

Strategic and contested use of food laws to ban smokeless tobacco products in India: a qualitative analysis of litigation

Riddhi Dsouza, Upendra Bhojani 📵



► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi. org/10.1136/tobaccocontrol-2020-056241).

Cluster on Chronic Health Conditions & Public Policy, Institute of Public Health, Bengaluru, Karnataka, India

Correspondence to

Dr Upendra Bhojani, Institute of Public Health, Bengaluru, Karnataka 560070, India; upendra@iphindia.org

Received 21 September 2020 Accepted 23 July 2021 Published Online First 20 August 2021

ABSTRACT

Objective To understand how food laws are used. contested and interpreted to ban certain forms of chewing tobacco in India.

Methods A qualitative study analysing all the tobaccorelated litigation under the food laws in India. We used an inductive thematic analysis of the litigation contents. **Results** The tobacco industry systematically deployed litigation to (1) challenge the categorisation of smokeless tobacco products as food, and hence, questioned the use of food laws for regulating these products; (2) challenge the regulatory power of the state government in banning tobacco products via the food laws; and (3) challenge the applicability of the general food laws that enabled stricter regulations beyond what is prescribed under the tobacco-specific law.

Conclusion Despite facing several legal challenges from the tobacco industry, Indian states optimised food laws to enable stricter regulations on smokeless tobacco products than were feasible through use of a tobaccospecific law.

INTRODUCTION

India has the second largest number of tobacco users in the world, after China. Although the prevalence of smokeless tobacco use (21.4%) in India is twice that of smoked tobacco (10.7%), smokeless tobacco has received much less research and policy attention.^{2–4}

A 2012 policy analysis⁴ of smokeless tobacco demonstrated how a range of laws-concerning food, environment, pharmaceuticals, railways, consumer protection and media—have been used in India to regulate smokeless tobacco, in addition to the prevailing tobacco-specific law(s). It highlighted the distinct use of food laws by Indian states to ban certain smokeless tobacco products, especially gutka and pan masala.

This was possible because the notifications under the food laws-the Prevention of Food Adulteration Act 1954 (PFA), and later the Food Safety and Standards Act 2006 (FSSA) that replaced the former law—prohibited the use of tobacco and nicotine in food products.^{5 6} Although both laws were enacted by the national government, they were strategically administered by Indian states in the interest of public health. The tobacco industry challenged these regulations in courts, primarily arguing that gutka and pan masala are not food products, and hence cannot be regulated by the food laws. 4 While the notifications banning the chewing tobacco products under the PFA were dismantled on the

grounds that only the national government had the power to ban a product under the PFA, the latter notifications issued under the FSSA continue to enable stricter regulations.4

Despite challenges from the tobacco industry, Indian states leveraged the food laws to issue orders prohibiting manufacture and sale of various smokeless tobacco products in their jurisdictions (see online supplemental file 1 for details). Unfortunately, these orders have been fraught with legal challenges, and hence, litigation has been crucial in shaping smokeless tobacco regulations in South Asia.4

The study presented in this paper is part of a broader research project to examine the role of the state and tobacco industry in India. This paper answers three specific questions: (1) what are the legal challenges posed by the tobacco industry to regulating smokeless tobacco through the food laws?; (2) how have courts historically dealt with these challenges?; and (3) what lessons can policymakers and tobacco control advocates draw for future smokeless tobacco regulations?

METHODS

We analysed tobacco-related litigation under the two prominent food laws in India: the PFA⁵ (repealed in 2011) and its successor, the FSSA⁶ (see online supplemental file 1 for overview of these laws).

Data collection

We sourced all the regulatory orders that used the two food laws to prohibit the sale of certain smokeless tobacco products in Indian states from the web portals of government agencies, the Resource Centre for Tobacco Control¹⁰ and the concerned government offices.

We then sourced litigation from the Supreme Court and the High Courts in India using a systematic search through the Indian legal database, Manupatra.¹¹ We first used 'Manu search' to generate cases related to the PFA and then searched within those cases using a combination of tobacco product terms (ie, tobacco, bidi/beedi, gutka, cigarette, hukka/hookah, zarda, gul, kharra, mishri, mawa, gudakhu, nastaar, khaini, chillum, cheroot and cigar) to identify tobacco-specific cases. Similarly, we used the 'legal search' to generate cases litigated under the FSSA and identified tobaccospecific cases by using tobacco product terms.

We excluded litigation where (1) the dispute was not related to tobacco; (2) the question of the law



@ Author(s) (or their employer(s)) 2023. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

To cite: Dsouza R, Bhojani U. Tob Control 2023;**32**:275-279.



Original research

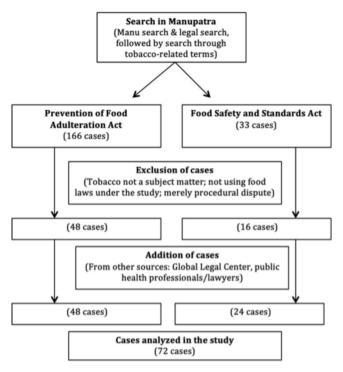


Figure 1 Search strategy for mapping litigation.

was not about the PFA or the FSSA; or (3) the cases merely dealt with procedural matters (eg, non-compliance to the product seizure procedure, or penalising vendors without following a due process). RD screened the litigation for this study. The list was discussed with and agreed on by UB.

We found the Manupatra Database fairly comprehensive, archiving cases adjudicated by High Courts since the time of their inception and by the Supreme Court since 1950 until the date we executed our search in 2018. It accounted for the majority of cases we studied. We discovered a few additional cases relevant to our study that we sourced from the Global Legal Center¹² and a lawyer who has supported tobacco litigation in India. Figure 1 depicts the search strategy and outputs (see online supplemental file 2 for the list of the cases analysed).

