

**FORTY-SEVENTH REPORT**

**COMMITTEE ON PETITIONS**

**(SEVENTEENTH LOK SABHA)**

**MINISTRY OF HEALTH & FAMILY WELFARE,**

**MINISTRY OF AGRICULTURE & FARMERS' WELFARE  
(DEPARTMENT OF AGRICULTURE, COOPERATION & FARMERS' WELFARE)**

**MINISTRY OF LABOUR & EMPLOYMENT,**

**MINISTRY OF COMMERCE & INDUSTRY  
(DEPARTMENT OF COMMERCE)**

**AND**

**MINISTRY OF MICRO, SMALL & MEDIUM ENTERPRISES**

**(Presented to the Speaker, Lok Sabha on 24.03.2023)**



**LOK SABHA SECRETARIAT  
NEW DELHI**

**March, 2023/Chaitra, 1945 (Saka)**

**CPB. NO. 1 Vol. LVII**

**Price: Rs.....**

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**Published under Rule 382 of the Rules of Procedure and Conduct of Business in Lok Sabha (Sixteenth Edition).**

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## COMPOSITION OF THE COMMITTEE ON PETITIONS

Shri Harish Dwivedi - *Chairperson*

### MEMBERS

2. Shri Anto Antony
3. Shri Hanuman Beniwal
4. Prof. Sanjay Sadashivrao Mandlik
5. Shri P. Ravindhranath
6. Dr. Jayanta Kumar Roy
7. Shri Brijendra Singh
8. Shri Sunil Kumar Singh
9. Shri Sushil Kumar Singh
10. Shri Manoj Kumar Tiwari
11. Shri Prabhubhai Nagarbhai Vasava
12. Shri Rajan Baburao Vichare
13. Vacant
14. Vacant
15. Vacant

### SECRETARIAT

1. Shri T.G. Chandrasekhar - Additional Secretary
2. Shri Raju Srivastava - Director
3. Shri Harish Kumar Sethi - Under Secretary

**FORTY-SEVENTH REPORT OF THE COMMITTEE ON PETITIONS  
(SEVENTEENTH LOK SABHA)**

**INTRODUCTION**

I, the Chairperson, Committee on Petitions, having been authorised by the Committee to present on their behalf, this Forty-Seventh Report (Seventeenth Lok Sabha) of the Committee to the House on the Action Taken by the Government on the recommendations made by the Committee on Petitions (Sixteenth Lok Sabha) in their Sixty-Eighth Report on the representation of Shri Sanjay Bechan regarding saving the livelihood of millions of tobacco farmers, labourers employed in Kevda and Mentha farming/tobacco industry and harmonization of definition of 'Food' under the Food Safety and Standards Act, 2006.

2. The Committee considered and adopted the draft Forty-Seventh Report at their sitting held on 23 March, 2023.
3. The observations/recommendations of the Committee on the above matters have been included in the Report.

**NEW DELHI;**

**23 March, 2023**

**02 Chaitra, 1945 (Saka)**

**HARISH DWIVEDI  
Chairperson,  
Committee on Petitions**



## REPORT

### **ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS MADE BY THE COMMITTEE ON PETITIONS (SIXTEENTH LOK SABHA) IN THEIR SIXTY EIGHTH REPORT ON THE REPRESENTATION RECEIVED FROM SHRI SANJAY BECHAN REGARDING SAVING THE LIVELIHOOD OF MILLIONS OF TOBACCO FARMERS, LABOURERES EMPLOYED IN KEVDA AND MENTHA FARMING/ TOBACCO INDUSTRY AND HARMONIZATION OF THE DEFINITION OF 'FOOD' UNDER THE FOOD SAFETY AND STANDARDS ACT, 2006.**

During the Sixteenth Lok Sabha, the Committee on Petitions had received a representation of Shri Sanjay Bechan dated 17.09.2016 regarding saving the livelihood of millions of tobacco farmers, labourers employed in Kevda and Mentha farming/tobacco industry and harmonization of definition of 'Food' under the Food Safety and Standards Act, 2006. In his representation, Shri Sanjay Bechan had *inter alia* stated, as under:-

- (i) India is the second largest producer of tobacco in the world which produces 900 million kilogram of tobacco and exports over 200 million kilogram of tobacco per year.
- (ii) Tobacco is grown in majority of the States in the country and over 8 million people are involved in Tobacco Farming and Processing Industry.
- (iii) On the issue of banning tobacco in the country, the representationist apprehended that if tobacco or any form of tobacco is banned, a legitimate business will be replaced with illicit trade of tobacco products across the country, leading way to tobacco *mafias*, thereby, jeopardizing livelihood of millions of farmers and labourers involved in the profession.
- (iv) The Food Safety and Standards Act, 2006 was established as an Act to consolidate the laws relating to Food and to establish the Food Safety and Standards Authority of India for laying down scientifically based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption and for matters connected therewith and

incidental thereto. Hence, the Act *ibid* aims at Food Safety as a National Movement.

- (v) Although the Act is for safety and standards of 'Food', the 'Food' itself has not been appropriately defined in the Statute Book, i.e., the Food Safety & Standards Act, 2006 and therefore, requested the Committee on Petitions to look into the matter and do the needful.

2. The Committee on Petitions took up the said representation for examination under Direction 95 of the Directions by the Speaker, Lok Sabha. After detailed examination of the representation of Shri Sanjay Bechan on the above subject, the Committee on Petitions presented their 68<sup>th</sup> Report to the Hon'ble Speaker, Lok Sabha on 9<sup>th</sup> March, 2019 and later on to the Lok Sabha on 26<sup>th</sup> June, 2019. A copy of the Report was forwarded to the Ministries/Departments concerned to furnish their action taken replies on the recommendations made therein for consideration of the Committee.

3. Action Taken Notes have since been received from the Ministries/Departments concerned in respect of all the observations/recommendations contained in the aforesaid Report except for the Recommendation at para No. 4.19 [Efficacy of imposing 'Ban' on any commodity/product].

4. The recommendations made by the Committee and the replies furnished thereto by the Ministries/Departments concerned have been detailed in the succeeding paragraphs.

5. In paragraphs number 4.1, 4.2, 4.3, 4.4, 4.5, 4.6 and 4.7 of the Report, the Committee had observed/recommended as follows:-

#### **I. Excessive Delegated Legislation**

*"The Committee note that under Section 3(j) of the Food Safety and Standards Act, 2006, the word 'Food' has been defined as follows:-*

*'Food means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk), genetically modified or*

*engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances.'*

The Committee also note that under Section 7(v) of the Prevention of Food Adulteration Act, 1954, the word 'Food' has been defined as follows:-

*"Food means any article used as food or drink for human consumption other than drugs and water and includes, any article, which ordinarily enters into, or is used in the composition or preparation of, human food and any flavoring matter or condiments."*

*In this context, the Committee further find that the Codex Alimentarius Commission (CAC) was created in 1961-62 by the Food and Agriculture Organisation (FAO) of the United Nations and the World Health Organisation (WHO) to develop Food Standards, Guidelines and related texts such as Codes of Practice under the Joint FAO/WHO Food Standards Programme. The main purpose of this Programme was to protect the health of consumers, ensure fair practices in the food trade, and promote coordination of all Food Standards work undertaken by the International Governmental and Non-Governmental Organisations. It is a collection of International Food Standards adopted by the Codex Alimentarius Commission. The Codex defines certain terms related to the processing of food. As per Codex Alimentarius, the word 'Food' has been defined as follows:-*

*"Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "Food" but does not include cosmetics or tobacco or substances used only as drugs."*

*Similarly, as per the European Commission's definition of food, 'Food' (or 'Foodstuff') means any substance or product whether processed, partially*

processed or unprocessed, intended to be, or reasonably expected to be ingested' by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC. 'Food' shall not include feed live animals unless they are prepared for placing on the market for human consumption, plants prior to harvesting medicinal products within the meaning of Council Directives 65/EEC(21) and 92/73EEC(22); cosmetics within the meaning of Council Directive 76/768/EEC(23); tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24); narcotic or psychotropic substances within the meaning of the United Nations Convention on Psychotropic Substances, 1971, residues and contaminants.

In the context of definition of 'Food' under the Food Safety and Standards Act, 2006 the Prevention of Food Adulteration Act, 1954 and the Codex Alimentarius Commission, the Ministry of Health & Family Welfare have submitted before the Committee, as follows:-

"Though there is no explicit mention of tobacco products including Smokeless Tobacco products in the definition of food, the definition of 'food' under Section 3(J) of the FSS Act, 2006 is very wide and includes products such as Gutkha, Zarda, Khaini (processed) and any other similar processed/flavoured Chewing Tobacco products."

"In the definition of 'food' under the PFA Act, 1954, there is no explicit mention of Tobacco products including Smokeless Tobacco products."

"The definition of 'food' in Codex differs from that of FSS Act, 2006 in respect of specific exclusion of Tobacco from food."

Notwithstanding the fact that there was no explicit mention of Tobacco products including Smokeless Tobacco products in the definition of 'food', either in the FSS Act, 2006 or the PFA Act, 1954, the Smokeless Tobacco products such as Gutkha, Zarda, Khaini (processed) and other similar processed/flavoured chewing tobacco products were included as food products within the definition of the word 'Food'. The Committee, therefore, specifically

enquired about the reasons for such inclusion. The Ministry of Health & Family Welfare had given the following reasoning for inclusion of Tobacco products such as Gutkha, Zarda and Khaini (processed) as food products within the definition of the word 'Food':-

- (i) *The Hon'ble Supreme Court, in the case of Godawat Pan Masala Products I.P. Ltd., held Gutkha, Pan Masala and Supari as food articles because under the FSS Act, 2006, chewing tobacco is listed in the category of food items.*
- (ii) *The Hon'ble Supreme Court, in the matter of State of Tamil Nadu vs. R. Krishnamurthy, (1980) 1 SCC 167, while interpreting the definition under PFA Act, 1954, held, that all that is required to classify a product as food is that it be commonly used for human consumption or in preparing human food.*
- (iii) *The Hon'ble Allahabad High Court in Manohar Lal vs. State of U.P., Criminal Revision No. 318 of 1982 and in Khedan Lal and Sons vs. State of U.P. and Ors., 1980 CriL J 1346, relying upon the judgment of State of Tamil Nadu vs. R. Krishnamurthy, (1980)1 SCC 167, held "Chewing Tobacco" as an article of food.*
- (iv) *The Hon'ble Supreme Court in the Godawat Pan Masala Products I.P. Ltd. vs. Union of India (2004) 7 SCC 68, held Gutkha, Pan Masala and Supari as food articles based on the definition of "food" under the PFA Act.*
- (v) *In exercise of the powers conferred under Section 92 read with Section 26 of the Food Safety and Standards Act, 2006, the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 was notified on 1 August, 2011. Clause 2.3.4 of the said Regulation expressly prohibits the use of tobacco and nicotine in all food products and reads as: "Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food products."*

Against the aforesaid backdrop, the Committee are astonished to find that the Ministry of Health & Family Welfare have not only relied upon the orders of various Courts including the Hon'ble Supreme Court of India to justify the inclusion of tobacco products in the definition of food under Section 3(j) of the FSS Act, 2006, but also referred to their notifying the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011; which expressly prohibits the use of tobacco and nicotine in all food products. In this connection, the Committee would like to point out that even though the various Courts of the country had interpreted the relevant Acts, thereby, prohibiting the use of tobacco and nicotine in all food products, the act of Ministry of Health & Family Welfare by way of merely notifying the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 for prohibiting the use of tobacco and nicotine in all food products, and not amending either the Food Safety and Standards Act, 2006 or the Prevention of Food Adulteration Act, 1954 is an exercise of excessive Delegated Legislation. The Committee would also like to mention that according to the traditional theory of Subordinate Legislation, the function of the Executive is to administer the law enacted by the Legislature, and in the ideal State like ours, the Legislative Powers must be exercised exclusively by the Legislatures who are directly responsible to the electorates. The Committee, therefore, strongly recommend that in case, the Ministry of Health & Family Welfare intends to further pursue the matter, they should work out modalities to amend the Food Safety and Standards Act, 2006 or the Prevention of Food Adulteration Act, 1954 for explicitly prohibiting the use of tobacco and nicotine in all food products and also bring about appropriate changes in the definition of 'Food' under the Act *ibid*. The Committee would like to be kept abreast of the steps taken by the Ministry of Health & Family Welfare in the matter."

6. The Ministry of Health & Family Welfare, in their action taken reply, have submitted as follows:-

"The definition of 'Food' whether under Prevention of Food Adulteration Act, 1954 or the Food Safety and Standards Act, 2006 is the same as far as Tobacco is concerned. Definition of 'food' in FSS Act is wide enough to include any product or substance which can be eaten/chewed/swallowed except the product/substance which are specifically excluded in the definition which are, animal feed, live animals unless they are prepared or processed for placing on

*the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic, or psychotropic substances.*

*It is felt the regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, which provides that tobacco and nicotine shall not be used as ingredients in any food products, has been enacted after due deliberations. Firstly, Section 44(J) was enacted in the Prevention of Food Adulteration Rules, 1955; and later, it was included as regulation 2.3.4 in the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 Regulation 2.3.4 of FSS (PRS) Regulations, 2011 extends to all food products, such as gutka (tobacco mix with areca nut and other flavouring agents) or Zarda or chewing tobacco (where flavouring agents are added to tobacco to make it edible. Kind attention is drawn to Article 47 of the Directive Principles of State Policy in the Constitution of India which reads, "The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health." The restriction on the use of tobacco and nicotine in any product which is consumed by human beings, as various research studies so far have revealed, is injurious to health. As per Tobacco Control of India Report 2004, the number of deaths attributed to tobacco is almost 8-9 lakhs per year. As per ICMR study 50% of cancers in males and 20% cancers in females can directly be attributed to tobacco use. If the use of these products is not curbed, the results are likely to be alarming.*

*Therefore, it is in the fitness of things if use of tobacco is restricted as much as possible and this would be in furtherance of noble objective as enshrined in Article 47 of the Constitution of India. It would therefore infer that regulation 2.3.4 of Food Safety and Standards Act (Prohibitions & Restrictions on Sales) Regulations, 2011 should not be categorized as 'excessive delegated legislation' and the definition of 'food' under Section 3 (1) (J) and Section 2 (v) of Prevention of Food Adulteration Act is wide enough, as confirmed by courts in catena of cases, that smokeless tobacco products (i.e. Gutkha, Khaini, Zarda etc.) are 'food' and thus can be regulated under PFA Act/FSS Act.*

*It is a fact that 'tobacco' is specifically excluded from the definition of 'food' by the 'Codex Alimentarius Commission' (CAC) as well as 'European Commission' (EC). In the context of CAC & EC 'tobacco' primarily refers to 'Smoking' one and not 'Smokeless' as the smokeless tobacco use (Gutkha, Zarda, Khaini etc.) is the phenomenon of South Asia and more particularly of India. In India also smoking is not part of food. Considering peculiarities, specific to India, the rules and regulations have been framed. Therefore, different position exists in India as far as use of tobacco and its products are concerned vis-a-vis European Commission countries and Codex Alimentarius Commission."*

## **II. Avoidance of narrow definition of 'Food' under the FSS Act, 2006**

*"The Committee note from the submissions made by the Ministry of Health & Family Welfare that the use of Tobacco is a prominent risk factor for 6 to 8 leading causes of death and almost 40% of the Non-Communicable Diseases (NCD) including cancers, cardiovascular diseases and lung disorders are directly attributable to tobacco use. The number of deaths every year in India which is attributable to tobacco use is almost 8-9 lakh (Tobacco Control In India Report, 2004) and 50% of cancers in males and 20% cancers in females can be directly attributed to tobacco use (ICMR Study). If the current trends continue and if effective steps are not taken to control Tobacco Consumption, it is estimated that by the year 2020, tobacco use will account for 13% of all deaths in India every year. Further, according to the WHO Global Report on "Tobacco Attributable Mortality" 2012, 7 percent of all deaths (for ages 30 and over) in India are attributable to Tobacco Use.*

*The Committee also note from the submissions made by the Ministry of Health & Family Welfare that besides being a major health risk, the use of Tobacco and the associated mortality and morbidity are a significant economic burden on the society. As per the findings of the study titled "Economic Burden of Tobacco Related Diseases in India" (2014) commissioned by Ministry of Health & Family Welfare, the total Economic Costs attributable to Tobacco Use from all diseases in the country in the year 2011 for persons aged 35-69 years amounted to Rs. 1,04,500 crore. This estimated cost was 1.16% of the GDP and was 12% more than the combined States and Central Government expenditures in Health Sector in 2011-12.*



The Committee further note that keeping in view harmful effects of tobacco, Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 expressly bans/prohibits the use of tobacco and nicotine in all the food products. However, thereafter, another subjective distinction was made by the Ministry of Health & Family Welfare by way of confining the harmful effects of tobacco only to smokeless tobacco such as Gutkha, Zarda, Khaini and any other similar processed/flavoured chewing tobacco products and conveniently excluded the smoking tobacco. While giving reasons for advocating the proscription of only smokeless/chewing tobacco products and not the entire range of products containing tobacco and nicotine, the Ministry of Health & Family Welfare have reasoned that smoking tobacco cannot be brought under the definition of 'food' as anything is eaten through mouth or chewed can only be 'food' under the definition at Section 3(l) of FSS Act, 2006. Given this backdrop, the Committee find it difficult to understand the logic behind making such a laughable distinction in view of the fact that the Ministry of Health & Family Welfare, in their submissions before the Committee, have themselves accepted not only the fact that the WHO Global Report on 'Tobacco Mortality Report 2012' had reached to the conclusion that seven percent of all deaths in the country are attributable to use of tobacco, but also revealed that the total economic cost attributable to tobacco use from all diseases in the country in the year 2011 amounted to Rs. 1,04,500 crore; which was 1.16 percent of the Gross Domestic Product (GDP) and was also 12 percent more than the combined States and Central Government expenditures in the Health Sector in 2011-12. Now that since the Committee have already recommended that in order to obviate excessive delegated legislation by way of amending the relevant provisions of the FSS Act, 2006, the Committee further recommend that the definition of 'Food' contained in the FSS Act, 2006 should not only include smokeless tobacco products but also all forms of products which contain tobacco and nicotine. The amendment in the Act *ibid*, should, therefore, explicitly prescribe that "the product not to contain any substance which may be injurious to health: Tobacco and Nicotine shall not be used as ingredients in any food product". The Committee would like to be apprised of the concrete action initiated by the Ministry of Health & Family Welfare, in this regard.

In this context, the Committee, after comprehending the various facets of reflective listening and submissions made by the Ministry of Health and Family

*Welfare, thereby, pointing towards the probable 'blind spots' as brought out in the foregoing paragraphs, are inclined to again refer to Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales), Regulation, 2011 which expressly prohibits the use of tobacco and nicotine in all food products. In case, the Committee, momentarily, ignores the aspect of excessive delegated legislation, then, in the context of said Regulation, the Committee find that when it has already been specified that 'Tobacco' and 'Nicotine' shall not be used as ingredients in any food products, then, what was the logic of continuous insistence on the part of the Ministry of Health and Family Welfare to consider Gutkha, Zarda, Khaini and other similar articles as 'Food Products' by way of interpreting the definition of 'Food' under Section 3(i) of the FSS Act, 2006. The Committee are of considered view that there appears an inherent contradiction in Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales), Regulation, 2011 vis-a-vis the definition of 'Food' under the FSS Act, 2006 which reverberate the non-usefulness of bringing various products such as Gutkha, Zarda, Khaini and any other similar chewing tobacco products as articles of 'Food'. The Committee, therefore, strongly recommend that the Ministry of Health and Family Welfare should redraw their entire strategy, with a pragmatic hypothesis of the need of imposing a complete ban or regulating the use of all tobacco products in the country and, thereafter, formulate a long term policy coupled with bringing out one-time, self-contained, legally tenable amendments in the Act(s) to insulate themselves from entering into yet another quagmire of legal complications/litigations and leveling of poppycock allegations from various, so called 'Lobbies'. The Committee would like to be apprised of the concrete action taken by the Ministry of Health and Family Welfare in this regard."*

7. The Ministry of Health & Family Welfare, in their action taken reply, have submitted as follows:-

*"Smoking Tobacco cannot be categorized as 'food' under FSS Act, 2006 by any stretch of imagination. It cannot be 'food' as it is not eaten. Inhaling of a substance would not be covered in the existing definition of 'food'.*

*The National Health Policy, 2017 envisages the targets for relative reduction in prevalence of current tobacco use as 15% by 2020 and 30% by 2025. The overall objectives of the policy is to reduce the consumption of tobacco*

*products, whether it is Smoking or Smokeless Tobacco through the adoption of balanced and systematic policy measures and to achieve the target envisaged in the National Health Policy 2017.*

*As per the second round of Global Adult Tobacco Survey (GATS-20, 28.6%) 266.8 million of adults. In India, aged 15 and above currently use tobacco in some form. Further, the prevalence of any form of tobacco use has decreased significantly by six percentage points from 34.6 percent (2009-10) to 28.6 percent (2016-17). The relative decrease in the prevalence of tobacco use is 17.3 percent. There has been considerable decrease in the prevalence of smoking and smokeless tobacco use. Prevalence of smoking has decreased by 3.3 percentage points from 14.0% (2009-10) to 10.7% (2016-17) and smokeless tobacco use has decreased by 4.5 percentage points from 25.9% (2009-10) to 21.4% (2016-17).*

*It may be seen that the prevalence of SLT use is more than that of smoking tobacco products. It may also be noted that mixing of tobacco or nicotine in any food product is already prohibited under Food Safety and Standards Act.*

*COTPA, 2003 discourages tobacco use and prohibits smoking in public places, restriction on advertising, promotion and sponsorship of tobacco products, ban on sale to and by minors and sale of tobacco products around 100 yards of educational institutions and mandates for statutory health warnings on all tobacco product packs. The National Health Policy, 2017 comprehensively articulates the tobacco control objectives. The National Health Policy was formulated after wide consultations with all the stakeholders especially the State Governments. This Ministry is increasingly working to achieve the said objectives envisaged in the National Health Policy, 2017."*

### **III. Imposing selective ban vis-a-vis enforcing regulation - A Case Study of 'Smokeless' and 'Smoking' Tobacco**

*"The Committee note that during the oral evidence, the representatives of the Ministries of Health & Family Welfare, Agriculture & Farmers Welfare (Department of Agriculture, Cooperation & Farmers' Welfare) and Labour & Employment deposed before the Committee and unambiguously submitted that it has been verified by the number of Reports that 'Tobacco' is harmful in all its*

forms. There is no difference between 'Smokeless' and 'Smoking' Tobacco as far as their harmful effects on human beings are concerned as both are harmful to health and cause cancer and other related diseases. The Committee was apprised that approximately, 8 lakh deaths are reported, every year, due to cancer caused by use of tobacco. The Committee have further been apprised that the Expert Committee on 'Use of Tobacco in Pan Masala, Gutkha, etc.', in its meeting held on 23.9.1997, stated that on the basis of literatures/studies available so far on the adverse effects of consumption of Pan Masala containing Tobacco/Gutkha/Chewing Tobacco, the Experts strongly recommended that use of chewing tobacco in Pan Masala/Gutkha or as an ingredient in any food item or as such, should be prohibited as consumption of these articles is definitely injurious to public health. The Committee have also analysed that imposing a ban or moving in the direction of proscribing all the activities connected with the manufacture, sale, consumption, etc., of all types of 'Smokeless/Chewing Tobacco' products is based on four premises, namely; (i) Leisure interpretation of definition of 'Food' under Section 2(j) of the FSS Act, 2006 by the Ministry of Health & Family Welfare; (ii) Taking out all types of 'Smoking Tobacco' products from the ambit of ban on the grounds that anything which is eaten through mouth or chewed can only be 'Food' as per the definition under the FSS Act, 2006; (iii) Ignoring the ill-effects of smoking tobacco on various vulnerable non-smoking classes, viz., women, senior citizens, children and other environmental hazards attributable to emission of hazardous/ toxic chemicals while smoking which has always remained a serious aspect of concern in almost all the countries of the world; and (iv) Observations/ Interpretations/Orders of various Courts, including the Supreme Court of India, affirming 'Chewing Tobacco' as an article of food.

The Committee, on the other hand, are astonished to note that when Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 expressly bans/prohibits the use of tobacco and nicotine in all the food products, provisions contained in the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA) were invoked only to regulate 'Smoking Tobacco' and not to impose any ban on these tobacco products.

*The Committee, after pondering over all the issues/aspects in detail, are of considered opinion that now it is high time that the Ministry of Health & Family Welfare should go in for an impregnable policy formulation either to consider that 'Tobacco' is harmful in all its forms and there is no difference between 'Smokeless' and 'Smoking' Tobacco as far as their harmful effects on human beings are concerned and impose a complete ban on all these products; or to regulate the trade and commerce, production, supply and distribution of all these products, i.e., both 'Smokeless' and 'Smoking' Tobacco in the country by way of implementing the provisions contained in the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 in an all encompassing and stringent manner and that too in effective co-ordination with State Governments and other stakeholders. In this connection, the Committee would also like to advise the Ministry of Health & Family Welfare that while going in for any of the aforementioned alternative, i.e., either imposing a complete ban on all 'Smokeless' and 'Smoking' items or only regulating these products, a two pronged strategy need to be adopted by them, i.e., firstly to work out concrete proposals for implementation of both the recommendations of the Committee contained at paragraphs 4.7, 4.10 and 4.11 of Chapter IV of the Report; and secondly, to formulate and submit appropriate averments, in the form of an Affidavit, before the Court(s), where the matter is currently, under their consideration. Notwithstanding the fact that this is an onerous task, the Committee desire that the Ministry of Health & Family Welfare should take all the necessary measures to achieve the intended objectives. The Committee would like to be apprised of the definite roadmap, including targeted dates for each of these activities, at the earliest."*

8. The Ministry of Health & Family Welfare, in their action taken reply, have submitted as follows:-

*"The intention of legislature (Parliament) while enacting FSS Act, 2006 (which subsumed PFA Act and other rules and orders relating to food administered by various Government Departments) has been to include 'smokeless' tobacco in the definition of 'food' under FSS Act and rules and regulations framed there under and to regulate the matters concerning smoking tobacco under the Cigarettes and Other Tobacco Products (Prohibitions and Advertisement and*

Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (popularly known as COTPA)."

#### **IV. Encouraging Tobacco Growing Farmers to shift to alternate Crops/Cropping Systems**

"The Committee note that 60 lakh farmers are involved in tobacco farming in the country and the number of people involved in tobacco farming, marketing and other allied activities runs in crores. As per the industry estimates, the Tobacco Industry provides livelihood to over 45.7 million people consisting of Farmers, Farm Labour, Merchant Traders, Processors, Manufacturers, Wholesalers and Retailers across the supply chain, out of which more than 48 lakh workers are registered as Beedi Rollers under the Labour Welfare Organisation of the Ministry of Labour and Employment. The Committee also note that in order to encourage tobacco growing farmers to shift to alternate crops/cropping systems, Department of Agriculture, Cooperation & Farmers' Welfare (DAC&FW), Ministry of Agriculture & Farmer's Welfare (MOAFW) has extended its Crop Diversification Programme (CDP), an ongoing sub-scheme of Rashtriya Krishi Vikas Yojana (RKVY), to 10 tobacco growing States, i.e., Andhra Pradesh, Bihar, Gujarat, Karnataka, Maharashtra, Odisha, Tamil Nadu, Telangana, Uttar Pradesh and West Bengal w.e.f. 2015-16. Under the scheme, assistance is being provided under four major components, viz., alternate crop demonstration, farm mechanization & value addition, site specific activities and contingency for awareness, training, implementation, monitoring, etc. through State Department of Agriculture. The Committee have also been informed that with the implementation of Crop Diversification Programme, out of the total tobacco area of 4.67 lakh hectares in the country, about 29,998 hectares in 2015-16 and 51,713.1 hectares in 2016-17 have been diversified with alternative crops/cropping system. Besides, in order to encourage tobacco workers to shift to alternative vocations, this Ministry have collaborated with Ministry of Labour & Employment to initiate 'Skill Development' programme for beedi rollers to facilitate them to shift to alternative vocations which are equally remunerative. The programme has been launched on a pilot basis in the year 2017 in the 5 States, viz. Sambhalpur-Bhubaneshwar Region; Rajnandgaon-Raipur Region; 24 Pargana-Kolkata Region; Kasargod-Kannur Region ; and Nizamabad-Hyderabad region.

*The Committee appreciate the various initiatives so far been undertaken by the Union Government, in coordination with the State Governments/UT Administration, to assist the farmers for adopting various alternative vocations or shifting to alternate crops/cropping systems. However, while analysing the statistical details of implementation of the Crop Diversification Programme in the country, the Committee have found that during 2015-16 and 2016-17, only 81,711 hectares of tobacco farming area have been diversified with alternative crops/ cropping system, which is a meager 17.49 percent of the 4.67 lakh hectares of total tobacco farming area in the country. On this issue, the Committee would like to clear their apprehension that had the Authorities concerned vehemently embarked upon the Crop Diversification Programme, especially for tobacco growing farmers earlier, i.e., before 2014-15, the results achieved would have been much more encouraging. The Committee, therefore, strongly recommend that the Ministry of Agriculture & Farmers' Welfare should give a renewed impetus to the entire Crop Diversification Programme, in coordination with the State Governments/ UT Administrations with a view to encouraging the tobacco growing farmers to shift to alternate crops/cropping systems. The Committee would like to be apprised of the action taken by the Ministry in this regard."*

9. The Ministry of Health & Family Welfare, in their action taken reply, have submitted as follows:-

*"It is for the Ministry of Agriculture and Farmers Welfare to persuade States/UTs as well as through Krishi Vigyan Kendras to incentivise and motivate farmers to switch over from growing tobacco to healthier crops and avail the assistance extended by Central/ State Governments under Crop Diversification Scheme as component of flagship scheme "Rashtriya Krishi Vikas Yojana" administered by the Ministry of Agriculture and Farmers Welfare."*

10. The Ministry of Agriculture & Farmers Welfare (Department of Agriculture, Cooperation & Farmers Welfare), in their action taken reply, have submitted as follows:-

*"The Ministry of Agriculture & Farmers Welfare (Department of Agriculture, Cooperation & Farmers Welfare) is supplementing the efforts of the State*

Governments to shift the tobacco growers to other alternative crops/cropping system under the Crop Diversification Programme (CDP), a sub scheme of Rashtriya Krishi Vikas Yojana. The Ministry of Agriculture & Farmers Welfare (Department of Agriculture, Cooperation & Farmers Welfare) is primarily concerned with Agriculture and Horticulture crops and Farmers Welfare.

Crop Diversification Programme is being continued during 2019-20 to encourage farmers to grow alternative crops/cropping system in tobacco growing States with an amount of Rs.667.00 lakh as central share (i.e. 33.35% of total allocation of Rs.2000.00 lakh made under CDP). In case the implementing States utilize the funds (central share) of previous and current year and demand of additional funds for replacing tobacco farming under CDP, the same are also considered for diversifying the tobacco area. The programme is being implemented on 60:40 sharing basis between Union Government and State Governments.

Crop Diversification Programme implementing States have been advised to give a renewed impetus to the CDP with a view to encourage the tobacco growing farmers to shift to alternate crops/cropping systems. Under Crop Diversification Programme, tobacco growing States have been given flexibility to take any suitable activities/interventions for replacing the tobacco crop to alternative crops/cropping system as per the cost norms approved under any Centrally Sponsored Scheme/State Scheme. Under Crop Diversification Programme for motivating the farmers, State may also organize study tours/exposure visits and campaigns etc., for highlighting harmful effects of tobacco and long term benefits of alternative crops."

11. The Ministry of Labour & Employment, in their action taken reply, have also submitted as follows:-

"Ministry of Labour & Employment has initiated a Skill Development Programme in collaboration with the Ministry of Skill Development & Entrepreneurship and National Skill Development Corporation to provide alternative livelihood to beedi workers and their dependents to enhance their life standards. Initially the pilot project was started at five centres, namely, Sambhalapur-Bhubaneswar Region; Rajnandgaon-Raipur Regions; North 24 Pargana- Kolkata Region; Kasargod-Kannur Region and Nizamabad-



Hyderabad region. Further, the programme was extended to all regions under the Labour Welfare Organisation in the year 2018. A total of 7262 beneficiaries have availed the Skill Development Training as on 31.12.2019 out of which 2746 beneficiaries have been provided placement in alternate jobs.

## **V. Promotion of Aromatic Plants Industry**

"The Committee note that the Ministry of Micro, Small and Medium Enterprises have setup MSME-Technology Centre "Fragrance and Flavour Development Centre (FFDC), Kannauj" in the year 1991 with a view to serving as an interface between Essential Oil, Fragrance & Flavour Industry and the R&D Institutions, both in the field of Agro-Technology and Chemical Technology. The main objective of the Centre is to serve, sustain and upgrade the status of farmers and industry engaged in the Aromatic Cultivation and its processing, so as to make them competitive, both in the Local and the Global Markets. Besides, the FFDC has been organizing various Awareness Programmes/Motivational Campaign/Kisan Goshthi for promotion of Mentha & Kevda Industry in the country. The Statistical data submitted by the Micro, Small and Medium Enterprises shows that during the last ten years, 154 Awareness Programmes on Mentha and Kewda training on cultivation of Aromatic Crops have been organized and 7783 persons have participated therein. The Committee further note that for promotion of Mint Industry/Farmers in the country, the FFDC is also imparting services to the Industry for analyzing the Samples of Mint Oils through Multi Commodity Exchange, Mumbai. During the last ten years, 39,085 Samples of Mint Oils have been analysed by the FFDC.

Notwithstanding the various initiatives taken by the Ministry of Micro, Small and Medium Enterprises for promotion of Aromatic Plants Industry, the Committee are constrained to specifically mention that till date, no specific Scheme to incentivize the Aromatic Plant Industry, viz., Kewda and Mentha has ever been conceived and implemented by any of the Ministry of Government of India, viz., the Ministry of Agriculture & Farmers' Welfare, Ministry of Labour and Employment, the Ministry of Commerce and Industry, or the Ministry of Micro, Small & Medium Enterprises - leaving much to be desired on this count. The Committee, therefore, strongly recommend that a Quick Study, in co-ordination with the State Governments, should be initiated by the Government to take a

call for the need for formulation of a specific Scheme to incentivize the Aromatic Plant Industry, viz., Kewda and Mentha. While analyzing this, care should also be taken by the Government to ensure that the Scheme is implemented in the right earnest. The Committee would like to be apprised of the concrete action taken and the results achieved thereby within the next three months."

12. The Ministry of Micro, Small & Medium Enterprises, in their action taken reply, have submitted as follows:-

"Fragrance and Flavour Development Centre (FFDC), Kannauj which has been set up by Ministry of Micro, Small & Medium Enterprises to serve, sustain and upgrade the status of farmers and industry engaged in the aromatic cultivation and processing, so as to make them competitive both in local and global market. It also provides techno-commercial inputs for selection of aromatic plants while conceptualizing 'Aroma Mission' of the Council of Scientific & Industrial Research - Central Institute for Medicinal and Aromatic Plants (CSIR-CIMAP).

