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 Once the FSSA regulations were implemented, the PFA was repealed.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. No. | Issue date   | State government          | Products prohibited under the regulation |
|---------|--------------|----------------------------|------------------------------------------|
| 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 issued under the Prevention of Food Adulteration Act, 1954

| Sr. No. | Issue date   | State government          | Products prohibited under the regulation |
|---------|--------------|----------------------------|------------------------------------------|
| 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 Pradesh           | Gutka and paan masala, masheri, khaini    |
| 10      | July, 2012   | Haryana, Maharashtra      | Gutka and paan masala containing tobacco 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, Jharkhand    | Gutka and paan masala containing tobacco 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 Pradesh    | Gutka and paan masala containing tobacco or nicotine |
| 19      | November, 2012 | Andaman & Nicobar Islands; | Gutka and paan masala containing tobacco or nicotine |
| Date       | State                | Product Description                                                                 |
|-----------|----------------------|-------------------------------------------------------------------------------------|
| 20 Dec, 2012 | Uttarakhand          | Gutka and paan masala containing tobacco or nicotine                                |
| 21 Jan, 2013 | Andhra Pradesh; Odisha | Gutka and paan masala containing tobacco or nicotine                                |
| 22 Feb, 2013 | Manipur              | Gutka, paan masala, zarda, khaini and other chewable, smokeless tobacco products containing tobacco or nicotine |
| 23 Mar, 2013 | Assam                | Gutka and paan masala containing tobacco or nicotine                                |
| 24 Apr, 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: 1 Reddy and Gupta (7); 2 Information received from Mr. Gaurav Gupta of the Campaign for Tobacco-Free Kids (India); 3 Copies 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.
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7. Reddy KS, Gupta PC, eds Report on tobacco control in India. New Delhi, India: Ministry of Health and Family Welfare, Government of India; 2004
## List of cases (litigations) analyzed in the study