Data analysis

We mapped these cases in a spreadsheet identifying the petitioners, petitioners' claims, respondents, respondents' arguments and summary of judgements. We organised the data chronologically, stratified by the adjudicating courts. RD mapped the cases and periodically discussed them with UB. Both authors jointly developed themes and narratives.

We used an inductive thematic analysis of litigation contents¹³ where we coded data guided by our inquiry. We constructed a chronological and thematic narrative of how food laws were used and challenged over time using a public health viewpoint. RD is trained as a lawyer with experience in legislative and policy research. UB is a public health researcher and engaged in tobacco control for about 15 years including being a petitioner representative on a tobacco-related public interest litigation. We attempted to dispassionately study the industry arguments and courts' adjudication of these challenges.

RESULTS

We present the results in two sections. We use narratives to highlight how the three broad themes defined the key legal

Box 1 Themes defining the legal challenges from the tobacco industry

- ⇒ Categorising chewing tobacco as food or food adulterant The tobacco industry argued that the chewing tobacco products are not food, challenging the use of food laws (PFA and FSSA) to regulate them. The courts mostly interpreted food comprehensively to encompass certain chewing tobacco products as well.
- The regulatory power of state vis-à-vis national government under the food laws

The tobacco industry argued that state government lacks regulatory power to ban a product under the PFA and FSSA, and that such power lies only with the national government. The Supreme Court first upheld this line of argument and subsequently disallowed the state government from banning a product, but in later cases courts rejected that claim and held that state governments do have such regulatory powers.

 \Rightarrow Applicability of the general food law vis-à-vis to bacco-specific law

The tobacco industry argued that the tobacco-specific law, COTPA, should govern their tobacco products and not general laws, the PFA or later, the FSSA. The Supreme Court agreed that COTPA being specific to tobacco and of later origin (than the PFA) should apply, but later courts rejected that claim and held that the COTPA and the FSSA are not conflictual, and state governments can use the FSSA to ban tobacco products as well.

COTPA, Cigarette and Other Tobacco Products Act 2003; FSSA, Food Safety and Standards Act 2006; PFA, Prevention of Food Adulteration Act 1954.

challenges that emerged in the use of the PFA (section I), and persisted, in some form, during the FSSA (section II) (see box 1 for the summary).

Section I (PFA 1954)

Categorising chewing tobacco as food or food adulterant In one of the earliest recorded cases, the state of Uttar Pradesh initiated criminal proceedings against a manufacturer engaged in the sale of chewing tobacco for adulterating the products with coal tar dye. Aggrieved by this, the manufacturer approached the Allahabad High Court, arguing that chewing tobacco was not food and hence could not be subjected to the provisions of the PFA.¹⁴ The main clause of the PFA defined food as 'any article used as food or drink for human consumption other than drugs and water'. In this case (Khedan Lal 1970), the court went on to gauge this form of tobacco against the ordinary, commonly understood meaning of the term food. Using a literal meaning of the term food, the court opined that '...'food' includes only those articles...which is eaten to maintain life and growth and provides nourishment'. 14 In that context, tobacco was perceived as the antithesis of food, and hence could not be regulated under

Immediately following this decision, the chief justice of the Allahabad High Court was to resolve the difference in opinion: whether zarda, a form of tobacco commonly used in the preparation of pan, was food. ¹⁵ Concurring with the reasoning adopted by the same court in its prior decision (*Khedan Lal 1970*), ¹⁴ the chief justice reiterated that the legal definition of food under the PFA mirrored the ordinary, dictionary meaning of the term, and it was to be read in that context. ¹⁵ However, transcending the main definitional clause, the chief justice reframed the question:

whether the inclusive/ancillary definitional clauses under the PFA allowed for a more capacious understanding of food? And to this, the answer was positive. Articles that ordinarily enter into or are used in the preparatory process including flavouring articles were encompassed by the ancillary provisions to the (main) definitional clause. Hence, zarda qualified as food given its role as part of the preparatory process or even as a flavouring agent in pan. By expanding the meaning of food to include chewing tobacco, the court underscored the legislative intent of the PFA, that is, to protect citizens from adulterated products, and enabled the state to administer the PFA in curbing adulterated tobacco products.

Several decades later, in the *Godawat 2004 case*, ¹⁶ the industry went to the Supreme Court with a slew of contentions that revolved around the role of the PFA in dealing with chewing tobacco, including the question of whether gutka and pan masala could be construed as food. Cursorily dismissing the issue, the Supreme Court merely expressed its inability to agree with the industry's contention that the products in question were not food. ¹⁶

The regulatory power of state vis-à-vis the national government under the PFA

Between 2001 and 2003, five Indian states issued prohibitory orders under the PFA banning certain chewing tobacco products within their jurisdiction (see online supplemental file 1).¹⁷ These states leveraged specific provisions of the law that enabled the Food (Health) Authority to temporarily prohibit the manufacture, sale and distribution of food articles, in the interest of public health.⁵

The tobacco industry challenged these prohibitory orders before the respective state High Courts. ¹⁸ ¹⁹ The *Dhariwal 2002 case*, ¹⁹ before the Bombay High Court, was a culmination of litigation challenging the prohibition of the sale of gutka and pan masala by the state of Maharashtra, where the industry argued that state government did not have the power to ban products under the PFA, as such power was vested with the national government. While the court acknowledged a situation where the power of state government may overlap with that of the national government, it ultimately dismissed the industry's claim, on grounds that the power conferred by law on the state government (Food Authority) '…is statutory, absolute to the extent provided therein and independent of the power conferred on Central Government'.¹⁹

Litigation attempts by the industry to challenge the state-driven prohibitory orders were largely unsuccessful, 4 18 until the Supreme Court of India was tasked with deciding their validity. 16 In the *Godawat 2004 case*, 16 the Supreme Court relied on the 'collocation of statutory provisions' from existing laws to conclude that power exercised by the state was not an independent source of power. The Supreme Court observed that while the state government was vested with statutory power under the PFA, the power was limited by subsequent provisions of the act. 16 In clarifying that the structure of the PFA disallowed the states from exercising their power to issue impugned orders, the Supreme Court collapsed the decentralised regulatory efforts by states via the PFA.