CSIR Aroma Mission has been conceptualized which aims to provide end-to-end technology and value-addition solutions across the country at a sizable scale. This mission will bring transformative change in the aroma sector through scientific interventions in the areas of agriculture, processing and product development for fuelling the growth of aroma industry and rural employment.

As per inputs from CSIR-CIMAP, details of the activities taken up by CSIR-CIMAP, Lucknow under this Aroma Mission are:-

**Activity 1:**

Development of superior varieties possessing any of the desired traits like higher yield potential, source of novel/in-demand aroma chemical, early maturing, suitable for stressed/degraded lands, low irrigation requirements/draught tolerance etc. This activity involves undertaking research work towards developing new and elite genotypes of MAPs suitable for different environments, rich in high value aroma chemicals with substantial

improvements in yields. Efforts are also being made in the mission program to develop varieties, which can mature early and can be accommodated in the existing cropping system. These varieties would also be assessed for their yield potential, chemical compositions, maturity period, etc., and the ones with desirable potential at specific locations are selected further for demonstrations in that specific area. All the existing varieties and newly developed varieties would also be assessed under different agro-climatic zones for fine-tuning the cultivation practices to be adopted under that region. Suitable agro techniques including planting and harvesting times to be optimized for achieving higher yields. Agro-technology including post harvest optimization for different agro-climate zones would also be developed.

### **Activity 2**

Promotion of cultivation and processing of aromatic crops, enhancing area under selected aromatic crops along with enabling interventions including setting up of distillation units and catalyzing, setting up of cooperatives for marketing of the produce. Under this activity, promotion of cultivation and processing of aromatic crops, enhancing area under selected aromatic crops along with enabling interventions including setting up of distillation units and catalyzing setting up of cooperatives for marketing of the produce. The activity would involve selection of crops, multiplication of planting material, selection of clusters of farmers and promotion of cultivation of these crops to newer suitable areas and setting up of distillation units and catalyzing setting up of farmer's cooperatives for marketing of the produce.

### **Activity 3**

Value-addition of aromatic crops (High-end aroma chemical and products). This activity involves optimization of processes for fractionation for isolation of high value aroma molecules and modulation of fragrance constituents by eco-friendly chemical/biochemical intervention in classical distillation process, development and optimization of chemical transformations and utilizing essential oils for products.

#### **Activity 4**

*Skill development activities. This activity involves conducting awareness programmes in different States/region of the country, skill up-gradation programmes on cultivation and processing of medicinal and aromatic plants and advanced training on value addition of the MAP produce and quality assessment.*

#### **Activity 5**

*Intellectual property generation, valuation and management. This activity aims to provide the primary as well as secondary research for product development and market forecasting. The primary information will include information from scientific and patent literature; while the secondary information will include extensive data mining from sources such as independent studies, government and regulatory published material, technical journals, trade magazines, etc.*

#### **Activity 6**

*Making public aware of mission activities and achievements using appropriate interface. This activity aims to develop a dynamic portal for posting the activities and achievements of the mission for the beneficiaries (farmers and entrepreneurs) to provide location specific advisories and participatory approaches and development of short video films under different categories for dissemination on good agricultural practices, processing technologies and success stories/achievements."*

### **VI. Efficacy of imposing 'Ban' on any Commodity/Product**

*"The Committee note that the Central Excise Duty collected by the Government on various types of Tobacco products for the financial year (s) 2015-16 and 2016-17 were Rs. 21,228 crore and Rs.21,937 crore respectively. In this context, the Committee intend to co-relate the total revenue generated by the Government by way of Central Excise Duty with the confabulations which are currently underway at various Fora on the aspect of imposing a ban on 'Smokeless Tobacco' products, or 'Smoking Tobacco' products or both vis-a-vis*

*loss of revenue and per se direct loss to the Government Exchequer and at the same time, the efficacy of proscribing any commodity/product. In this connection, the Committee are of considered view that the past experience of imposing a 'ban' on any commodity/product in our country has failed to produce the intended objectives and on the other hand, it has not only affected the revenue generation of the Government, which could have otherwise utilised for the betterment of masses through various Social Security Schemes/Welfare Programmes, but also paved way for blackmarketing of the specific commodity/product, production of spurious and substandard commodity, mushrooming of unregulated 'Mafia' and other corrupt practices by the Industry concerned with the active/passive involvement of various Enforcement Agencies. In this chronology, the Committee would like to remind the Government that a couple of years ago, a 'ban' on plastic bag (s) was imposed in almost all the States/UTs. Even though the efficacy of imposing ban on plastic bags could be a debatable issue, it is an irrefutable fact that plastic bags are being rampantly used at every nook and corner of the country for carrying goods and other commodities bought by households from the market place. In the opinion of the Committee, the non-existence of a delegated Enforcement Agency, other than Police, is one of the primary reasons for failure of effective implementation of imposing a ban. The Committee are, therefore, of firm opinion that in case, the Government intend to go ahead with the intention of imposing a ban on all the 'Tobacco Products' in the country, whether it is 'Smokeless/Chewing' Tobacco or 'Smoking' Tobacco or both, the Ministry of Health & Family Welfare should first of all, work out a fool-proof strategy for establishing a distinct Enforcement Agency, in coordination with various State Governments/UT Administrations to ensure its effective, fullest and tangible implementation. The Committee would like to be apprised of the action taken by the Ministry of Health & Family Welfare, in this regard."*

13. The recommendation on efficacy of imposing 'Ban' on any Commodity/Product, made by the Committee in their 68<sup>th</sup> Report on the subject pertains to the Ministry of Health & Family Welfare and 'no action taken reply' had been furnished by them.

14. Keeping in view the fact that examination of aspects concerning the livelihood of millions of tobacco farmers, labourers employed in Kevda and Mentha farming/tobacco industry along with the need for harmonization of definition of 'Food' under

the Food Safety and Standards Act, 2006 as contained in the representation of Shri Sanjay Bechan by the Committee on Petitions, Lok Sabha resulted in presentation of Report to the Hon'ble Speaker, Lok Sabha on 9<sup>th</sup> March, 2019 and later on to the Lok Sabha on 26<sup>th</sup> June, 2019. However since the Action Taken Replies furnished by the Ministry of Health & Family Welfare were merely reiteration of their view point, the Committee took a conscious decision to undertake further deliberations on this intricate issue, which included formulation of detailed list of points, oral evidence of the representatives of the Ministry of Health & Family Welfare, constitution of an 'Expert Committee' to examine all the intertwined issues and furnish their Report to the Committee so that a comprehensive Action Taken Report is formulated and presented to Lok Sabha.

15. The aforementioned aspects have, accordingly, been discussed in the succeeding paragraphs:-

I. **Replies to the List of Points furnished by the Ministry of Health & Family Welfare**

- (A) Ministry of Health & Family Welfare Office Memoranda No(s) H-11013/01/2016 – TC dated 11 May, 2021 and H-11013/01/2021 – TC dated 18 June, 2021

**Clarification sought by Committee on Petitions**

- (i) The chewing tobacco is essentially Tobacco with some food additives. Further, both 'Tobacco' and 'Food' have been categorized as different product categories as is evident from the fact that there are two distinct Acts which govern both these items, i.e., the Food Safety & Standards Act, 2006 and the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003?

- (ii) When Regulation 2.3.4 says that 'Tobacco' and 'Nicotine' shall not be added as an ingredient in any food product, it can never mean that food product refers to tobacco, else it shall tantamount to mean that 'tobacco cannot be added to tobacco', which becomes a meaningless argument?
- (iii) In view of 1 (i) & (ii) above, it is not a fact that the Regulation ibid is a declaration in itself that 'Tobacco' and 'Food' are two distinct products and the intent of the said legislation, by all means, is to avoid usage of tobacco or nicotine as an ingredient in any food product, which are duly standardized under the FSS Act so as to avoid any unintended consumption by non-tobacco consumers?
- (iv) Is it not a fact that COTPA, 2003 is a special Act which deals with 'Tobacco Products' in all its forms and under Section 2 of the said Act, the Union Government had intended of having taken control of the tobacco industry. Therefore, no other Act including the FSSA can legislate on Tobacco, either directly or indirectly? Therefore, 2.3.4 is a Regulation and therefore cannot supersede the Central Act under delegated Legislation.

**Reply given by the Ministry of Health & Family Welfare**

- (i) The objective of COTPA, 2003, as enshrined in its preamble is to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarette and other tobacco products, with an aim to discourage the use or consumption of tobacco, while the objective of the Food Safety and Standards Act, 2006 is to ensure safe and wholesome food for the people.

- (ii) The primary concern and purpose of FSS Act, 2006, is that of promotion of public health and protection of the right to life of the citizens of this country and that the purpose behind Food Safety Regulations 2.3.4 is to ensure the safety/health of the citizens of this country by prohibiting any articles of food which are injurious to the health of general public. It is a universal fact that tobacco and nicotine are injurious to health, and therefore, addition of tobacco and nicotine in article of food, has been prohibited under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 dated 1st August 2011.
- (iii) The mention of Chewing Tobacco, Gutkha etc., in the schedule of COTPA, 2003 will not preclude the said products from applicability of provisions of other Laws, Rules and Regulations, for example to a food item having tobacco and nicotine and ingredients. The schedule of COTPA, 2003 merely gives a list of products that can be termed as 'tobacco products'. Mention of a product in the Schedule of COTPA does not preclude action on these products in public interest and from the point of view of public safety, under other laws, rules and regulations for the time being in force.
- (iv) It is pertinent to mention that in the matter of Laxmikant Vs UOI & Ors.1997(4) SCC 739, the Hon'ble Supreme Court of India upheld the notification prohibiting the use of tobacco in tooth-pastes/toothpowders under Section 33(EED) of the Drugs and Cosmetics Act, 1940, with the observations that imposition of total ban is in public interest. The schedule of COTPA, 2003 also mentions "tooth powder containing tobacco" as a tobacco product, it does not mean that the said mention in the schedule of COTPA, 2003 removes the applicability of the provisions of the other laws, in this case the Drugs and Cosmetics Act, 1940.



- (v) The FSS Act, 2006, is a legislation which standardizes and regulates all articles of food, without any exclusion, whereas COTPA, 2003, relates to prohibition of advertisement and regulation of trade and commerce and production, supply and distribution of, cigarette and other tobacco products and has a limited scope. The objective of both the Acts are different and may go parallel to each other. If necessary, both laws may be applicable.

### **Clarification sought by Committee on Petitions**

**Codex Alimentarius is a body jointly formed by Food and Agriculture Organisation and World Health Organisation. Whether it is not a fact that CAC is a body responsible for all matters regarding implementation of the Joint FAO/WHO Food Standards Programme?**

### **Reply given by the Ministry of Health & Family Welfare**

Yes. As per the Codex procedural manual, the Codex Alimentarius Commission is the body responsible for all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is –

- a) protecting the health of the consumers and ensuring fair practices in the food trade;
- b) promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations;
- c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;

- d) finalizing standards elaborated under (c) above and publishing them in a Codex Alimentarius either as regional or worldwide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable; and
- e) amending published standards, as appropriate, in the light of developments.

### **Clarification sought by Committee on Petitions**

**FAO and WHO define 'Tobacco', in their definition clause, as under:-**

#### **FAO**

**"Tobacco is an annual plant that is cultivated for its narcotic leaves, which are used for smoking, chewing or sniffing. The main varieties include Oriental, Maryland, Burley and Tropical. The partially dried leaves are fermented, cured and then further dried by various methods, including sun curing, air curing, flue curing and fire curing."**

#### **WHO FCTC**

**"(f) 'tobacco products' means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing."**

- (i) **In view of the above definitions, is it not a fact that the word 'Tobacco' covers both 'chewing' as well as 'smoking'?**
- (ii) **Whether any inference to the effect that 'Tobacco' in CAC only covers 'smoking' and not 'smokeless' could be regarded as misrepresentation of facts, especially, in**

view of the fact that both the parent organizations of CAC recognizes the fact that Tobacco covers both 'smoking' and 'smokeless'?

- (iii) In the Action Taken Replies, the Ministry of Health & Family Welfare had placed their reliance on ICMR Report to the effect that as per ICMR study, 50 per cent of cancers in male and 20 per cent of cancers in females can directly be attributed to tobacco use. However, no rationale has been provided as to why the use of 'smokeless' Tobacco products could only be curbed and not the use of 'smoking' products, like cigarettes, hookah, etc. It is also not clear from the statement that the harm being mentioned is attributed to which form of tobacco?
- (iv) In view of (i), (ii) & (iii) above, is it not a fact that the arguments advanced by the Ministry of Health & Family Welfare, in their Action Taken Replies are unscientific and ambiguous to the effect that when it comes to harm attributed to tobacco, the entire blame is shifted to 'smokeless' tobacco. Therefore, for the sake of harm, 'smokeless' tobacco is 'Tobacco'. However, when it comes to imposition of ban related regulations, 'smokeless' tobacco products are projected as 'Food'?

#### **Reply given by the Ministry of Health & Family Welfare**

The Ministry of Health & Family Welfare considers tobacco in any form and quantity is harmful. In addition to the death and diseases it causes, tobacco also impacts the economic development of the country. As per WHO study titled "Economic Costs of Diseases and Deaths Attributable to Tobacco Use in India, 2017-18" has estimated that the economic burden of diseases and deaths attributable to tobacco use alone in 2017-18 in India was as high as Rs. 1.77 lakh crores, amounting to 1% of GDP. The estimated

economic costs for the year 2017–2018 is 21.5% higher, in real terms, compared to 2011.

As per the existing laws and rules under the Food Safety and Standards Act, 2006 (FSS Act, 2006), the ban operates on use of tobacco and nicotine as an ingredient in any food articles.

Smoking tobacco cannot be brought under the definition of 'food' as anything which is eaten through mouth or chewed can only be 'food' as per definition at Section 3 (I) (J) of FSS Act, 2006. Except, of course, a few items which are specifically excluded. It is well settled that –

- (i) Both smoking and smokeless tobacco products are covered under the ambit of COTPA, 2003;
- (ii) That the smokeless (or chewing) tobacco or nicotine are not food products but these cannot be mixed in any food item as provided by the Food Safety Act; and
- (iii) The smoking tobacco products are not food items.

#### **Clarification sought by Committee on Petitions**

**In the National Health Policy 2017, it has been inter alia stated that the overall objectives of the policy is to reduce the consumption of tobacco products – whether it is 'smoking' or 'smokeless' tobacco through the adoption of balanced and systematic policy measures and to achieve the target envisaged in the National Health Policy 2017.**

- (i) How the exclusion of 'smoking' will help achieving the target envisaged by the National Health Policy?**
- (ii) With a view to achieving the objectives of National Health Policy, is it not necessary for the Ministry of Health & Family Welfare to ban all products that**

contain 'nicotine', irrespective of the fact that it is chewed or smoked or placed under the definition of 'food' or not?

- (iii) On the observations/recommendations of the Committee relating to 'Avoidance of narrow definition of 'Food' as contained in para(s) 4.8 to 4.10 of the Report *ibid*, the Ministry of Health & Family Welfare had *inter alia* submitted before the Committee that smoking tobacco cannot be categorized as 'Food' under the FSS Act, 2006 by any stretch of imagination as inhaling of substance would not be covered in the existing definition of 'Food'.

#### **Reply given by the Ministry of Health & Family Welfare**

Smoking tobacco products are not covered under the definition of food under the Food Safety Act. However, suitable provisions are included in the COTPA, 2003 under which these products are regulated. Application of COTPA, 2003 has had a meaningful impact on prevalence of smoking tobacco use as is brought out by the findings under the GATS-2, wherein a significant decline in use of smoking tobacco products has been achieved.

The National Health Policy, 2017 envisages the targets for relative reduction in Prevalence of current tobacco use as 15% by 2020 and 30% by 2025. The overall objective of the policy is to reduce the consumption of tobacco products, whether it is smoking or Smokeless Tobacco through the adoption of balanced and systematic Policy measures and to achieve the target envisaged in the National Health Policy, 2017.

As per the second round of Global Adult Tobacco Survey [GATS-2016-17], 28.6% [26.7 crore] of adults in India, aged 15 and above currently use tobacco in some form. Further, the Prevalence of any form of tobacco use has decreased significantly by 6 percentage Points from 34.6 percent [2009-10]

to 28.6 percent [2016-17]. The relative decrease in the Prevalence of tobacco use is 17.3%. There has been considerable decrease in the Prevalence of smoking tobacco use. Prevalence of smoking has decreased by 3.3 Percentage points from 14.0% [2009-10] to 10.7 % (2016-17).

COTPA, 2003 discourages tobacco use and prohibits smoking in public places; restriction on advertising & promotion and sponsorship of tobacco products; ban on sale to & by minors and sale of tobacco products around 100 yards of educational institutions and mandates for statutory health warnings on all tobacco product packs.

The National Health Policy, 2017 comprehensively articulates the tobacco control objectives. The National Health Policy was formulated after wide consultations with all the stakeholders especially the State Governments. This Ministry is increasingly working to achieve the said objectives envisaged in the National Health Policy 2017.

#### **Clarification sought by Committee on Petitions**

**Pursuant to the aforementioned averments, the Ministry of Health & Family Welfare may please furnish their detailed and unequivocal comments on the following aspects:-**

- (i) Is it not a fact that 'smokeless' tobacco, by any stretch of imagination, cannot be considered as food. It is, in fact, not recommended for consumption by any Authority. Rather COTPA, a Special Act, regulating Tobacco products, in all its forms, like sale, production, distribution, etc., in fact impose restriction on its consumption to person below the age of 18 years. Further, the Packaging Label under the COTPA prescribes printing of 'Pictorial Warning' depicting the ill-effects of tobacco and also mandate giving Quit Tobacco helpline number on tobacco packs. In such a**

scenario, whether such products could, in any circumstances, be equated to food or considered as food, merely because it goes into the mouth?

- (ii)(a) From the health hazard perspective, even though smokeless tobacco is invariably spit and on the other hand, cigarette smokes is inhaled through mouth and directly goes into the lungs and the nicotine forms a cancer causing substance, like 'tar'. Is it, therefore, logical not to ban 'smoke' tobacco and only regulate the same?
- (ii)(b) Alternately, whether the Ministry of Health & Family Welfare acknowledge the fact that both 'smoking' and 'smokeless' cannot be held as 'food' as both are indisputably 'nicotine delivery devices' and not articles of food?

**Reply given by the Ministry of Health & Family Welfare**

It is well settled that –

- (i) Both smoking and smokeless tobacco products are covered under the ambit of COTPA, 2003.
- (ii) That the smokeless tobacco such as chewing tobacco, gutkha, pan Masala and Supari are articles of food as held by the Supreme Court of India in the case of Godawat Pan Masala Vs UOI (2004) 7 SCC 68 and the Madras High Court in the State of Tamil Nadu Vs. R. Krishnamurthy (1980) 1 SCC 167.

It is submitted that the smoking tobacco products are being regulated within the scope of the provisions of COTPA, 2003, enacted by the Parliament. The provisions provide only for regulation.

It is agreed that the smokeless tobacco products are nicotine delivery products and these cannot be mixed into any food item as per the provisions of the Food Safety Act.

### Clarification sought by Committee on Petitions

US FDA's definitions of 'smoking' and 'smokeless' further contradicts the stated position/assumption of the Ministry of Health & Family Welfare, as under:-

*“Nicotine Delivery Device – A nicotine delivery device is any device that delivers a dose of nicotine either with or without combustion. This includes all forms of smoke and smokeless tobacco as well as mechanical devices such as electronic cigarettes and medical devices such as nicotine replacement therapy.”*

*“Tobacco Products – According to the Food and Drug Administration (FDA), the term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part or accessory of a tobacco product).”*

In view of above stipulations, whether the Ministry of Health & Family Welfare also acknowledge that smokeless tobacco delivers nicotine in doses similar to those received in cigarette smoking but does not expose the user to the toxic combustion gases and particles that are responsible for most tobacco-induced disease?

Is it also not a fact that differentiating between two forms of tobacco, i.e., 'smoking' and 'smokeless' purely on the basis of consumption is not a tenable proposition?



### Reply given by the Ministry of Health & Family Welfare

Tobacco products in India are dealt with as defined under the COTPA, 2003. It is submitted that both forms of tobacco use, smoking and smokeless, are harmful. A comparison between the degree of harms is not possible as the evidence available regarding the same is limited. It is however also submitted that, tobacco use in either form, is one of the biggest risk factor for most of the non-communicable diseases such as diabetes, hypertension and cancer etc.

The two forms of tobacco use, i.e., smoking and smokeless, have in fact to be dealt with differently, due to difference in nicotine delivery mechanism and also the difference in the various factors involved in prevalence of tobacco use, such as social, cultural and economic.

On the observations/ recommendations of the Committee on the need of imposing a complete ban or regulating all tobacco products in the country as contained in para 4.11 of the Report *ibid*, the Ministry of Health & Family Welfare had *inter alia* submitted before the Committee that the National Health Policy 2017 envisages the targets for relative reduction in prevalence of current tobacco use as 15 per cent by 2020 and 30 per cent by 2025. It has also been submitted that prevalence of Smokeless Tobacco use is more than that of smoking products, COTPA, 2003 discourages tobacco use and prohibits smoking in public places, ban on sale of tobacco products to and by minor. The National Health Policy, 2017 comprehensively articulates the tobacco control objectives and the Ministry is increasingly working to achieve the said objectives envisaged in the National Health Policy, 2017.

### **Clarification sought by Committee on Petitions**

Pursuant to the aforementioned averments, the Ministry of Health & Family Welfare may please furnish their detailed and unequivocal comments on the following aspects:-

- (i) Whether the Ministry of Health & Family Welfare are aware of the fact that as per GATS Report, in addition to 10 crore of Indian who smoke tobacco, there is impact of second-hand smoke on non-smokers vulnerable class, which is almost four times the active smokers, thus, taking the effective number to almost 50 crore. Notwithstanding this, a perception is created as to the prevalence of smokeless tobacco as compared to smoking tobacco that smokeless tobacco consumption is more, hence bulk of the tobacco legislation targets smokeless tobacco?
- (ii) Is it not a fact that with the excessive legislation banning Chewing Tobacco products, the consumers would shift to smoking cigarettes? This 'shift' would not be confined to around 20 crore chewers of tobacco, but it will also create around 80 crore secondhand smokers. Therefore, the number of active smokers and passive smokers will multiply progressively, so does the fatality rate because of smoking, which might increase to an unprecedented level?

### **Reply given by the Ministry of Health & Family Welfare**

This Ministry considers tobacco in any form and quantity is harmful and does not emphasize on regulation of any particular form of tobacco products. As per GATS-2 [2016-17], the prevalence of smokeless tobacco use is 21.4 %, while the current tobacco smokers are 10.7%. The GATS-1 [2009-10] also revealed that the prevalence of smokeless tobacco use was

25.9%, while the current tobacco smokers were 14.0%, indicating that there is reduction in prevalence of tobacco use for both forms of tobacco.

The COTPA, 2003 has additional provisions for smoking tobacco products such as prohibition of smoking in public place to prevent harm due to second hand smoke.

The inference that the prevalence of smoking tobacco use would increase due to shift from such smokeless tobacco users who switch to smoking forms, is not supported with evidence as brought out by the finding of the GATS-2 (2016- 17), which has clearly indicated that the prevalence of tobacco use has reduced for both forms of tobacco use (as mentioned above).

The Ministry of Health & Family Welfare has taken a consistent stand before the Courts by way of affidavits/written submissions in several cases stating that this Ministry considers tobacco in any form and quantity is harmful and does not emphasize on any particular form of tobacco products. However, as per existing statutes/rules, the provisions under the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 at present only empower the Government to regulate the smoking tobacco products including a ban on their sale to or by minors and within the radius of 100 yards of educational institutions.

#### **Clarification sought by Committee on Petitions**

**As per GATS-2, there is reduction of 30 percent in consumption of smokeless tobacco. As against this, the consumption of smoking has been on an increase, which irrefutably, substantiate the fact that smokeless consumer does not quit, but switch to smoking.**

**In spite of the above facts and in utter disregard to GATS 1& 2 and preamble to COTPA 2003, which talks about legislation and effective measures for protecting citizens with special attention to risk groups, such as pregnant women and children from involuntary exposure to tobacco smoke, no concrete measures are being taken by the Government and no provisions have been proposed for the safety and benefit of the vulnerable class? Please furnish your comments in this regard.**

**Whether banning of chewing Tobacco products would not tantamount to indirectly pushing and promoting the use of cigarettes and other smoking tobacco products?**

**Whether the Ministry of Health & Family Welfare also endorse the views that tobacco products should not be dealt on the basis of 'prevalence' but on the basis of 'harm'?**

**Reply given by the Ministry of Health & Family Welfare**

The inference that the prevalence of smoking tobacco use would increase due to shift from such smokeless tobacco users who switch to smoking forms, is not supported with evidence as brought out by the finding of the GATS-2 (2016- 17), which has clearly indicated that the prevalence of tobacco use has reduced for both forms of tobacco use (as mentioned on para 5(i) above).

Public Health being a state subject, the responsibility of implementation of the various provisions of COTPA, 2003, primarily lies with the state/UT Governments.

The provisions for ban on smoking in public place, ban on advertising, ban on sale to minors and sale within 100 yards of educational institutions are all targeted to also protect the citizens from involuntary exposure to tobacco use, especially for vulnerable groups such as children and pregnant women.

As per Section 77 of The Juvenile Justice (Care and Protection of Children) Act, 2015, that makes giving or causing to be given, to any child any tobacco products punishable with rigorous imprisonment for a term which may extend to seven years & shall also be liable to a fine which may extend up to one lakh rupees. The specified health warning on tobacco product packs is mandated under the COTPA, 2003, which enables the Ministry to specify the health warning to be displayed on tobacco product packs. The objective of the larger specified health warnings (currently 85% of principal display areas) is to create better visibility and noticeability, especially amongst tobacco users, about the harmful effects of tobacco use.

The pictorial warnings have graphic images, the text message and the national tobacco quit line number (1800- 112-356).

The Government has also developed and deployed a mobile-based strategy called m-Cessation (011-22901701) to encourage and support those who are desirous of quitting. In this strategy, those desirous of quitting give a missed call to a toll free number.

The inference that the prevalence of smoking tobacco use would increase due to shift from such smokeless tobacco users who switch to smoking forms, is not supported with evidence as brought out by the finding of the GATS-2 (2016- 17), which has clearly indicated that the prevalence of tobacco use has reduced for both forms of tobacco use (as mentioned above).

The Ministry is of the view that use of all form of tobacco in any quantity is harmful. It is with this premise that the legislative provisions have been put in place. The Ministry undertakes the exercise of periodic assessment of prevalence of tobacco use through surveys such as the Global Adult Tobacco Survey (GATS) and the Global Youth Tobacco Survey (GYTS).

### Clarification sought by Committee on Petitions

In W.P.(C) No. 1583/2014 [Dharampal Satyapal Vs. Union of India], the Guwahati High Court observed as under:-

“Article 47 is not a source of legislative power. It is only a guiding principle for the State in the governance of the country. Without dilating on the harmful effects of tobacco, both smoking and non-smoking, it has to be admitted that Article 47 talks about prohibiting consumption of intoxicating drinks and drugs which are injurious to health; tobacco is conspicuous by its absence. In Koluthara Export Ltd. (supra), Supreme Court has held that Part-IV of the Constitution contains fundamental principles in the governance of the country; they indicate and determine the directions for the State but they are not legislative heads or field of legislation like the entries in Lists I, II and III of the 7th Schedule of the Constitution.”

- (i) Please furnish your considered view in relation to the comments furnished by the Ministry of Health & Family Welfare vide Office Memorandum No. P.15025/27/2020-FR dated 15 June, 2020 and the stipulations inter alia to the effect that ‘smoking tobacco’ cannot be ‘food’ as it is not eaten. Inhaling of a substance would not be covered in the existing definition of ‘food’.
- (ii) Whether it is a fact that the Report on Tobacco Control in India 2004 reveals that death attributed to tobacco is almost 8-9 lakh per year. 7.30 lakh death is due to smoking and 80 thousand deaths is attributable to second-hand smoking?

### **Reply given by the Ministry of Health & Family Welfare**

The Food Safety and Standards Act, 2006, as well as the earlier, Prevention of Food Adulteration Act, 1954, give a wide definition of 'food' and includes therein any article/substance which is intended for human consumption. The Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011 issued under the FSS Act lays down that tobacco and nicotine shall not be used as ingredients in any food products. Helpfully, the Hon'ble Supreme Court in Godawat Pan Masala Vs UOI (2004) has also held that "Since Pan Masala, Gutkha or Supari are eaten for taste and nourishment, these are all food within the meaning of Section 2 (v) of the Prevention of Food Adulteration Act". The definition of 'food' under FSS Act is *pari materia* of the definition under PFA in such matters.

The estimates given in the 2004 report are based on the late 1980's estimates. As per the estimates given in the 2<sup>nd</sup> round of Global Adult Tobacco Survey (GATS-2) report (2016-17), mortality due to tobacco in India is estimated at upwards of 1.3 million (13.5 lakh). It is again reiterated that the Ministry is of the view that use of all form of tobacco in any quantity is harmful.

### **Clarification sought by Committee on Petitions**

**On the observation/recommendations of the Committee on imposing selective ban vis-à-vis enforcing regulation as contained in the Report *ibid*, the Ministry of Health & Family Welfare had inter alia differentiated between smokeless tobacco and smoking tobacco by saying that the intention of the legislature while enacting FSS Act, 2006 (which subsumed PFA Act and other Rules and orders relating to food administered by various Government Departments) has been to include 'smokeless tobacco' in the definition of food under FSS Act and Rules and Regulations framed thereunder and to regulate matters concerning 'smoking tobacco' under**

**the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (popularly known as COTPA).**

- (i) In the above context, whether the Ministry share the same views that COTPA is a special Act to deal with all tobacco products and specifically covers smokeless tobacco in its Schedule. It is, in fact, the same Schedule which covers smoking tobacco. Therefore, there is no difference contemplated between 'smokeless tobacco' and 'smoking tobacco' Under COTPA?**
  
- (ii) After the enactment of FSS Act, whether COTPA has been subsumed or proposed to be subsumed?**

**Reply given by the Ministry of Health & Family Welfare**

Yes. It is confirmed that both smoking and smokeless tobacco products are considered as tobacco products under the COTPA, 2003. Suitable provisions have been incorporated in the Act for regulation of both these two forms of tobacco products.

The COTPA has not been subsumed in the FSS Act.

**Clarification sought by Committee on Petitions**

**The preamble to FSS ACT, 2006 stipulates as under:-**

**“An Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human**



consumption and for matters connected therewith or incidental thereto.”

The preamble to COTPA 2003 stipulates as under:-

“An Act to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarettes and other tobacco products and for matters connected therewith or incidental thereto.”

The Declaration made under Section 2 of the FSS Act, 2006 stipulates as under:-

“Declaration as to expediency of control by the Union. It is hereby declared that is expedient in the public interest that the Union should take under its control the food industry.”

The Declaration made under Section 2 of the COTPA 2003 stipulates as under:-

“Declaration as to expediency of control by the Union. It is hereby declared that is expedient in the public interest that the Union should take under its control the tobacco industry.”

Section 3(p) of COTPA further stipulates as under:-

“3(p) ‘tobacco products’ means the products specified in the Schedule.

1. Cigarette
2. Cigars
3. Cheroots
4. Beedis

5. Cigarette tobacco, pipe tobacco and hookah tobacco
6. Chewing Tobacco
7. Snuff
8. Pan Masala of any chewing material having tobacco as one of its ingredients (by whatever name called)
9. Gutkha
10. Tooth powder containing tobacco

- (i) Whether it is an established fact that FSS Act is an Act to legislate on Food Products, whereas, COTPA is a Special Act to deal and legislate on Tobacco Products?
- (ii) The averments made by the Ministry of Health & Family Welfare, in their action taken replies, contradict the Preambles of FSS Act and the COTPA. Please furnish your detailed comments in this regard.
- (iii) The Schedule of COTPA shows that it covers 'smokeless tobacco' in the same manner as the smoking tobacco', if so, on what basis, the Ministry of Health & Family Welfare had differentiated between the two?
- (iv) The very fact that pictorial Warning has been imposed on both the products, i.e., 'smokeless' as well as 'smoking' tobacco under COTPA and all the restriction and regulations under COTPA applies to both 'smokeless' as well as 'smoking' tobacco belies the comments of the Ministry of Health & Family Welfare. Please furnish your detailed comments in this regard.

### **Reply given by the Ministry of Health & Family Welfare**

The objective of COTPA, 2003, as enshrined in its preamble is to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarette and other tobacco products, with an aim to discourage the use or consumption of tobacco, while the objective of the Food Safety and Standards Act, 2006 is to ensure safe and wholesome food for the people.

The primary concern and purpose of FSS Act, 2006, is that of promotion of public health and protection of the right to life of the citizens of this country and that the purpose behind Food Safety Regulations 2.3.4 is to ensure the safety/health of the citizens of this country by prohibiting any articles of food which are injurious to the health of general public. It is a universal fact that tobacco and nicotine are injurious to health, and therefore, addition of tobacco and nicotine in article of food, has been prohibited under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 dated 1<sup>st</sup> August 2011.

The mention of Chewing Tobacco, Gutkha etc., in the schedule of COTPA, 2003 will not preclude the said products from applicability of provisions of other Laws, Rules and Regulations, for example to a food item having tobacco and nicotine as ingredients. The schedule of COTPA, 2003 merely gives a list of products that can be termed as 'tobacco products'. Mention of a product in the Schedule of COTPA does not preclude action on these products in public interest and from the point of view of public safety, under other laws, rules and regulations for the time being in force.

It is pertinent to mention that in the matter of Laxmikant Vs UOI & Ors. 1997(4) SCC 739, the Hon'ble Supreme Court of India upheld the notification prohibiting the use of tobacco in toothpastes/tooth-powders under Section 33(EED) of the Drugs

and Cosmetics Act, 1940, with the observations that imposition of total ban is in public interest. The schedule of COTPA, 2003 also mentions "tooth powder containing tobacco" as a tobacco product, it does not mean that the said mention in the schedule of COTPA, 2003 removes the applicability of the provisions of the other laws, in this case the Drugs and Cosmetics Act, 1940.

The FSS Act, 2006, is a legislation which standardizes and regulates all articles of food, without any exclusion, whereas COTPA, 2003, relates to prohibition of advertisement and regulation of trade and commerce and production, supply and distribution of, cigarette and other tobacco products and has a limited scope. The objective of both the Acts are different and may go parallel to each other. If necessary, both laws may be applicable.

The Ministry of Health & Family Welfare has taken a consistent stand before the Courts by way of affidavits/written submissions in several cases stating that this Ministry considers tobacco use in any form and quantity is harmful and does not emphasize on the degree of regulation for any particular form of tobacco products.

