzoate, sodium nitrite, sulphur dioxide, FSSAI, India, food safety, toxicology

Introduction

Food preservatives are the chemicals that are added to the food to prevent microbial growth, to retard oxidative spoilage and to prevent fermentation or acidification (CAC, 2021; FSSAI, 2011) [1, 2]. In India, preservatives play an important role in public health as post-harvest losses of grains are 4–8% and fruits and vegetables 5–16% (ICAR-CIPHET, 2015; NABCONS, 2022) [3, 4]. The economic liberalisation in the 1990s saw the packaged food market grow rapidly, bringing in synthetic Class II additives like sodium benzoate (INS 211), sodium nitrite (INS 250) and sulphur dioxide (INS 220). The market is now worth USD 121.3 billion (IMARC Group, 2024) [5]. At the same time, India is grappling with an increasing burden of NCDs with > 100 million people living with diabetes and 136 million with prediabetes (Anjana *et al.*, 2023) [6]. In 2022, about 0.87 million people died of cancer (ICMR-NCDIR, 2022) [7]. The temporal association warrants systematic investigation but no direct causation has been established. The present report reviews data on toxicological risk, regulatory framework and preservative efficacy in India.

Classification of food preservatives

Preservatives are classified into two categories as per FSSAI Regulations (2011) [2]. Class I (natural) preservatives include salt, sugar, vinegar, honey, spices and edible oils, and have been used safely for millennia with no maximum consumption restrictions. Class II (synthetic) preservatives, such as benzoates, sulphites, nitrites, sorbates, and propionates, are more powerful, strictly regulated, and limited to certain maximum permissible levels (MPLs) per food matrix. The simultaneous use of more than one Class II preservative in a single food product is generally prohibited (FSSAI, 2011) [2].

Methodology

The present research follows a systematic narrative review approach. The peer-reviewed content was searched from PubMed, *Scopus* and Google scholar (2000–2024) with the phrases “food preservatives India”, “sodium benzoate toxicology”, “sodium nitrite carcinogenicity”, and “sulphur dioxide food safety. Regulatory documents were collected from FSSAI (fssai.gov.in), Codex Alimentarius (fao.org) and WHO (who.int). Three case cases were chosen based on documented Indian surveillance evidence and public health significance.

Industrial usage and permissible limits

Table 1 summarises key Class II preservatives, their food applications, and regulatory limits per FSSAI (2011) [2] and JECFA (2021) [8].

Table 1. Class II preservatives: applications and regulatory limits. Sources: FSSAI (2011) [2]; JECFA (2021) [8].

Preservative (INS)	Primary Applications	FSSAI MPL	JECFA ADI
Sodium Benzoate (211)	Fruit juices, beverages, pickles, sauces	750 mg/kg	0–5 mg/kg bw/day
Sodium Nitrite (250)	Cured meats, sausages	125 mg/kg	0–0.07 mg/kg bw/day
Sulphur Dioxide (220)	Dried fruits, wines, dehydrated vegetables	2,000 mg/kg	0–0.7 mg/kg bw/day
Potassium Sorbate (202)	Bakery, cheese, beverages	1,000 mg/kg	0–25 mg/kg bw/day

Health implications and toxicological risks

Sodium Benzoate

Sodium benzoate is safe, approved at approved levels, as approved by FDA (GRAS) and FSSAI. However, it can also react with ascorbic acid in acidic beverages to form benzene, a known carcinogen (Gardner *et al.*, 1993) [9]. A large RCT published in The Lancet by McCann *et al.* (2007) [10] showed a strong association between artificial food colouring and sodium benzoate and increased hyperactivity in children, which led to an EFSA review (EFSA, 2016) [11]. Hypersensitivity reactions such as urticaria and asthma exacerbation have been reported in susceptible individuals (Nair, 2001) [12].

Sodium Nitrite

N-nitroso compounds (NOCs) are very powerful carcinogens and are formed when sodium nitrite reacts with amines, in the stomach environment (Santarelli *et al.*, 2008) [13]. The IARC (2015) [14] classified processed beef as carcinogenic to humans (Group 1) and ingested nitrite under endogenous nitrosation conditions as probably carcinogenic (Group 2A), mainly based on the risk of colorectal cancer (WHO, 2015) [15]. In 2023, a study showed that lowering the level of nitrite in processed beef resulted in a significant reduction in precancerous lesions in experimental mice (Luc *et al.*, 2023) [16].