Applicability of the general food law vis-à-vis tobacco-specific law By the time the Supreme Court of India examined the role of the PFA in regulating tobacco products, tobacco control policy had experienced a sweeping change. India enacted a comprehensive national law to regulate tobacco products: the Cigarettes and Other Tobacco Products (prohibition of advertisement and regulation of Trade and commerce, production, supply and distribution) Act 2003 (COTPA).²⁰

The enactment of COTPA presented the Supreme Court with a new set of claims. In the Godawat 2004 case, 16 the industry argued that COTPA—the tobacco-specific law—was to be read as parliament's intention to occupy (or lay claim over) the entire field of tobacco, and its provisions merely restricted the sale of tobacco products to minors. In contrast to that, the prohibitory order issued under the PFA mandated a complete ban on the manufacturing/sale of certain tobacco products. Hence, the industry argued that unlike COTPA, the PFA was conceived as a 'general law' intended to deal with food adulteration and its relationship with tobacco products was merely incidental. 16 Citing precedents of the established legal principle, the industry maintained that in such circumstances the general law inevitably yields to the special law. The Supreme Court upheld this reasoning and held that 'COTPA is a special Act intended to deal with tobacco...the Act being a special Act and of later origin, overrides the PFA...'16 This further compromised the scope of state-driven tobacco control efforts under the food law.

Section II (FSSA, 2006)

Categorising chewing tobacco as food under the FSSA

In an attempt to consolidate the plethora of food laws, India enacted the FSSA in 2006. More than half a decade later, the FSSA came into effect along with a set of regulations, the Food Safety and Standards Regulations (Prohibition and Restriction of Sales) 2011, ²¹ and subsequently, the PFA was repealed.

The FSSA restricted the use of certain anticaking agents including carbonates of magnesium (commonly used in gutka and pan masala), and prohibited the use of tobacco and nicotine as ingredients in any food items. Following a tried and tested method, several Indian states, starting with Madhya Pradesh, issued orders under the FSSA banning the sale, manufacture, storage and distribution of various forms of chewing tobacco (see online supplemental file 1). Like before, these prohibitory orders were challenged by the tobacco industry. 22-28

Tobacco (control) may not have been central to the new law, but the definition of food under the FSSA encompassed a more layered understanding, with implications for the way tobacco was to be regulated. In the *Dhariwal 2012 case*, ²⁹ the Bombay High Court observed that the expression 'any substance which is intended for human consumption' used in the FSSA⁶ for defining food had a wider scope than the expression 'any article used as food or drink for human consumption' used in the PFA. ²⁹ To further nuance the meaning of consumption, the court used a chewing gum analogy, comparing how chewing gum, like gutka or pan, could be consumed without necessarily being ingested. ²⁹ Adopting such reasoning allowed the court to construe the tobacco products in question as food under the FSSA. ²⁹

Gutka and pan masala were only two of the myriad forms of indigenous tobacco curbed by the prohibitory orders. Since other High Courts are not bound by the decision of the Bombay High Court—it only has persuasive value for other courts—the industry kept contesting the categorisation of chewing tobacco products as food, attempting to exempt their tobacco products from state-led prohibitory orders. However, with a few exceptions, like a case where the Kerala High Court³⁰ adopted a contrary view, the industry was quite unsuccessful.

Original research

The regulatory power of state vis-à-vis national government under the FSSA

While challenging the prohibitory orders under the new law (FSSA), the industry reproduced the law laid down by the Supreme Court in in the *Godawat 2004 judgement*¹⁶ that the state government did not have independent power to ban tobacco products under the PFA. In *Dhariwal 2012 case*,²⁹ they further argued that unlike the PFA, the structure of the FSSA does not confer power on either state or the national government to enact prohibitory orders. However, negating the application of the *Godawat 2004 case*¹⁶ to the FSSA, the Bombay High Court held that, unlike the PFA, the FSSA makes it a statutory duty of food business operator(s) to produce safe food while also conferring independent power on state government (Food Authority) to issue prohibitory regulations.²⁹ This decision by the Bombay High Court was instrumental in paving the way for states to ban chewing tobacco products under the FSSA.

Applicability of food law vis-à-vis tobacco-specific law

To strengthen its claim, the industry highlighted the alleged tension between the tobacco-specific law, COTPA and the FSSA, forcing the Bombay High Court to reconcile how two disparate laws could regulate the same product differently.²⁹ Once again, the industry leveraged the decision of the Supreme Court in the *Godawat 2004 case*, ¹⁶ where the Supreme Court held that the power to prohibit manufacturing/sale of tobacco products under the PFA conflicted with the provisions of the COTPA. They argued that this legal position should ideally be transferred and applied to (the PFA's successor) the FSSA, as well.²⁹

However, the Bombay High Court clarified that the Supreme Court in the *Godawat 2004 case*¹⁶ had not invalidated the role of PFA in regulating the manufacture and sale of gutka and pan masala.²⁹ Instead, the Supreme Court's interpretation of the law entrusted the national government with the power to ban products, and while doing so refused the industry's argument that COTPA was the only legislation occupying the field of tobacco products.²⁹ By refusing to read the decision of the Supreme Court in the *Godawat 2004 case*¹⁶ as a subordination of the food law to the tobacco-specific law, the Bombay High Court set a precedent for the working of the FSSA as a tobacco control mechanism, independent of the COTPA.²⁹ This decision both helped states to administer stricter tobacco control measures while also shielding them from the legal challenges posed by the industry.