**(B) Ministry of Health & Family Welfare Office Memorandum No. H-11013/01/2021 – TC dated 17 December, 2021**

**Clarification sought by Committee on Petitions**

**In the replies/inputs dated 26 July 2021, it has been submitted before the Committee that "It is also reiterated that there is no ban on 'Tobacco' either under the COTPA 2003 or under the Food Safety Act, 2006. However, 'Tobacco' or 'Nicotine' cannot be mixed in any food product as per the provisions of the FSS Regulations, 2011."**

**Does it imply that manufacture, distribution and sale of 'Tobacco' has neither been proscribed in the country nor there is any intention on the part of the Ministry to impose a**

**ban on 'Chewing Tobacco', but to regulate it under the provisions contained in the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 [COTPA] as is being done in the case of 'Smoking Tobacco'? Please comment.**

**Reply given by the Ministry of Health & Family Welfare**

Yes Sir, under the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 [COTPA], there is no ban on manufacture, distribution and sale of tobacco products, both smoking and smokeless. All forms of tobacco are covered under COTPA, 2003 and are regulated by its provisions. Further, as per Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, Regulation 2.3.4 provides that tobacco and nicotine shall not be used as ingredients in any food products.

**Clarification sought by Committee on Petitions**

**If there is no ban on 'Tobacco' either under the COTPA 2003 or under the Food Safety Act 2006, does it mean that FSS Regulations, 2011 stipulating that 'Tobacco' or 'Nicotine' cannot be mixed in any food product have precedence over the two Principal Act(s) passed by Parliament? Please comment.**

**Reply given by the Ministry of Health & Family Welfare**

There has been no inconsistency between the provisions of FSS Regulations, 2011 and COTPA, 2003 and FSS Act, 2006. In exercise of the powers conferred under section 92 of FSS Act, the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 were notified. These Regulations have a specific provision viz., Regulation 2.3.4 which provides for that

tobacco and nicotine shall not be used as ingredients in any food products.

FSS Act empowers FSSAI to regulate manufacture of food products. Actual standards for food products are not a part of the principal Act. Mixing of tobacco or nicotine with food products has not been allowed under Regulations as a part of restrictions imposed on manufacture of food items. There is no contradiction of any kind with FSS Act. In fact, these restrictions flow from the powers conferred by the FSS Act. Therefore, it may not be appropriate to deduce that the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 are taking precedence over FSS Act and COTPA. These are validly notified regulations well within the mandate of FSS Act.

The FSS Act, 2006, is a legislation which standardizes and regulates all articles of food, without any exclusion, whereas COTPA, 2003, relates to prohibition of advertisement and regulation of trade and commerce and production, supply and distribution of cigarette and other tobacco products.

#### **Clarification sought by Committee on Petitions**

**Does it further imply that restrictions on the manufacture, distribution and sale of Gutkha [Tobacco mixed with various other food ingredients] would continue to be operative in the country? Please comment.**

#### **Reply given by the Ministry of Health & Family Welfare**

Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, provide that tobacco and nicotine shall not be used as ingredients in any food products.

### **Clarification sought by Committee on Petitions**

Notwithstanding the above, whether it is a fact that in reply to a Starred Question No. 391, answered in Lok Sabha on 12 August, 2016, wherein, it was inter alia asked to clarify as to whether the Apex Court has ordered to ban the sale, purchase and storage of all forms of chewable/smokeless tobacco in the country, the Ministry had categorically averred that "No such specific order has been given by the Apex Court. However, the Government of India has issued regulations under the Food Safety & Standards Act, 2006 which lays down that tobacco or nicotine cannot be used as ingredients in food products"? If so, what was the objective of quoting Regulation 2.3.4 of the Regulations of 2011, in the said reply, to the Parliamentary question? Please comment.

### **Reply given by the Ministry of Health & Family Welfare**

Parliament was informed that there is no such specific order of the Hon'ble Court, to ban the sale, purchase and storage of all forms of chewable/smokeless tobacco in the country. Further, in order to bring the clarity on the issue, the reply included the mention of Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, provide that tobacco and nicotine shall not be used as ingredients in any food products.

### **Clarification sought by Committee on Petitions**

In the replies/inputs dated 26 July 2021, the following have been submitted before the Committee:-

**"It is true that the Food Safety and Standard Act, 2006 and the Food Safety and Standards Rules, 2011 do not have any express mention of Tobacco and Nicotine. However, the definition of 'Food' under Section 3(1)(j)**

of FSS Act includes articles, which are ingested, except those which are specifically excluded as part of 'Food' under Section 3(1)(j) of the FSS Act."

During the oral evidence before the Committee on Petitions held on 24 June 2021, when the Hon'ble Chairperson, Committee on Petitions sought clarification to the effect that based on the replies to the list of points dated 11 May 2021, in reply to Question, why the Ministry has stated that 'smoking tobacco' cannot be brought under the definition of 'food' as anything which is eaten through mouth or chewed can only be 'food' as per the definition at Section 3(1)(j) of FSS Act, 2006. On this, the representative of the Ministry acknowledged that an error had taken place which was subsequently rectified because the preliminary information as received from the Food Safety and Standards Authority, was sent to the Committee. Thereafter, the said error was formally rectified and informed.

#### Reply given by the Ministry of Health & Family Welfare

The contents of this Para are confirmed.

#### Clarification sought by Committee on Petitions

In reply to the List of Points forwarded by the Committee on Petitions, the Ministry vide OM No. H-11013/01/2016-TC dated 11 May, 2021/18 June, 2021, in relation to Question No. 2(iv) had inter alia replied as under:-

Smoking tobacco cannot be brought under the definition of 'food' as anything which is eaten through mouth or chewed can only be 'food' as per the definition at Section 3(1)(j) of FSS Act, 2006. Except, of course, few item which are specifically excluded. It is well settled that-



- (1) Both smoking and smokeless tobacco products are covered under the ambit of COTPA, 2003; and**
- (2) That the smokeless [or chewing] tobacco or nicotine are not food products but these cannot be mixed in any food items as provided by the Food Safety Act.**
- (3) The smoking tobacco products are not food items.**

**Reply given by the Ministry of Health & Family Welfare**

It is submitted that the reply given for Point No. 2 (i-iv) by this Department vide OM No. H- 11013/01/2016-TC dated 11 May, 2021, was revised vide OM of this Department No. H- 11013/01/2021-TC dated 18th June, 2021 as 4(i) and 4(ii)(b) which is reproduced as under:-

"That smokeless tobacco such as chewing tobacco, gutkha, pan masala and supari are articles of food as held by the Supreme Court of India in the case of Godawat Pan Masala Vs. UOI (2004) 7 SCC 68 and the Madras High Court in the State of Tamil Nadu Vs. R. Krishnamurthy (1980) 1 SCC 167"

**Clarification sought by Committee on Petitions**

**As per the established principles of Law Making/Subordinate Legislation, since the wording(s) actually contained in any Act, Rules, Regulations, or Order only has the legal validity/sustainability before law, whether the phrase often used by the Ministry, namely, "as anything which is eaten through mouth or chewed can only be 'food' as per the definition at Section 3(1)(j) of FSS At, 2006" and "Smoking Tobacco products are not food items" actually form part of Section 3(1)(j) of FSS Act, 2006 or it is an interpretation/deduction made by the Ministry? Please comment.**

### **Reply given by the Ministry of Health & Family Welfare**

As per Article 141 of the Constitution of India, the law declared by the Supreme Court shall be binding on all Courts within the territory of India. As per the law of the land the Supreme Court is the final Authority as to the interpretation of any statute and or any provisions of any Act / Rules etc. is concerned. The Supreme Court has held in catena of cases decided by that Court that the tobacco products such as chewing tobacco, gutkha etc are 'food' within the meaning of section 3 (1) (j) of FSS Act. On the other hand, till date there are no judicial interpretations on the point whether smoking tobacco products are food product or not.

### **Clarification sought by Committee on Petitions**

**In case, it is an interpretation/deduction made by the Ministry in regard to definition of 'Food' as contained in Section 3(1)(j) of FSS Act, 2006, with a view to attaining the objectives of Article 47 of the Directive Principles of State Policy, National Health Policy 2017 and the established fact that 'tobacco' and 'nicotine', in all its form [smoking and smokeless] are harmful for human consumption as it causes cancer and other life threatening diseases, whether the Ministry now intends to explicitly mention 'Tobacco' and 'Nicotine' in any product irrespective of its mode/manner of consumption in the FSS Act, 2006 itself, by way of bringing an amendment to the Act ibid before the Parliament? Please comment.**

**Whether the Ministry also agree that by bringing amendment to the FSS Act, 2006 as suggested at (ii) above, there would neither be any ambiguity or further litigation nor any allegation of changing the narrative from the 'element of harm/harmful effects of tobacco' to the 'mode of consumption'? Please furnish your detailed comments.**

### **Reply given by the Ministry of Health & Family Welfare**

The definition of 'food' is very wide and broad to include any article of food which is used for human consumption or in preparing human food. Hon'ble Supreme Court in the case of Godawat Pan Masala I.P. Ltd Vs. Union of India has held that gutkha, pan masala and supari are food articles. Hon'ble Supreme Court in the case of State of Tamil Nadu Vs. R. Krishnamurthy has held that 'Chewing Tobacco' is an article of food. In view of settled law based on interpretation of courts on the issue, there does not appear to be any need to go in for amendment in FSS Act for the purpose.

### **Clarification sought by Committee on Petitions**

In the replies/inputs dated 26 July 2021, the following have been submitted before the Committee: "Regulations 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sale) Regulations 2011 is not a new one but is a continuation of provision already in force since 1955, under Rule 44J of the Prevention of Food Adulteration Rules, 1955. Rule 44J of Prevention of Food Adulteration Rules, 1955 reads as:

**"Product not to contain any substance which may be injurious to health: Tobacco and Nicotine shall not be used as ingredients in any food product'. The same provision has been incorporated in the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 as Regulation 2.3.4."**

**Whether it is a fact that Rule 44J of the Prevention of Food Adulteration Rules, 1955 was inserted vide G.S.R. 491(E) dated 21 August, 2006 published in Part-II, Section 3, Subsection (i) at pages 1-41 of the Gazette of India, Extraordinary? If so, what were the reasons for furnishing an**

**ambiguous information to the effect that 'Regulations 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sale) Regulations 2011 is not a new one but is a continuation of provision already in force since 1955, under Rule 44J of the Prevention of Food Adulteration Rules, 1955", which gives an impression that the said provision is in place since the year 1955? Please comment.**

**Reply given by the Ministry of Health & Family Welfare**

It is factually correct that the Prevention of Food Adulteration Act, 1954 is in force since 1955. Rule 44 J was amended in 2006 vide GSR 491 (E) dated 21.08.2006, which reads as Product not to contain any substance which may be injurious to health: Tobacco and Nicotine shall not be used as ingredients in any food products". Further, Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, provide that tobacco and nicotine shall not be used as ingredients in any food products.

**Clarification sought by Committee on Petitions**

**Whether the litigations in various Courts, primarily due to making a distinction between 'smoking tobacco' and 'chewing tobacco' based on the mode of consumption started only after inserting Rule 44J in the Prevention of Food Adulteration (7th Amendment) Rules in the year 2006? Please comment.**

**Reply given by the Ministry of Health & Family Welfare**

It is not a fact that the litigations in various courts have commenced only after insertion of Rule 44 J in Prevention of Food Adulteration Rules, 1955. The famous case decided by the Hon. Supreme Court of India before insertion of rule 44 J is Godawat Pan Masala Vs. UOI where the Supreme Court *vide* its

Order dated 02.08.2004, held that Pan Masala and Chewing tobacco are 'food' within the meaning as defined in PFA Act.

### **Clarification sought by Committee on Petitions**

**Whether it is a fact that Section 97 of the Food Safety and Standards Act, 2006 explicitly provides that "with effect from such date as the Central Government may appoint in this behalf, the enactment and orders specified in the Second Schedule [The Prevention of Food Adulteration Act, 1954] shall stand repealed? Please comment.**

**What is the extant legal position in regard to the Prevention of Food Adulteration Act and Rules, i.e., whether the same stand repealed/cease to exist? If so, what were the reasons of referring to the Prevention of Food Adulteration Rules, 1955 while furnishing replies/inputs in relation to Point No. 5 vide OM dated 26 July, 2021? Please comment.**

### **Reply given by the Ministry of Health & Family Welfare**

It is a fact that with the implementation of the Food Safety and Standards Act, 2006 the enactments and orders specified in the second schedule of the Act shall stand repealed. However, Section 98 of FSS Act provides that "Notwithstanding the repeal of the enactment and Orders specified in the Second Schedule, the standards, safety requirements and other provisions of the Act and the rules and regulations shall be made thereunder and Orders listed in that Schedule shall continue to be in force and operate till new standards are specified under this (FSS) Act or rule and regulations made thereunder". After the Food Safety and Standards Rules and six Principal regulations were notified in the year 2011, the implementation of FSS Act, 2006 and rules and regulations framed thereunder commenced since 5th August 2011. Since this date the PFA Act as well as PFA rules are no longer in operation. However, as per provisions of Section 97 such repeal shall not affect the previous operations of the

enactment and orders under repeal or anything duly done or suffered thereunder.

### **Clarification sought by Committee on Petitions**

Section 44J containing the phrase "Tobacco and Nicotine shall not be used as ingredients in any food products" was inserted in the Prevention of Food Adulteration (7th Amendment) Rules, 2006 vide GSR 491(E) dated 21 August 2006. Subsequently, in 2006 itself, while enacting the Food Safety and Standards Act, 2006 [FSS Act], the Food Adulteration Act was repealed. Later on, Regulation 2.3.4 contained in the Food Safety and Standards (Prohibition and Restriction on Sale) Regulations was issued in the year 2011.

Going by the above sequence of events, is it not a fact that the insertion of Rule 44J in the Prevention of Food Adulteration Rules of the year 2006 automatically stands deleted after repealing of the Food Adulteration Act and Rules in the year 2006 itself and after that, the phrase "Tobacco and Nicotine shall not be used as ingredients in any food products" also stands deleted from the Statute and had no relevance? If so, please furnish your comments as to why the Ministry did not feel appropriate to re-insert the said phrase in the FSS Act, 2006?

### **Reply given by the Ministry of Health & Family Welfare**

Even after enactment of Food Safety and Standards Act, 2006 and its coming into force along with six Principal Regulations, including the Food Safety and Standards (Prohibition, Restrictions and Sales), Regulations, 2011, the provision of Rule 44 J of the Prevention of Food Adulteration Rules, 1955 continued to be in force on account of section 98 of FSS Act, until it was replaced by Regulations framed under FSS Act in 2011. Thus, there was no change of legal position in so far as this aspect was concerned.

FSS Act empowered FSSAI to formulate Rules and Regulations and the ban on mixing tobacco or nicotine in food products was incorporated into Regulations. It may be mentioned that this ban was not a part of the PFA Act itself, but was a part of the Rules made thereunder.

**Clarification sought by Committee on Petitions**

Does it also mean that during the interregnum period, i.e., the enactment of FSS Act, 2006 and the Regulations of 2011, the said phrase was not in existence/operation? Please comment.

**Reply given by the Ministry of Health & Family Welfare**

As stated above.

**Clarification sought by Committee on Petitions**

Based on the oral evidence before the Committee on Petitions held on 24 June 2021, please furnish unambiguous replies/inputs on the following aspects:

Whether chewing/smoking tobacco has ever been sold by any retailer/ shopkeeper/person in the country by terming it as a 'food product'? If not, in relation to Regulation 2.3.4 of Regulations, 2011, whether mixing of any food product, even in the form of additives, fragrance or sugar with tobacco, the final food product is transformed to 'food'? Please comment.

**Reply given by the Ministry of Health & Family Welfare**

Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, provide that tobacco and nicotine shall not be used as ingredients in any food products.

### **Clarification sought by Committee on Petitions**

Whether it is a fact that all forms of tobacco, whether chewing or smoking, emit nicotine for which there is an intermittent demand for imposing ban on these products. However, the matrix of 'harm' changes to 'mode of consumption' whenever, any proposal for imposition of ban on these items gains momentum? Please comment.

Whether the Ministry also endorse that cigarettes, tobacco, gutkha, etc., are actually 'nicotine delivery devices' and the main product which causes harm/damage to the human body is the 'nicotine' which is emitted by these 'nicotine delivery devices'? Please comment.

### **Reply given by the Ministry of Health & Family Welfare**

Based on the scientific evidence the Department considers all tobacco products as harmful to human health. It is submitted that the smoking tobacco products are being regulated within the scope of the provisions of COTPA, 2003, enacted by the Parliament. The provisions provide only for regulation. There is no discrimination while regulating under COTPA, 2003, based on the nature of the product.

### **Clarification sought by Committee on Petitions**

Whether the Ministry has come across any reliable study that establishes that cigarettes emits more nicotine vis-a-vis chewing tobacco when it is consumed/burnt at around 700 degrees? Please comment.



**Reply given by the Ministry of Health & Family Welfare**

No, Sir, Department has not come across any such reliable study.

**Clarification sought by Committee on Petitions**

**Whether the Ministry has undertaken any empirical study to know the extent and hazardous impact of 'passive smoking as well as third-hand smoking' in the country? Please comment.**

**Reply given by the Ministry of Health & Family Welfare**

No, Sir, Department has not undertaken any such study. However, Third-hand smoke contains some of the same toxic chemicals as first- and second hand smoke, including tobacco-specific nitrosamines, polycyclic aromatic hydrocarbons, heavy metals, nicotelline, and ultrafine particles with a median diameter overwhelming evidence that exposure to this mixture of toxic chemicals and ultrafine particulate matter is harmful to human health.

**Clarification sought by Committee on Petitions**

**Whether it is also a fact that there is no health risk to second and third hand smokers in the case of smokeless tobacco users vis-a-vis smoking tobacco users?**

**Reply given by the Ministry of Health & Family Welfare**

Yes Sir, Smokeless Tobacco (SLT) does not produce smoke. Hence, there is no second and third hand smokers in case of use of SLT products.

### **Clarification sought by Committee on Petitions**

**Notwithstanding the fact that India is a signatory to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), why so much reliance has been placed on WHO vis a-vis various Parliamentary apparatus, including the Committee on Petitions, in reviewing/examining the policies and programmes, suiting to the needs of the country? Please furnish your comments.**

**Please furnish the details of WHO officials positioned in the Tobacco Control Division of the Ministry of Health & Family Welfare, Government of India. What is the extent of their participation involvement while examining/formulating the tobacco related policies and programmes of the Government?**

### **Reply given by the Ministry of Health & Family Welfare**

There is no WHO officials positioned in the Tobacco Control Division of the Ministry of Health & Family Welfare, Government of India. It is clarified that Ministry seeks technical assistance from WHO only on information related to international best practices as emerging evidence on tobacco use, relevant from the perspective of public health and related information.

### **Clarification sought by Committee on Petitions**

**Is it a fact that a tobacco plant takes at least five years to grow and in the event of banning the usage of tobacco, whether smoking tobacco or smokeless tobacco, the source of livelihood of farmers would be severely affected? Please comment.**

### **Reply given by the Ministry of Health & Family Welfare**

As advised by the Hon'ble Committee during the Sitting of the Committee on Petitions on 24th June, 2021, banning the usage of tobacco products does have an adverse impact on livelihood of tobacco growing farmers.

### **Clarification sought by Committee on Petitions**

**Whether the Ministry also acknowledge the fact that proscribing any commodity has not worked on a long term basis and if anything these 'proscription' had created, is the underground mafia and once, any illegal trade starts, no regulation, no law is followed and that's when, the accountability diminishes along with the Government's revenue and the deaths due to unregulated supply of these proscribed items increases. If so, what long term policy formulation for regulation of trade & commerce, production, supply & distribution of cigarettes and other tobacco products, in a strictest possible manner, has been conceived by the Ministry? Please comment.**

### **Reply given by the Ministry of Health & Family Welfare**

It is submitted that tobacco use in either form, is one of the biggest risk factor for most of the non-communicable diseases such as diabetes, hypertension and cancer etc. In addition to the death and diseases it causes, tobacco also impacts the economic development of the country. COTPA, 2003 was enacted by the Parliament with the objective, as enshrined in its preamble is to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarette and other tobacco products, with an aim to discourage the use or consumption of tobacco.

As per WHO study titled “Economic Costs of Diseases and Deaths Attributable to Tobacco Use in India, 2017-18” has estimated that the economic burden of diseases and deaths attributable to tobacco use alone in 2017-18 in India was as high as Rs. 1.77 lakh crores, amounting to 1% of GDP. The estimated economic costs for the year 2017–2018 is 21.5% higher, in real terms, compared to 2011.

It is also submitted that the National Health Policy, 2017 envisages the targets for relative reduction in Prevalence of current tobacco use as 30% by 2025. Strengthening of tobacco control measures is also well articulated in the Sustainable Development Goals (SDGs).

Further, as per the second round of Global Adult Tobacco Survey [GATS-2016-17], 28.6% [26.7 crore] of adults in India, aged 15 and above currently use tobacco in some form. Further, the Prevalence of any form of tobacco use has decreased significantly by 6 percentage Points from 34.6 percent [2009-10] to 28.6 percent [2016-17]. The relative decrease in the Prevalence of tobacco use is 17.3%.

Hence, with the overall objective of the policy to reduce the consumption of tobaccos products, whether it is smoking or Smokeless Tobacco through the adoption of balanced and systematic Policy measures and to achieve the target envisaged in the National Health Policy, 2017, Department is preparing the necessary amendments to COTPA, 2003.

It is agreed and submitted by Secretary, Department of Health & Family Welfare during the Sitting of the Committee on Petitions on 24th June, 2021 that banning of tobacco products lead to increase in illicit trade in tobacco products. Hence, it is submitted that India is leading the Presidency of Meeting of Parties under the Protocol of WHO Framework Convention for Tobacco Control (WHO FCTC) and necessary steps are being taken to develop the

track and trace mechanism for cigarettes by 2023 and other tobacco products by 2028.

**Clarification sought by Committee on Petitions**

Whether it is a fact that in the Affidavit submitted in the Supreme Court in some related case, the Ministry has themselves acknowledged that 'smoking tobacco' is at least, ten times more harmful than 'smokeless tobacco'. If so, please furnish a copy of the said Affidavit to the Committee on Petitions.

**Reply given by the Ministry of Health & Family Welfare**

Information will be sent separately.

**Clarification sought by Committee on Petitions**

In Point No. 4(i) of the replies/inputs submitted by the Ministry of Health & Family Welfare (Tobacco Control Division) vide OM No. H-11013/01/2016-TC dated 11 May, 2021, it has been submitted before the Committee "That smokeless tobacco such as chewing tobacco, gutkha, pan masala and supari are articles of food as held by the Supreme Court of India in the case of Godawat Pan Masala Vs. UOI (2004) 7 SCC 68 and the Madras High Court in the State of Tamil Nadu Vs. R. Krishnamurthy (1980) 1 SCC 167".

Please furnish copy of the relevant extract/para from the judgement/orders passed by the Supreme Court as well as Madras High Court, as quoted by the Ministry, wherein, it was held that all the four smokeless tobacco products, viz., (a) Chewing Tobacco; (b) Gutkha; (c) Pan Masala; and (d) Supari are articles of "Food" within the meaning of the definition in Section 2(v) of the Prevention of Food Adulteration Act or Section 3(1)(j) of the Food Safety and Standards Act, 2006.

In case, 'Chewing Tobacco' and 'Supari' have not been named in the relevant judgement of the Supreme Court and there is also no mention of any of the four smokeless tobacco products in the relevant judgment of the Madras High Court, what were the reasons for furnishing wrong facts in reply to Point No. 4(i) of the replies/inputs submitted by the Ministry of Health & Family Welfare (Tobacco Control Division) vide OM No. H-11013/01/2016-TC dated 11 May, 2021 before the Committee on Petitions? Please comment.

**Reply given by the Ministry of Health & Family Welfare**

In this regard it is humbly submitted that in the earlier replies/inputs submitted by this Ministry, "Supreme Court of India" was inadvertently mentioned as "Madras High Court" which is regretted.

Copy of the judgement(s) of Hon'ble Supreme Court of India dated 15.11.1979 in the case of State of Tamil Nadu Vs. R. Krishnamurthy (relevant matter at Para 5) on the issue is enclosed at Annexure-I. Copy of the judgement of Hon'ble Supreme Court of India in the case of Godawat Pan Masala Vs. UOI (2004) 7 SCC 68 dated 02.08.2004 (relevant matter at Para 64-66) is placed at Annexure-II.

The applicability of FSS Act, 2006 and food regulations to chewing tobacco has been examined in a number of judicial pronouncements. It is submitted that the definition of 'food' under Food Safety and Standards Act, 2006 is very broad and includes within it all articles except those which are specifically excluded there from. 'Tobacco' though not mentioned specifically in the definition of food under section 3 (1) (j) of FSS Act, it is 'food' under FSS Act. That being the case, the Authorities under the Act have power to regulate the same. The definition is *pari materia* of the definition under the Prevention of Food Adulteration Act.

The Hon'ble Supreme Court in the case of State of Tamil Nadu Vs. R. Krishnamurthy has held that all that is required to classify a product as 'food' is that it has to be used commonly for human consumption or in preparation of human food. Not only this, the Hon'ble Supreme Court in the case of Godawat Pan Masala Products Ltd Vs. UOI has held that Gutkha, Pan Masala and Supari are food articles. The Allahabad High Court in the case of Manohar Lal Vs. State of UP and in the case of Khedan Lal and Sons has held that 'chewing tobacco' is an article of food.

Very recently, the Hon'ble High Court of Telangana in their order dated 30.11.2021, held that the definition of 'food' is very wide and exhaustive and includes any substance whether processed, partially processed or unprocessed, which is intended for human consumption and would include smokeless tobacco products like gutkha, pan masala, kharra, khaini or any other similar product like chewing tobacco/ flavoured tobacco.

(C) **Ministry of Health & Family Welfare Office Memorandum No. H-11013/01/2021 – TC dated 26 July, 2021**

**Clarification sought by Committee on Petitions**

**Whether it is true that the Food Safety and Standards Act was enacted in 2006? Is it also true that the Food Safety and Standards Rules were made in 2021?**

**Reply given by the Ministry of Health & Family Welfare**

Yes, the Food Safety and Standards Act was enacted in the year 2006 after the same was passed by the Parliament and assented to by the President of India. It is also true that the Food Safety and Standards Rules 2011 and six key Regulations under the FSS Act were notified in 2011.

Yes, it is true that the Food Safety and Standards Act, 2006 and the Food Safety and Standards Rules, 2011 do not have any

express mention of Tobacco and Nicotine. However, the definition of 'Food' under Section 3 (1) (j) of FSS Act includes articles which are ingested, except those which are specifically excluded are part of 'Food'. It is submitted that "Tobacco" and "Nicotine" are excluded from the definition of 'Food' under Section 3 (1) (j) of the FSS Act.

### **Clarification sought by Committee on Petitions**

**Is it true that a Regulation was also issued in the year 2011? What was the need for making the Regulation since the Rules had already been notified under the FSS Act 2006?**

### **Reply given by the Ministry of Health & Family Welfare**

The Food Safety and Standards Act, 2006 is the Principal Act, enacted to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down scientific evidence-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

The Food Safety and Standards Rules were framed in 2011 in exercise of the powers conferred on the Central Government under Section 91 of the FSS Act. The purpose of the Rules is to enable the Food Authority to carry out the provision of the Act.

In addition to the Act and Rules, which provide the broad framework under which the Food Authority operates, Section 92 of FSS Act empowers the Food Authority, with the previous approval of the Central Government and after previous publication, by notification to make Regulations consistent with the Act and the Rules made thereunder, to carry out the provisions of the Act.



The purpose of the Regulations, under Section 92 of the Act is to formulate and notify various standards for food products consistent with the objective of ensuring safe and wholesome food for the people of the country.

It is submitted that the Regulations have been made since the purposes of the Rules and the Regulations under the FSS Act 2006, are distinct and separate; and that the Rules and Regulations cannot substitute for each other. Accordingly, there are separate provisions under the Act for making Rules (under Section 91) and Regulations (under Section 92).

### **Clarification sought by Committee on Petitions**

**Whether the hypothesis of the Ministry regarding Regulation 2.3.4 is legally correct?**

### **Reply given by the Ministry of Health & Family Welfare**

Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 is not a new one but is continuation of provision already in force since 1955, under Rule 44J of the Prevention of Food Adulteration Rules, 1955. The Rule 44J of Prevention of Food Adulteration Rules, 1955 reads as –

*“Product not to contain any substance which may be injurious to health: Tobacco and Nicotine shall not be used as ingredients in any food products.”*

The same provision has been incorporated in the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 as Regulation 2.3.4.

The Regulations under the FSS Act are prepared after extensive public consultations and by following due process as laid down under Section 92 of the Act.

Various Courts too, from time to time, have upheld the provisions of the Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 which does not ban tobacco but merely prohibits mixing of tobacco in any food product.

**II. Deposition of the representatives of the Ministry of Health & Family Welfare during the sittings of the Committee**

**(A) Sitting of the Committee held on 24.06.2021:**

- (i) There is no intention of the Ministry of Health & Family Welfare to exclusively ban 'smokeless tobacco' or in other words, the chewing tobacco. The objective is only to regulate the consumption of tobacco so that large number of people should not be addicted to it.
- (ii) Presently, tobacco is sold in the country as *beedi* or *tendu leafs*, in dried forms, which is legal and there is no ban on it. However, there is prohibition and restrictions on sale of products when tobacco or nicotine is mixed with any other food item as per provision of the Food Safety and Standards (Prohibition & Restrictions on Sales) Regulations, 2011 (Regulation 2.3.4) formulated under the Food Safety and Standards Act, 2006 which *inter alia* stipulates that- "*tobacco and nicotine shall not be used as ingredients in any food products.*"
- (iii) In terms of section 3(1)(j) of the Food Safety and Standards Act, 2006, which *inter alia* states that 'Food' means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption. In other words, any substance whether processed, partially processed or unprocessed which intended for human consumption, i.e., through ingestion (which goes through alimentary canal), is to be categorized as 'Food' and

therefore, something which is inhaled (*which goes through lungs*) cannot be considered as 'Food'. There has been no change in this definition since the enactment of this Act in 2006, and at present, *pan masala*, *gutkha* and *zarda* are considered to be food products. However, whether this definition of 'Food' is illogical as it emphasizes on the 'mode of consumption' and not the 'element of harm' would have to be re-examined by the Ministry of Health & Family Welfare and the matter would also be discussed with the Committee on Petitions, Lok Sabha.

- (iv) The Regulation 2.3.4 under the Food Safety and Standards Act, 2006, on the one hand, states that "*tobacco and nicotine shall not be used as ingredients in any food products*" and on the other hand, the two forms of tobacco use, i.e., smoking and smokeless have been dealt with differently on the basis of difference in 'nicotine delivery mechanism', this self-devised categorization has also been agitated/contended in various legal *fora* including the High Courts and the Supreme Court.
- (v) Imposing a blanket ban on all forms of tobacco product(s), i.e., 'smokeless' and 'smoking tobacco' is to be considered by the Ministry of Health and Family Welfare cautiously after taking into consideration various complexities as discussed above as also its implications and ramifications in view of the fact that such a decision would also give rise to illegal trade and/or black marketing.
- (vi) Although, strict regulation on tobacco products could also be an option, the most important aspect which is connected with the livelihood and employment of farmers, traders, etc., who are neither socially prosperous nor financially opulent would also be taken into account while finalising the COTPA Amendment Bill. The objective of the Bill is to achieve reduction in the supply and demand of tobacco products as it is an undeniable fact that their consumption is harmful to

human health irrespective of their 'forms' and 'mode of consumption'.

**(B) Sitting of the Committee held on 22.12.2021:**

- (i) The Ministry of Health & Welfare would constitute a 'Special Committee' consisting of 2-3 Senior Officials of the Government of India, who have never been associated with any of these issues at any point of time, to look into the various facets of the case with an independent perspective. The said 'Special Committee' would formulate a report, taking into account the public health related issues, legal implications, chronological analysis of the orders/judgments pronounced by various High Courts and Supreme Court, etc., and submit the same to the Committee.
- (ii) Apart from examining legal and administrative aspects of the case, the 'Special Committee' would also undertake a study on the matter of policy decision on issues of livelihood of farmers and economic repercussions.
- (iii) Since the Ministry are already pre-occupied with various health-related issues connected with Covid-19 pandemic, it would be appreciable if the Committee consider giving two month's time to the said 'Special Committee' to submit its report to them.
- (iv) Gutkha is a product, wherein, pan masala is mixed with tobacco. Therefore, there is a ban on 'Gutkha', whereas, there is no ban on 'tobacco'. Today also, any consumer has the freedom to purchase pan masala and tobacco separately and consume it by mixing both of them. There is *per se* no ban on 'tobacco' and/or 'pan masala'.
- (v) Section 2.3.4 of Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011 only provides that 'nicotine' or 'tobacco' should not be mixed in any food

product. There is no provision in Section 2.3.4 of the Regulation *ibid* that restricts selling of pan masala and tobacco separately. The policy is only confined to regulation, *i.e.*, as to how tobacco could be sold. As a matter of fact, tobacco could be sold separately and should not be pre-mixed with pan Masala and to this extent only, it comes under Section 2.3.4 of the Regulation of 2011.

**(C) Sitting of the Committee held on 17.10.2022:**

- (i) As per the directions of the Committee on Petitions, the Ministry of Health & Family Welfare had constituted an 'Expert Committee' consisting of Senior Officials of the Government of India, who have never been associated with any of these issues at any point of time, to look into the various facets of the case with an independent perspective, which was not an Internal Committee of the Ministry. The said 'Expert Committee' consisted of representatives from the CGHS, NITI Aayog, AIIMS, Department of Agriculture & Farmers' Welfare, Department of Legal Affairs, Non Communicable Diseases Division (ICMR) and FSSAI.
- (ii) The Ministry of Health & Family Welfare had already asked the said 'Expert Committee' to examine and give their opinion on the alternate formulation in regard to Regulation 2.3.4 of the Food Safety and Standards Regulations, 2011 as suggested by the Committee on Petitions *vide* Lok Sabha Secretariat O.M. dated 15 July, 2022.
- (iii) The Ministry has been waiting for the final judgment of the Areca Nut Case (tagged with 70 other related cases), wherein, the question as to whether tobacco is a food product or not is expected to be resolved, which is pending in the Supreme Court since 2016-17. Besides, the Ministry is not in favour of challenging the recent judgement of the High Court of Delhi and at the same time.

- (iv) As regards formulation and enactment of any Subordinate Legislation, the final decision is taken by the highest level. The Competent Authority has already been briefed about the alternate formulation in regard to Regulation 2.3.4, in question and a formal meeting for discussing the matter would be held soon.
- (v) The Ministry fully endorses the views of the Committee that consumption of 'tobacco', in any form is harmful for public health and does not want to discriminate the same on the basis of its form which is evident from the mandatory graphic warning on the packets of 'smoking tobacco' as well as 'smokeless/ chewing tobacco'.