### Cases involving the Prevention of Food Adulteration, 1954

| Case Description                                                                 | Reference Number |
|----------------------------------------------------------------------------------|------------------|
| Godawat Pan Masala Products I.P. Ltd. and Ors. vs. Union of India (UOI) and Ors. | MANU/SC/0574/2004 |
| Khedan Lal and Sons vs. The State of UP and Ors.                                 | MANU/UP/0245/1970 |
| Khedan Lal and Sons vs. State of U.P. and Ors.                                  | MANU/UP/0376/1980 |
| Kothari Chemicals vs. Union of India (UOI)                                       | MANU/UP/0739/1995 |
| State of U.P. vs. Shri Ram Gupta                                            | MANU/UP/0408/1971 |
| Manohar Lal vs. State of U.P.                                                   | MANU/UP/0921/1989 |
| Chandra Shekhar and Ors. vs. State                                             | MANU/UP/0909/1982 |
| Society for Cancer in Oral-Cavity Prevention through Education, Hyderabad vs. Union of India (UOI) and Ors. | MANU/UP/1185/2002 |
| The Food Inspector, Div. II vs. D. Ravindranath and Ors.                        | MANU/AP/1125/2004 |
| Dharhiwal Industries Ltd. and Ors. vs. Union of India (UOI) and Ors.            | MANU/MH/0300/2006 |
| Dilipsinh vs. The State of Maharashtra                                           | MANU/MH/0571/2010 |
| Vishnu Packaging, a Partnership firm and Ors.                                   | MANU/MH/1571/2011 |
| Sainath Traders and Ors. vs. Commissioner of Food and Drug Administration and Ors | MANU/MH/1519/2012 |
| Sat Traders and Ors. vs. State of Goa and Ors.                                   | MANU/MH/2896/2016 |
| State of Maharashtra vs. Ramnath Punamchand Dayama and Ors.                      | MANU/MH/2823/2017 |
| Municipal Corporation of the City of Amravati vs. Ghanshyam Uttamchand Batra and Ors. | MANU/MH/2326/2018 |
| The Ahmednagar Municipal Council vs. Dullabhadas Haridas Patel and Ors.          | MANU/MH/1444/2009 |
| Rajiv Kumar Gupta and Ors. vs. The State of Maharashtra                          | MANU/MH/1299/2005 |
| Raskikal and Prakash vs. The State of Maharasthra                                 | MANU/MH/0846/2013 |
| State vs. Mustawueen Mohammad and Ors.                                          | MANU/MH/0684/2013 |
| K.P. Sugandh Limited and Etc. vs. State of Chhattisgarh and Ors.                 | MANU/C/0032/2008 |
| Sonal Food Products and Ors. vs. State                                           | MANU/DE/9839/2006 |
| Ram Babu Rastogi and Ors. vs. State                                             | MANU/DE/7058/2011 |
| Prince Gutka Ltd. vs. State and Ors.                                             | MANU/DE/0868/1999 |
| Bishan Dass Mehta and Ors. vs. Union of India and Ors.                           | MANU/DE/0011/1970 |
| Kirikumar Budhalal Patel vs. State of Gujarat                                    | MANU/GJ/0438/2000 |
| Royal Marvar Tobacco Pvt Ltd. and Ors. vs. State of Gujarat                      | MANU/GJ/1014/2011 |
| State of Gujarat vs. M/s Chetna Jarda Company (Manufacturing Firm)              | MANU/GJ/0261/1992 |
| State of Gujarat vs. Sanjay Kumar Nagindas Shah Vendor and Ors.                  | MANU/GJ/1625/2010 |
| State of Gujarat vs. M/s Chetna Jarda Company (Manufacturing Firm)              | MANU/GJ/1014/2011 |
| Kirikumar Budhalal Patel vs. State of Gujarat                                   | MANU/GJ/0438/2000 |
| Case                                      | Date of Judgment | Reference                                |
|-------------------------------------------|------------------|------------------------------------------|
| State of Assam vs. Ram Karani and Ors.    | 10.09.1986       | MANU/GH/0033/1986                        |
| Tirupati Products (P1) and Haji Shah(P2)  | 07.03.2005       | JHRHC                                    |
| Hussain Buksh Khand Sons Khan and Sons    |                  | MANU/HJ/0081/2005                        |
| and Anr. vs. State of Jharkhand and Ors.  |                  |                                          |
| Raju Laxman Pachapure v. State of         |                  |                                          |
| Karnataka and Ors. WP No. 15119 of 2006   |                  |                                          |
| The Mahad Areca Marketing Co-operative   | 04.04.2007       | MANU/KA/7098/2007                        |
| Society Ltd. and Ors. vs. Union of India  |                  |                                          |
| (UOI) and Anr.                           |                  |                                          |
| Shivraj Tobacco Company Pvt. Ltd. vs.     | 02.11.1989       | MANU/MP/0290/1989                        |
| State of Madhya Pradesh                   |                  |                                          |
| R.P. Sharma vs. State                     | 18.11.2004       | MANU/TN/1353/2004                        |
| Lekhraj vs.                              |                  |                                          |
| The State of Tamil Nadu                   | 01.09.2006       | MANU/TN/6098/2006                        |
| Indradeo Dwarika Singh vs. State of       |                  |                                          |
| Bihar and Ors. (03.10.2017 - PATNAHC)     |                  | MANU/BH/1651/2017                        |
| Md. Sagir and Md. Mkhtar Alam vs. State   | 19.03.2009       | MANU/BH/0122/2009                        |
| of Bihar and Anr.                         |                  |                                          |
| R.P. Patel vs. State of Punjab            | 09.08.1997       | MANU/PH/0898/1997                        |
| Shivraj Tobacco Company Pvt. Ltd. vs.     | 04.04.2007       | MANU/KA/7098/2007                        |
| State of Madhya Pradesh                   |                  |                                          |
| Sanjay Anjpal Stores and Ors. vs.         | 01.01.2017       | CALHC                                    |
| The Union of India and Ors.               |                  |                                          |
| Court on its own motion vs. State of      |                  |                                          |
| Himachal Pradesh and Ors.                 | 06.11.2018       | Citation                                 |
| Yadav v. State of Bihar, et al., No.       |                  | MANU/HP/1706/2018                        |
| 10297, High Court of Judicature at Patna   |                  |                                          |
| M/S R.K. Products Company v. Union of     |                  |                                          |
| India et al. Patna High Court CWJC No.    |                  |                                          |
| 12871 of 2012 (2)                          | 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 | 23.12.2014       |                                          |
| No. 20129 of 2014. dated                  |                  |                                          |
| 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.  |                  | MANU/BH/0504/2016                        |
| Javvila Tobacco Traders LLP vs.           |                  |                                          |
| The Designated Officer, Food Safety and    |                  |                                          |
| Drugs Control Dept. (09.06.2017 - MADHC)   |                  | MANU/TN/2146/2017                        |
| J. Anbazhagan vs. The Union of India and   |                  |                                          |
| Ors. (26.04.2018 - MADHC)                 |                  | MANU/TN/2109/2018                        |
| Ghoi Foods Private Limited v. UOL WP No.   |                  |                                          |
| 3131, Madhya Pradesh, Gwalior High Court   |                  |                                          |
| 2012.                                    |                  |                                          |
| Manoj Kumar Jain vs. State of M.P.        |                  | MANU/MP/1089/2017                        |
| Joshy vs. State of Kerala (20.12.2012 -   |                  | MANU/KE/2254/2012                        |
| KERHC)                                    |                  |                                          |
| Ghodawat Pan Masala v. State of Karnataka  |                  | MANU/MH/1519/2012                        |
| Doctors for You v. State of Delhi, W.P.(C)|                  | MANU/MH/2486/2013                        |
| Vishnu Pouch Packaging Pvt. Ltd. vs.      |                  | MANU/MH/2486/2013                        |
| Bluish Dental Association U.P. State and   |                  | MANU/MH/2065/2016                        |
| Ors. (17.09.2012 - ALLHC)                 |                  |                                          |

**Cases involving the Food Safety and Standards Act, 2006**

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