DISCUSSION

Historically, Indian states have strategically and innovatively used the national food law(s) to ban dominant forms of smokeless tobacco products. Interestingly, state governments leveraged food laws for stricter regulations of tobacco products compared with the tobacco-specific law, COTPA, which did not facilitate a complete sales prohibition but merely regulated the sales of tobacco products. Our findings have implications for tobacco control policy and practice.

First, tobacco control advocates should consider engagement with laws/regulations across other sectors that could be used to regulate tobacco, instead of focusing all their efforts on health-oriented tobacco-specific regulations. By decentring their efforts away from the health sector, they may harness the potential of other sectoral laws for shaping more effective regulations of tobacco products and create the possibility of catching the industry off guard, reducing their interference in such regulations.³¹

Second, countries with federal structures may learn from the way Indian states innovatively worked the national legal framework at the local level to deal with the tobacco epidemic. This mode of governance is especially useful for countries which are plagued with highly localised forms of tobacco products. Governments at the local level may be better suited to regulate these products. A prerequisite to the efficiency of such regulatory approach is a strong coordination between the national and subnational government, ensuring that local laws are not weakened by pre-emption. In the USA, for example, the tobacco industry has acquired a reputation for persisting with pre-emptive strategies to frustrate some state and local tobacco control efforts. Tortunately, Indian courts have interpreted the law to allow more leeway, enabling states to protect their local tobacco control measures.

Third, tobacco control agencies at various levels—national, state and municipal/district—should enhance their legal resources and capacity to effectively respond to hectic litigation by the tobacco industry challenging tobacco control regulations. States, districts and municipal authorities should actively invest in knowledge-sharing infrastructure that has potential to help other (neighbouring) jurisdictions develop complementary responses to the (often similar) legal challenges posed by the industry.

Fourth, policymakers ought to harmonise the content and working of new (tobacco control) laws to ensure that they do not disrupt the working of existing laws that either directly or incidentally regulate tobacco. Acknowledging the need for complementary regulatory action, the COTPA Amendments Bill 2020 proposed that COTPA act as a minimum bar for tobacco regulations while allowing other stricter laws to prevail.³⁴

Finally, our study adds to the limited research in India on aggressive use of litigation by the tobacco industry to stall tobacco control regulations. Our fine-grained analysis of the legal challenges by the industry can potentially help both the governments as well as tobacco control advocates anticipate

What this paper adds

What is already known on this subject

⇒ Indian states have historically used food laws to ban sale of certain forms of smokeless tobacco, especially chewing tobacco products.

What important gaps in knowledge exist on this topic

⇒ How did tobacco interests mount legal challenges to use food laws to ban smokeless tobacco in India?

What this paper adds

- ⇒ This study analyses and synthesises tobacco-related litigation done under the food laws from 1970 onwards.
- ⇒ The tobacco industry systematically deployed litigation to challenge regulations under the food laws, forcing Indian states—often stretched for resources—to respond.
- ⇒ Three themes defined the major challenges posed by the tobacco industry, where the industry (1) challenged the categorisation of smokeless tobacco products as food, and thereafter, contested the use of food laws to regulate these products; (2) challenged the regulatory power of the state government in the use of the food laws for banning tobacco products; and (3) challenged the applicability of the general food laws that enabled stricter regulations beyond what is prescribed under the tobacco-specific law.

future challenges and strengthen the response mechanisms to protect strong tobacco control policies.

Twitter Upendra Bhojani @UpendraBhojani

Acknowledgements We thank Aparna Vincent for help in the earlier stages of this work; Pranay Lal and Ranjit Singh for useful inputs; Pragati Hebbar, Adhip Amin and anonymous reviewers for their useful comments on the manuscript.

Contributors UB conceived the study. RD collected data. RD and UB analysed and interpreted the data. RD drafted the manuscript. UB commented and critically revised the manuscript. Both the authors approved the version submitted for publication.

Funding This work was funded through the DBT/Wellcome Trust India Alliance fellowship awarded to UB (IA/CPHI/17/1/503346).

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study forms the initial phase of a broader research project that was reviewed by the Institutional Ethics Committee of the Institute of Public Health (Bengaluru). It was exempted from the full review (IPH/18-19/E/260) given the absence of human participation and the use of data available in the public domain

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available in a public, open access repository. This paper analyses the judgements of tobacco-related litigation. Online supplemental file 2 provides a list of cases analysed in this paper. The judgement copies of these cases are available in the public domain through web portals of the respective Indian courts.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iD

Upendra Bhojani http://orcid.org/0000-0002-9179-6248

REFERENCES

- 1 Drope J, Schluger N, Cahn Z. *The tobacco atlas Atlanta*. American Cancer Society and Vital Strategies. 2018.
- 2 Mehrotra R, Sinha DN. Global challenges in smokeless tobacco control. *Indian J Med Res* 2018:148:1–3.
- 3 Khan A, Huque R, Shah SK, et al. Smokeless tobacco control policies in South Asia: a gap analysis and recommendations. Nicotine Tob Res 2014;16:890–4.
- 4 Arora M, Madhu R. Banning smokeless tobacco in India: policy analysis. *Indian J Cancer* 2012;49:336–41.
- 5 The Prevention of Food Adulteration Act & Rules (as on 01.10.2004). Available: https://fssai.gov.in/upload/uploadfiles/files/pfa-acts-and-rules.pdf [Accessed 15 Sep 2020]
- 6 The food safety and standards act, 2006. Available: https://fssai.gov.in/upload/uploadfiles/files/FOOD-ACT.pdf [Accessed 15 Sep 2020].
- 7 Yadav A, Singh A, Khadka BB, et al. Smokeless tobacco control: Litigation & judicial measures from Southeast Asia. *Indian J Med Res* 2018;148:25–34.
- 8 Bhojani U, Hebbar P, Rao V. Litigation for claiming health rights: insights from tobacco control. health hum rights 2014. Available: http://www.hhrjournal.org/2014/07/15/litigation-for-claiming-health-rights-insights-from-tobacco-control/ [Accessed 15 Sep 2020].