**III. Reports of the Expert Committee constituted by the Ministry of Health & Family Welfare for examination of impact of banning indigenous chewing tobacco products**

**(A) Volume I**

Consequent upon directions of the Committee of Petitions, Lok Sabha, the Ministry of Health and Family Welfare set-up a Committee vide their Order No. H. 11013/01/2021-TC dated 29th December, 2021 to examine the impact of banning indigenous chewing tobacco products viz-a-viz the action taken replies on the 68<sup>th</sup> Report of the Committee on Petitions (16th Lok Sabha). The Constitution of the Committee is at Annexure III Dr. Narender Kumar, Deputy Commissioner (Crops) could not attend any meeting of the Committee.

The terms of reference (TORs) of the Committee are as follows:-

- (i) To identify administrative and legal issues regarding definition of "food" as defined under the Food Safety and Standards (FSS) Act, 2006, keeping in view the various judicial pronouncement regarding chewing tobacco, khaini, zarda, gutkha, and chewing tobacco products in any other form.

- (ii) In view of the issues identified, to determine whether any amendment is required in the definition of 'Food' under Food Safety and Standards (FSS) Act, 2006.
- (iii) If any such amendment is not required, is there any need to issue any clarification regarding the definition of "food", with regard to tobacco products.
- (iv) Whether a complete ban on all forms of tobacco products is advisable? And if so, the feasibility of its implementation.

The Committee has been asked to submit its Report within two months. The Ministry of Health and Family Welfare has directed Food Safety and Standards Authority of India to convene the meeting as convener. The minutes of meeting of the Committee, which met on 3 occasions on 28.04.2022, 17.05.2022 & 23.05.2022 are at Annexure IV. The report of the Committee was finalized in the meeting on 23.05.2022. This report is Volume 1 and the subsequent report will follow in due course.

The report is divided in 4 Chapters. Chapter I comprises of the background & genesis of The Prevention of Food Adulteration Act, 1954, The Prevention of Food Adulteration Rules, 1955, The Food Safety and Standards Act, 2006 and the Cigarettes and Tobacco Products - Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003; and the definition of food' thereon. Chapter II contains the summary of important decisions of the courts governing the area of tobacco and tobacco products. Chapter III comprises the ongoing cases on the subject matter pending in the Hon'ble Supreme Court and their interim orders and directions. Chapter IV has the recommendations of the Committee on ToRs.

## **Chapter 1**

Before going into the TORS it may be pertinent to delve on the genesis of the enactment of Prevention of Food Adulteration Act, 1954, the Prevention of Food Adulteration Rules, 1955, The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce,

Production, Supply and Distribution) Act, 2003 (COTPA) and the Food Safety and Standards Act, 2008, (FSS Act).

The Prevention of Food Adulteration Act, 1954 was enacted for prevention of adulteration of the 'Food' Section 2 (v) of PFA Act defines 'food' which reads:

"Food" means any article used as food or drink for human consumption other than drugs and water and includes:-

- (a) any article which ordinarily enters into, or is used in the composition or preparation of, human food,
- (b) any flavouring matter or condiments, and
- (c) any other article which the Central Government may having regard to its use, nature, substance or quality, declare by notification in the official Gazette, as food for the purposes of this Act. It may thus be seen the definition of 'Food' under PFA Act does not include 'water' but wide enough to include any article which ordinarily enters into, or is used in the composition or preparation of human food. Tobacco is not specifically excluded in the definition.

FSS Act was enacted to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

The 'food' has been defined in Section 3 (1) (j) of FSS Act which reads:

"food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, to the extent defined in clause (ZK) genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture,



preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substance.

Provided that the Central Government may declare, by notification in the Official Gazette, and other article as food for the purposes of this Act having regards to its use, nature, substance or quality.”

Here also, under the FSS Act, 2016, the ‘tobacco’ is neither excluded nor included in the definition of ‘food’. In the Prevention of Food Adulteration Rules, 1955, Rule 44 (j) was inserted in the year 2006 which reads –

*“44 J Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food products.”*

It may be noted that though Rule 44 J was not originally in PFA Rules, it was added subsequently in the year 2006 probably because the state food authorities could legitimately issue orders banning food products found mixed with ‘tobacco’ and/or ‘nicotine’ as various studies and research had revealed that these substances (tobacco and nicotine) if consumed as part of food will be very harmful for public health & unintended consequences of the same being huge burden on health sector.

The Prevention of Food Adulteration Act and Rules were superseded by the Food Safety and Standard Act, 2006 and various regulations which were notified and came into force, w.e.f., 5 August, 2011. One of the principal regulations is the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011. Regulation 2.3.4 of Food Safety and Standards (PRS) Regulations, 2011 corresponds with Rule 44 J of PFA Rules.

Though tobacco products are not specifically included or excluded in the definition of ‘food’ under Food Safety and Standards Act, nor under the repealed PFA Act 1954, it has been under rule 44J of PFA Rules, 1955 and later under Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, it has been provided that tobacco

and nicotine shall not be used as ingredients in any food products. The Commissioners of Food Safety of States/UTs have been issuing orders from time to time banning tobacco products for sale in their respective States/UTs under the powers vested in them under Section 30 of the FSS Act, 2006 read with regulation 2.3.4 of Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011. The ban orders by the Commissioners of Food Safety of States/UTs have been challenged by the food business operators in High Courts through Writ Petitions. In the cases decided by the courts under both regimes i.e. under the Prevention of Food Adulteration Act and the Food Safety and Standard Act; in majority of the cases, it has been held that tobacco and tobacco products are 'food' within the definition of 'food' under both the said legislations. The pith and substance of various judicial pronouncements by High Courts as well as in Supreme Court is that since 'tobacco' and 'tobacco products', which are put in the mouth, are naturally ingested into the food pipe and are thus food even if these are consumed for taste and/or for nourishment.

The COTPA, 2003 has been enacted by Parliament to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarettes and other tobacco products and for matters connected therewith or incidental thereto.

Going by the language of FSS Act and COTPA, it would seem that there is conflict between these enactments, both legislated by the Central Legislature, the former being a general act to cover within its ambit any product which is consumed by human being, the later being a special act dealing exclusively with tobacco and tobacco products. However, the courts have struck a fine balance between these enactments in preponderance of cases and more or less observed that both these acts are not in conflict and can run parallel to each other as evident from the summary of various decisions as contained in Chapter 2.

While the definition in the PFA Act excluded drugs and water, the definition in the FSS Act, 2006 excludes animal feed, live animals, plants prior to harvesting, drugs and medicinal products, cosmetic, narcotic and psychotropic substance. Obviously, gutkha and pan masala do not fall in any of these excluded categories. The expression, 'any substance which is intended for

human consumption' in FSS Act, 2006 is also wider than the expression 'any article used as food or drink for human consumption' in PFA Act, 1954. It is also pertinent to note that the definition of food in the FSS Act, 2006 specifically includes 'chewing gum' and any substance used into the food during its manufacture, preparation or treatment. Hence, even if gutkha or pan masala were not to be ingested inside the digestive system, any substance which goes into the mouth for human consumption is sufficient to be covered by the definition as food just as chewing gum may be kept in the mouth for some time and thereafter thrown out. Similarly, gutkha containing tobacco may be chewed for some time and then thrown out. Even if it does not enter into the digestive system, it would be covered by the definition of 'food' which is in the widest possible terms. The definition of 'food' under section 2 of the PFA Act was narrower than the definition of food under FSS Act, still the Supreme Court in Godawat case held that pan masala and gutkha were 'food' within the meaning of PFA Act.

#### **Status of tobacco in Codex Alimentarius:**

Codex Alimentarius is a compilation of international food standards developed by the Codex Alimentarius Commission, a body jointly established by the FAO & WHO of the United Nations. Codex standards are voluntary in nature but are considered as reference standards for international food trade under various WTO agreements. The Codex has defined food as "Food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs." It may be seen that in the definition of 'food' by Codex, tobacco has been excluded. The possible reasons for exclusion of tobacco from the Codex definition of food might have been as follows:-

- (i) Codex texts (standards/Guidelines/Codes of Practice) are generally developed on the basis of consensus. Use of chewing tobacco largely being a phenomenon in the Asian region (mainly India), probably there were no discussions on considering tobacco as a food from international point of view or a consensus in the context was elusive.

- (ii) Further, Codex develops standards for a commodity only if the commodity is traded across countries and regions in significant quantities and, therefore, the commodity being important from international trade perspective. In case a commodity is largely traded within a region only, Codex does not frame an international standard but allows regions to develop a regional standard for such commodity. Within Code Alimentarius, currently regional texts are significantly less in number (around 20) in comparison to international texts (around 300).
- (iii) WHO policies in respect of certain products like tobacco, alcoholic beverages are stringent and prohibitive in nature due to their negative impact on health. While tobacco is not included in the Codex definition of food itself, WHO also discourages any proposal for framing of standards for alcoholic beverages in the Codex system although drinks are included in the Codex definition of food.

## **Chapter 2**

In this Chapter, the Committee would like to give a glimpse of cases decided by various High Courts and Supreme Court elaborating and declaring the law concerning tobacco, tobacco products, pan masala etc. Efforts have been made to summarize the facts and the rulings of the respective courts.

### **I. Pyarali K. Tejani vs Mahadeo Ramchandra Dange 1974 AIR 228 (Supreme Court)**

#### **Issue:**

Supari sample was duly analysed by the Public Analyst and the report revealed the presence of two artificial sweeteners namely, saccharin and cyclamate.

#### **Held:**

The court decided that supari is food for the purpose of the Prevention of Food Adulteration Act. The meaning of common words relating to common articles consumed by the common people, available commonly and contained in a statute intended to protect the community generally, must be gathered from the

common sense understanding of the word. The Act defines 'food' very widely as covering any article used as food and every component which enters into it, and even flavoring matter and condiments. It is common place knowledge that the word "food" is a very general term and applies to all that is eaten by man for nourishment and takes in subsidiaries. Since Supari is eaten with relish by man for taste and nourishment it is food within the meaning of Section 2(v) of the Act.

## II. State of Tamil Nadu Vs. R. Krishnamurthy AIR1980 SC 538 (Supreme Court)

### Issue:

Gingelly oil mixed with 15% of groundnut oil was sold as gingelly oil by the respondent to the Food Inspector, Thanjavur Municipality. The defence of the respondent was that he kept the oil in his shop to be sold, not for human consumption, but, for external use. **While adjudicating on the issue the Hon'ble Supreme Court discussed the definition of food under the Prevention of Food Adulteration Act.**

### Held:

1. According to the definition of "food" any article used as food or drink for human consumption and any article which ordinarily enters into or is used in the composition or preparation of human food is "food". It is not necessary that it is intended for human consumption or for preparation of human food. It is also irrelevant that it is described or exhibited as intended for some other use. It is enough if the article is generally or commonly used for human consumption or in the preparation of human food. To quote the Court:

"It is notorious that there are, unfortunately, in our vast country, large segments of population, who living as they do, far beneath ordinary subsistence level, are ready to consume that which may otherwise be thought as not fit for human consumption. In order to keep body and soul together, they are often tempted to buy and use as food, articles which are adulterated and even unfit for human consumption but which are

sold at inviting prices, under the pretence or without pretence that they are intended to be used for purposes other than human consumption. It is to prevent the exploitation and self destruction of these poor, ignorant and illiterate persons that the definition of "food" is couched in such terms as not to take into account whether an article is intended for human consumption or not. In order to be "food" for the purposes of the Act, an article need not be "fit" for human consumption; it need not be described or exhibited as intended for human consumption; it may even be otherwise described or exhibited; it need not even be necessarily intended for human consumption; it is enough if it is generally or commonly used for human consumption or in the preparation of human food."

### **III. Khedan Lal & Sons v. State of UP (under PFA Act) High Court of Allahabad**

#### **Issue:**

In 1975, various Food Inspectors obtained from the various dealers, samples of tobacco manufactured by M/s. Khedan Lal & Sons which, on analysis, were found to contain colouring material, use of which is prohibited by the Prevention of Food Adulteration Act. Consequently, the Petitioners were being prosecuted in various criminal cases at Lucknow, Gonda and Agra for committing offences punishable under the Prevention of Food Adulteration Act.

#### **Held:**

1. 'Food' means not only an article which normally a person eats or drinks with a view to nourish his body (as ordinarily understood) but also an article which normally is not considered to be food, but which ordinarily enters into or is used in the composition or preparation of human food, Accordingly such ingredients also would in the circumstances mentioned in Section 2(v) of the Act, be deemed to be adulterated and any person dealing in such ingredients can also be dealt with under the provisions of the Act.

2. According to the definition of the word 'food' any article which ordinarily enters into or is used in the composition or preparation of human food also is food. The definition does not state that an article which ordinarily enters into or used in the composition or preparation of human food becomes food only when it has actually been made an ingredient of some human food.
3. According to the Court, an article which ordinarily enters into or is used in the composition or preparation of food will remain food as defined by Prevention of Food Adulteration Act irrespective of the fact whether it has actually gone into the composition or preparation of human food or not. Accordingly once it is held that chewing tobacco of the nature involved in this case is an article which ordinarily enters into or is used in the composition or preparation of human food it would be food within the meaning of the Act even though it has not actually been sold by making it an ingredient of pan and it will fall within the purview of Prevention of Food Adulteration Act.

**IV. Manohar Lal v. State of UP Criminal Revision No. 318 of 1982 (High Court of Allahabad)**

**Issue:**

Food inspector took sample of tobacco from the appellant and sent it to public analyst. Food analyst reported that tobacco was coloured by coal tar dye while use of colour was prohibited in case of tobacco. Prosecution was launched under the Prevention of Food Adulteration Act. Out of several contentions raised by the petitioner against the enforcement procedure one contention was that tobacco is not food and cannot be adulterated.

**Held:**

1. The term "food" is defined in section 2(v) of the Prevention of Food Adulteration Act. It means any article used a food for human consumption. It also includes any article which is used in preparation of human food or enters into its composition and it also includes any flavouring matter.

2. Anything that is eaten by human being is food in the sense in which common man understands it. Of course, some get an impression that food is something which is essential for growth and it has nutrition. It may be argued that tobacco has no nutrition. The meaning of the term is judged in the background in which the Act is passed. The PFA does not seem to have been passed merely for preventing adulteration of articles which are nutritious.; rather the intention seems to be prevent adulteration of all articles that human being ordinarily consume except drug or water which have been excluded in the definition.
3. Tobacco is something which is consumed by human beings and it is eaten. So it should be food. Moreover it is added as a flavouring matter to betel leaves and it enters into composition of betel leaves. Betel leaves along with its components supply nutrition to the human being as it has calcium. So betel leaves can be said to be food and tobacco is an article which enters into the composition of betel leaves or flavours it. Therefore tobacco will be food.

**V. Laxmikant v. Union of India Civil Appeal No. 3000 of 1997 (Supreme Court of India)**

**Issue:**

The appellant was a manufacturer of tooth-paste, using tobacco as one of the ingredients in his toothpaste. The appellants had challenged a notification of the Ministry of Health whereby total ban on use of tobacco in the preparation of tooth-paste was imposed.

**Held:**

Relying on various reports of several committees and the reports of World Health Organisation the Hon'ble High Court held that, the view taken by the Government of India imposing total prohibition on the use of tobacco in the preparation of tooth-powder and tooth-paste is well justified in the public interest covered by Article 19(8) of the Constitution, though it offends the right



to carry on trade guaranteed under Article 19(1) of the Constitution. The imposition of total ban is in the public interest.

**VI. Godawat Pan Masala v. Union of India AIR2004SC4057 Supreme Court of India.**

**Issue:**

To adjudicate on the power of the Food (Health) Authority to issue an order of prohibition, whether permanently or quasi-permanently, under Section 7(iv) of the Act.

**Held:**

1. Section 7(iv) of the Act is not an independent source of power for the state authority;
2. The source of power of the State Food (Health) Authority is located only in the valid rules made in exercise of the power under Section 24 of the Act by the State Government, to the extent permitted thereunder;
3. The power of the Food (Health) Authority under the rules is only of transitory nature and intended to deal with local emergencies and can last only for short period while such emergency lasts;
4. Pan Masala or Gutkha amounts to "food" within the meaning of definition in Section 2(v) of the PFA Act.
5. The power of banning an article of food or an article used as ingredient of food, on the ground that it is injurious to health, belongs appropriately to the Central Government to be exercised in accordance with the rules made under Section 23 of the Act, particularly, Sub-section (1A)(f).
6. The State Food (Health) Authority has no power to prohibit the manufacture for sale, storage, or distribution of any article, whether used as an article or adjunct thereto or not used as food. Such a power can only arise as a result of wider policy decision and emanate from

Parliamentary legislation or, at least, by exercise of the powers by the Central Government by framing rules under Section 23 of the Act;

7. The provisions of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 are directly in conflict with the provisions of Section 7(iv) of the Prevention of Food Adulteration Act 1954. The former Act is a special Act intended to deal with tobacco and tobacco products particularly, while the latter enactment is a general enactment. Thus, the Act 34 of 2003 being a special Act and of later origin, overrides the provisions of Section 7(iv) of the Prevention of Food Adulteration Act, 1954 with regard to the power to prohibit the sale or manufacture of tobacco products which are listed in the Schedule to the Act 34 of 2003;
8. The impugned notifications are ultra vires the Act and, hence, bad in law;
9. The impugned notifications are unconstitutional and void as abridging the fundamental rights of the appellants guaranteed under Articles 14 and 19 of the Constitution.

**VII. Dhariwal Industries Limited and Ors. Vs. The State of Maharashtra Writ Petition No. 1631 of 2012 (Bombay High Court)**

**Issue:**

The petitioners had challenged the validity of the following provisions of two different Regulations under the Food Safety and Standards Act, 2006 ("the Food Safety Act "or FSS Act or Act of 2006") as well as the statutory order dated 19 July 2012 of the Commissioner of Food Safety, State of Maharashtra under Section 30(2)(a) of the Food Safety Act. The regulations impugned in this petition were -

- (i) Regulation 2.3.4 of the Food Safety and Standards (Prohibition & Restrictions on Sales) Regulations, 2011 ("The Prohibition and Restrictions Regulations") and

- (ii) Regulation 3.1.7 of the Food Safety and Standards (Food Products Standards & Food Additives) Regulations, 2011 ("the Standards Regulations"). Both the Regulations taken together are referred to as "2011 Regulations".

The Food Safety Act, 2006 is a general Act which does not refer to tobacco or any tobacco product and, therefore, the matter is still governed by the COTPA Act of 2003. There is no implied repeal of the COTPA Act, 2003. Hence, the impugned order is ultra vires the power of State Government under the COTPA Act 2003.

Prior to order dated 19 July 2012, the respondent authorities were not taking action against the manufacturers or distributors of gutkha or pan masala and, therefore, the authorities themselves had not interpreted the 2011 Regulations as imposing a total ban on gutkha having tobacco or on pan masala having magnesium carbonate.

**Held:**

Does the Cigarettes act of 2003 occupy the entire field or the Food Safety Act of 2006 is the comprehensive law on the subject?

- 1.1 While the definition in the 1954 Act excluded drugs and water, the definition in the Food Safety Act, 2006 excludes animal feed, live animals, plants prior to harvesting, drugs and medicinal products, cosmetic, narcotic and psychotropic substance. Gutkha and Pan Masala do not fall in any of these excluded categories. The expression "any substance which is intended for human consumption" in FSS Act 2006 is also wider than the expression "any article used as food or drink for human consumption" in PFA Act, 1954. The definition of food in the Act of 2006 specifically includes "chewing gum" and any substance used into the food during its manufacture, preparation or treatment. Hence, even if gutkha or pan masala were not to be ingested inside the digestive system, any substance which goes into the mouth for human consumption is sufficient to be covered by definition of food just as chewing gum may be kept in the mouth for some time and thereafter thrown out. Similarly gutkha containing tobacco may be chewed for

some time and then thrown out. Even if it does not enter into the digestive system, it would be covered by the definition of "food" which is in the widest possible terms.

The definition of "food" under section 2 of the PFA Act was narrower than the definition of food under Food Safety Act, still the Supreme Court in Godawat case held that pan masala and gutkha were "food" within the meaning of PFA Act. The very fact that the petitioners themselves had obtained licences under the PFA Act and have also obtained licences under the Food Safety Act, 2006 is sufficient to stop them from raising the contention that gutkha and pan masala do not fall within the definition of "food" under the Food Safety Act, 2006.

- 1.2 Whether the provisions of the Food Safety Act, 2006 make any difference to the legal position which was laid down by the Supreme Court in Godawat case?

The court held that while holding the Cigarettes Act to be a special Act, the Supreme Court did not accept the contention of the petitioners that the PFA Act had no role to play in the matter of regulation of manufacture and sale of gutkha and pan masala. In fact, the Supreme Court in turn held that the power to ban gutkha or pan masala under the PFA Act, 1954 was vested in the Central Government under Section 23(1A)(f) thereof and not in the State Government under section 7(iv) thereof. The Supreme Court did not accept the petitioners' contention in Godawat case that Cigarettes Act was the only legislation occupying the field of tobacco and tobacco products and that PFA Act had nothing to do with any tobacco product.

By an order dated 7 December 2010 in SLP No. 16308 of 2007 (Ankur Gutkha v. Asthma Care Society & Ors.), the Supreme Court had directed the Central Government "to undertake a comprehensive analysis and study of the contents of gutkha, tobacco, pan masala and similar articles manufactured in the country, and harmful effects of consumption of such articles." The Report of National Institute of Health and Family Welfare submitted, pursuant to the above analysis and study, reveals that more than one-third of adults in India use tobacco in some or other form, more

than 16 crore people are users of only smokeless tobacco and 4 crore people are users of both smoking and smokeless tobacco. Several studies in India have reported a strong association between smokeless tobacco use and oral pre-malignant/ pre-cancerous lesions. The risk increases with the duration and frequency of smokeless tobacco use. There are consistent results of an increased risk of oral cancer with the use of different forms of smokeless tobacco used in the country. There is also strong association between smokeless tobacco and pancreatic cancer, throat cancer, esophageal cancer, renal cancer and higher mortality rate. The use of smokeless tobacco also causes non-cancerous diseases/ conditions including nervous system diseases, metabolic abnormalities, reproductive complications and other diseases like gastrointestinal and respiratory diseases.

- 1.3 The important difference is in the phraseology of the provisions of the two Acts. Section 7(iv) of PFA Act, 1954 provided that no person shall manufacture etc. "any article of food, the sale of which is for the time being prohibited by the Food (Health) Authority in the interest of public health."

The corresponding provision in section 26(2)(a) of the Food Safety Act casts obligation on the food business operator not to manufacture, etc. "any article of food - (i) which is unsafe", without limiting the obligation to any time frame, much less "for the time being". Hence, the idea of an emergent situation which would go with the expression "for the time being ..." does not apply to the obligation of the Food business operator to provide safe food.

Secondly, in Godawat case, the Supreme Court noticed that the power to prohibit a food article as injurious to health was conferred by section 23(2A)(f) only on the Central Government without conferring similar power on the State Government. Therefore, now in section 30(2)(a), Parliament has expressly conferred power on the Food Safety Commissioner of the State, subject to the only limitation of one year period at a time.

- 1.4 The 2011 Regulations have been made by the Food Authority of India in exercise of the powers under sections 16 and 92 of the Act after previous consultation with the Central Government and have been placed before each House of Parliament without any modifications having been made by Parliament. Section 30(2)(a) confers independent power on the Food Safety Commissioner in the State. Section 26 of the Food Safety Act directs that every food business operator shall not manufacture or distribute any article of food which is unsafe and that it is not necessary for the said obligation to be enforced that such a food article must be first prohibited by the Food Authority of India or the Central Government or the State Government.
- 1.5 Having examined the scheme of PFA Act, 1954, Cigarettes Act, 2003 and the Food Safety Act, 2006 and 2011 Regulations framed thereunder, which were laid before Parliament and not modified and having regard to the fact that Food Safety Act, 2006 is a later Act and a comprehensive legislation on food safety and contains a non-obstante clause in section 89 thereof, Court was prima facie of the view that in the field of safety and standards of food (which includes gutkha, pan masala and supari) the Food Safety Act, 2006 occupies the entire field.
- 1.6 Are Principles of Natural Justice to be followed while exercising powers under section 30(2)(a) of Food Safety Act?

The Food Safety Act of 2006 admittedly empowers the Food Authority of India to lay down the standards of food products. The definition of food in Food Safety Act includes gutkha and pan masala. When the Parliament has specifically conferred power on the Food Safety Commissioner of the State to prohibit in the interest of public health, the manufacture, storage, distribution or sale of any article of food in the interest of public health, the Parliament has done what Article 258(2) of the Constitution exactly permits.

The Food Safety Commissioner, Maharashtra State exercising his powers under section 30(2)(a), is thus a delegate of Parliament.

**VIII. Omkar Agency and Ors. Vs. The Food Safety and Standards Authority of India and Ors. High Court of Patna Civil Writ Jurisdiction Case Nos. 3805, 18244, 18282 and 18351 of 2015**

**Issue:**

Petitioners aggrieved by the orders of the Commissioner of Food Safety, Patna, whereby the Commissioner, in exercise of powers, under Section 30(a) of the Food Safety and Standards Act, 2006, had prohibited the manufacture, storage, distribution or sale of Zarda, Pan Masala and Gutkha filed the present petition to set aside the notifications.

**Held:**

1. In respect of the issue as to whether the Provisions of COTPA are in conflict with The Food Act and The Regulations and, If So, Which one will prevail? The Hon'ble court held that Godawat Pan Masala has held that trade, in tobacco, is permissible subject to restrictions imposed under COTPA. By virtue of the various provisions of COTPA, the sale, production and distribution of tobacco products have been regulated, but not prohibited in its entirety.
2. That the Preamble to COTPA coupled with Section 2 leads to the conclusion that COTPA is a comprehensive law dealing with the prohibition of advertisement and Regulation of trade and commerce, production, supply and distribution of tobacco and tobacco products. It is seen that much after the enactment of Food Act, 2006, Rules are being made by the Central Government under the COTPA Act (latest being in 2014). The Food Regulations were made in the year 2011. Hence, the question of former legislation having been impliedly repealed by the latter legislation pales into insignificance. Reading the scope of COTPA in the light of the Food Act, it becomes transparent that the preamble to the Food Act provides that it is an Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to

ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

3. On the issue of whether tobacco is food or not, the court held that even if it is assumed that tobacco is food within the meaning of Food Act, then, as the preamble to the Food Act, warrants, there must be a science based standards for tobacco and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome tobacco for human consumption. If the standards can be possibly laid down, tobacco can be termed as food or else, the answer has to be in negative. The fact that tobacco is not food is further strengthened by the fact that Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, does not define tobacco, because no standards can be possibly laid down for tobacco. Hence, it is found that COTPA is exclusive law, which deals with tobacco and tobacco products; whereas the Food Act is exclusive law, which deals with foods other than tobacco.

4. The third issue framed by the court was as to whether by subsequent enactment of Food Act, the COTPA has been impliedly repealed?

The doctrine of implied repeal cannot be applied because COTPA applies to tobacco industries, whereas the Food Act applies to food industry. The conflict is not between the two statutes; rather, the conflict is between COTPA, a central legislation, and a Regulation in the form of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. Hence, the question is if there is a conflict between a Central law and a Regulation made under Central law, which would prevail.

5. The Food Act, nowhere, provides that tobacco business operators are required to obtain licences under the Food Act. Tobacco, being not a food within the meaning of Food Act, there can be no business operator under the Food Act and, consequently, no prohibition order, even under Section 33, can be passed.



6. On Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 the court observed that the Regulations mandate that tobacco and nicotine shall not be used as ingredients in any food product. The Regulations have been framed in exercise of powers conferred by Section 92 of the Food Act.

In exercise of the power under Section 92 of the Food Act that Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011, prescribes that tobacco and nicotine shall not be used as ingredients in any food products. This prescription cannot be said to be regulating manufacture of tobacco or nicotine; rather, it amounts to regulating standard of food within the meaning of the Food Act. The said Regulation 2.3.4 prohibits use of tobacco and nicotine in food products and, therefore, the said Regulation cannot be said to be in conflict with any provisions of COTPA. The said provisions, under the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011, appear to be in tune with the general principle of food safety as laid down in Chapter III of the Food Act.

7. On the question whether Pan Masala is a food or not, it was held that Pan Masala occurs in the schedule to COTPA as 8th item. For Pan Masala to be a scheduled item under COTPA, it must have tobacco as one of its ingredients. There is apparent distinction between Pan Masala occurring at Regulation 2.11.5 of the Food Safety & Standards (Food Products Standards & Food Additives) Regulations, 2011, and the one occurring at 8th item of the schedule to COTPA. Whereas, the latter must have tobacco as one of its ingredients, the former must not have. The moment tobacco is added to Pan Masala, as occurring at Regulation 2.11.5 of the Food Safety & Standards (Food Products Standards & Food Additives) Regulations, 2011, it will take the colour of Pan Masala under COTPA.

Under Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011, what is regulated, is food without tobacco and it, therefore, prohibits mixing tobacco with a food item. The Regulation 2.3.4 cannot, be said to be ultra vires.

8. Whether it is permissible to give effect to both the enactments as far as possible? Tobacco can be used only in the manufacture and preparation of the tobacco products mentioned in the Schedule of COTPA. The schedule to COTPA has, therefore, to be read as an entity of tobacco product, which are permitted to be sold and manufactured. Central Legislation, having allowed manufacture and production of tobacco and tobacco product on the permission so granted by COTPA, cannot be hindered by a Regulations of another Central Legislation, more particularly, Food Authority. In view of the evident conflict, the Regulation has to yield to those tobacco products, which have been mentioned in the Schedule to the COTPA.
9. COTPA, being a principal legislation, is the comprehensive law, which deals with the sale, manufacture and production of tobacco and tobacco products notified in the Schedule of the COTPA.
10. The order of the Commissioner of the Food Safety, in so far as it prohibits the use of tobacco and nicotine with respect to scheduled tobacco products under COTPA, is arbitrary and beyond the scope of powers conferred by the Food Act.
11. Omkar Agency has already been challenged before the Hon'ble Apex Court in SLP (C) No. 032155 of 2016, filed on 5/9/2016, and has been tagged with SLP (C) No. 30090 of 2016 and other matters pending before the Hon'ble Apex Court, wherein the provisions of the FSS Act are under consideration.

**IX. Sanjay Anjay Stores and Ors. v. The Union of India and Ors.2017  
Calcutta High Court**

**Issue:**

To issue a declaratory writ to the effect that the petitioners are producers within the meaning of Sec. 3(k) of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 and are outside the scope and

applicability, of the Food Safety and Standards Act, 2006 and Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011. The petitioners also challenged a notification dated 29 September, 2014 issued by the Commissioner of Food Safety, West Bengal prohibiting Zarda, Khaini, and all tobacco products in the State of West Bengal in exercise of powers under Sec. 30(2)(a) of the FSS Act read with Regulation 2.3.4 of the FSS Regulations.

**Held:**

The Hon'ble court adjudicated on the following two issues:

1. Whether the said products are food" within the meaning of FSSA?

The definition of 'food' in FSSA is very wide and apparently includes any product that can be consumed by human beings, tobacco products, in my opinion, cannot be understood to be covered by the definition. Food as we have always understood means edibles including liquid food that is drunk rather than eaten, which has nutritional value. Food is a source of energy to human beings and indeed to all living creatures, to sustain life. Food cannot be meant to include stimulant like zarda or other tobacco products which temporarily stimulate the human body without infusing any nutrient. Such tobacco products appear to provide stimulant which is more psychological in my opinion rather than real. People who are used to taking such tobacco products experience a sudden surge of energy which is more psychological than real. Nobody in his right senses would say that cigarette or other tobacco products are food.

If consumption of tobacco or products containing tobacco or nicotine was considered to be so inherently dangerous for human health, the Parliament could have banned altogether trade and commerce in tobacco and tobacco products even in the face of Article 19(1)(g) of the Constitution of India. But the Parliament did not do so. It has instead chosen to regulate rather than prohibit trade and commerce in tobacco and tobacco products by promulgating COTPA. Hence, on the strength of a delegated legislation in the form of FSS Regulations framed under the FSSA, the authorities cannot seek to prohibit trade and commerce in

the said products. That would be an exercise of a power that they do not have.

2. Whether the FSSA would apply to such products or whether the COTPA would apply for regulating the manufacture/storage/distribution/sale of such products?

“That since the said products are not food within the meaning of FSSA, there is no conflict between the FSSA and COTPA. The two statutes operate in different fields and there is no repugnancy between them. The conflict is between the COTPA and the FSS Regulations. It is trite law and I need not cite any authority for it that if there is a conflict between a central legislation and a delegated legislation, the later must yield to the former.

FSSA has been enacted to ensure minimum standard of food for human consumption in the interest of public health and the COTPA has been promulgated to regulate the trade and commerce in tobacco and tobacco products also in the interest of public health. There is no overlapping and hence no repugnancy or conflict between the two enactments. Reasonable restrictions may be imposed on the trade and commerce in tobacco and allied products under the COTPA but the Commissioner of Food Safety has no jurisdiction to impose any such restriction or prohibition under the FSSA.

The Commissioner of Food Safety or any other authority does not have the power or jurisdiction under the FSS Regulations or the FSSA to prohibit the trade and commerce in the said products. Restriction may be imposed on the trade and commerce of the said products only to the extent permitted under the COTPA.

COTPA is in full operation. The provisions of COTPA would override the provisions of FSSA. It is too well-established that a general provision should yield to a special provision. This is based upon the reasoning that in passing a special Act Parliament devotes its entire consideration to a particular subject. When a general Act is subsequently passed, it is logical to presume that Parliament has not repealed or modified the

former special Act unless anything to the contrary appears from the subsequent general Act.

Section 3 of COTPA is the definition Section. Sec. 3(p) defines 'tobacco products' as products specified in the schedule to the Act, which has been set out above. The said schedule includes chewing tobacco, pan masala or any chewing material having tobacco as one of its ingredients (by whatever name called) and gutkha. In other words, the said schedule includes the said products. COTPA is a comprehensive legislation to regulate trade and commerce in tobacco products. FSSA, no doubt is a subsequent legislation. Sec. 97(1) of FSSA provides that the statutes specified in the Second Schedule to the said Act shall stand repealed. The Second Schedule does not include COTPA. Hence, COTPA remains an effective piece of legislation in its own field, not being touched by FSSA.

The FSS Regulations is a delegated piece of legislation. The same cannot in any manner operate beyond the scope of the parent statute i.e. the FSSA. The trade and commerce in tobacco products including the said products can be regulated only to the extent permitted by COTPA. Even if the said products come within the very wide definition of 'food' as provided in the FSSA it is impermissible that two central legislations shall operate in the same field and will regulate the trade and commerce in the same products. The Parliament was conscious not to touch the COTPA while promulgating the FSSA and hence, the FSS Regulations, in my opinion, did not empower the Commissioner of Food Safety, West Bengal to issue the notification that has been challenged in the present writ applications. The Commissioner of Food Safety does not have the authority or jurisdiction to issue such notifications in respect of the said products."