Sulphur dioxide and sulphites

Between 5% and 10% of asthmatics are sensitive to SO₂ and sulphites and may experience adverse reactions ranging from bronchospasm to anaphylaxis (Vally *et al.*, 2012) [17]. Freedman (1980) [18] reports that even small amounts of SO₂ released from sulphite-containing foods result in bronchoconstriction in asthmatic patients. This basic finding has led to regulations in a number of jurisdictions requiring the disclosure of sulphites.

Case studies: Indian surveillance evidence

Case study 1: Sodium benzoate in packaged fruit juices (North India, 2022)

During 2022–2023, FSSAI monitoring identified 44,626 non-conforming samples out of the 1,77,511 samples analysed (FSSAI, 2023) [19]. Packaged fruit juices emerged as a common source of concern. State-level sampling in northern India identified batches exceeding the FSSAI maximum of 750 mg/kg of sodium benzoate (FSSAI, 2011) [2]. Such infractions reveal a systemic conflict: a lack of cold chain infrastructure incentivising the use of higher dosages of preservatives instead of refrigeration. Legal action was taken per Food Safety and Standards Act, 2006 and the products were withdrawn.

Case study 2: Sodium nitrite in processed meat (Urban India, 2021)

In urban markets, FSSAI surveillance during 2021–2022 revealed non-conformance in processed meat products, with some banger products having nitrite contents of 125 mg/kg or more (FSSAI, 2022) [20]. The health relevance is further supported by the IARC Group 1 classification and mechanistic evidence for endogenous formation of NOCs (Santarelli *et al.*, 2008) [13]. The research gap is the lack of a nationally representative epidemiological study in India that explicitly links the incidence of colorectal cancer to nitrite exposure from processed meat.

Case study 3: Sulphite use in dried fruits — Maharashtra grape industry

Nashik and Sangli districts of Maharashtra are important sultana producing areas. Pre-drying with potassium metabisulphite (INS 224) and SO₂ is common. APEDA's testing has rejected consignments exceeding the more stringent limit of EU (1,500 mg/kg) and India's domestic MPL (2,000 mg/kg) for export (APEDA, 2021) [21]. In the U.S., products that are poorly labelled continue to be a risk for people with asthma.

Results and Discussion

Three main findings are evident from this review. First, the food preservative regulatory system of India is comparable to international standards and sulphur dioxide, sodium benzoate and sodium nitrite are effective antimicrobials when used within the permitted limits. Secondly, non-compliance is common in fruit juices and processed meats, especially in small and informal businesses. Third, these additives pose a health risk to vulnerable groups, such as sulfite-sensitive asthmatics, hyperactive children, and regular consumers of processed meats. Despite improvements in FSSAI monitoring (samples tested increased from 1,07,829 in 2020–21 to over 4,51,000 in 2023–24) [22], low conviction rates and uneven laboratory capacity across states remain major challenges.

Recommendations

- Strengthened Enforcement: Prioritise targeted surveillance in fruit juices and processed meats with annual compliance reports.
- Standards Harmonisation: Review India's 2,000 mg/kg SO₂ limit against the EU's 1,500 mg/kg.
- Mandatory Labelling: Require sulphite labelling for products above 10 mg/kg SO₂ as per Codex standards.
- Exposure Research: ICMR should conduct a national study on preservative intake and NCD linkages.
- Natural Alternatives: Promote research on bacteriocins, essential oils, and modified atmosphere packaging.

Conclusion

Food preservatives are important tools to assure food safety, but they may present toxicological risks in cases of misuse or consumption by sensitive populations. These risks are not always well managed in India due to supply chain gaps, inconsistent regulatory enforcement and the rapid growth of the processed food sector. These three case studies reviewed here demonstrate the breadth and complexity of the issue. The way forward is stronger enforcement, better harmonisation of standards, focused research and a gradual shift to safer natural alternatives.

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