- 9 India Alliance. Research summary Deciphering an epidemic of epic proportion: the role of State and tobacco industry in tobacco control in post-liberalized India, 2018.
- 10 Policies and legislations. resource center for tobacco control an initiative by PGIMER in collaboration with The Union. Available: https://www.rctcpgi.org/ [Accessed 15 Sep 2020].
- 11 Manupatra company information. Available: http://www.manupatrafast.com/Default/ CompanyInfo.aspx [Accessed 15 Sep 2020].
- 12 Campaign for tobacco-free kids. tobacco litigation: explore 1055 tobacco control Judicial decisions from around the world. Available: https://www.tobaccocontrollaws. org/litigation [Accessed 15 Sep 2020].
- 13 Patton M. Qualitative research and evaluation methods. Thousand Oaks: Sage Publications. 2002.
- 14 High Court of Allahabad. Khedan LAL and sons vs. state of up and Ors. (CR. Misc. Application No. 164 of 1969, 1970.
- 15 High Court of Allahabad (Lucknow Bench). State of up vs. Shri ram Gupta (CR. as. NOS. 394, 395 and 750 of 1968 and 107 of 1969, 1971.
- 16 The Supreme Court of India. Godawat pan Masala products i.p. Ltd. and Ors. vs. Union of India and Ors, 2004.
- 17 Reddy KS, Gupta PC, eds. Report on tobacco control in India. New Delhi, India: Ministry of Health and Family Welfare, Government of India, 2004.
- 18 High Court of Andhra Pradesh. Shivshakti agencies vs. state of AP and Ors. (W.P.M.P. No. 17690 of 2002 in W.P. No. 14153 of 2002, 2002.
- High Court of Bombay. Dhariwal industries Ltd. and Ors. vs. Union of India and Ors. (write Petition NOS. 1982, 2001, 2002, 2024, 2251 of 2002, 2002.
- 20 The Government of India. The cigarette and other tobacco products (Prohibition of advertisement and regulation of Trade and Commerce, production, supply and distribution) act, 2003.
- 21 Government of India. Food safety and standards (prohibition and restrictions on sales) regulations, 2011.
- 22 High Court of Judicature at Patana. Lal Babu Yadav vs. The state of Bihar and Ors, 2012
- 23 High Court of Madhya Pradesh. Ghoi foods private limited vs. UOI, 2012.
- 24 High Court of Judicature at Patana. M/s Prabhat Zarda factory India PVT. LTD. vs. The state of Bihar and Ors.; Rajat Insustries PVT. LTD. vs. The state of Bihar and Ors.; M/s R. K. Enterprises vs. The Union of India and Ors.; M/s Khan brothers vs. The Union of India and Ors., 2014.
- 25 High Court of Calcutta. Sanjay Anjay stores and Ors. vs. The Union of India and Ors, 2014.
- 26 High Court of Bombay (Aurangabad bench). Vijay Shantilal Chopada vs. The state of Maharashtra and Ors, 2016.
- 27 High Court of Bombay. Vishnu pouch packaging PVT. LTD. vs. The state of Maharashtra and Ors, 2012.
- 28 High Court of Karnataka. Ghodawat pan Masala vs. state of Karnataka, 2013.
- 29 High Court of Bombay. Dhariwal industries limited and Ors. vs. The state of Maharashtra and Ors, 2012.
- 30 High Court of Kerala. Joshy vs. state of Kerala, 2012.
- 31 Marfatia A, Vora R. Guerrilla advocacy: lessons for civil society. India development review, 2019. Available: https://idronline.org/guerrilla-advocacy-lessons-for-civilsociety/ [Accessed 10 Mar 2021].
- 32 Nixon ML, Mahmoud L, Glantz SA. Tobacco industry litigation to deter local public health ordinances: the industry usually loses in court. *Tob Control* 2004;13:65–73.
- 33 The High Court of Bombay. Sai Traders and ors vs state of Goa and Ors Writ Petition NOS 396 and 397 of 2005, 2006.
- 34 Government of India. The cigarettes and other tobacco products (prohibition of advertisement and regulation of Trade and commerce, production, supply and distribution) (Amendment) bill, 2020. Available: http://ntcp.nhp.gov.in/assets/document/Cigarettes_and_Other_Tobacco_Products_Prohibition_of_Advertisement_and_Regulation_of_Trade_and_Commerce_Production_Supply_and_Distribution_Amendment_Bill_2020.pdf [Accessed 10 Mar 2021].

Supplementary File 1

In this Supplementary File, we provide (I) a brief profile of India in terms of tobacco consumption; (II) a brief overview of the two food laws including their specific provisions that have been used for regulating smokeless tobacco products; and (III) a chronology of regulatory orders issued under the food laws by various Indian states prohibiting certain forms of smokeless tobacco.