**X. Mohammad Yamin Naeem Mohammad and Ors. V. The State of Maharashtra and Ors. Criminal Writ Petition No. 543/2020**

**Issue:**

The petition challenged the order dated 15/7/2020 issued by the Food Safety Commissioner, Food and Drugs Administration, Maharashtra State, passed under Section 30 (2) (a) of the Food Safety and Standards Act, 2006 to the extent it prohibits transport of banned products such as tobacco, Pan Masala, etc. from one State to another through the State of Maharashtra, as being unconstitutional and ultra vires, the powers of the said authority under the FSSA. The petition also sought to quash F.I.R. No. 358 of 2020 registered for offences punishable under Section 26 (2) (i), 26 (2) (iv), 26 (3), 59 of the FSSA and Sections 188, 272, 273 and 328 of IPC.

**Held:**

1. Relied on Dhariwal Industries Ltd. and another Vs. State of Maharashtra and others.
2. Held disagreement with Sanjay Anjay Stores (supra), which held that tobacco and tobacco products do not fall within the definition of 'food'.
3. By use of the expressions 'means any substance', 'containing such ingredients', and widest possible scope and ambit has been given to the word "food" under the FSS Act 2006.
4. That the definition of food', does not in any manner make it dependent upon its nutritional value nor that such substance can be consumed or digested in the stomach. No such position is reflected from a plain reading of the word 'food' as defined in Section 3(j). This is clearly fortified from the fact that even chewing gum, has been included in the definition of the word 'food'. It is axiomatic, that chewing gum is not ingested but is only chewed for the juices/flavor it is laced with and then thrown out. Same is the case with tobacco and tobacco products, including Pan Masala, which are used for the juices they generate, in

conjunction with saliva in the mouth, when chewed, which juices are ingested and the residue, thrown out. Thus no distinction could have been made in Sanjay Anjay Stores (supra) on the basis of nutritional value or ingestion, as the same is absent in Section 3(j) of the FSSA itself.

5. The court expressed its disagreement with the premise in Omkar Agency that for the exercise of the powers under Section 30(2)(a) of the FSSA, the report of the Designated Officer appointed under Section 36 of the FSSA is mandatory, is not borne out by the language of Section 30 of the FSSA. Section 30 of the FSSA nowhere stipulates that the powers under Section 30(2) (a) to (f) can be exercised by the Food Safety Commissioner, only upon receipt of a report by the Designated Officer appointed under Section 36 of the FSSA and not otherwise.
6. The judgment in Omkar Agency (supra), which takes into consideration the provisions of Sections 3 (zm), 24 and 36 of the FSSA, for putting fetters upon the powers of the Commissioner for Food Safety under Section 30 (2) (a) of the FSSA, is not within the four corners of the law as applicable.
7. Whether COTPA, holds the field against the FSSA, the court held that COTPA was enacted on 18/5/2003, in which Section 3 (p) defines "tobacco products" to mean the products specified in the schedule. The schedule at Serial No. 8, specifies Pan Masala or any chewing material having tobacco as one of its ingredients.
8. The FSSA, is a more comprehensive Act, dealing with the larger issue of Safety and Standards of Food in the country and in view of Regulation 2.3.4, prohibiting use of tobacco and nicotine as ingredients in any food products in the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011; by including Pan Masala in Regulation 2.11.5, Anti-caking agents in Regulation 3.1.7 in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, has included tobacco and tobacco products, including Gutkha and Pan Masala within the definition of food as enumerated in Section 3 (j) of the FSSA.

9. Section 89 of the FSSA, gives the provisions of the FSSA, an overriding effect on all other food related laws. Once it is held that tobacco and other products, fall within the definition of food as enumerated in Section 3 (j) of the FSSA, the overriding effect of Section 89 of the FSSA, would make the FSSA hold the field instead of COTPA. Joshi K.V. Omkar Agency and Sanjay Anjay Stores, which take a contrary view, do not lay down the correct law.
10. Issue of the order is within the competence and jurisdiction of the Food Safety Commissioner under the powers as conferred upon him, by the provisions of Section 30(2) (a) of the Food Safety and Standards Act, 2006.
- XI. **Kamadhenu Traders v. The State of Telangana and Ors. W.P. No. 19928/2021 (and 128 WPs )Telengana High Court - date of judgment 30.11.2021**

**Issue:**

All the petitions challenging the Notification no. 505/FSS-1/2021, dated 06.01.2021 issued by Commissioner of Food Safety, Telangana which prohibited the manufacture, storage, distribution, transportation and sale of Gutkha/Pan masala which contains tobacco and nicotine. The court upheld the validity of the notification, declaring the restriction to be reasonable. This is latest judgment of a High Court and has quoted the rulings in various judgments of High Courts and Supreme Court extensively. As this is most recent judgment with ample reasons the summary of submissions made by the petitioners and the response of respondents thereto and orders of the Court is given below:-

Petitioners' Arguments:

- COTPA - a central legislation dealing exclusive with tobacco industry and occupying the field.
- Legislative policy for tobacco products is not to impose complete ban on



tobacco products but to regulate and impose restrictions on trade and business.

- Country's taxing statutes permit trade and business in tobacco products.
- FSS Act regulate food standards; a general law: does not define 'tobacco products' nor provides any power for prohibition in trade and business in such products.
- COTPA — A Special Law that overrides FSS Act- A General Law.
- FSS Act cannot encroach upon areas covered by COTPA.
- Tobacco is not food within FSS Act; FSS Act: regulation 2.3.4 does not empower the authorities to impose a ban in respect of trade and business of tobacco.
- Except 'Pan Masala' as defined under regulation 2.11.5 of the Additive Regulations, no other products where tobacco can be mixed find any mention in food safety and standards regime.
- Power of Commissioner of food safety under section 30 (2) of the FSS Act, 2006 does not extend to prohibit the tobacco products, which is the sole prerogative of COTPA, 2003.
- Regulation 2.3.4 does not conform to the parent statute (FSS Act) meaning thereby the subordinate legislation cannot violate a plenary legislation.
- Regulation 2.3.4 does not empower the Commissioner of Food Safety to ban the products covered under the COTPA.
- The prohibition under regulation 2.3.4 can extend to any food which is consumed, except the product specifically covered under COTPA.
- Exercise of power under section 30 of FSS Act and the regulation 2.3.4

amounts to colourable exercise of power, which is not permissible.

- Regulation 2.3.4 does not cover chewing tobacco; the regulation makes a dichotomy between 'tobacco' on one hand and 'food products' on the other hand, which implies that chewing / chewable tobacco product were never intended to be covered under Food Safety Regulations, 2011.
- FSSAI license not needed for carrying on business in products covered under COTPA.
- The Commissioners of Food Safety of all States are not interpreting section 30 (2) (a) uniformly. E.G. CFS Telangana has issued notification whereas CFS Karnataka has not done.
- Non-obstante clause under section 89 of FSS Act does not enable overriding the provisions of COTPA as such clause in a subsequent general law cannot override a prior special law.
- Power has been given to CFS to be exercised only in emergent cases for a maximum period of one year, its continuance year after year amounts to colourable exercise of powers.

Arguments by respondents and Court's decision:

- Gutkha including tobacco fall within the definition 'food' as it is intended for human consumption.
- Supreme Court in State of Tamil Nadu Vs. R Krishnamurthy has held that a product be classified as a 'food' in case it is used for human consumption or in preparing human food. In the Godawat Pan Masala, the Supreme Court held that Gutkha, Pan Masala and Supari are food articles; Allahabad High Court in Manohar Lal Vs. State of UP and in Khedan Lal & Sons held that 'Chewing tobacco' is an article of food.
- Supreme Court in SLP 16308 of 2007 (Order dated 3.4.2013) directed States/UTs to file affidavits of total compliances of ban imposed on manufacturing and sale of Gutkha and Pan Masala with tobacco and/ or

nicotine.

- COTPA enacted to discourage the use of tobacco with great emphasis on protection of children and young people from being addicted.
- COPTA and FSS Act occupy different fields.
- Gutkha containing tobacco and tobacco are great threat to the public health.
- FSS (PRS) Regulations notified under section 92 of FSS Act and these are valid. As per section 89 of FSS Act, the Act has overriding effect on all legislations including COTPA, the former takes precedence over the latter Act.
- Pan Masala with tobacco and tobacco certainly falls under the definition of 'food' as they are intended for human consumption.
- Expert Committee by Ministry of Health & Family Welfare recommended a complete ban on Gutkha containing tobacco/ tobacco products/ tobacco.
- COTPA enacted with an aim and object to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply, and distribution of, cigarettes and other tobacco products with an aim to discourage the use or consumption of tobacco.
- The primary concern of FSS Act is promotion of public health and protection of the right to life of the citizens of the country and the purpose, aim and object of food safety regulations, 2011 is to ensure safety, health of citizens of this country by prohibiting any article of food which are injurious to health of general public. Quoting the Hon'ble Supreme Court in Allahabad Bank, Anay Kumar Banerjee and S. Prakash which held that a later Act, even if it is general Act, can prevail over an earlier special Act, in case of a repugnancy if there is no express provision to the contrary in the earlier special Act. The FSS Act was enacted later to the COTPA and therefore, the FSS Act to prevail.

- Supreme Court in R. Krishnamurthy has held that any article used as food or drink for human consumption and any article which ordinarily enters into or is used in the composition or preparation of human food is 'food'. It is not necessary that it is intended for human consumption or in preparation of human food. It is also irrelevant that it is described or exhibited as intended for some other use. It is enough if the article is generally or commonly used for human consumption. In order to keep body and soul together, the poor people of this country, are often tempted to buy and use as food, articles which are adulterated and even unfit for human consumption but which are sold at inviting prices, under the pretence or without the pretence that they are intended to be used for purposes other than human consumption. Therefore, 'food' has been couched in language so that the exploitation and self-destruction of the poor could be prevented.
- Under FSS Act- definition of 'food' has witnessed sea-change. Section 89 of FSS Act has overriding effect over other statutes.
- In Laxmikant case, the Supreme Court held that prohibition on the use of tobacco in preparation of toothpowder and toothpaste is well justified in the public interest covered under Article 19 (6) of constitution. Imposition of total ban is in public interest.
- Bombay High Court in M/s Dhariwal Industries Ltd. rejected the prayer for interim stay against orders of Commissioner Food Safety, Maharashtra in public interest in exercise of power conferred by Section 30 (2) (a) of FSS Act.
- Bombay High Court in Case of Mohd. Yamin Naeem Mohammad Vs. State of Maharashtra upheld the notification issued by the Commissioner of Food Safety banning tobacco products. Court held that the regulatory mechanism in COTPA is restricted to enduring that sale, storage, distribution of cigarettes and other tobacco products is not without the warning label and is to persons above the restricted age and to discourage the use of tobacco. FSS Act is more comprehensive.

- Section 89 of FSS Act, gives the provisions of the Act, an overriding effect on all other food related laws. Once it is established / held that tobacco and other products, fall in the definition of 'food', the overriding effect of Section 89, the FSS Act would hold the field instead of COTPA.

### Chapter 3

The Hon'ble Supreme Court of India is presently seized of the issue concerning banning of tobacco products in food products. The details of cases and Court's directions and interim orders are given hereunder.

#### I. **SLP(C) 16308 of 2007 in the matter of Ankur Gutkha v. Indian Asthma Society and others:**

Hon'ble Supreme vide their order dated 07.12.2010 directed the Learned Solicitor General of India to instruct the concerned Ministries to approach the National Institute of Health and Family Welfare to undertake a comprehensive analysis and study of the contents of gutkha, tobacco, pan masala and similar articles manufactured in the country and harmful effects of consumption of such articles. The Ministry of Health and Family Welfare (Government of India) pursuant to the said directions of the Apex Court, in consultation with the National Institute of Health and Family Welfare constituted a committee of technical experts and compiled a health report (NIHFW Health Report) on the contents of gutkha, tobacco, pan masala and similar articles manufactured in the country, and Areca-Nut or Betel Quid or Supari and harmful effects of consumption of such articles. As per that report there are over 3095 chemical components in smokeless tobacco products, among them 28 are proven carcinogen. The NIHFW health report further indicates a strong association between smokeless tobacco usage and incidence of oral, esophageal, stomach, pancreatic, throat and renal cancers. The Report also contains the decision of expert Committee dated 23.09.1997 recommending the prohibition on consumption of pan masala/ gutkha, chewing tobacco as an ingredient in any food item or as such, as they are injurious to public health.

The NIHFW health Report was submitted to the Court on 17.02.2011. The Report filed was in to two parts viz. (i) Analysis of scientific literature on the

contents of gutkha, tobacco, pan masala and similar articles manufactured in the country, and harmful effect of consumption of such articles, (ii) Analysis of the scientific literature on the harmful effect of consumption of Areca Nut or Betel Quid or Supari. The Hon'ble Supreme Court allowed all parties to file affidavit in response to the Report.

**II. Special Leave to Appeal (Civil) No.16308/2007 and other clubbed WPs led by Ankur Gutkha v. Indian Asthma Care Society and Ors:**

The Hon'ble Supreme Court of India in their order dated 03.04.2013 ordered issue of notice to the Chief Secretaries of the States and the Administrators of the Union Territories which had not so far issued notification in terms of 2006 Act to apprise the Court with reasons as to why they had not taken action pursuant to letter dated 27.08.2012 of the Special Secretary, Ministry of Health and Family Welfare, to the Chief Secretaries of all States. In this letter dated 27.08.2012 of Special Secretary (Health), the compliance of Regulation 2.3.4 of the Food Products Standards (Prohibition and Restrictions on Sales) Regulations, 2011 was requested. The Court also directed the Secretaries, Health Department of all the States and Union Territories to file their affidavits within 4 weeks on the issue of total compliance of the ban imposed on manufacturing and sale of gutkha and pan masala with tobacco and/or nicotine.

**III. Transfer Cases (Civil) No(s). 1/2010 in the matter of Central Areca-Nut Marketing Corporation and ors. vs. Union of India (tagged around 70 transfer and other cases including Ankur Gutkha case):**

The Court heard the cases on 01.09.2016, 07.09.2016, 15.09.2016, 16.09.2016, 20.09.2016 & 21.09.2016. The Court took note of submissions and acceding to the request of the learned counsels of the parties that more submissions were to be made, came to the conclusion that it was not possible to decide the matter within the time available. The Court took note of submissions of Learned Amicus Curiae that the Court had not granted an stay of Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 and directed that the concerned authorities were duty bound to enforce the said regulation framed under Section 92 read with Section 26 of the Food Safety and Standards Act, 2006.

The Court, accordingly, directed the concerned statutory authorities to comply with the said mandate of law and directed Secretaries, Health Departments of all the States and UTs to file their affidavits before the next date of hearing on the issue of total compliance of the ban imposed on manufacturing and sale of gutkha and pan masala with tobacco and/or nicotine. The case is still pending consideration of hon. Supreme Court and has not been listed since 23.09.2016.

## Chapter 4

### Recommendations of the Committee:

It may be seen from the judgments of various High Courts and the Supreme Court that there is no finality as regards inclusion or exclusion of 'tobacco' and 'tobacco products' within the ambit of the definition of 'food' as in Section 3(1) (j) of Food Safety and Standards Act. Some Courts have taken the stand that COTPA being special Act, it would take precedence over the Food Safety and Standards Act, which is a general legislation about food safety as a whole.

As summarised in Chapter 2, the Hon'ble supreme Court in Godawat Pan Masala Products (2004) 7 SCC 68 held that Gutkha, Pan Masala and Supari as food articles. The Hon'ble Allahabad High court in Manohar Lal vs. state of UP, Criminal Revision No. 318 of 1982 and in Khedan Lal and sons vs. State of UP, 1980 Cri LJ 1346, relying upon judgment of State of Tamil Nadu Vs. R. Krishnamurthy (1980) 1 SCC 167, held 'chewing tobacco' as an article of food.

In the latest judgment delivered by Telangana High Court on 30.11.2021, whereby around 130 writ petitions were dismissed, it has been held unambiguously that despite the fact that COTPA is a special Act, it cannot impinge and transgress the provision of FSS Act. The Court has observed that COTPA 2003 has been enacted with the aim and object to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarettes and other tobacco products with an aim to discourage the use or consumption of tobacco. The object for FSS Act is to ensure safe and wholesome food for the people. The primary concern and purpose of FSS Act is that promotion of public health and protection of right to life of the citizens of the country and the purpose, aim and

the object of Food Safety Regulations, 2011 is to ensure safety health of citizens of this country by prohibiting any article of food which is injurious to health of general public. The Court has further observed that it is an undisputed fact that tobacco products which are subject matter of the impugned notification are injurious to general health of the public. The Court has further said that by virtue of Section 89, the FSS Act will have overriding effect over the other statutes.

The Hon'ble Supreme Court of India had heard the parties on this subject matter in September, 2016 at length and it failed to conclude its findings due to paucity of time and large number of respondents was left to make submissions. The Supreme Court is, therefore, seized of the issue and in view of that the issue is pending consideration of the Apex Court, it will not be advisable for the Committee to give any opinion about amendment or otherwise of the definition of 'food' so as to make it clear if the tobacco and tobacco products are included or excluded. As the law declared by the Supreme Court as per Article 141 of the Constitution of India shall be binding on all courts within the territory of India, therefore, any interpretation on the intent and ambit of a provision as declared by the Supreme Court is sacrosanct.

Considering the facts as stated above and the Hon'ble Supreme Court being seized of the issue and different orders issued by the Authorities under FSS Act are under challenge, the Committee, refrains from expressing any opinion at this stage as regards the definition of 'food' under FSS Act, ToR (i), the ToRs (ii) and (iii) are connected and flows from ToR (i), it is not appropriate for the Committee to express any opinion/offer comments thereon due to its limitations, as expressed as regards the need of amendment.

As regards ToR (iv), it is submitted that the issue regarding banning completely all forms of tobacco products if advisable or not and its feasibility of implementation is a larger issue for the country as a whole. Therefore, to take a view about banning of tobacco and tobacco products is an issue which has huge implications and a decision impinge on livelihood of large number of people. A conscious decision would need to be taken balancing the interests of all and would therefore require large scale consultations with stake-holders including farmers, industry, States and concerned Ministries/Departments in



the Government of India. It is suggested this exercise is under way and the outcome thereof may form part of Volume 2 of this Report.

## **(B) Volume II**

### **I. Background**

The Expert Committee set-up by the Ministry of Health and Family Welfare vide their order dated 29.12.2021 to examine the impact of banning indigenous chewing tobacco products had submitted Volume I of their Report on 24.05.2022.

2. It is understood the Ministry sent the Report to the Hon'ble Committee on Petitions, Lok Sabha Secretariat, for their kind perusal. The Hon'ble Committee on Petitions vide their OM dated 15.07.2022 took cognizance of the Report and gave suggestions to the Ministry to amend Regulation 2.3.4 of the Food Safety and Standards (Prohibition, Restrictions and Sales) Regulations, 2011. The Committee also directed the Ministry that their suggestion to amend the said Regulation be explored and it should form part of the final Report (Vol. II) to be submitted latest by 16<sup>th</sup> August, 2022.

3. Volume I of the Report of the expert Committee contained four Chapters. Chapter 1 comprised of the background and genesis of the Prevention of Food Adulteration Act, 1954, the Prevention of Food Adulteration Rules, 1955, the Food Safety and Standards Act, 2006 and the Cigarettes and Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003; and the definition of 'food' thereon. Chapter II contained the summary of important decisions of the Courts governing the area of tobacco and tobacco products. Chapter III comprised of the ongoing cases on the subject matter pending in the Hon'ble Supreme Court, their interim orders and directions. Chapter IV contains the recommendations of the Committee on ToRs.

4. In the recommendations, the Committee summarised the outcome of decisions of various High Courts and Supreme Court, interpretation of Courts as regards mutual relation between Food Safety and Standards Act, 2006 and the COTPA. The Committee also pointed out that a law declared by the

Supreme Court pertaining to interpretation of any provisions of Act is the final law as per Article 141 of the Constitution of India. The Committee also pointed out that in the latest orders dated 23<sup>rd</sup> September, 2016, the Hon'ble Supreme Court had directed all States and Union Territories to comply with Regulation 2.3.4 of the Food Safety and Standards (Prohibition, Restriction and Sales) Regulations, 2011 and file compliance Reports thereon.

5. Since Hon'ble Supreme Court of India is already seized of the matter, the Committee refrained from expressing any opinion as regards the definition of 'food' under FSS Act. The Committee also didn't express their opinion on terms of reference (ii) and (iii) as the same flowed from ToR(i). As regards ToR (iv), the Committee submitted that the issue regarding banning completely all forms of tobacco products if advisable or not and its feasibility of implementation was a very large issue for the country as a whole and with huge implication. That being so, it was suggested by the Committee that to firm up a view thereon would require inputs from various stakeholders including farmers, industry, States and concerned Ministries/Departments of the Government of India. Accordingly, the Committee requested the Ministry of Health and Family Welfare to favour with stakeholders' comments thereon for assistance to the Committee in its deliberations.

6. Tobacco is not specifically included in the definition of 'food' as is the case with several other products. The definition of 'food' under FSS Act is, however, very wide and includes everything and anything not excluded from the definition. There is specific exclusion from the definition of 'food' of animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances. The tobacco and tobacco products if chewed/ eaten, these would form part of 'food' as has been declared by Hon'ble High Courts and Supreme Court in catena of cases. The Committee in their Report (Volume I) had apprised about the pending cases on the issue in the Hon'ble Supreme Court.

II. The Expert Committee went through the research articles on the impact of consumptions of tobacco/ tobacco products on the health of the people and would like to summarise the findings of the said research papers as below:

## (a) Tobacco Consumption and Disability-Adjusted Life Years (DALY)

Over 8 million people die yearly from the tobacco epidemic, severely threatening public health<sup>1</sup>(WHO). There are several ways to use tobacco, including smoking and smokeless tobacco, which are dangerous. Tobacco is a leading cause of premature death<sup>2</sup> (GBD 2017). To analyse the smoking prevalence among various countries, the Global Burden of Disease study provides diverse data to produce comparable estimates of tobacco-attributable disease burden and deaths by age and sex, which can be measured by disability-adjusted life years (DALY). A study by Wen et al. on trends in deaths and DALY attributable to tobacco, smoking, second hand smoke, and smokeless tobacco in China from 1990 to 2017 using GBD study 2017 data.<sup>3</sup> It was concluded that tobacco was the leading cause of death in China. Around 2.60 million deaths were attributed to tobacco. The tobacco-attributable death rates increased by 50% from 1990 to 2017. Tobacco attributable to DALY was 1489.05 and 6994.02 person-years per 100,000 in females and males, respectively. These figures mean that the health-adjusted life expectancy would increase by ~0.15 and 0.7 years in Chinese females and males, respectively, if tobacco could be controlled effectively (Wen et al., 2020). A systematic analysis of the Global burden of disease study 2019 conducted by GBD Tobacco Collaborators estimated the pattern of smoking prevalence attributable to disease burden by age and sex in 204 countries from 1990 to 2019. They estimated 1.14 billion (95% uncertainty interval 1.13–1.16) were current smokers globally in 2019, consumed 7.41 trillion (7.11–7.74) cigarette-equivalents of tobacco. About 7.69 million (95% UI 7.16–8.20) deaths and 200 million DALYs were attributable to tobacco use.<sup>4</sup>

YLLs from smoking tobacco accounted for 168 million (156-180) YLLs, which exceeded YLDs of 31.6 million (23.7-40.0) YLDs. The study interpreted that the annual toll of 7.69 million deaths and 200 million DALYs would increase in the coming decades if substantial efforts were

<sup>1</sup>WHO: <https://www.who.int/news-room/fact-sheets/detail/tobacco> (Accessed on 11.08.2022)

<sup>2</sup>Global Burden of Disease Study 2017. The Lancet

<sup>3</sup>Wen, H., Xie, C., Wang, F., Wu, Y., & Yu, C. (2020). Trends in disease burden attributable to Tobacco in China, 1990–2017: Findings from the global burden of disease study 2017. *Frontiers in public health*, 8, 237. (Wen et al., 2020)

<sup>4</sup>Reitsma, M. B. (2021). Spatial, temporal, and demographic patterns in prevalence of smoking tobacco use and attributable disease burden in 204 countries and territories, 1990–2019

not made to implement more robust tobacco control policies to end the tobacco epidemic. (Reitsma et al., 2021)

A study in Sweden mapped the 1990 to 2010 burden of disease attributable to alcohol, drugs, and tobacco. They reported DALYs that differed among the substances. In this study, tobacco smoking caused approximately 1,91,000 DALYs among men and women in 2010, corresponding to 7.7% of the total disease burden. The majority was due to premature death (approx. 154,000 YLL). In contrast, alcohol and drugs caused 84,000 DALYs and 32,000 DALYs, respectively, contributing to 3.4% and 1.3% of the total disease burden.<sup>5</sup>

Although the above literature contributes to tobacco smoke, another study conducted by Siddiqi et al. presented estimates of the disease burden due to smokeless tobacco by analysing data from 127 countries. Smokeless tobacco prevalence was more common in men than women in 95 countries. Among males, Myanmar (62.2%), Nepal (31.3%), India (29.6%), Bhutan (26.5%), and Sri Lanka (26.0%) had the highest consumption rates. Among females, Mauritania (28.3%), Timor Leste (26.8%), Bangladesh (24.8%), Myanmar (24.1%), and Madagascar (19.6%) had the highest consumption rates. According to our 2017 estimates, 2,556,810 DALYs lost and 90,791 deaths due to oral, pharyngeal, and esophageal cancers can be attributed to ST use. The global burden of disease wasted was 8,69,1827 DALYs and 3,48,798 deaths attributable to smokeless tobacco.<sup>6</sup> (Siddiqi et al., 2020)

## (b) Tobacco and infertility

Tobacco consumption is a global phenomenon posing a serious public health threat to people's general health and the reproductive system in particular. Around 1.3 billion people consume tobacco, 80% of whom reside in low and middle-income countries.<sup>7</sup> (WHO). The impact of

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<sup>5</sup>Kellerborg, K., Danielsson, A. K., Allebeck, P., Coates, M. M., & Agardh, E. (2016). Disease burden attributed to alcohol: how methodological advances in the Global Burden of Disease 2013 Study have changed the estimates in Sweden. *Scandinavian journal of public health*, 44(6), 604-610.

<sup>6</sup>Siddiqi, K., Husain, S., Vidyasagar, A., Readshaw, A., Mishu, M. P., & Sheikh, A. (2020). Global burden of disease due to smokeless tobacco consumption in adults: an updated analysis of data from 127 countries. *BMC medicine*, 18(1), 1-22.

<sup>7</sup>WHO: <https://www.who.int/news-room/fact-sheets/detail/tobacco>

tobacco, both smokeless and smoking, on infertility and reproductive health is well established<sup>8</sup>(Khan et al., 2021). One systematic review and meta-analysis evaluated the semen quality in infertile male participants. A total of 10,823 participants (5257 smokers and 5566 non-smokers) were included in the analysis. The results showed oligozoospermia to be a significant difference between smokers and non-smokers (RR: 1.29, 95% CI: 1.05–1.59; P = 0.02). on the other hand, teratozoospermia, (RR: 1.22, 95% CI: 0.96–1.56; P = 0.10) Asthenozoospermia (RR: 1.42, 95% CI: 0.97–2.09; P =0.07) and azoospermia (RR: 3.02, 95% CI: 0.23–40.01; P = 0.40) showed to be not significant between smokers and non smoker. Motility and pH of semen were not significantly different MD: 1.26, 95% CI: [- 0.64– 3.17]; P = 0.19). & MD: 0.04, 95% CI: [- 0.03–0.11]; P = 0.30) respectively. However, the study observed a significant increase in morphological defects in spermatozoa (MD: 2.44, 95% CI: [0.99–3.89 P=0.001). The analysis concluded that smoking has a major impact on the quantity and quality of sperm in the participants.<sup>9</sup>(Bundhun et al., 2019).

A study conducted on Palauan women evaluated the lifetime prevalence of self-reported infertility and investigated its association with tobacco and betel nut use. The study reported that the use of any tobacco and any betel nut were both highly prevalent amongst the women(n= 874) 50 and above years of age (50-59years, 22.4% 95% CI: 19.7%, 25.3%; ≥ 60 years: 21.9%, 95% CI: 19.2%, 24.7%). Approximately n= 315 (36%) of women reported they have ever attempted to get pregnant. Amongst these, 39.7% reported a lifetime episode of infertility. Women reporting tobacco and betel nut use were significantly higher in self-report infertility. (PR: 2.0; 95% CI: 1.4, 2.7). Furthermore, the study also showed that obese women have a higher prevalence of self-reported infertility than women of normal weight. BMI was a confounding factor between tobacco and/or betel nut use and infertility.<sup>10</sup> (Kreisel et al., 2020)

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<sup>8</sup>(Khan et al., 2021

<sup>9</sup>Bundhun, et al (2019). Tobacco smoking and semen quality in infertile males: a systematic review and meta-analysis. *BMC public health*, 19(1), 1-11.

<sup>10</sup>Kreisel KM, et al. An Evaluation of Infertility Among Women in the Republic of Palau, 2016. *Hawaii J Health SocWelf*. 2020 Jan;79(1):7-15.

Another study that studied the effects of tobacco and cannabis use on semen and endocrine parameter in infertile males showed a non-significant decrease in sperm count, LH and testosterone levels. The study included cigarette smokers, dipping tobacco users, cannabis users and healthy infertile males without habit history. Analysis of semen and hormonal profiles of participants showed higher FSH levels in cannabis users than controls [3.06 (2.26–4.15) vs. 1.72(1.32–2.22), p =0.024]. No significant difference in FSH between the control group and other tobacco users.

The morphological evaluation revealed tail malformations highest among cannabis users, followed by dippers, smokers, and the control group. In contrast, neck malformations were highest in the smokers' group, followed by the cannabis, dippers and infertile healthy participant group. Smoking more than ten cigarettes and 11- 15 cigarettes per day significantly affected testosterone levels. Higher FSH levels were observed in cannabis users [4.78 (2.38–9.61) and p= 0.043]) as than in controls. The study concluded that substance users have decreased sperm count; low sperm motility associated with raised levels of FSH, and decreased testosterone and LH levels compared to non-smoker infertile males.<sup>11</sup>(Khan et al., 2021)

(c) **Report from All India Institute of Medical Sciences, New Delhi**

- Smokeless tobacco (SLT) products are known to contain more than 30 carcinogens. Majority of SLT studies/papers reported from **SEAR and EMR** are on tobacco chewing whereas those from European and the American regions are on non-chewing SLT types.
- Region-wise analysis of SLT products **revealed pan tobacco/areca nut + lime + tobacco (47.8%) as the most common type** in the Southeast Asia region whereas **snus (100%) and oral snuff (100%)** are the most common SLT types in Europe and the America.

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<sup>11</sup>Khan, N., Shah, M., Malik, M. O., Badshah, H., Habib, S. H., Shah, I., & Shah, F. A. (2021). The effects of tobacco and cannabis use on semen and endocrine parameters in infertile males. *Human Fertility*, 1-9.

- It was noted that SLT use was associated with an increased risk of oral cancer in both men (RR, 2.94; 95%CI, 2.05–4.20; P < 0.001) and women (RR, 6.39; 95%CI, 3.16–12.93; P < 0.001).
- The overall pooled RRR (Relative Risk Ratio) suggested that SLT use in women was associated with an increased risk of oral cancer compared with that in men (RRR, 1.79; 95%CI, 1.21–2.64; P = 0.003).
- A significant positive relationship was observed between SLT use and oral cancer risk, especially in women and users from Southeast Asian and Eastern Mediterranean regions.

The individual products that showed the highest association of OR with

- 8.67 (95% CI = 3.59 to 20.95) were gutkha
- 7.18 (95% CI = 5.48 to 9.41) for pan tobacco/areca nut + lime + tobacco
- 4.18 (95% CI = 2.37 to 7.38) for oral snuff
- 3.32 (95% CI = 1.32 to 8.36) for Mainpuri.
- Nasal snuff and sinus were not associated with oral cancer risk

Relative risk of oral cancer by using smokeless tobacco

<b>Tobacco</b>	<b>Relative Risk</b>
Moist snuff and chewing tobacco	Very low risk
Dry snuff	Higher risk
Other smokeless tobacco	Intermediate risk

- The prevalence of smoking and SLT usage was found to be higher in medium wealth quintiles groups in all Regions of SEAR.
- Policymakers should consider the smokeless forms of tobacco used and social distribution in each country to provide context-specific tobacco prevention and control strategies and target vulnerable groups.

- Policymakers need to consider SLT use separately in tobacco control efforts, since the economic and health effects of SLT use are different from that of smoking.

### **III. Inputs received from the Department of Agriculture and Farmers' Welfare**

- a. Tobacco is grown in an area of 3.57 lakh ha with production of 7.55 lakh tonnes (2020-21). State-wise area, production & yield of tobacco as per Directorate of Economics and Statistics (DES) is attached at Annexure-V
- b. Production, distribution (for domestic consumption and exports) and development of tobacco comes under the purview of Ministry of Commerce and Industry as per Government of India Allocation of Business.
- c. Tobacco Board under the Ministry of Commerce & Industry gives permission & keeps record of production of Flue Cured Virginia (FCV) tobacco and also constantly monitors Virginia tobacco market, both in India and abroad and ensures fair and remunerative price to the growers.
- d. The Department of Agriculture & Farmers Welfare is not implementing any tobacco development scheme for tobacco growers/farmers since 2000. The Directorate of Tobacco Development located at Chennai has also been closed w.e.f 31.05.2014. However, in order to encourage tobacco growing farmers to shift to alternate crops/cropping system, Crop Diversification Programme; an ongoing sub scheme of Rashtriya Krishi Vikas Yojana has been extended to 10 tobacco growing States w.e.f 2015-16.
- e. Indian Council of Agricultural Research-Central Tobacco Research Institute (ICAR CTRI), Rajahmundry conducts basic and strategic research on domestic and exportable types of tobacco, improvement in quality and value added products. The institute is also mandated with identification of alternative crops/cropping systems for tobacco growing regions of the country.



**IV.** As mentioned by the Expert Committee in Volume 1 of their Reports, on the orders of Hon'ble Supreme Court of India dated 07.12.2010, the Central Government undertook a comprehensive analysis and study of the contents of Gutkha, Tobacco, Pan Masala and similar articles manufactured in the country, and harmful effects of consumption of such articles. The National Institute of Health and Family Welfare undertook the study with the help of technical experts from reputed organisations. The study primarily focused on smokeless tobacco. To summarise the study by the Technical Committee observed that most of the relevant studies identified are from India, Sweden and USA with studies from India making the biggest contribution. There is strong and consistent evidence from a number of studies to indicate significant risk of oral cancer and pharyngeal cancer, oesophageal cancer, and pancreatic cancer with smokeless tobacco use. The risk of these cancers is found to increase with increasing dosage and frequency of smokeless tobacco use.

Results from several studies suggest presence of strong and consistent evidence that smokeless tobacco is significantly associated with poor oral-dental health, risk of hypertension and cardiovascular diseases, and adverse effects on reproductive health (especially during pregnancy with birth complications, foetal (Fetal) loss, low birth weight, prematurity). The evidence available for other disease/conditions is limited but consistent in reporting increased risk of all-cause mortality and all-cause cancer mortality in female users, and increased risk of cerebro-vascular stroke, metabolic abnormalities, oesophageal diseases, and respiratory diseases among all users.

**V.** The Hon'ble Committee on Petitions has taken cognizance of the fact that 'Tobacco' and 'Nicotine' used as ingredients in any food product(s) should not be sold in the market as food product under any circumstances. They have, however, suggested an amendment to the Regulation 2.3.4 of the Food Safety and Standards Regulations, 2011 which reads as:-

*"Product not to contain any substance which may be injurious to health;*

*Tobacco and Nicotine shall not be used as ingredients in any food products as otherwise all such items shall be included as 'tobacco products' and regulated through relevant Rules, Regulations etc."*

The suggestion of the Hon'ble Committee on Petitions, if accepted, would imply that tobacco if consumed in any form would not be part of 'food' as to be within the definition of 'food' in Section 3(1)(j) of the FSS Act 2006. Considering the fact that tobacco products if eaten have been declared as a food by the Hon'ble Supreme Court and various High Courts in catena of cases and there are bunch of writ petitions still pending adjudication of the Supreme Court of India, the Committee is of the view that better course in the matter would be to await for the judgement of the Hon'ble Apex Court.

FSS Act, 2006 and the COTPA, 2003 are the principal enactments by the Central Government duly passed by the Parliament. The FSS Act has been enacted for laying down science based standards for articles of food and to regulate their manufacture, sale, distribution and import, to ensure availability of safe and wholesome food for human consumption. COTPA has been enacted primarily to discourage the use of tobacco, with emphasis on protection of children and young people from being addicted to the use of tobacco with a view to achieve improvement of public health in general as enshrined in the Article 47 of the Constitution of India. Both these enactments have been held by the Courts in several cases not to be in conflict with each other and in fact they run parallel to each other. Despite the fact that COTPA is a special Act and FSS Act a general one, the courts in most of the cases have held that owing to obstante Section 89 of the FSSAI Act which has the effect of over-riding the provisions of the other enactments would hold field and would prevail. Even if there is some ambiguity in the interpretation of the specific provisions of both these enactments it seems advisable for the MoHFW to bring the same to the attention of the Hon'ble Parliament through the Standing Committee of Parliament on Health and Family Welfare for elucidation and guidance.

**VI.** It may not be out of place to mention that the Departmentally Related Parliamentary Standing Committee on Health & Family Welfare in their 139<sup>th</sup> Report has recommended to the Government to take measures to ban Gutkha/Flavoured Chewing Tobacco/ Flavoured Areca (Pan Masala) and prohibit direct and indirect advertisements of Pan Masala, para(s) 1.6.4 and 1.6.5 of the Report in this regard are reproduced hereunder for kind information and perusal of the Committee on Petitions.

*"1.6.4 The Committee is of the firm view that there is an urgent need to disincentivize the consumption of tobacco and alcohol in the country. The Committee accordingly recommends the Government to formulate effective*

*policies on alcohol and tobacco control. The Committee also notes that India has one of the lowest prices for tobacco products and there is a need to increase taxes on tobacco products. The Committee accordingly recommends the Government to raise taxes on tobacco and utilize the additional revenue gained for cancer prevention and awareness.*

*1.6.5 Attention of the Committee is also brought to the fact that more than 80% of tobacco consumption is in the form of chewing Tobacco with or without Areca Nut. These products are being aggressively marketed as mouth fresheners. The Committee accordingly recommends the Government to take measures to ban Gutka/Flavored Chewing tobacco/Flavored Areca (Pan Masala) and prohibit direct and indirect advertisements of Pan Masala.”*

**VII.** As regards ToR (iv) in the Terms of Reference constituting the Expert Committee, the Committee in their Report (Volume I) had suggested large scale consultations with stakeholders including farmers, industry, States and concerned Ministries/Departments in the Government of India about banning of Tobacco/Tobacco Products due to its huge implications in cross sections of the society. It is submitted that the Ministry has been requested to arrange for these consultations and apprise the Expert Committee of the inputs thereon to firm up its view thereon. The Ministry seems to be in the process of such consultations and for want of inputs from the stakeholders the Expert Committee is unable to firm up and give any recommendations thereon.

## OBSERVATIONS/RECOMMENDATIONS

### Erroneous formulation on the harmful effects of 'Tobacco' & 'Nicotine' – A Neutral Perspective

16. On 17 September 2016, Shri Sanjay Bechan submitted a representation *inter alia* regarding harmonization of the definition of 'Food' under the Food Safety and Standards Act, 2006 [FSS Act]. The representation was, accordingly, forwarded to the Ministry of Health & Family Welfare for seeking preliminary comments, which were furnished by them *vide* OM No. H-11013/01/2016-TC (FTS:3076064) dated 8 December 2016. Since the preliminary comments furnished by the Ministry raised more queries *vis-à-vis* the answers sought, therefore, with a view to put forth various points raised by the representationist in conjunction with the clarifications furnished by the Ministry, the Committee on Petitions, Lok Sabha decided to take up the representation for detailed examination under Direction 95 of the Directions by the Speaker. Consequently, the Committee raised pertinent queries by way of several List of Points for obtaining written answers from the Ministry along with convening numerous sittings of the Committee for taking oral evidence of the representatives of the Ministry. Based on the detailed deliberations, the Committee formulated its 68<sup>th</sup> Report, which was presented to the Hon'ble Speaker, Lok Sabha on 9 March 2019 and later on, to the Lok Sabha on 26 June 2019.

17. The 68<sup>th</sup> Report of the Committee contained the following recommendations:-

- (i) Excessive Delegated Legislation.

- (ii) Avoidance of narrow definition of 'Food' under the FSS Act, 2006.
- (iii) Imposing selective ban *vis-a-vis* enforcing regulation – A case study of 'smokeless' and 'smoking' tobacco.
- (iv) Encouraging tobacco growing farmers to shift to alternate crops/ cropping systems.
- (v) Promotion of aromatic plant industry.
- (vi) Efficacy of imposing 'ban' on any commodity/product.

18. Pursuant to this, the Ministry of Health & Family Welfare along with other Ministries, *viz.*, the Ministry of Agriculture & Farmers' Welfare, the Ministry of Labour & Employment and the Ministry of Micro, Small & Medium Enterprises submitted their action taken replies to the Committee on Petitions, Lok Sabha. Since the action taken replies furnished by the Ministry of Health & Family Welfare were repetitive and non-coherent and did not clarify upon the observations/ recommendations of the Committee, it was decided to undertake further deliberations with the Ministry of Health & Family Welfare to ensure that the Action Taken Report of the Committee would contribute towards safeguarding the formulations from being deficient and inaccurate.

19. Further, the Committee on Petitions, forwarded detailed List of Points thrice which was also followed by oral evidence of the representatives of the Ministry of Health & Family Welfare on 24 June 2021, 22 December 2021 and 17 October, 2022. Since the representatives of the Ministry of Health & Family Welfare, especially, the officials of Tobacco Control Division and the Food

Safety and Standards Authority of India [FSSAI] gave rhetorical answers/response rather than convincing replies based on a legally sound proposition, the Committee, in their considered opinion, urged the Ministry to constitute an 'Expert Committee' to look into the various dimensions of the case with an independent perspective and submit its report to the Committee.

20. The 'Expert Committee' submitted its report(s) to the Committee on Petitions, Lok Sabha, Volume – I of the report on 24 May 2022 and Volume – II of the report on 14 October, 2022 respectively. The report(s) of the said 'Expert Committee' were based on the following terms of reference, which were formulated by them:-

- (i) To identify administrative and legal issues regarding definition of "food" as defined under the Food Safety and Standards (FSS) Act, 2006, keeping in view the various judicial pronouncement regarding chewing tobacco, khaini, zarda, gutkha, and chewing tobacco products in any other form.
- (ii) In view of the issues identified, to determine whether any amendment is required in the definition of 'Food' under Food Safety and Standards (FSS) Act, 2006.
- (iii) If any such amendment is not required, is there any need to issue any clarification regarding the definition of "food", with regard to tobacco products.
- (iv) Whether a complete ban on all forms of tobacco products is advisable? And if so, the feasibility of its implementation.

21. In Volume - I of the Report, the 'Expert Committee' made recommendations on all the, self-devised 'Terms of Reference', as under:-

*"It may be seen from the judgments of various High Courts and the Supreme Court that there is no finality as regards inclusion or exclusion of, tobacco, and 'tobacco products' within the ambit of the definition of ,food' as in Section 3(1) (j) of Food Safety and Standards Act. Some Courts have taken the stand that COTPA being special Act, it would take precedence over the Food Safety and Standards Act, which is a general legislation about food safety as a whole.*

*As summarised in Chapter 2, the Hon'ble Supreme Court in Godavat Pan Masala Products (2004) 7 SCC 68 held that Gutkha, Pan Masala and Supari as food articles. The Hon'ble Allahabad High court in Manohar Lal Vs. State of UP, Criminal Revision No. 318 of 1982 and in Khedan Lal and sons vs. State of UP, 1980 Cri LJ 1346, relying upon judgment of State of Tamil Nadu Vs. R. Krishnamurthy (1980) 1 SCC '167, held 'chewing tobacco' as an article of food.*

*In the latest judgment delivered by Telangana High Court on 30.11.2021, whereby around 130 writ petitions were dismissed, it has been held unambiguously that despite the fact that COTPA is a special Act, it cannot impinge and transgress the provision of FSS Act. The Court has observed that COTPA 2003 has been enacted with the aim and object to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarettes and other tobacco products with an aim to discourage the use or consumption of tobacco. The object for FSS Act is to ensure safe and wholesome food for the people. The primary concern and purpose of FSS Act is that promotion of public health and protection of right to life of the citizens of the country and the purpose, aim and the object of Food Safety Regulations, 2011 is to ensure safety/ health of citizens of this country by prohibiting any article of food which is injurious to health of general public The Court has further observed that it is an undisputed fact that tobacco products which are subject matter of the impugned notification are injurious to general health of the public. The Court has*

**further said that by virtue of Section 89, the FSS Act will have overriding effect over the other statutes.**

**The Hon'ble Supreme Court of India had heard the parties on this subject matter in September, 2016 at length and it failed to conclude its findings due to paucity of time and large number of respondents were left to make submissions. The Supreme Court is, therefore, seized of the issue and in view of that the issue is pending consideration of the Apex Court, it will not be advisable for the Committee to give any opinion about amendment or otherwise of the definition of 'food' so as to make it clear if the tobacco and tobacco products are included or excluded. As the law declared by the Supreme Court as per Article 141 of the Constitution of India shall be binding on all courts within the territory of India, therefore, any interpretation on the intent and ambit of a provision as declared by the Supreme Court is sacrosanct.**

**Considering the facts as stated above and the Hon'ble Supreme Court being seized of the issue and different orders issued by the Authorities under FSS Act are under challenge, the Committee, refrains from expressing any opinion at this stage as regards the definition of food under FSS Act [TOR (i) The ToRs (ii) and (iii) are connected and flows from ToR (i)], it is not appropriate for the Committee to express any opinion/offer comments thereon due to its limitations, as expressed as regards the need of amendment.**

**As regards ToR (iv), it is submitted that the issue regarding banning completely all forms of tobacco products if advisable or not and its feasibility of implementation is a larger issue for the country as a whole. Therefore, to take a view about banning of tobacco and tobacco products is an issue which has huge implications and a decision impinge on livelihood of large number of, people. A conscious decision would need to be taken balancing the interests of all and would therefore require large scale consultations with stake holders including farmers, industry, States and concerned Ministries/Departments in the Government of India It is suggested this exercise is under way and the outcome thereof may form part of Volume – II of this Report.**



22. In Volume – II of the Report, the 'Expert Committee' summarised their findings, as under:-

***"The Hon'ble Committee on Petitions has taken cognizance of the fact that 'Tobacco' and 'Nicotine' used as ingredients in any food product(s) should not be sold in the market as food product under any circumstances. They have, however, suggested an amendment to the Regulation 2.3.4 of the Food Safety and Standards Regulations, 2011 which reads as:-***

***"Product not to contain any substance which may be injurious to health;***

***Tobacco and Nicotine shall not be used as ingredients in any food products as otherwise all such items shall be included as 'tobacco products' and regulated through relevant Rules, Regulations etc."***

***The suggestion of the Hon'ble Committee on Petitions, if accepted, would imply that tobacco if consumed in any form would not be part of 'food' as to be within the definition of 'food' in Section 3(1)(j) of the FSS Act 2006. Considering the fact that tobacco products if eaten have been declared as a food by the Hon'ble Supreme Court and various High Courts in catena of cases and there are bunch of writ petitions still pending adjudication of the Supreme Court of India, the Committee is of the view that better course in the matter would be to await for the judgement of the Hon'ble Apex Court.***

***FSS Act, 2006 and the COPTA, 2003 are the principal enactments by the Central Government duly passed by the Parliament. The FSS Act has been enacted for laying down science based standards for articles of food and to regulate their manufacture, sale, distribution and import, to ensure availability of safe and wholesome food for human consumption. COPTA has been enacted primarily to discourage the use of tobacco, with emphasis on protection of children and young people from being addicted to the use of tobacco with a view to achieve improvement of public health in general as enshrined in the Article 47 of the Constitution***

**of India. Both these enactments have been held by the Courts in several cases not to be in conflict with each other and in fact they run parallel to each other. Despite the fact that COTPA is a special Act and FSS Act a general one, the courts in most of the cases have held that owing to obstante Section 89 of the FSSAI Act which has the effect of over-riding the provisions of the other enactments would hold field and would prevail. Even if there is some ambiguity in the interpretation of the specific provisions of both these enactments it seems advisable for the MoHFW to bring the same to the attention of the Hon'ble Parliament through the Standing Committee of Parliament on Health and Family Welfare for elucidation and guidance.**

**It may not be out of place to mention that the Departmentally Related Parliamentary Standing Committee on Health & Family Welfare in their 139<sup>th</sup> Report has recommended to the Government to take measures to ban Gutkha/Flavoured Chewing Tobacco/ Flavoured Areca (Pan Masala) and prohibit direct and indirect advertisements of Pan Masala, Para(s) 1.6.4 and 1.6.5 of the Report in this regard are reproduced hereunder for kind information and perusal of the Committee on Petitions.**

**"1.6.4 The Committee is of the firm view that there is an urgent need to disincentivize the consumption of tobacco and alcohol in the country. The Committee accordingly recommends the Government to formulate effective policies on alcohol and tobacco control. The Committee also notes that India has one of the lowest prices for tobacco products and there is a need to increase taxes on tobacco products. The Committee accordingly recommends the Government to raise taxes on tobacco and utilize the additional revenue gained for cancer prevention and awareness.**

**1.6.5 Attention of the Committee is also brought to the fact that more than 80% of tobacco consumption is in the form of chewing Tobacco with or without Areca Nut. These products are being aggressively marketed as mouth fresheners. The Committee accordingly recommends the Government to take measures to ban Gutka /Flavored Chewing tobacco/Flavored Areca (Pan Masala) and prohibit direct and indirect advertisements of Pan Masala."**

***As regards ToR (iv) in the Terms of Reference constituting the Expert Committee, the Committee in their Report (Volume I) had suggested large scale consultations with stakeholders including farmers, industry, States and concerned Ministries/Departments in the Government of India about banning of Tobacco/Tobacco Products due to its huge implications in cross sections of the society. It is submitted that the Ministry has been requested to arrange for these consultations and apprise the Expert Committee of the inputs thereon to firm up its view thereon. The Ministry seems to be in the process of such consultations and for want of inputs from the stakeholders the Expert Committee is unable to firm up and give any recommendations thereon."***

**23. Meanwhile, the High Court of Delhi, while disposing of an exceptional 50 Petitions on various tobacco-related matters [WP(C) 3362/2015 and C.M. No(s) 6020/2015, 9243/2015, 17726/2015, 16999/2017, 17859-860/2017, 19505/2018 and 7957/2021, etc.], had pronounced the judgement on 27 September 2022.**

**24. The said comprehensive and one of its kind judgement of the High Court of Delhi has brought down all the relevant aspects of the theory propounded by the officials of the Tobacco Control Division of the Ministry of Health & Family Welfare and FSSAI right from the issue of Food Safety and Standards (Prohibition and Restriction of Sales) Regulation of 2011 and thereafter, correlating Regulation 2.3.4 with the absurd classification of 'smoking' and 'smokeless' tobacco with the definition of 'food' defined under Section 3(1)(j) of the Food Safety and Standards Act, 2006. The relevant paragraphs of the judgment have been reproduced and its emphasis on the various determining factors have also been appropriately provided for easy discernment by readers/public at large, as under:-**

190. The power to establish standards of quality for goods under the FSSA would not include within its purview the power to “prohibit” the “manufacture, sale, storage and distribution” of any goods, moreover, when the goods sought to be prohibited pertain to the scheduled tobacco products under the COTPA.
191. The Hon’ble Supreme Court in the case of Himat Lal K. Shah (supra) has explicitly held that the power to regulate does not normally include the power to prohibit. A power to regulate implies the continued existence of that which is to be regulated. In view of ratio laid down by Himat Lal (supra) and bare perusal of the entire scheme of the FSSA, it is apparent that power to frame Regulations does not include the power to prohibit manufacture, distribution, storage and sale of a product.
192. The Regulations, 2011 have been made by the FSSAI in exercise of the powers conferred by Section 92(2)(l) read with Section 26 of the FSSA. Section 26 of the FSSA provides for responsibilities of the food business operators. The terms, ‘food business’ and ‘food business operator’ are defined under the FSSA. Moreover, Section 31(1) of the FSSA provides that no person shall commence or carry on any food business except under a license as per the provisions of the FSSA. However, as per the FSSA, the persons dealing with tobacco and tobacco products are not required to obtain any license(s) under the FSSA.
193. On the bare perusal of Regulation 2.3.4, it is apparent that the intention is not to prohibit but restrict the use of tobacco or nicotine as ingredients in any food product. In the considered view of this Court, the language of Regulation 2.3.4 does not suggest regulating manufacture, distribution, storage or sale of tobacco or nicotine but amounts to regulating standards of food within the purview of the FSSA. Therefore, what has to be regulated under Regulation 2.3.4 is food without tobacco and not tobacco itself which is a scheduled item under the COTPA, which has to accordingly be regulated under the provisions of COTPA.

195. It is further significant to note that the executive power of the State is not to act as an independent law-making agency in as much as the function of enacting law under the Constitution does not vest with the executive and its function is only to fill up the gaps. It is settled that the power to make the laws lies with the Legislature and not with the Executive. The Executive has to merely implement the policies/laws made by the Legislature. If the State is permitted to take recourse to its executive powers to make laws, then the same would result in laws being made by the Executive and not by the Legislature in contravention to the intent of the Constitution of India.
196. In view of the aforementioned, the impugned Notifications passed by the Commissioner of Food Safety in view of Regulation 2.3.4 in exercise of powers under Section 30(2)(a), in so far as they prohibit the use of tobacco and nicotine with respect to scheduled tobacco products covered under the COTPA, are beyond the scope of powers conferred by the FSSA.
197. Section 2 of FSSA provides that it is expedient in public interest that the Union should take under its control the food industry, whereas Section 2 of COTPA provides that it is expedient in the public interest that the Union should take under its control the tobacco industry. On a comparative reading of the aforementioned provisions, it can be seen that the FSSA concerns "food industry" and the COTPA relates to the "tobacco industry". It is pertinent to note that in view of Entry 52 of List I, the Parliament has assumed to itself the legislative power to legislate upon tobacco and food industry. The declaration under Section 2 of FSSA purporting to take over the "food industry" cannot cover tobacco within its ambit as the same has already been covered under the "tobacco industry" with the enactment of the COTPA.
200. The COTPA is a special enactment dealing with tobacco and exclusively and comprehensively deal with tobacco and tobacco products. As held in the case of Godawat Pan Masala (supra),

COTPA is a special Act intended to deal with tobacco and tobacco products, while the PFA is a general enactment, therefore, the COTPA overrides the provisions of the PFA with regard to the power to prohibit the sale or manufacture of tobacco products which are listed in the Schedule of the COTPA. In Godawat Pan Masala (supra), the Hon'ble Supreme Court further held that COTPA is a special Act intended to deal with tobacco and tobacco products and hence it will override Section 7(iv) of the PFA....

201. The Hon'ble Supreme Court, in the case of Godawat Pan Masala (supra), observed that the legislation enacted to deal with tobacco does not suggest that the Parliament has ever treated tobacco as res extra commercium nor has the Parliament ever attempted to ban its use absolutely. Merely licensing regulation, duties and taxes have been imposed on tobacco products....
202. Even the COTPA does not ban the sale and distribution of tobacco and tobacco products except for imposition of certain conditions and various checks and balances to regulate the advertisement and sale thereof. Furthermore, whether an article is to be prohibited as res extra commercium is a matter of legislative policy and must arise out of an Act of the Legislature and not merely by a Notification issued by an executive authority. Thus, the trade, sale and distribution of tobacco is permissible subject to certain restrictions imposed under the COTPA and the same has only been regulated and not prohibited.
205. Considering the aforesaid, it clearly emerges that the FSSA is an Act to consolidate the laws relating to food and for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure safe and wholesome food for human consumption and incidental matters. Whereas the COTPA is a comprehensive legislation which deals with advertisement, trade, sale and distribution of tobacco and tobacco products. The Union Government assumed control to legislate with regard to both the food industry and the

tobacco industry, therefore, it is certain that at the time of enactment of the FSSA, the Legislature was not only aware and conscious of the existence of the COTPA, which was enacted in 2003 but made various rules under the COTPA and carried out multiple amendments in provisions and rules framed thereunder even after the enactment of the FSSA in 2006.

206. Accordingly, it can be observed that the COTPA, being a “special law”, occupies the field for tobacco and tobacco products and would prevail over the FSSA which is a “general law”.

208. It has been argued on behalf of the Petitioners that a general law does not abrogate an earlier special law by mere implication. Section 97 of the FSSA specifically repeals certain Central Acts, as specified in the Second Schedule of the FSSA. However, the COTPA has not been repealed either expressly or by implication.

211. In view of the aforementioned, the doctrine of implied repeal has no application to the present case because both the aforementioned Acts i.e., FSSA and COTPA occupy different fields i.e., the former applies to the food industry while the latter applies to the tobacco industry. Hence, in the considered view of this Court, the FSSA does not impliedly repeal the provisions of the COTPA.

212. Now the next question to be examined is whether tobacco and tobacco products can be termed as “food” under the FSSA. The FSSA was enacted to consolidate the laws relating to food....

213. It has been argued on behalf of the Respondents that Section 2(v) of the PFA had a narrower definition of food as compared to Section 3(1)(j) of the FSSA. These are beneficial legislations and therefore while interpreting the provisions thereof, liberal interpretation is to be adopted so that maximum benefits can be extended to the public at large. The Respondents have relied on various judgments to substantiate their said contention.

214. The Petitioners, on the contrary, have argued that chewing tobacco is a scheduled product under the COTPA and cannot be construed as “food” under the FSSA. Moreover, chewing tobacco has no health or nourishment value. It has further been argued that chewing tobacco can be differentiated from Gutka, Pan Masala and other similar products as the former contains 100% pure tobacco whereas the latter comprises of other food items such as betel nut, saffron, lime, cardamom, etc. besides tobacco. Chewing tobacco is also a product different from Gutka, Pan Masala, etc. under various taxing statutes.
215. With regard to the question whether tobacco and tobacco products fall within the definition of Section 3(1)(j) of the FSSA, different High Courts have given divergent views on this aspect, which have been discussed in detail herein above.
216. It can be safely presumed that at the time of enactment of the FSSA, a legislation governing the food industry, the Legislature would have known the existence of the COTPA, a Central Act enacted to take control of the tobacco industry. Various amendments and framing of rules under COTPA even after the enactment of the FSSA explains and strengthens the aforementioned presumption and belies the theory of an implied repeal of the COTPA by the FSSA.
217. It is noteworthy to mention that the FSSA warrants to lay down science-based standards for food and regulate their manufacture, storage, distribution, sale and import to ensure availability of wholesome food for human consumption. In view of the aforesaid, tobacco cannot be termed as “food” within the meaning of the FSSA as no science-based standards can be laid down for tobacco to regulate its sale, distribution and storage in order to ensure safe and wholesome tobacco for human consumption.
218. In addition to the aforesaid, Regulation 2.3.4 prescribes that tobacco and nicotine shall not be used as ingredients in any food products. The said regulation has been framed under the FSSA,



admittedly to regulate standards of food within the ambit of the FSSA and in the considered view of this Court, cannot be said to regulate standards and/or manufacture and sale of tobacco. In fact, the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, does not define tobacco, because no standards can be possibly laid down for tobacco, which further reinforces the fact that tobacco is not "food". If "tobacco" is construed and interpreted as "food" within the meaning of FSSA, then intent/objective with which Regulation 2.3.4 is framed (i.e., to regulate standards of food under the FSSA) would be rendered redundant. Moreover, such an interpretation would be in complete contravention of the provisions of the FSSA, which is a comprehensive legislation dealing with the food industry.

219. It is further worthwhile to note that Regulation 2.3.4 prohibits use of tobacco and nicotine as ingredients in food products thereby regulating the standards for "food" and not standards or trade in "tobacco". Hence, the said Regulation cannot be said to be in conflict with any of the provisions of the COTPA. The said Regulation merely lays down general principle for food safety and cannot in any manner be read to construe that "tobacco" is "food" within the meaning of the FSSA.

220. After considering the arguments advanced and the judgments relied by the parties, "food" as defined in the FSSA does not include tobacco within its ambit or scope and therefore, tobacco cannot be termed as "food" within the meaning of the FSSA.

228. It has been argued on behalf of the Petitioners that the Respondents are purporting to ban an artificially created sub-category of tobacco, namely, "smokeless tobacco" which includes chewing tobacco, pan masala, gutka, etc. and other scheduled tobacco products listed under the COTPA. However, there appears to be no rational nexus to the object sought to be achieved by the impugned Notifications prohibiting manufacture, storage, sale and distribution of smokeless tobacco products. Admittedly, the object

sought to be achieved by the said prohibitory order(s) in the nature of the impugned Notifications, is "public health". However, there is no justification whatsoever for making such a differentiation in smokeless and smoking tobacco, which may be different in their forms but are no different in terms of their impact on public health. It is worthwhile to note that the COTPA, which is the Central Act governing the tobacco industry, does not make any such distinction between smokeless and smoking tobacco under its Schedule.

229. In the light of the aforesaid observations, it is apparent that the said classification/distinction between smokeless and smoking tobacco has no connection with the object sought to be achieved by the impugned Notifications. In fact, the said discrimination which is being promoted by the impugned Notifications encourages smoking tobacco over smokeless tobacco, thereby being not only clearly discriminatory but in violation of Article 14 of the Constitution.
230. Further, the impugned Notifications have purportedly being issued in the garb of Regulation 2.3.4 which bars the usage of tobacco and nicotine in any food article. However, admittedly, tobacco and nicotine are not only found in smokeless tobacco but also in smoking tobacco, which has conveniently been excluded from the rigors of the impugned Notifications. Therefore, there is no justification for the classification between smokeless and smoking tobacco sought to be created by the impugned Notifications issued by the Respondents. Moreover, the prohibition imposed by virtue of the impugned Notifications by discriminating between smokeless and smoking tobacco does not fall under reasonable restrictions on exercise of fundamental rights under Article 19(6) of the Constitution.
231. It has further been argued on behalf of the Petitioners that the burden of proof rests upon the Respondents to justify that the creation of an artificial sub-classification within tobacco products, i.e., smokeless and smoking tobacco, bears a clear or reasonable

nexus to the object sought to be achieved by the impugned Notifications i.e., public interest. However, considering the arguments and submissions advanced by the Respondents, this Court is of the view that the said burden has not been sufficiently discharged by the Respondents, which makes the said classifications/distinctions falling short of passing the test of Article 14 of the Constitution. Consequently, there is no nexus with the object sought to be achieved by the impugned Notifications, so as to justify a valid classification under Article 14 of the Constitution.

232. In view of the detailed arguments advanced on behalf of the parties and for the explanation and the reasons as discussed herein above, this Court is of the considered view that the classification sought to be created between smokeless and smoking tobacco is clearly violative of Article 14 of the Constitution.

234. It is to be noted that it has been submitted before the Hon'ble Supreme Court in the matter of Ankur Gutka (supra) and Central Arecanut (supra) that notwithstanding the complete ban imposed on Gutka and Pan Masala with tobacco and/or nicotine in such States, the manufacturers have devised a subterfuge for selling Gutka and Pan Masala in separate pouches and the ban is being flouted in this manner. In view of the interim directions issued by the Hon'ble Supreme Court, it is clear that compliance of the ban imposed on manufacturing and sale of Gutka and Pan Masala with tobacco and/or nicotine has to be ensured. Even though the main matter(s) is pending adjudication, the aforesaid direction passed by the Hon'ble Supreme Court is in line with Regulation 2.3.4 as it directs "for compliance of the ban imposed on manufacturing and sale of Gutkha and Pan Masala with tobacco and/or nicotine". The essence of Regulation 2.3.4 is to prohibit use of tobacco and nicotine as ingredients in any food products and not prohibit the manufacture and sale of tobacco and/or nicotine per se. In view thereof, the present case is distinguishable as it relates to chewing

tobacco in itself and not with Gutka and Pan Masala with tobacco and/or nicotine.

236. This Court is conscious of the harmful effects and various diseases caused by the use of tobacco, both smokeless and smoking. In addition to the ill-effects of smokeless tobacco pointed by the Respondents, this Court is of the view that tobacco, in any form, not only smokeless but also smoking, is injurious to public health and this Court accordingly condemns and discourages the use of any form of tobacco. Public health is one of the most important part of the society and country and therefore, it is necessary to take all steps to preserve the same in all possible manners.
237. Undisputedly, this Court agrees that tobacco and nicotine are injurious to health, however, the present case involves certain questions of law which cannot be decided merely on the basis of public conscious and sentiments but have to be decided and settled based on the fair interpretation of law in the light of the judicial precedents.
238. Considering the submissions made and documents and judgments relied by the parties and in view of the detailed discussion and reasoning mentioned herein above, this Court is of the considered view that:
- (a) The impugned Notifications passed by the Commissioner of Food Safety in view of Regulation 2.3.4 in exercise of powers under Section 30(2)(a), is beyond the scope of powers conferred upon him by the FSSA.
  - (b) The COTPA is a comprehensive legislation dealing with the sale and distribution of scheduled tobacco products and therefore, occupies the entire field relating to tobacco products. Therefore, the COTPA, being a special law, occupies the entire field for tobacco and tobacco products and would prevail over the FSSA which is a general law.

- (c) It has never been the intention of the Parliament to impose an absolute ban on manufacture, sale, distribution and storage of tobacco and/or tobacco products. However, the intention of the Parliament is to regulate the trade and commerce of tobacco and tobacco products in accordance with the COTPA, a Central Act which deals with tobacco industry.
- (d) The doctrine of implied repeal has no application to the present case as the FSSA and the COTPA occupy different fields i.e., the former applies to the "food industry" while the latter applies to the "tobacco industry". Therefore, the FSSA does not impliedly repeal the provisions of the COTPA.
- (e) Tobacco cannot be construed as "food" within the meaning of the provisions of FSSA.
- (f) Section 30(2)(a) of the FSSA has to be read in consonance with Section 18 of the FSSA. The power under Section 30(2)(a) is transitory in nature and the Commissioner of Food Safety can issue prohibition orders only in emergent circumstances after giving an opportunity of being heard to the concerned food operator(s). The impugned Notifications, however, have been issued by Respondent No.1 year after year in a mechanical manner without following the general principles laid down under Section 18 and 30(2)(a) of the FSSA, which is a clear abuse of the powers conferred upon him under the FSSA.
- (g) The classification sought to be created between smokeless and smoking tobacco for justifying the issuance of the impugned Notifications is clearly violative of Article 14 of the Constitution.