(I) Tobacco consumption in India

India is home to the second-largest number of tobacco users in the world, after China.(1) In 2017, an estimated 266.8 million adults (28.6% of the Indian population) reported using tobacco in some form or the other.(2) Smokeless tobacco is a dominant form of tobacco consumption in India, with its prevalence (21.4%) being double the prevalence of smoking tobacco (10.7%).(2) India accounts for over a million tobacco-related deaths, annually.(3–5) India ratified the WHO Framework Convention on Tobacco Control, enacted a national legislation, and continues to deploy and innovate regulatory measures to effectively control tobacco use with an aim to achieve 30% of the relative reduction in the prevalence of tobacco use by 2025.(6)

(II) The food laws and their specific provisions that have been used for smokeless tobacco regulations

The Prevention of Food Adulteration Act, 1954 (PFA)	The Food Safety and Standards Act, 2006 (FSSA)
The PFA was one of the many food laws enacted by the Central Government to exclusively deal with the proliferation of adulterated food.	In an attempt to consolidate a plethora of laws concerning food (including the PFA), the Central Government enacted the FSSA by declaring its control over the food industry, expedient in the public interest. Inevitably, certain provisions of the PFA have been incorporated in the FSSA. However, the FSSA is a comprehensive enactment to deal with all aspects of food safety. Once the FSSA regulations were implemented, the PFA was repealed.
The definition of food under the PFA included any article used or consumed as food; and included articles commonly used in preparing food, flavoring matter/condiments.	The definition of food under the FSSA includes any substances intended to be consumed (by humans) and includes some inclusive and exclusive illustrative examples. This definition enables a wider and more comprehensive understanding of food. The inclusive illustrations demonstrate how articles like chewing gum that are not normally associated with food for nutrition or development of the human body, are to be read as food to be regulated by the FSSA.
Section 7(iv) of the PFA prohibited a person from manufacturing for sale/storage/distribution, any article of food deemed prohibited by the state Food Health Authority in the interest of public health.	Section 30(2)(a) of the FSSA empowers the Commissioner of Food Safety to prohibit the manufacture/ storage/ distribution/ sale of any article of food, within its jurisdiction, in the interest of public health.
Prevention of Food Adulteration Rules, 1955	Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011
Rule 44J requires food product not to contain any substances which may be injurious to health. Tobacco and nicotine shall not be used as ingredients in any food products.	Regulation 2.3.4: requires food product not to contain any substance which may be injurious to health. It is mentioned that tobacco and nicotine shall not be used as ingredient in any food product.

(III) Chronology of tobacco-related regulations issued under the food laws in India*

Sr.	Issue date	State	Products prohibited under the regulation
No.		government	
	Orders issued	under the Prevent	ion of Food Adulteration Act, 1954
	I	T =	Tanana a
1	November 2001	Tamil Nadu	Chewing tobacco, paan masala or gutka
			containing tobacco
2	February 2002	Andhra Pradesh	Paan masala (containing tobacco) and
			chewing tobacco/zarada/khaini
3	July, 2002	Maharashtra	Gutka or paan masala containing tobacco or
			not containing tobacco
4	January, 2003	Goa	Gutka or paan masala containing tobacco or
			not containing tobacco
5	March, 2003	Bihar	Gutka or paan masala containing tobacco or
			not containing tobacco
	Orders issue	d under the Food	Safety and Standards Act, 2006**
6	March, 2012	Madhya Pradesh	Gutka containing tobacco and nicotine
7	May, 2012	Kerala, Bihar	Gutka and paan masala containing tobacco
			or nicotine
8	July, 2012	Himachal	Gutka and paan masala, masheri, khaini
		Pradesh	
10	July, 2012	Haryana,	Gutka and paan masala containing tobacco
		Maharashtra	or nicotine
11	July, 2012	Rajasthan	Gutka and paan masala and other food
			products containing tobacco or nicotine
12	July, 2012	Chandigarh	Food items containing tobacco and nicotine
13.	July, 2012	Chhattisgarh,	Gutka and paan masala containing tobacco
		Jharkhand	or nicotine
14.	August, 2012	Gujarat	Gutka and paan masala containing tobacco
			or nicotine
15.	August, 2012	Mizoram	Gutka, paan masala, zarda, and any other
			chewable product containing tobacco and
			nicotine
16.	September, 2012	Punjab	Gutka, paan masala and any other food
			product containing tobacco and nicotine
17.	September, 2012	Delhi; Sikkim	Gutka and paan masala containing tobacco
			or nicotine
18.	October, 2012	Nagaland; Uttar	Gutka and paan masala containing tobacco
		Pradesh	or nicotine
19.	November, 2012	Andaman &	Gutka and paan masala containing tobacco
	ĺ	Nicobar Islands;	or nicotine

		Arunachal Pradesh; Daman & Diu; Dadar & Nagar Haveli	
20.	December, 2012	Uttarakhand	Gutka and paan masala containing tobacco or nicotine
21.	January, 2013	Andra Pradesh; Odisha	Gutka and paan masala containing tobacco or nicotine
22.	February, 2013	Manipur	Gutka, paan masala, zarda, khaini and other chewable, smokeless tobacco products containing tobacco or nicotine
23.	March, 2013	Assam	Gutka and paan masala containing tobacco or nicotine
24.	April, 2013	Tripura; West Bengal	Gutka and paan masala containing tobacco or nicotine
25.	May, 2013	Karnataka	Gutka and paan masala containing tobacco or nicotine

*Sources: ¹Reddy and Gupta(7); ²Information received from Mr. Gaurav Gupta of the Campaign for Tobacco-Free Kids (India); ³Copies of regulations issued by certain state governments available in the public domain, including the litigation surveyed for this study. **This list is not exhaustive as a few remaining states issued similar regulations after May 2013.

References

- Drope J, Schluger N, Cahn Z et al. The Tobacco Atlas Atlanta: American Cancer Society and Vital Strategies 2018.
- GATS 2: Global Adult Tobacco Survey, factsheet India 2016-17. 2017. Available from: https://www.mohfw.gov.in/sites/default/files/GATS-2 FactSheet.pdf (accessed 15 Sep 2020)
- 3. World Health Organization Regional Office for South-East Asia. Factsheet 2018:
 India. 2018. Available from:
 https://apps.who.int/iris/bitstream/handle/10665/272672/wntd_2018_india_fs.pdf?sequence=1 (accessed 15 Sep 2020)
- 4. Sinha DN, Palipudi KM, Gupta PC et al. Smokeless tobacco use: a meta-analysis of risk and attributable mortality estimates for India. *Indian J Cancer* 2014;51:73–7.
- 5. Jha P, Jacob B, Gajalakshmi V et al. A nationally representative case-control study of smoking and death in India. *N Engl J Med* 2008:358(11):1137–47.
- 6. Government of India. National action plan and monitoring framework for prevention and control of noncommunicable diseases (NCDs) in India. Available from:
 https://main.mohfw.gov.in/sites/default/files/National%20Multisectoral%20Action%2
 OPlan%20%28NMAP%29%20for%20Prevention%20and%20Control%20of%20Common%20NCDs%20%282017-22%29 1.pdf (accessed 15 Sep 2020)
- Reddy KS, Gupta PC, eds Report on tobacco control in India. New Delhi, India:
 Ministry of Health and Family Welfare, Government of India; 2004