25. The deliberations made by the Committee on Petitions after the receipt of action taken replies from the Ministry of Health & Family Welfare in the form of formulating and forwarding detailed list of points for obtaining legally tenable clarifications, subsequent holding of oral evidence of the representatives of the Ministry of Health & Family Welfare, including the senior functionaries of the Tobacco Control Division and FSSAI, constitution of an 'Expert Committee' to examine this contested issue independently and with an entirely new perspective were primarily aimed at making the Ministry aware of visible 'fault-lines' in conceptualizing the tobacco-related issue(s) from the year 2011 onwards, especially upto the year 2014 which has led to continuous litigations in various Courts, thereby, stretching the resources of the Ministry and the already burdened Courts. It was in this context that the Committee on Petitions, Lok Sabha made six self-contained recommendations in their 68<sup>th</sup> Report during the Sixteenth Lok Sabha. However, the Committee wish to express their anguish on the manner in which the action taken replies were contemplated and furnished by the officials of Tobacco Control Division and FSSAI. In order to further reinforce the Committee's perspective regarding lackadaisical approach demonstrated by all the concerned officials in not deciphering the intent of the Committee on Petitions, which was a result of their extensive study and research work on all the connected issues, a comparative analysis of the observations/recommendations made by the Committee in their 68<sup>th</sup> Report with the action taken replies furnished by the Ministry along with the aspects on which the Ministry preferred 'not to respond', has been made by the Committee, as under:-

Recommendations made by the Committee	Action taken replies of the Ministry	Aspects on which the Ministry has preferred not to respond
<b>Observation/Recommendation No. 1 – Excessive Delegated Legislation</b>		
<p>(i) Even though the various Courts of the country had interpreted the relevant Acts, thereby, prohibiting the use of tobacco and nicotine in all food products, the act of Ministry of Health &amp; Family Welfare by way of merely notifying the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 for prohibiting the use of tobacco and nicotine in all food products, and not amending either the Food Safety and Standards Act, 2006 or the Prevention of Food Adulteration Act, 1954 is an exercise of excessive Delegated Legislation.</p> <p>(ii) According to the traditional theory of Subordinate Legislation, the function of the Executive is to administer the law enacted by the Legislature, and in the ideal State like ours, the Legislative Powers must be exercised exclusively by the Legislatures who are directly responsible to the electorates.</p> <p>(iii) <i>In case, the Ministry of Health &amp; Family Welfare intends to further pursue the matter, they should work out modalities to amend the Food Safety and Standards Act, 2006 or the Prevention of Food Adulteration Act, 1954 for explicitly prohibiting the use of tobacco and nicotine in all food products and also bring about appropriate changes in the definition of 'Food' under the Act ibid.</i></p>	<p><u>Ministry of Health &amp; Family Welfare</u> It would therefore infer that regulation 2.3.4 of Food Safety and Standards Act (Prohibitions &amp; Restrictions on Sales) Regulations, 2011 should not be categorized as 'excessive delegated legislation' and the definition of 'food' under Section 3 (1) (J) and Section 2 (v) of Prevention of Food Adulteration Act is wide enough, as confirmed by courts in catena of cases, that smokeless tobacco products (i.e. Gutkha, Khaini, Zarda etc.) are 'food' and thus can be regulated under PFA Act/FSS Act.</p>	<p><u>Ministry of Health &amp; Family Welfare</u> (i) Why the issue of Regulation 2011 and co-relating it with the FSS Act, 2006 is not an act of Excessive Delegated Legislation. (ii) Why the Legislative Powers of the Legislatures have been exercised by the Executive in the context of issuing Regulation 2011 and applying this in Rule 3(i)(j) of the FSS Act, 2006. (iii) Why there is not necessity to bring appropriate changes in the definition of 'Food' under the FSS Act, 2006 in the context of Regulation 2.3.4 and its continuous insistence on the interpretation made by the Ministry.</p>
<b>Observation/Recommendation No. 2 – Avoidance of narrow definition of 'Food' under the FSS Act, 2006</b>		
(i) Keeping in view harmful effects of	Ministry of Health & Family	Ministry of Health & Family

<p>tobacco, Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 expressly bans/prohibits the use of tobacco and nicotine in all the food products. However, thereafter, another subjective distinction was made by the Ministry of Health &amp; Family Welfare by way of confining the harmful effects of tobacco only to smokeless tobacco such as Gutkha, Zarda, Khaini and any other similar processed/flavoured chewing tobacco products and conveniently excluded the smoking tobacco.</p> <p>(ii) The Ministry of Health &amp; Family Welfare have reasoned that smoking tobacco cannot be brought under the definition of 'food' as anything is eaten through mouth or chewed can only be 'food' under the definition at Section 3(l) of FSS Act, 2006. Given this backdrop, the Committee find it difficult to understand the logic behind making such a laughable distinction in view of the fact that the Ministry of Health &amp; Family Welfare, in their submissions before the Committee, have themselves accepted not only the fact that the WHO Global Report on 'Tobacco Mortality Report 2012' had reached to the conclusion that seven percent of all deaths in the country are attributable to use of tobacco, but also revealed that the total economic cost attributable to tobacco use from all diseases in the country in the year 2011 amounted to Rs. 1,04,500 crore; which was 1.16 percent of the Gross Domestic Product (GDP) and was also 12 percent more than the combined States and Central Government expenditures in the Health Sector in 2011-12.</p> <p>(iii) <i>The definition of 'Food' contained in the FSS Act, 2006 should not only</i></p>	<p><u>Welfare</u> Smoking Tobacco cannot be categorized as 'food' under FSS Act, 2006 by any stretch of imagination. It cannot be 'food' as it is not eaten. Inhaling of a substance would not be covered in the existing definition of 'food'.</p> <p>As per the second round of Global Adult Tobacco Survey (GATS-20, 28.6%) 266.8 million of adults. In India, aged 15 and above currently use tobacco in some form. Further, the prevalence of any form of tobacco use has decreased significantly by six percentage points from 34.6 percent (2009-10) to 28.6 percent (2016-17). The relative decrease in the prevalence of tobacco use is 17.3 percent. There has been considerable decrease in the prevalence of smoking and smokeless tobacco use. Prevalence of smoking has decreased by 3.3 percentage points from 14.0% (2009-10) to 10.7% (2016-17) and smokeless tobacco use has decreased by 4.5 percentage points from 25.9% (2009-10) to 21.4% (2016-17).</p>	<p><u>Welfare</u> (i) Why the harmful effects of tobacco have only been confined to smokeless tobacco products and smoking tobacco has been conveniently excluded.</p> <p>(ii) When the WHO Global Report on 'Tobacco Mortality Report 2012' had reached to the conclusion that seven percent of all deaths in the country are attributable to use of tobacco, what were the reasons on the basis of which the Ministry has reasoned that smoking tobacco cannot be brought under the definition of 'food' as anything is eaten through mouth or chewed can only be 'food' under the definition at Section 3(l) of FSS Act, 2006.</p>
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<p>include smokeless tobacco products but also all forms of products which contain tobacco and nicotine.</p> <p>(iv) The Ministry of Health and Family Welfare should redraw their entire strategy, with a pragmatic hypothesis of the need of imposing a complete ban or regulating the use of all tobacco products in the country and, thereafter, formulate a long term policy coupled with bringing out one-time, self-contained, legally tenable amendments in the Act(s) to insulate themselves from entering into yet another quagmire of legal complications/ litigations and leveling of poppycock allegations from various, so called 'Lobbies'.</p>		
<p><b>Observation/Recommendation No. 3 – Imposing selective ban <i>vis-a-vis</i> enforcing regulation – A Case Study on 'smokeless' and 'smoking' tobacco</b></p>		
<p>(i) The Committee have also analysed that imposing a ban or moving in the direction of proscribing all the activities connected with the manufacture, sale, consumption, etc., of all types of 'Smokeless/Chewing Tobacco' products is based on four premises, namely; (i) Leisure interpretation of definition of 'Food' under Section 2(j) of the FSS Act, 2006 by the Ministry of Health &amp; Family Welfare; (ii) Taking out all types of 'Smoking Tobacco' products from the ambit of ban on the grounds that anything which is eaten through mouth or chewed can only be 'Food' as per the definition under the FSS Act, 2006; (iii) Ignoring the ill-effects of smoking tobacco on various vulnerable non-smoking classes, viz., women, senior citizens, children and other environmental hazards attributable to emission of hazardous/ toxic chemicals while smoking which has always remained a serious aspect of concern in almost all the countries</p>	<p><u>Ministry of Health &amp; Family Welfare</u> The intention of legislature (Parliament) while enacting FSS Act, 2006 (which subsumed PFA Act and other rules and orders relating to food administered by various Government Departments) has been to include 'smokeless' tobacco in the definition of 'food' under FSS Act and rules and regulations framed there under and to regulate the matters concerning smoking tobacco under the Cigarettes and Other Tobacco Products (Prohibitions and Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (popularly known as COTPA).</p>	<p><u>Ministry of Health &amp; Family Welfare</u> (i) Whether the Ministry agree with the averments made by the Committee for imposing a ban or moving in the direction of proscribing all the activities connected with the manufacture, sale, consumption, etc., of all types of 'Smokeless/ Chewing Tobacco' products.  (ii) When Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 expressly bans/prohibits the use of tobacco and nicotine in all the food</p>

<p>of the world; and (iv) Observations/ Interpretations/Orders of various Courts, including the Supreme Court of India, affirming 'Chewing Tobacco' as an article of food.</p> <p>(ii) The Committee, on the other hand, are astonished to note that when Clause 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 expressly bans/prohibits the use of tobacco and nicotine in all the food products, provisions contained in the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA) were invoked only to regulate 'Smoking Tobacco' and not to impose any ban on these tobacco products.</p>		<p>products, then, what why the provisions contained in the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA) were invoked only to regulate 'Smoking Tobacco' and not to impose any ban on these tobacco products.</p>
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**Observation/Recommendation No. 4 – Encouraging tobacco growing farmers to shift to alternate crops/cropping systems**

<p>The Ministry of Agriculture &amp; Farmers' Welfare should give a renewed impetus to the entire Crop Diversification Programme, in coordination with the State Governments/ UT Administrations with a view to encouraging the tobacco growing farmers to shift to alternate crops/cropping systems.</p>	<p><u>Ministry of Agriculture &amp; Farmers' Welfare</u> The Ministry of Agriculture &amp; Farmers Welfare (Department of Agriculture, Cooperation &amp; Farmers Welfare) is supplementing the efforts of the State Governments to shift the tobacco growers to other alternative crops/cropping system under the Crop Diversification Programme (CDP), a sub scheme of Rashtriya Krishi Vikas Yojana.</p> <p>Crop Diversification Programme is being continued during 2019-20 to encourage farmers to grow alternative crops/cropping system in tobacco growing States with an</p>	<p><u>Ministry of Agriculture &amp; Farmers' Welfare</u> The Ministry has furnished appropriate reply to the relevant observations/ Recommendations made by the Committee.</p> <p><u>Ministry of Labour &amp; Employment</u> The Ministry has furnished appropriate reply to the relevant observations/ Recommendations made by the Committee.</p>
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	<p>amount of Rs.667.00 lakh as central share (i.e. 33.35% of total allocation of Rs.2000.00 lakh made under CDP). In case the implementing States utilize the funds (central share) of previous and current year and demand of additional funds for replacing tobacco farming under CDP, the same are also considered for diversifying the tobacco area. The programme is being implemented on 60:40 sharing basis between Union Government and State Governments.</p> <p>Crop Diversification Programme implementing States have been advised to give a renewed impetus to the CDP with a view to encourage the tobacco growing farmers to shift to alternate crops/cropping systems. Under Crop Diversification Programme, tobacco growing States have been given flexibility to take any suitable activities/interventions for replacing the tobacco crop to alternative crops/cropping system as per the cost norms approved under any Centrally Sponsored Scheme/State Scheme. Under Crop Diversification Programme for motivating the farmers, State may also organize study tours/exposure visits and campaigns etc., for highlighting harmful effects of tobacco and long term benefits of alternative crops.</p> <p>Ministry of Labour &amp;</p>	
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	<p><u>Employment</u></p> <p>The Ministry has initiated a Skill Development Programme in collaboration with the Ministry of Skill Development &amp; Entrepreneurship and National Skill Development Corporation to provide alternative livelihood to beedi workers and their dependents to enhance their life standards. Initially the pilot project was started at following five centres, Sambhalapur,- Bhubaneswar Region; Rajnandgaon- Raipur Regions; North 24 Pargana- Kolkata Region; Kasargod- Kannur Region and Nizamabad- Hyderabad region. Further, the programme was extended to all regions under the Labour Welfare Organisation in the year 2018. A total of 7262 beneficiaries have availed the Skill Development Training as on 31.12.2019 out of which 2746 beneficiaries have been provided placement in alternate jobs.</p>	
<b>Observation/Recommendation No. 5 – Promotion of Aromatic Plant Industry</b>		
<p>Ministry of Micro, Small &amp; Medium Enterprises should initiate a Quick Study, in co-ordination with the State Governments, for the need for formulation of a specific Scheme to incentivize the Aromatic Plant Industry, viz., Kewda and Mentha. While analysing this, care should also be taken by the Government to ensure that the Scheme is implemented in the right earnest.</p>	<p><u>Ministry of Micro, Small &amp; Medium Enterprises</u></p> <p>Fragrance and Flavour Development Centre (FFDC), Kannauj which has been set up by Ministry of Micro, Small &amp; Medium Enterprises to serve, sustain and upgrade the status of farmers and industry engaged in the aromatic cultivation and processing, so as to make them competitive both in local and global market. It also provides techno-</p>	<p><u>Ministry of Micro, Small &amp; Medium Enterprises</u></p> <p>The Ministry has furnished appropriate reply to the relevant observations/ Recommendations made by the Committee.</p>

	<p>commercial inputs for selection of aromatic plants while conceptualizing 'Aroma Mission' of the Council of Scientific &amp; Industrial Research - Central Institute for Medicinal and Aromatic Plants (CSIR-CIMAP).</p> <p>CSIR Aroma Mission has been conceptualized which aims to provide end-to-end technology and value-addition solutions across the country at a sizable scale. This mission will bring transformative change in the aroma sector through scientific interventions in the areas of agriculture, processing and product development for fuelling the growth of aroma industry and rural employment.</p> <p>As per inputs from CSIR-CIMAP, various activities are being taken up by CSIR-CIMAP, Lucknow under the Aroma Mission.</p>	
<b>Observation/Recommendation No. 6 – Efficacy of imposing 'ban' on any commodity/product.</b>		
<p>The Central Excise Duty collected by the Government on various types of Tobacco products for the financial year (s) 2015-16 and 2016-17 were Rs. 21,228 crore and Rs.21,937 crore respectively. In this context, the Committee intend to co-relate the total revenue generated by the Government by way of Central Excise Duty with the confabulations which are currently underway at various Fora on the aspect of imposing a ban on 'Smokeless Tobacco' products, or 'Smoking Tobacco' products or both vis-a-vis loss of revenue and per se direct loss to the Government Exchequer and at the same time, the</p>	<p><u>Ministry of Health &amp; Family Welfare</u> No reply has been furnished.</p>	<p><u>Ministry of Health &amp; Family Welfare</u> No reply has been furnished.</p>

efficacy of proscribing any commodity/  
product.

The past experience of imposing a 'ban' on any commodity/product in our country has failed to produce the intended objectives and on the other hand, it has not only affected the revenue generation of the Government, which could have otherwise utilized for the betterment of masses through various Social Security Schemes/Welfare Programmes, but also paved way for black marketing of the specific commodity/product, production of spurious and substandard commodity, mushrooming of unregulated 'Mafia' and other corrupt practices by the Industry concerned with the active/passive involvement of various Enforcement Agencies.

The Committee would like to remind the Government that a couple of years ago, a 'ban' on plastic bag (s) was imposed in almost all the States/UTs. Even though the efficacy of imposing ban on plastic bags could be a debatable issue, it is an irrefutable fact that plastic bags are being rampantly used at every nook and corner of the country for carrying goods and other commodities bought by households from the market place. In the opinion of the Committee, the non-existence of a delegated Enforcement Agency, other than Police, is one of the primary reasons for failure of effective implementation of imposing a ban.

The Committee are, therefore, of firm opinion that in case, the Government intend to go ahead with the intention of imposing a ban on all the 'Tobacco Products' in the country, whether it is 'Smokeless/Chewing' Tobacco or 'Smoking' Tobacco or both, the Ministry of Health & Family Welfare should first of all, work out a fool-proof strategy for establishing a distinct Enforcement Agency, in coordination with various State

Governments/UT Administrations to ensure its effective, fullest and tangible implementation.		
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26. From the point-by-point and sequential narration of the events, it has now become abundantly clear that the High Court of Delhi *vide* its judgement dated 27.09.2022 has completely demolished the entire edifice put forth by the officials of Tobacco Control Division and the FSSAI, all through the last ten years, starting from the year 2011. Besides, the recommendations made by the Expert Committee constituted by the Ministry of Health & Family Welfare have also become redundant owing to the said judgement.

27. Notwithstanding the above, the Committee on Petitions, Lok Sabha have devoted a lot of time, effort and resources to go into the details of this fiasco and the embarrassment caused thereof not only to the Secretary of the Ministry of Health & Family Welfare, who was forthcoming enough in assuring the Committee during the Twenty Fourth sitting of the Committee held on 17 October, 2022 that the Ministry is not in favour of challenging the recent judgement of the High Court of Delhi, but also to the Parliamentary Committee on Petitions.

28. Therefore, an in-depth analysis to identify the role, involvement and the manner on the basis of which some of the officials of Tobacco Control Division and FSSAI might be instrumental in a blatantly erroneous and misleading formulation on the harmful effects of 'Tobacco' & 'Nicotine' has, therefore, been

attempted by the Committee on Petitions, Lok Sabha, in the succeeding paragraphs.

I. Furnishing misleading information to the Committee on Petitions

29. The Food Safety and Standards Bill [Bill No. 123 of 2005] was introduced in Lok Sabha on 19 August, 2005. The main objective of the Bill, as explicitly stated in the 'Statement of Objects and Reasons', was to bring out a single statute relating to food and to provide for a systematic and scientific development of Food Processing Industries. Besides, Section 97 of the Bill provides for repeal of following enactments:-

- (i) The Prevention of Food Adulteration Act, 1954.
- (ii) The Fruit Products Order, 1955.
- (iii) The Meat Food Products Order, 1973.
- (iv) The Vegetable Oil Products (Control) Order, 1947.
- (v) The Edible Oils Packaging (Regulation) Order, 1998.
- (vi) The Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order, 1967.
- (vii) The Milk and Milk Products Order, 1992.
- (viii) Any other order issued under the Essential Commodities Act, 1955.

30. The said Bill, after being passed in both the Houses of Parliament and assented to by the Honourable President of India, became the Food Safety and Standards Act, 2006. Subsequently, in exercise of powers conferred by Clause



(l) of sub-Section (2) of Section 92 read with Section 26 of the Food Safety and Standards Act, 2006, the FSSAI issued the Food Safety and Standards (Prohibition and Restriction on Sales) Regulation in the year 2011 in the form of 'Delegated Legislation'. In the said Regulation, a proviso, namely 'Regulation 2.3.4' was, surreptitiously, added, as under:-

*"Product not to contain any substance which may be injurious to health.*

*Tobacco and nicotine shall not be used as ingredients in any food products."*

31. The above Regulation was in fact, a re-insertion of Rule 44-J of the Prevention of Food Adulteration Rules, 1955, which were superceded along with the Act by the Food Safety and Standards Act, 2006. However, when the Committee enquired from the Ministry the need for issuing the Regulation in the year 2011, especially the Regulation 2.3.4, when the Rules had already been notified under the FSS Act, 2006, the Ministry vide their OM No. H.11013/01/2021-TC dated 26 July, 2021 informed, as under:-

*"Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 is not a new one but is continuation of provision already in force since 1955, under Rule 44-J of the Prevention of Food Adulteration Rules, 1955."*

32. The aforementioned averments of the Tobacco Control Division were erroneous in view of the fact that Rule 44-J was not originally in PFA Rules and it was added only in the year 2006. This fact was actually revealed by the Expert Committee, in Volume – I of the Report, which was forwarded by the Ministry vide OM dated 24 May, 2022 for which the Committee wish to appreciate their

truthful and well-researched endeavour. However, the officials of Tobacco Control Division furnished misleading information to the Committee with a view to digress their findings, which is a serious 'breach of privilege' and 'contempt of the House and its Committee', which is an act calls for immediate initiation of strict Departmental Proceedings against the errant officials - serving, transferred from the Tobacco Control Division or superannuated on attaining the age of retirement.

33. In this regard, the Committee also wish to refer to a news report, prominently published in various leading Newspapers in the Month of May 2018, wherein, a five-judge Constitution Bench of the Supreme Court *inter alia* unequivocally recognised the importance of Parliamentary Committees and its Reports, as under:-

*"...Parliamentary Committee systems have emerged as a creative way of Parliaments to perform their basic functions. They serve as the focal point for legislation and oversight.*

*A Parliamentary Standing Committee Report being in the public domain was a public document. It [Parliamentary Committee Report] can be taken aid of to understand and appreciate a statutory provision if it is unclear, ambiguous or incongruous. It can also be taken aid of to appreciate what mischief the legislative enactment intended to avoid...."*

II. Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011 – An extended proposition

34. The Committee are not in argument with FSSAI on the efficacy of issuing Regulation, 2011 and inserting, therein, Regulation 2.3.4, which was in a state of hibernation during the years, from 2006 to 2011, i.e., when it was it was

introduced, for the first time, in the form of 44-J in the PFA Rules in 2006, followed by repealing of PFA Rules and again its re-insertion in the year 2011. The controversy, in fact, started when the officials of Tobacco Control Division, in a most irresponsible manner, co-related Regulation 2.3.4 with the definition of 'Food' as contained in Section 3(1)(j) of the Food Safety and Standards Act, 2006, by making the following assertions to the Committee on Petitions:-

- (i) As per the existing laws and rules under the Food Safety and Standards Act, 2006 [FSS Act, 2006], the ban operates on the use of tobacco and nicotine as an ingredient in any food articles.
- (ii) The Food Safety and Standards Act, 2006 as well as the earlier Prevention of Food Adulteration Act, 1954, give a wide definition of 'food' and include, therein, any article/substance which is intended for human consumption. The Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011 issued under the FSS Act lays down that tobacco and nicotine shall not be used as ingredients in any food products.

35. Since the definition of 'food' under Section 3(1)(j) of the FSS Act, 2006 does not mention anything about tobacco and/or tobacco products, which has now also been held by the Delhi High Court, the Committee made an effort to make a legally-sound dissection of Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011. The findings of the Committee could be summarised, as under:-

- (i) Regulation 2.3.4 stipulates that 'tobacco' and 'nicotine' shall not be used as ingredients in any food product, as otherwise, there would be restrictions on sale of such products. It could, therefore, be inferred that whenever, 'tobacco' or 'nicotine' will be mixed in any food product, it will not be allowed to be sold to the customers.

- (ii) From the above-stated wordings of Regulation 2.3.4, a pertinent question arises as to whether 'tobacco' and/or 'nicotine' are being mixed in any 'food product' or any 'food product', such as, cardamom, clove, peppermint, etc., are mixed in tobacco.
- (iii) The distinction mentioned at (ii) above raises yet another question to the effect that in case, food products [Cardamom, Clove, Peppermint, etc.] are mixed in Tobacco, whether that 'final product' is being sold in the market as 'tobacco' or 'food product'.
- (iv) The plausible answer to queries (ii) & (iii) above is that in the context of our country, 'food product', such as, cardamom, clove, peppermint, etc., are mixed in tobacco. However, after mixing of such food items, the final product continues to be sold in the market only as 'Tobacco' and/or 'Tobacco Products' and not as 'food' or 'food products'.
- (v) It is, therefore, need of the hour to undergo amendment in Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales) Regulation 2011, as under:-

*"Product not to contain any substance which may be injurious to health.*

*'Tobacco' and 'Nicotine' shall not be used as ingredient in any food products as otherwise all such products would be categorized as 'tobacco' and 'tobacco products' and would be regulated under the relevant provisions of the Cigarettes and Other Tobacco Products Act 2003."*

36. The Committee wish to express their anguish regarding the fact that during the prolonged deliberations with the officials of the Tobacco Control Division and FSSAI, whenever such aspects were raised by the Committee, the officials of Tobacco Control Division and the FSSAI preferred to give evasive

replies and often referred to various Court cases, GATS Report, WHO Study, National Health Policy, 2017, etc., to mislead the Parliamentary Committee and digress from the issues at hand.

37. Now that the entire narrative formulated by the Tobacco Control Division and FSSAI, all along the last 10 years, notwithstanding the erroneous formulation of the harmful effects of 'Tobacco' & 'Nicotine', artificial classification of 'tobacco products' into 'smoking' and 'smokeless tobacco' and bringing the 'smokeless tobacco' products within the ambit of the definition of 'food' under the FSS Act, 2006 along with putting the 'smoking tobacco' under the ambit of COTP Act, 2003 has been demolished in light of the recent judgement of the High Court of Delhi. Also, the Secretary, Ministry of Health & Family Welfare, while deposing before the Committee, had assured that they are not in favour of challenging the said judgment. In this regard, the Committee strongly recommend that urgent remedial action should be initiated by the Ministry to work out policy formulations by unambiguously demarcating 'food' & 'food products' and 'tobacco' & 'tobacco products' respectively. The Committee also urge the Ministry of Health & Family Welfare to initiate definitive action on all the observations/recommendations made by the Committee in this Report, including the revamping of entire Tobacco Control Division and FSSAI along with initiating strict Departmental Proceedings against all the errant officials – serving and/or transferred from the Tobacco Control Division or superannuated on attaining the age of retirement in accordance with relevant Rules/Orders/Guidelines on the subject, under

intimation to the Committee within three months of the presentation of the Report to the House.

NEW DELHI;

HARISH DWIVEDI  
*Chairperson,  
Committee on Petitions*

23 March, 2023

02 Chaitra, 1945 (Saka)

MANU/SC/0258/1979

ANNEXURE-I

Equivalent Citation: AIR1980SC538, 1980(1)APLJ (SC) 21, 1980CrLJ402, (1980)1SCC167, (1980)SCC(CrI)200, [1980]2SCR59

**IN THE SUPREME COURT OF INDIA**

Criminal Appeal No. 236 of 1973

Decided On: 15.11.1979

Appellants: **State of Tamil Nadu****Vs.**Respondent: **R. Krishnamurthy****Hon'ble Judges/Coram:***O. Chinnappa Reddy and R.S. Sarkaria, JJ.***Counsel:***For Appellant/Petitioner/Plaintiff: A.V. Rangan, Adv**For Respondents/Defendant: A.T.M. Sampath, Adv.***JUDGMENT****O. Chinnappa Reddy, J.**

1. Gingelly oil mixed with 15% of groundnut oil was sold as gingelly oil by the respondent to the Food Inspector, Thanjavur Municipality. The defence of the respondent was that he kept the oil in his shop to be sold, not for human consumption, but, for external use. The Trial Magistrate did not accept the defence. He convicted him under Section 16(1)(a)(i) read with Section 2(1)(a) of the Food Adulteration Act and sentenced him to suffer imprisonment till the rising of the Court and to pay a fine of Rs. 200. On appeal, the learned Sessions Judge accepted the defence of the respondent and acquitted him to the charge. According to the learned Sessions Judge, the respondent could not be convicted unless it was established that the sale of the gingelly oil was for human consumption. The State of Tamil Nadu preferred an appeal to the Madras High Court. The High Court confirmed the order of acquittal. The State of Tamil Nadu has filed this appeal by special leave of this Court. The learned Counsel for the State of Tamil Nadu made it clear to us at the hearing that the State was not anxious, at this distance of time (the occurrence was on 26-5-69) to secure a conviction, but was anxious that the legal position should be clarified. We accordingly proceed to do so.

2. Section 16(1)(a)(i) as it stood at the relevant time was as follows:

**16. (1) If any person-**

(a) whether by himself or by any other person on his behalf imports into India or manufactures for sale, or stores, sells or distributes any article of food-

(i) which is adulterated or misbranded or the sale of which is prohibited by the Food (Health) authority in the interest of public health;

x x x

he shall, in addition to the penalty to which he may be liable under the provisions of Section 6, be punishable with imprisonment for a term which shall not be less than six months but which may extend to six years, and with fine which shall not be less than one thousand rupees:

Provided that-

(i) if the offence is under Sub-clause (i) of Clause (a) and is with respect to an article of food which is adulterated under Sub-clause (1) of Clause (i) of Section 2 or misbranded under Sub-clause (k) of Clause (ix) of that section; or

(ii) if the offence is under Sub-clause (ii) of Clause (a), the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than six months or of fine of less than one thousand rupees or of both imprisonment for a term of less than six months and fine of less than one thousand rupees.

Section 7 is also relevant and it was as follows:

**7.** No person shall himself or by any person on his behalf manufacture for sale, or store, sell or distribute-

(i) any adulterated food; (ii) any misbranded food;

(iii) any article of food for the sale of which a licence is prescribed, except in accordance with the conditions of the licence.

(iv) any article of food the sale of which is for the time being prohibited by the Food (Health) Authority in the interest of public health; or

(v) any article of food in contravention of any other provision of this Act or of any rule made thereunder.

**3.** "Food" is defined by Section 2(v) as meaning "any article" used as food or drink for human consumption other than drugs and water and includes-

(a) any article which ordinarily enters into, or is used in the composition or preparation of human food, and

(b) any flavouring matter or condiments." "Sale" is defined by Section 2(xiii) as follows:

"Sale" with its grammatical variations and cognate expressions, means the sale of any article of food, whether for cash or on credit or by way of exchange and whether by wholesale or retail, for human consumption or use, or for analysis, and includes an agreement for sale, an offer for sale, the exposing for sale or having in possession for sale of any such article, and includes also an attempt to sell any such article;



4. Section 16(1)(a)(i) read with Section 7(i) prohibits and penalises the sale of any article of food which is adulterated or misbranded etc. The question for consideration is whether the sale of adulterated gingelly oil which is sold or offered for sale for external use is sale of an article of food which is adulterated. This must depend upon the definitions of "sale" and "food" in the Act.

5. According to the definition of "food" which we have extracted above, for the purposes of the Act, any article used as food or drink for human consumption and any article which ordinarily enters into or is used in the composition or preparation of human food is "food". It is not necessary that it is intended for human consumption or for preparation of human food. It is also irrelevant that it is described or exhibited as intended for some other use. It is enough if the article is generally or commonly used for human consumption or in the preparation of human food. It is notorious that there are, unfortunately, in our vast country, large segments of population, who living as they do, far beneath ordinary subsistence level, are ready to consume that which may otherwise be thought as not fit for human consumption. In order to keep body and soul together, they are often tempted to buy and use as food, articles which are adulterated and even unfit for human consumption but which are sold at inviting prices, under the pretence or without pretence that they are intended to be used for purposes other than human consumption. It is to prevent the exploitation and self destruction of these poor, ignorant and illiterate persons that the definition of "food" is couched in such terms as not to take into account whether an article is intended for human consumption or not. In order to be "food" for the purposes of the Act, an article need not be "fit" for human consumption; it need not be described or exhibited as intended for human consumption; it may even be otherwise described or exhibited; it need not even be necessarily intended for human consumption; it is enough if it is generally or commonly used for human consumption or in the preparation of human food. Where an article is generally or commonly not used for human consumption or in the preparation of human food but for some other purpose, notwithstanding that it may be capable of being used, on rare occasions, for human consumption or in the preparation of human food, it may be said, depending on the facts and circumstances of the case, that it is not "food". In such a case the question whether it is intended for human consumption or in the preparation of human food may become material. But where the article is one which is generally or commonly used for human consumption or in the preparation of human food, there can be no question but that the article is "food". Gingelly oil, mixed or not with groundnut oil or some other oil, whether described or exhibited as an article of food for human consumption or as an article for external use only is "food" within the meaning of the definition contained in Section 2(v) of the Act.

6. Most of the High Courts appear to have so understood the meaning of the word "food", though there appears to have been some confusion because of a misunderstanding of certain observations of this Court in *Andhra Pradesh Grain and Seed Merchants' Association v. Union of India* MANU/SC/0081/1970 : 1971CriLJ1556 and *Shah Ashu Jaiwant v. State of Maharashtra* MANU/SC/0204/1975 : 1975CriLJ1868 .

In the first case it was observed:

We are again unable to accept the argument that under the Act even when an article is purchased not as an article of food, but for use otherwise, the vendor will be deemed guilty if the article does not conform to the prescribed standards, or is as an article of food adulterated or misbranded. Counsel said

that coconut oil is used in the State of Kerala as a cooking medium, and sale of adulterated coconut oil may in Kerala be an offence under Section 16, but in other parts of the country where coconut oil is not used as a cooking medium and is used as a component of hair oil or for other purposes, it amounts to imposing an unreasonable restriction to penalise the vendor who sells coconut oil knowing that the purchaser is not buying it as a cooking medium. But there are no articles which are used as food only in one part, and are not at all used as food in another part of the country. Even coconut oil is used as a cooking medium by certain sections of the people in parts of India other than Kerala. In any event it is always open to a person selling an article capable of being used as an article of food as well as for other purpose to inform the purchaser by clear notice that the article sold or supplied is not intended to be used as an article of food. What is penalised by Section 16(1) is importation manufacture for sale, or storage, sale or distribution of any article of food. If what is imported manufactured or stored, sold or distributed is not an article of food, evidently Section 16 can have no application.

In the second case it was observed:

Hence, where Section 7 prohibits manufacture, sale or storage or distribution of certain types of "food", it necessarily, denotes articles intended for human consumption as food. It becomes the duty of the prosecution to prove that the article which is the subject-matter of an offence is ordinarily used for human consumption as food whenever reasonable doubts arise on this question. It is self-evident that certain articles, such as milk, or bread, or butter, or food-grains are meant for human consumption as food. These are matters of common knowledge. Other articles may be presumed to be meant for human consumption from representations made about them or from circumstances in which they are offered for sale.

**7.** The seeming confusion created by the observations in the two cases will disappear if they are properly understood in the context in which they were made. In the first case the Court was considering the argument based upon the supposition that there might be articles which were "food" somewhere and not "food" elsewhere. The Court first remarked that there were no articles which were used as food only in one part, and were not at all used as food in another part of the country. In such an unlikely event, the person selling the article could inform the purchaser that the article sold was not meant to be used as an article of food. If prosecuted he could establish that in that area what he sold was not an article of food at all. That was all that was observed. If the expression "food" is understood as we have explained earlier, there would be no occasion for any confusion.

**8.** The observations in the second case are in accord with what we have said. The Court merely observed that if there was any doubt in a particular case whether an article was ordinarily used for human consumption in order to fall within the definition of "food", the prosecution would have to prove the same

**9.** That gingelly oil, however describes or exhibited, is an article of food is not an end of our problem. We have further to investigate the definition of "sale". Now, the definition is designedly wide. It seems a real sale as well as an 'embryonic' sale (like agreement for sale, offer for sale, exposure for sale, possession for sale, attempt at sale) are sales for the purposes of the Act. The sale may be for cash or credit or by

way of exchange. The sale may be by wholesale or retail. Thus every kind, manner and method of sale are covered. Finally, the sale may be "for human consumption or use, or for analysis". In the context, these words can only mean 'whether for human consumption or for any other purpose (including analysis)'. The object is to emphasise that whatever be the purpose of the sale it is a sale for the purposes of the Act, just as the words "whether by wholesale or retail" or "whether for cash or credit or by way of exchange" are intended to emphasise that it is immaterial for the purposes of the Act what manner and method of sale is adopted, To give any other interpretation to the definition of "sale" would be to exclude from the ambit of the Act that which has been included, by the definition of "food". Further, a sale "for analysis" can never be a sale "for human consumption" but it is nonetheless a sale within the meaning of the definition. It is an unqualified sale for the purposes of the Act. To insist that an article sold for analysis should have been offered for sale for human consumption would frustrate the very object of the Act. A person selling an adulterated sample to a Food Inspector could invariably inform him that it was not for human consumption and thereby insure himself against prosecution for selling adulterated food. If sale for analysis is an unqualified sale for the purposes of the Act, there is no reason why other sales of the same article should not be sales for the purposes of the Act. The question may be asked why sale for analysis should be specially mentioned if all manner of sales are included in the definition. It is only to prevent the argument that sale for analysis is not a consensual sale and hence no sale, an argument which was advanced and rejected in *Mangaldas v. State of Maharashtra* A.I.R. 1966 S.C. 121.

**10.** We are therefore of the opinion that the sale of gingelly oil mixed with groundnut oil is punishable under Section 16(1)(a)(i) read with Section 2(1)(a) notwithstanding the fact that the seller had expressly stated at the time of sale that it was intended for external use only. We declare the illegal position as indicated in the earlier paragraphs but we refrain from passing any further order in the appeal which we accordingly dismiss. We have not referred to any of the decisions of the various High Courts which were considered by us and all of which, we may add, have been studiously collected and scrupulously considered by Madhusudana Rao, J. in *Public Prosecutor v. Rama Chandra Raju* [1977] 1 An. W.R. 356.