Supplementary File 2

List of cases (litigations) analyzed in the study

	Cases involving the Prevention of Food Adulteration, 1954
1	Godawat Pan Masala Products I.P. Ltd. and Ors. vs. Union of India (UOI) and Ors. (02.08.2004 - SC) : MANU/SC/0574/2004
2	Khedan Lal and Sons vs. The State of UP and Ors. (30.01.1970 - ALLHC): MANU/UP/0245/1970
3	Khedan Lal and Sons vs. State of U.P. and Ors. (18.08.1980 - ALLHC): MANU/UP/0376/1980
4	Kothari Chemicals vs. Union of India (UOI) (27.09.1995 - ALLHC) : MANU/UP/0739/1995
5	State of U.P. vs. Shri Ram Gupta (23.12.1971 - ALLHC) : MANU/UP/0408/1971
6	Manohar Lal vs. State of U.P. (22.07.1989 - ALLHC) : MANU/UP/0921/1989
7	Chandra Shekhar and Ors. vs. State (02.03.1982 - ALLHC): MANU/UP/0909/1982
8	Shivshakti Agencies vs. State of A.P. and Ors. (16.08.2002 - APHC): MANU/AP/1388/2002
9	Md. Mahmood and Ors. vs. The State of Andhra Pradesh (05.04.2006 - APHC) : MANU/AP/0571/2006
10	Society for Cancer in Oral-Cavity Prevention through Education, Hyderabad vs. Union of India (UOI) and Ors. (23.04.2002 - APHC): MANU/AP/0422/2002
11	The Food Inspector, Div. II vs. D. Ravindranath and Ors. (18.11.2004 - APHC): MANU/AP/1125/2004
12	Dhariwal Industries Ltd. and Ors. vs. Union of India (UOI) and Ors. (18.09.2002 - BOMHC): MANU/MH/1185/2002
13	Sainath Traders and Ors. vs. Commissioner of Food and Drug Administration and Ors
	Sai Traders and Ors. vs. State of Goa and Ors. (07.06.2006 - BOMHC): MANU/MH/0300/2006
15	Dilipsinh vs. The State of Maharashtra (26.02.2010 - BOMHC) : MANU/MH/0157/2010
16	Vishnu Packaging, a Partnership firm and Ors. vs. Union of India and Ors. (07.12.2011 - BOMHC) : MANU/MH/1571/2011
17	Dhariwal Industries Limited and Ors. vs. The State of Maharashtra and Ors. (15.09.2012 - BOMHC): MANU/MH/1519/2012
18	Sainath Traders and Ors. Vs. Commissioner of Food and Drug Administration and Food (Health) Authority and Ors. MANU/MH/2048/2016
19	Rasiklal and Ors. vs. The State of Maharashtra and Ors. (05.05.2016 - BOMHC): MANU/MH/2896/2016
20	State of Maharashtra vs. Ramnath Punamchand Dayama and Ors. (08.05.2017 - BOMHC) : MANU/MH/2823/2017
21	Municipal Corporation of the City of Amravati vs. Ghanshyam Uttamchand Batra and Ors. (31.07.2018 - BOMHC) : MANU/MH/2326/2018
22	The Ahmednagar Municipal Council vs. Dullabhadas Haridas Patel and Ors. (01.12.2009 - BOMHC) : MANU/MH/1444/2009
23	Rajiv Kumar Gupta and Ors. vs. The State of Maharashtra (28.10.2005 - BOMHC): MANU/MH/1299/2005
24	Rasiklal and Prakash vs. The State of Maharashtra and Ors. (02.07.2013 - BOMHC): MANU/MH/0846/2013
25	State vs. Mustawueen Mohammad and Ors. (15.04.2013 - BOMHC): MANU/MH/0684/2013
26	K.P. Sugandh Limited and Etc. vs. State of Chhattisgarh and Ors. (28.02.2008 - CGHC): MANU/CG/0032/2008
	Sonal Food Products and Ors. vs. State (17.11.2006 - DELHC) : MANU/DE/9839/2006
28	Ram Babu Rastogi and Ors. vs. State (22.12.2011 - DELHC) : MANU/DE/7058/2011
29	Prince Gutka Ltd. vs. State and Ors. (01.03.1999 - DELHC) : MANU/DE/0868/1999
	Bishan Dass Mehta and Ors. vs. Union of India and Ors. (24.04.1970 - DELHC): MANU/DE/0011/1970
31	Kiritkumar Budhalal Patel vs. State of Gujarat (05.10.2000 - GUJHC) : MANU/GJ/0438/2000
32	Royal Marvar Tobacco Pvt Ltd and Ors. vs. State of Gujarat and Ors. (13.10.2010): In the High Court of Gujarat at Ahmedabad Special Criminal Application No. 1839 of 2010.
33	State of Gujarat vs. M/s Chetna Jarda Company (Manufacturing Firm) & Samp; 1 (13.09.2011 - GUJHC): MANU/GJ/1014/2011
34	Iqbal Musabhai Hunani vs. State of Gujarat and Anr. (31.07.1992 - GUJHC) : MANU/GJ/0261/1992
35	State of Gujarat vs. Sanjay Kumar Nagindas Shah Vendor and Ors. (13.01.2010 - GUJHC) : MANU/GJ/1625/2010
36	State of Gujarat vs. M/s Chetna Jarda Company (Manufacturing Firm) & Samp; 1 (13.09.2011 - GUJHC): MANU/GJ/1014/2011
	Kiritkumar Budhalal Patel vs. State of Gujarat (05.10.2000 - GUJHC) : MANU/GJ/0438/2000

24 MANU/UP/1686/2012

38 State of Assam vs. Ram Karani and Ors. (10.09.1986 - GUHC): MANU/GH/0033/1986 Tirupati Products (P1) and Haji Shah(P2) Hussain Buksh Khand Sons Khan and Sons and Anr. vs. State of 39 Jharkhand and Ors. (07.03.2005 - JHRHC) : MANU/JH/0081/2005 40 Raju Laxman Pachapure v. State of Karnataka and Otrs. WP No. 15119 of 2006 The Malnad Areca Marketing Co-operative Society Ltd. and Ors. vs. Union of India (UOI) and Anr. (04.04.2007 -41 KARHC): MANU/KA/7098/2007 42 Shivraj Tobacco Company Pvt. Ltd. vs. State of Madhya Pradesh (02.11.1989 - MPHC) : MANU/MP/0290/1989 43 R.P. Sharma vs. State (18.11.2004 - MADHC) : MANU/TN/1353/2004. 44 Lekhraj vs. The State of Tamil Nadu (01.09.2006 - MADHC): MANU/TN/6098/2006 45 Indradeo Dwarika Singh vs. State of Bihar and Ors. (03.10.2017 - PATNAHC): MANU/BH/1651/2017 Md. Sagir and Md. Mukhtar Alam vs. State of Bihar and Anr. (19.03.2009 - PATNAHC): MANU/BH/0122/2009 47 R.P. Patel vs. State of Punjab (09.08.1997 - PHHC) : MANU/PH/0898/1997 48 Kailash vs. The State of Rajasthan (29.01.1985 - RAJHC): MANU/RH/0339/1985 Cases involving the Food Safety and Standards Act, 2006 1 Central Arecanut Marketing Company and Others v. Union of India, Transfer Case (Civil) No. 1/2010 (2016). Ankur Gutkha v. India Asthma Care Society, Petition(s) for Special Leave to Appeal (Civil) No(s). 16308/2007, 2 Supreme Court of India (April 3, 2013). Jeetmal Ramesh Kumar vs. The Commissioner, Food Safety and Drug Administration Department and Ors. 3 (14.02.2019 - MADHC) : MANU/TN/2513/2019 4 Order dated 2.08.2012 W.P.(C) Nos. 12352, 12932, 13271 & 13773 of 2012 Kerala HC Sanjay Anjay Stores and Ors. vs. The Union of India and Ors. 2014 (01.11.2017 - CALHC): 5 MANU/WB/0846/2017 Court on its own motion vs. State of Himachal Pradesh and Ors. (06.11.2018 - HPHC): Citation: 6 MANU/HP/1706/2018 7 Yadav v. State of Bihar, et al., No. 10297, High Court of Judicature at Patna (2012) M/S R.K. Products Company v. Union of India et al. Patna High Court CWJC No.12871 of 2012 (2) dt.20-07-2012 M/s Prabhat Zarda Factory India v. State of Bihar, Case No. 19286 of 2014; Rajat Industries v. State of Bihar, Case No. 19232 of 2014; M/s R.K. Enterprises v. Union of India, Case No. 19960 of 2014; M/s Khan Brothers v. Union of India, Case No. 20129 of 2014. dated 9 23.12.2014 10 Pankaj Chhabra and Ors. vs. The State of Bihar and Ors. (01.06.2016 - PATNAHC): MANU/BH/0582/2016 Omkar Agency and Ors. vs. The Food Safety and Standards Authority of India and Ors. (19.07.2016 - PATNAHC) 11 MANU/BH/0504/2016 Jayavilas Tobacco Traders LLP vs. The Designated Officer, Food Safety and Drugs Control Dept. (09.06.2017 -12 MADHC): MANU/TN/2146/2017 13 J. Anbazhagan vs. The Union of India and Ors. (26.04.2018 - MADHC): MANU/TN/2109/2018 14 Ghoi Foods Private Limited v. UOI, WP No. 3131, Madhya Pradesh, Gwalior High Court (2012). 15 Amarchand Upadhyay And Anr. vs Union Of India, W. P. No.10998/2012, High Court of Madhya Pradesh 16 Manoj Kumar Jain vs. State of M.P. (24.10.2017 - MPHC) : MANU/MP/1089/2017 17 Joshy vs. State of Kerala (20.12.2012 - KERHC) : MANU/KE/2254/2012 Ghodawat Pan Masala v. State of Karnataka, W.P. No. 78378-78380/2013, High Court of Karnataka, Dharwad 18 (2013). 19 Doctors for You v. State of Delhi, W.P.(C) 5103/2012, High Court of Delhi at New Delhi (2012) Dhariwal Industries Limited and Ors. vs. The State of Maharashtra and Ors. (15.09.2012 - BOMHC): 20 MANU/MH/1519/2012 S.J.J. Exports Company v. Food Safety Commissioner, W.P. No. 2266 of 2012, High Court of Judicature at Bombay 21 (2013). Vishnu Pouch Packaging Pvt. Ltd. vs. The State of Maharashtra and Ors. (01.02.2013 - BOMHC): 22 MANU/MH/2486/2013 23 Vijay Shantilal Chopada vs. The State of Maharashtra and Ors. (29.09.2016 - BOMHC): MANU/MH/2065/2016 Indian Dental Association U.P. State and Ors. vs. State of U.P. and Ors. (17.09.2012 - ALLHC):