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MANU/SC/0574/2004

**Equivalent Citation:** 2005(1)ACR525(SC), AIR2004SC4057, 2004 (Suppl.) ACC 760, 2004(5)ALLMR(SC)970, 2005(1)BomCR194, 2004(106(4))BOMLR724, JT2004(6)SC179, (2004)4MLJ67(SC), 2004(4)PLJR62, 2004(3)RCR(Criminal)930, 2004(6)SCALE388, (2004)7SCC68, [2004]Supp(3)SCR239, 2004(2)UC1148, 2004(2)UJ1449

**IN THE SUPREME COURT OF INDIA**

Civil Appeal No. 4674 of 2004 (Arising out of SLP (C) No. 24449 of 2002), Civil Appeal No. 4677/2004 (Arising out of SLP (C) No. 23635 of 2002), Civil Appeal No. 4676/2004 (Arising out of SLP (C) No. 24292/02), Civil Appeal No. 4675/2004 (Arising out of SLP (C) No. 533/03), Civil Appeal No. 4678/2004 (Arising out of SLP (C) No. 834/03) and Civil Appeal No. 4679/2004 (Arising out of SLP (C) No. 2186/03) and Writ Petition (C) No. 173 of 2003

Decided On: 02.08.2004

Appellants: **Godawat Pan Masala Products I.P. Ltd. and Ors.****Vs.**Respondent: **Union of India (UOI) and Ors.****Hon'ble Judges/Coram:***K.G. Balakrishnan and B.N. Srikrishna, JJ.***Counsel:**

*For Appellant/Petitioner/Plaintiff: Shanti Bhushan, Jayant Bhushan, R.F. Nariman, Kapil Sibal and Anil B. Divan, Sr. Advs., S.K. Pathak, S. Pathak, Ejaz Maqbool, Indu Malhotra, Deepa Vishwanathan, N. Talwar, D. Krishnan, Vanita Bhargava, Nina Gupta, Bina Gupta, S. Parekh, K. Javeri, Fatek, Lalit Chauhan, P.D. Gupta, Pramod Dayal, P. Sharma, K.R. Nagaraja, E.R. Sumathy, K. Vijayan, Anand P. Jain, Savita Aggarwal, Hari, Punit Dutt Tyagi, Advs,*

*For Respondents/Defendant: K. Amareshwari, Sr. Adv., Atmaram N.S. Nadkarni, Adv. General for State of Goa, Uday Umesh Lali, Arun R. Pednekar, S.S. Shinde, A. Singh, P. Keswani, Mukesh K. Giri, R.K. Rathore, Pinky Anand, Ajay Sharma, D.S. Mahra, B. Ramana Murthy, G. Prabhakar, Anil Katiyar, Ravindra Keshavrao Adsure, Dhruv Mehta, M. Choudhary and Shalini Gupta, Advs.*

**JUDGMENT****B.N. Srikrishna, J.**

1. Leave granted in the special leave petitions and the writ petition is admitted.
2. These appeals and writ petition arise from different areas and, though marginally differing on facts, raise substantially similar issues of law. They can, therefore, be conveniently disposed of by a common judgment
3. The common issue raised for consideration of this Court in all these cases is the validity of notifications issued by the Food (Health) Authority under Section 7(iv) of the Prevention of Food Adulteration Act, 1954 (hereinafter referred to as the 'Act') by which the manufacture, sale, storage and distribution of pan masala and gutka (pan masala containing tobacco) were banned for different periods. We shall take the facts in the civil appeal arising out of special leave petition No. 24449 of 2002 as typical of the cases.

**Facts:**Civil Appeal arising out of SLP(C) No. 24449 of 2002

**4.** The appellants manufacture gutka within the state of Maharashtra, which is stored in convenient godowns and sold both within and outside the state of Maharashtra. By a notification dated 23<sup>rd</sup> July, 2002 issued by the Commissioner, Food and Drug Administration and Food (Health) Authority for the State of Maharashtra, the manufacture, sale, storage and distribution of pan masala and gutka (pan masala containing tobacco) were banned for a period of five years with effect from 1<sup>st</sup> August, 2002. The appellants challenged the validity of this notification by a writ petition No. 2024 of 2002 before the High Court of Judicature at Bombay. By its judgment dated 18<sup>th</sup> /19<sup>th</sup> September, 2002, the division bench of the Bombay High Court dismissed the writ petition upholding the validity of the notification. Aggrieved thereby, the appellants challenge the said judgment by the present appeal.

Writ Petition No. 173 of 2003:

**5.** Petitioners Nos. 1 to 5 are associations and cooperative societies of arecanut growers, petitioners Nos. 6 and 7 are engaged in the manufacture and sale of pan masala and gutka in the State of Karnataka. They are aggrieved by a notification dated 27<sup>th</sup> February, 2002, issued by the competent officer appointed as Food (Health) Authority for the State of Andhra Pradesh under Section 7(iv) of the Act, by which the sale of all brands of pan masala (containing tobacco) and chewing tobacco/ zarda/ khaini under any brand name was prohibited "in the interest of public health" in the entire state of Andhra Pradesh with immediate effect.

**6.** The petitioners also challenge another notification dated 19<sup>th</sup> November, 2001 issued by the Director for Public Health and Preventive Medicine and State Food (Health) Authority, Government of Tamil Nadu, under Section 7(iv) of the Act directing that no person shall himself or by any person on his behalf, manufacture for sale or store, sell or distribute: (i) chewing tobacco; (ii) pan masala; (iii) gutka, containing tobacco in any form or any other ingredients injurious to health, under whatever name or description in the State of Tamil Nadu. This notification is purported to have been issued in the "interest of public health", for a period of five years with effect on and from 19<sup>th</sup> November, 2001.

**7.** The third notification which is challenged in the writ petition is the notification dated 23<sup>rd</sup> July, 2002 issued by the Commissioner of Food and Drug Administration and Food (Health) Authority for the State of Maharashtra. By the said notification, issued purportedly in exercise of the powers under Section 7(iv) of the Act, "in the interest of public health", the sale of gutka and pan masala, containing tobacco or not containing tobacco, is prohibited for a period of five years effective from 1<sup>st</sup> August, 2002. The notification directs that "no person shall himself or any person on his behalf shall manufacture for sale or store, sell or distribute gutka or pan masala, containing tobacco or not containing tobacco, by whatever name called.

**8.** The fourth notification challenged in the writ petition is the notification dated 24<sup>th</sup> January, 2003 issued by the Directorate of Food and Drugs Administration and Food (Health) Authority for the State of Goa. By this notification, purportedly issued under Section 7(iv) of the Act, the "sale of gutka and pan masala, containing tobacco or not containing tobacco, by whatever name called," is prohibited within the state of Goa

and it is directed that "no person shall himself or any person on his behalf, shall manufacture for sale or store, sell or distribute gutka or pan masala, containing tobacco or not containing tobacco, by whatever name called." The prohibition in the notification is made effective from 26<sup>th</sup> January, 2003.

**9.** All the four notifications are under challenge.

Civil Appeals arising out of S.L.P. Nos. 23635/02, 24292/02, 533/03, 834/03 and 2186/03

**10.** The appellants are engaged, inter alia, in the manufacture and trade of pan masala and gutka, pan masala containing tobacco and other allied tobacco products. They sell their products all over India including State of Maharashtra. They have a wide network of dealers through whom their products are sold to the public at large in the state of Maharashtra. They also have operating depots in the state of Maharashtra. The appellants challenge the notification dated 23<sup>rd</sup> July, 2002, issued by the Commissioner, Food and Drug Administration and Food (Health) Authority for the state of Maharashtra. The High Court by its common judgment dated 18<sup>th</sup>/19<sup>th</sup> September, 2002 negated the challenge.

Civil Appeal arising out of SLP No. 24292 of 2002

**11.** The appellant carry on the business of manufacture and sale of pan masala, gutka and other tobacco related items. Aggrieved by the notification dated 19<sup>th</sup> February, 2002 issued by the Food (Health) Authority, State of Andhra Pradesh, prohibiting the sale of pan masala under any brand name with a emblem of gutka, containing tobacco, within the state of Andhra Pradesh, with immediate effect and the notification dated 27<sup>th</sup> February, 2002 issued by the same authority which prohibited the sale of all brands of pan masala containing tobacco and chewing tobacco/zarda/khaini under any brand name in the entire State of Andhra Pradesh, with immediate effect, the appellant challenged the validity of both notifications before the High Court of Andhra Pradesh. The division bench of the high court by its judgment dated 16<sup>th</sup> August, 2002 dismissed the writ petition. Being aggrieved thereby, the appellant is before this Court.

**Core Issue:**

**12.** These appeals and the writ petition raise the common issue as to the power of the Food (Health) Authority to issue an order of prohibition, whether permanently or quasi-permanently, under Section 7(iv) of the Act.

**Challenge:**

**13.** The broad grounds of challenge formulated by the appellants/petitioners are as under:

- 1.** The Act vests the power to declare a substance as injurious to health only with the Central Government under Section 23 of the Act and no such power is vested with the State Government.
- 2.** Each of the manufacturers has been issued a licence to manufacture the banned product by the Central Government under the provisions of the Act. As long as the conditions stipulated in the licence are fulfilled, and there is

no violation of the terms of the licence or the provisions of the concerned statute, it is not open to the state Government, by any administrative order, to prohibit the manufacture of the concerned product undertaken under a licence issued by the Central Government.

**3.** The power of the State Government to frame rules under Section 24 of the Act is extremely narrow and limited to the field which is not covered by Section 23, the exclusive domain of the Central Government.

**4.** The Act is concerned with the prevention of adulterated articles of food and not intended to prohibit any article used as food or otherwise.

**5.** The impugned notification dated 23<sup>rd</sup> July, 2002, issued by the State of Maharashtra operates extra territorially, and, to that extent, is ultra vires of the powers of the State.

**6.** By enacting the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003, (Act 34 of 2003), Parliament has evinced its intent to occupy the whole field with regard to prohibition of advertisement and regulation of trade and commerce, production, supply and distribution of tobacco products. While the central legislation prohibits the sale of tobacco products only to persons below age of 18 years, the impugned notification purports to impose a wholesale ban without any qualification. Thus, there is a conflict between the powers exercisable under two central statutes dealing with the same subject and, therefore, provisions of the Act 34 of 2003 must prevail.

#### **Legal provisions:**

**14.** In order to appreciate the contentions of the learned counsel, it will be necessary to briefly notice the relevant provisions of the Act. As the preamble of the Act indicates, "it is an Act to make provision for the prevention of adulteration of food." Section 2(ia) defines what is 'adulterated food'. Broadly speaking, the definition covers situations where a food article is sub-standard, or contains injurious ingredients or has become injurious to health by reason of packing or keeping under unsanitary conditions or having become contaminated or is otherwise not fit for consumption. The definition also extends to cases of articles which fall below the prescribed standards of purity or quality. The Act also deals with misbranding of food articles, which is not of concern to us for the present. For the purpose of administration of the Act, any urban or rural area may be declared by the Central Government or the State Government by a notification to be a 'local area' for the purpose of the Act. In relation to such local area, an officer is appointed by the Central Government or the State Government by notification in the Official Gazette to be in-charge of the Health administration in such area with such designation as specified therein and such officer is defined to be a 'Local (Health) Authority' by Section 2(viia). Section 2(vi) defines 'Food (Health) Authority' as the Director of Medical and Health Services or the Chief Officer in-charge of Health administration in a State, by whatever designation he is known, and includes any officer empowered by the Central Government or the State Government, by notification in the Official Gazette, to exercise the powers and perform the duties of the Food (Health) Authority under the Act with respect to such local area as may be specified in the notification. Section 7, upon which most of the arguments turn, needs to be noticed. Section 7

reads as under:

"7. Prohibitions of manufacture," sale, etc., of certain articles of food. - No person shall himself or by any person on his behalf manufacture for sale, or store, sell or distribute -

(i) any adulterated food;

(ii) any misbranded food;

(iii) any article of food for the sale of which a licence is prescribed, except in accordance with the conditions of the licence;

(iv) any article of food the sale of which is for the time being prohibited by the Food (Health) Authority in the interest of public health;

(v) any article of food in contravention of any other provision of this Act or of any rule made thereunder; or

(vi) any adulterant.

Explanation.-For the purposes of this section, a person shall be deemed to store any adulterated food or misbranded food or any article of food referred to in Clause (iii) or Clause (iv) or Clause (v) if he stores such food for the manufacture therefrom of any article of food for sale."

Section 22A empowers the Central Government to give such directions as it may deem necessary to a State Government regarding the implementation of the Act. Section 23 empowers the Central Government to make rules to carry out the provisions of the Act. In particular, and without prejudice to the generality of the rule making power, the power of the Central Government includes the one in Clause (f). Section 24 of the Act is the section which grants rule making power to the State Government. The State Government may, after consultation with the Committee, and subject to the condition of previous publication, thereunder make rules for the purpose of giving effect to the provisions of the Act in matters not falling within the purview of section 23. Sub-section (2) of Section 24 grants power to the State Government to make rules with regard to the powers and duties of the different authorities under the Act. Prescription of forms of licences for the manufacture for sale, storage, sale and distribution of articles of food, the conditions subject to which such licences may be issued and the fees payable therefor, analysis of any article of food or matter and provision for further delegation of power by the State Government to the Food (Health) Authority or the subordinate authorities are the matters covered within this delegated power.

**15.** Part IX of the Prevention of Food Adulteration Rules, 1955 (hereinafter referred to as the 'Rules') deals with the conditions for sale and licence. Rules 49 and 50 lay down detailed conditions applicable to different types of licences granted for manufacturing of different products used as food articles.

**16.** In Appendix B there is prescription of definitions and standards of quality of different food articles. Of relevance to us is paragraph A.30 which deals with pan masala. Paragraph A.30 reads thus:

"A.30 PAN MASALA means the food generally taken as such or in conjunction



with pan, it may contain-

Betelnut, lime, coconut, catechu, saffron, cardamom, dry fruits mulathi, sabermusa, other aromatic herbs and spices, sugar, glycerine, glucose, permitted natural colours, menthol and non-prohibited flavours.

It shall be free from added coaltar colouring matter, and any other ingredient injurious to health.

It shall also conform to the following standards, namely:-

Total ash.-Not more than 8.0 per cent by weight (on dry basis).

Ash insoluble in dilute hydrochloric acid.-Not more than 0.5 per cent by weight (on dry basis)."

**17.** Significantly, in this specification of standard the prescription is that the article is "Free from added coaltar colouring matter, and any other ingredient injurious to health". It is also required to conform to the prescribed standard with regard to total ash.

**18.** As far as the rules made by the State Government are concerned, the Maharashtra Prevention of Food Adulteration Rules, 1962 and the Goa, Daman and Diu Prevention of Food Adulteration Rules, 1982 may be noticed. The relevant Goa rules are as under:

"3. Powers and duties of Food (Health) Authority:

(1) The Director of Health Services for the Union Territory of Goa, Daman and Diu being the Chief Officer in charge of the Health Administration in the Union Territory shall be the Food (Health) Authority.

(2) The Food (Health) Authority shall be responsible for the general superintendence of the administration and enforcement of the Act.

(3) The Food (Health) Authority shall, for the purpose of giving effect to the provisions of the Act, have control over the Public Health Laboratories maintained by the Government and Local Authorities and Local (Health) Authorities, Licensing Authorities, the Public Analyst and Food Inspectors appointed under the Act.

(4) The Food (Health) Authority may give to a Local (Health) Authority such directions as he may consider necessary in regard to any matter connected with the enforcement of the Act and the Rules made thereunder and the Local (Health) Authority shall comply with such directions.

(5) The Food (Health) Authority whenever called upon to do so shall advise the Government in matters relating to the administration and enforcement of the Act.

(6)(a) If the Union Territory or any part thereof is visited by, or threatened with any outbreak of any infectious diseases, the Food (Health) Authority shall ascertain the cause of such outbreak of the

infectious disease.

(b) If in the opinion of the Food (Health) Authority the outbreak of any infectious disease is due to any article of food, the Food (Health) Authority shall take such measures as it shall deem necessary to prevent the outbreak of such disease or the spread thereof.

(7) The Food (Health) Authority may issue from time to time guidelines for the efficient working of the Act.

(8) The Food (Health) Authority may from time to time issue guidelines to the Public Analyst for efficient working of the Act.

(9) The Food (Health) Authority may also have powers to inspect, control and superintend the operation of other functionaries working under the Act viz. Licensing Authority, Local Authority etc. etc.

#### 4. Powers and duties of Local (Health) Authority:

(1) Subject to the provisions of Sub-rule (3), the Local (Health) Authority shall be responsible for the proper day to day administration and enforcement of the Act and the Rules within its jurisdiction.

(2) The Local (Health) Authority or Health Officer/Medical Officer authorised by it shall be the Licensing Authority for local area concerned.

(3) The Local (Health) Authority or Health Officer/Medical Officer/Food Inspector authorised by it shall have powers to inspect all the establishments engaged in the manufacture, for sale or for distribution of articles of food in respect of which a licence is required under the Act and the Rules.

#### 5. Licences:

(1) Any person desiring for the manufacture for sale, for the storage, for the sale or for the distribution of articles of food in respect of which a licence is required under Rule 48A and Rule 50 of the Central Rules, shall apply for a licence in Form A to the Licensing Authority concerned.

(2) Any person desiring for the manufacture for sale, for the storage, for the sale or for the distribution of articles of food in a mobile van shall apply in Form B to the Licensing Authority and if such mobile van is to move in any one or more than one local area to the Local (Health) Authority, District of Goa.

(3) The applicant shall furnish in the application in Form A detailed information regarding location of the business premises which are intended for the manufacture for sale, for the storage, for the sale or for the distribution of any article of food and in Form B the details about the locality in which, the mobile van is intended to be moved and its registration number issued by the Road Transport Authority.

(4) On receipt of such application, the Licensing Authority shall, if on inspecting the said premises is satisfied that the premises are free from sanitary defects and are in proper hygienic conditions and the applicant complies with other conditions for holding licence, grant the applicant a licence in Form as specified below on payment of fees laid down in the Schedule appended to the rules.

(i) Form 'C' in respect of any premises.

(ii) Form 'D' in respect of any mobile van.

(iii) Form 'E' in respect of any temporary stall.

(5) If the information furnished in the application appears to be incorrect or incomplete or if the prescribed fee has not been paid, the Licensing Authority shall make such enquiry as he considers necessary and after giving the applicant an opportunity of proving the correctness and completeness of the information so furnished, may if he is satisfied that the applicant is eligible for the licence applied for grant or renew the licence.

(6) If the articles of food are manufactured, stored or exhibited for sale at different premises situated in more than one local area, separate applications shall be made and a separate licence shall be issued in respect of such premises not falling within the same local area.

Provided that the itinerant vendors who have no specified place of business, shall be licensed to conduct business in a particular area within the jurisdiction of the Licensing Authority.

(7) The licensee shall abide by the provisions of the Act and the Rules made thereunder and the conditions of licence granted to him.

#### **6. Fees for grant and renewal of licences:**

The fees to be paid for the grant or renewal of licence shall be as specified in the Scheduled appended to the Rules.

#### **7. Validity of licence:**

A licence granted under these rules shall be valid for the period beginning on the date of its issue and ending on 31<sup>st</sup> day of March, next following.

#### **8. Renewal of licences :**

A licence granted under the rules may be renewed by the Licensing authority on an application made in that behalf, thirty days before the day on which such licence is due to expire and on payment of fees specified in the Schedule.

Provided that, if the application for renewal is made after the expiry of the licence but not later than one month from the date of such expiry, the licence may be renewed only on payment of a fee equal

to one and half times of the fee payable for the renewal of the licence.

**9. Conditions for grant or renewal of licences :**

The Licensing Authority shall not grant or renew the licence until such officer as may be specified by him by general or special order has inspected the place in respect of which the licence for grant or renewal is applied for and has recommended the grant or renewal of the licence. The Licensing Authority shall however use his own judgment in granting/renewal of licences."

**19.** Rule 13 deals with the circumstances under which the Licensing Authority may by order in writing refuse to grant or renew a licence. Rule 14 prescribes the procedure for cancellation or suspension of the validity of a licence. Rule 15 gives a right to appeal to any person aggrieved by an order of the Licensing Authority passed under Rule 13 or Rule 14.

**20.** The relevant rules of the Maharashtra Prevention of Food Adulteration Rules, 1962 are as under:

"3. Food (Health) Authority and its powers and duties -

(1) The Director of Public Health for the State of Maharashtra being the Chief Officer-in-charge of the Health Administration in the State of Maharashtra shall be the Food (Health) Authority (hereinafter referred to as the authority).

(2) The authority shall be responsible for the general superintendence of the administration and enforcement of the Act.

...

(6)(a) If the State or any part thereof is visited by, or threatened with an outbreak of any infectious disease, the authority shall ascertain the cause of such outbreak of the infectious disease.

(b) If in the opinion of the authority the outbreak of any infectious disease is due to any article of food, the authority shall take such measures as it shall deem necessary to prevent the outbreak of such disease or the spread thereof."

**21.** Rule 5 deals with licences and the manner of suspension or cancellation of licences.

**Submissions:**

**Ex visceribus actus:**

**22.** The first contention urged on behalf of the appellants is that Section 7 of the Act is not declaratory of the power of any authority, but merely of the consequences of certain acts. The section prohibits the manufacture for sale, store or distribution of (i) any adulterated food; (ii) any misbranded food; (iii) any article of food for the sale of which a licence is prescribed, except in accordance with the conditions of the licence; (iv) any article of food the sale of which is for the time being prohibited by

the Food (Health) Authority in the interest of public health; (v) any article of food in contravention of any other provision of this Act or of any rule made thereunder; or (vi) any adulterant. Although, Section 2(vi) defines as to who is a Food (Health) Authority, there is no corresponding provision in the Act which delineates the powers of the Food (Health) Authority. On the other hand, Section 24(2) of the Act empowers the State Government to "define the powers and duties of the Food (Health) Authority, local authority and Local (Health) Authority under this Act". The source of the powers of the Food (Health) Authority is to be found only under the rules, if any, made under Section 24(2) of the Act, subject to the restriction that it can be made only "for the purpose of giving effect to the provisions of this Act in matters not falling within the purview of Section 23".

**23.** Learned counsel for the appellants contend that in view of the nature of the limitations placed on the State Government's power under Section 24(1), a reading of Sections 23 and 24 would lead to the irresistible conclusion that the powers exercisable by the State Government under Section 24 can only be in the field not occupied by Section 23. As we have already noticed, Section 23(1A)(f) empowers the Central Government to prescribe rules for prohibiting the sale or defining the conditions of sale of any substance which may be "injurious to health" when used as food or restricting in any manner its use as an ingredient in the manufacture of any article of food or regulating by the issue of licences the manufacture for sale of any article of food. Learned counsel, therefore, contend that the power of the Food (Health) Authority has to be necessarily found under the rules made by the State Government and subject to the limitation that they cannot operate in the field covered by Section 23. Since Section 23(1A)(f) empowers the Central Government to make rules for prohibition of any substance which may be injurious to health, it is contended that the state Food (Health) Authority is denuded of such power.

**24.** There appears to be merit in the contentions of the appellants. Rule 3 of the Maharashtra Prevention of Food Adulteration Rules, 1962 and the corresponding rule in the Goa, Daman & Diu Prevention of Food Adulteration Rules, 1982 suggest that the power given to the Food (Health) Authority is only a pro tem power to deal with an emergent situation, such as outbreak of any infectious disease, which may be due to any article of food. In such a contingency, the Food (Health) Authority is empowered to take all such action as it deemed necessary to ascertain the cause of such infectious disease and to prevent the outbreak of such disease or the spread thereof. Certainly, such power would include the power to ban "for the time being" the sale of such injurious articles of food. Hence, correspondingly Section 7(iv) of the Act provides that no person shall manufacture for sale, or store, sell or distribute "any article of food the sale of which is for the time being prohibited by the Food (Health) Authority in the interest of public health." In other words, when a contingency envisaged by Rule 3, or one similar thereto, arises and it becomes necessary for the Food (Health) Authority to take immediate steps, the Food (Health) Authority is empowered to prohibit "for the time being" the concerned injurious article and to take any appropriate step "in the interest of public health".

**25.** On the collocation of the statutory provisions, we are unable to accept the contention of the learned counsel for the States that Clause (f) of Section 7 of the Act is an independent source of power. This conclusion of ours is also supported by the legislative history. Prior to the amendment by Act 49 of 1964, with effect from 1.3.1965, Clause (iv) of Section 7 read as under:

"Any article of food the sale of which is for the time being prohibited by the

Food (Health) Authority with a view to preventing the outbreak or spread of infectious diseases."

**26.** Learned counsel for the State Governments contend that as a result of the amendment and the substitution of the words "in the interest of public health" for the words "with a view to preventing the outbreak or spread of infectious diseases", the legislature has expanded the power of Food (Health) Authority so that it can act to prohibit the sale of any article, the only limitation being that the power exercised is "in the interest of public health". It is not possible for us to accept this submission. It is, undoubtedly, true that the intention of Parliament in bringing forth the amendment to Clause (iv) of Section 7 was to expand the area of operation of the said clause. As originally intended, it was to operate only in the event of a contingency aimed at preventing the outbreak or spread of infectious diseases. This certainly was restricted. There could be several situations in which there may not be any apprehension of outbreak or spread of infectious diseases and yet it may become necessary for the Food (Health) Authority to act by taking appropriate steps to control a situation which has arisen. It is with this view that the prohibition in Clause (iv) of Section 7 of the Act was expanded to apply to such contingencies also.

**27.** It is unfortunate that despite the amendment made in Clause (iv) of Section 7 of the Act, (by Act 49 of 1964) the rules have not been correspondingly updated. Going strictly by the state rules, which actually determine the extent of the power of the Food (Health) Authority, it appears to us that the arguments of the State Governments that this amendment was intended to give a *carte blanche* to the Food (Health) Authority cannot be accepted. On the contrary, the construction canvassed by the appellants appears to be more reasonable. We are inclined to the view that the power of the state authority, which is discernible under Section 24(2)(a) read with the state rules, operates only for a temporary period during which an emergent situation exists which needs to be controlled. It is not possible to accept the State Governments' contention that Clause (iv) of Section 7 of the Act is an independent provision which clothes the Food (Health) Authority with the power to issue an order of ban for a long period.

**28.** Mr. Lalit, learned counsel for the state of Maharashtra, took us through the affidavit filed by the state Government and the voluminous data presented therein by the state to indicate that gutka and pan masala are addictive and, in the long run, deleterious to human health. He also referred to certain scientific reports on the subject by the National Toxicology center, an International Agency for Research on Cancer, part of the World Health Organisation, and so on. In our view, it is not necessary to make any pronouncement thereupon. Even if we accept that the scientific data supports the view that chewing of pan masala with or without tobacco is injurious to health, the question which remains to be answered is whether the Food (Health) Authority in the state has the power of prohibiting the manufacture for sale, or storage, sale or distribution of any article assuming it to be injurious to health. A contrast of the powers of the Central Government with those of the state Government with particular reference to the power of the Central Government to make rules to prohibit the manufacture, sale and distribution of such articles which are injurious to health when used as food, enumerated in Clause (f) of Sub-section (1A) of Section 23 of the Act, leads us to believe that even assuming that, gutka and tobacco products are injurious to health, the power of their prohibition is only vested with the Central Government and not with the state Food (Health) Authorities. The State (Food) Health authorities have only a limited power of issuing an order of prohibition for a short term while they investigate local problems and take appropriate measures

to control the situation. Beyond that the state authorities have no power as urged by the learned counsel for the state Governments and as accepted in the impugned judgment of the Bombay High Court.

**29.** It is an accepted canon of Construction of Statutes that a statute must be read as a whole and one provision of the Act should be construed with reference to other provisions of the same act so as to make a consistent harmonious enactment of the whole statute. The court must ascertain the intention of the legislature by directing its attention not merely to the clauses to be construed, but to the scheme of the entire statute. The attempt must be to eliminate conflict and to harmonise the different parts of the statute for it cannot be assumed that Parliament had given by one hand what it took away by the other. [See in this connection **Commissioner of Income Tax v. Hindustan Bulk Carriers**, MANU/SC/1215/2002 : (2003)179CTR(SC)362 and **C.I.T. Central, Calcutta v. National Taj Traders**, MANU/SC/0310/1979 : (1980) 2 SCR 277 This Court in **O.P. Singla and Anr. v. Union of India and Ors.**, MANU/SC/0350/1984 : (1985)IILLJ309SC (*vide* para 17), said: "However, it is well recognised that, when a rule or a section is a part of an integral scheme, it should not be considered or construed in isolation. One must have regard to the scheme of the fasciculus of the relevant rules or sections in order to determine the true meaning of any one or more of them. An isolated consideration of a provision leads to the risk of some other interrelated provision becoming otiose or devoid of meaning."

**30.** Against the background of these principles, it is not possible to agree with the view taken by the High Court that Section 7(iv) of the Act, is an independent source of power of such amplitude as held. In our view, the power of the state under Section 7(iv) of the Act is statutory; absolute to the extent provided therein, and limited to the extent indicated by Section 23(1A) of the Act.

**31.** Learned counsel for the appellants urged that the expression "for the time being" used in Clause (iv) of Section 7 of the Act is significant and indicates the transient nature of the power that is conferred on the Food (Health) Authority under the rules to ban or otherwise take any other appropriate action in relation to an article of food even if it be "in the interest of public health". This too lends support to their contention. Learned counsel for the state of Maharashtra and the learned Advocate General for the state of Goa relied on the judgments of this Court in **Pukhraj Jain v. Padma Kashyap and Anr.**, MANU/SC/0208/1990 : [1990]2SCR25 and **Jivendra Nath Kaul v. Collector/District Magistrate and Anr.**, MANU/SC/0519/1992 : [1992]3SCR642 to contend that the expression "for the time being" would suggest the time period for which the order is in force and not necessarily the transient nature of the order. Even if this be correct the fact still remains that the state authority has no power to make an order of prohibition, either of a permanent nature or enduring for such long time as to be deemed to be permanent.

**Contemporanea expositio:**

**32.** The appellants point out that despite the amendment having been made in the year 1964, even the state of Maharashtra kept on corresponding with the Central Government to suggest that it was necessary to carry out an amendment in the law to enable it to permanently ban the article concerned. Reliance is placed on pp. 152 - 154, Vol. II of S.L.P No. 834 of 2003, the annexure to the counter affidavit filed by F.K. Pandey on behalf of the Government of India. Particular reference is made to the letter dated 1<sup>st</sup> August, 1997 from the Commissioner, Food and Drug Administration and Food (Health) Authority to the Secretary, Medical Education and Drug

Department, Mumbai about the ill-effects of gutka and requesting the state Government to amend the Maharashtra Prevention of Food Adulteration Rules and also to make a request to the Central Government to amend the Prevention of Food Adulteration Act so as to enable the state of Maharashtra to exercise the powers of a permanent ban. While this may not be really conclusive, it certainly indicates the manner of the state authority viewing its power and the rules under which it was exercising the power. The court can certainly take into account this situation on the doctrine of *Contemporanea expositio*.

**33.** It is significant that, while dealing with the powers of food inspector under Section 10(1)(c) of the Act, the Act provides that a food inspector shall have power, with the previous approval of the Local (Health) Authority having jurisdiction in the local area concerned, or with the previous approval of the Food (Health) Authority, to prohibit the sale of any article of food in the interest of public health. Secondly, this clause does not include the phrase "for the time being". If the arguments of the learned counsel for the state Governments were to prevail, then this provision would give to the food inspector, a lower authority in the hierarchy, an extraordinary power of banning permanently - which power can only be the result of a policy decision to be taken at the highest level of the state Government. In our view, it is not possible to interpret these clauses disparately or disjunctively. Clause (iv) of Section 7 and Clause (c) of Sub-section (1) of Section 10 of the Act and their interplay unmistakably suggest that the power conferred on the Food (Health) Authority and the food inspector, being derived from the Rules made in exercise of the powers exercised under Section 24 of the Act are necessarily subservient to the powers derivable from the rules made under Section 23 of the Act. Hence, neither the Food (Health) Authority, nor the food inspector can be said to have such power which could be available to the Central Government by prescription of a rule in exercise of power under Section 23(1A)(f).

**34.** Reliance was placed by the respondents on the decision of a learned Single Judge in **Gandhi Irwin Salt Manufacturers Association v. The Government of Tamil Nadu**, MANU/TN/0020/1996 : AIR1996Mad109 . Having perused the judgment we are unable to approve of it. We notice that neither the interplay between Sections. 23 and 24, nor the question as to whether Section 24 can be the source of power, is discussed or decided therein.

#### **Conflict with Central Act 34 of 2003:**

**35.** Mr. Nariman, learned counsel appeared for the appellants in the appeals arising out of SLP Nos. 23635 of 2002 and 533 of 2003, attacked the judgment of the Bombay High Court from a different perspective. He contends that the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003, (Act 34 of 2003), referable to entry 52, List I and entry 18, List III to the Seventh Schedule of the Constitution of India, now occupies the entire field in relation to tobacco. The preamble to the Act 34 of 2003 reads as under:

"An Act to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarettes and other tobacco products and for matters connected therewith or incidental thereto"

**36.** The Statement of Objects and Reasons accompanying the Bill reads as under:



"1. Tobacco is universally regarded as one of the major public health hazards and is responsible directly or indirectly for an estimated eight lakh deaths annually in the country. It has also been found that treatment of tobacco related diseases and the loss of productivity caused therein cost the country almost Rs. 13,500/- crore annually, which more than offsets all the benefits accruing in the form of revenue and employment generated by tobacco industry. The need for a comprehensive legislation to prohibit advertising and regulation of production, supply and distribution of cigarettes and tobacco products was recommended by the Parliamentary Committee on Subordinate Legislation (Tenth Lok Sabha) and a number of points suggested by the Committee on Subordinate Legislation have been incorporated in the Bill.

2. The proposed Bill seeks to put total ban on advertising of cigarettes and other tobacco products and to prohibit sponsorship of sports and cultural events either directly or indirectly as well as sale of tobacco products to minors. It also proposes to make rules for the purpose of prescribing the contents of the specified warnings, the languages in which they are to be displayed, as well as displaying the quantities of nicotine and tar contents of these products. For the effective implementation of the proposed legislation, provisions have been proposed for compounding minor offences and making punishments for offences by companies more stringent. The objective of the proposed enactment is to reduce the exposure of people to tobacco smoke (passive smoking) and to prevent the sale of tobacco products to minors and to protect them from becoming victims of misleading advertisements. This will result in a healthier life style and the protection of the right to life enshrined in the Constitution. The proposed legislation further seeks to implement article 47 of the Constitution which, inter alia, requires the State to endeavour to improve public health of the people.

3. The Bill seeks to achieve the aforesaid objects."

37. The aforesaid internal evidence in the statute, by reason of the preamble, and the external evidence in the Statement of Objects and Reasons, indicate that Parliament has evinced its intention to bring out a comprehensive enactment to deal with tobacco and tobacco products. However, the provisions of the statute do not suggest that Parliament had considered it to be expedient to ban tobacco or tobacco products in public interest or to protect public health. Act 34 of 2003 passed by Parliament does not totally ban the manufacture of tobacco or tobacco products. Section 6 merely prohibits sale of cigarettes and tobacco products to a person under the age of eighteen years. There are stringent provisions made in the Act containing the prohibition of advertisement of cigarettes and tobacco products. Section 3(p) defines the expression "tobacco products" as the products specified in the Schedule. Entry 8 of the Schedule to the Act reads "pan masala or any chewing material having tobacco as one of its ingredients (by whatever name called)." Thus, pan masala or any chewing material having tobacco is also one of the products in respect of which the Act could have imposed a total prohibition, if Parliament was so minded. On the other hand, there is only conditional prohibition of these products against sale to persons under eighteen years of age.

38. Against this backdrop of Act 34 of 2003, learned counsel contended that inasmuch as Act 34 of 2003 occupies the whole field of tobacco and tobacco products and does not completely ban the sale of 'tobacco products' except to under aged

persons, while the impugned notification expressly bans manufacture or sale to any person of the very same product (viz. Pan masala and gutka), there is legislative repugnancy which calls for resolution. Reliance was placed on the judgment of this Court in **Deep Chand v. The State of U.P. and Ors.** MANU/SC/0023/1959 : (1959) (2) Supp. SCR wherein this Court considered the constitutional validity of a state enactment. This Court's earlier judgment in **Ch. Tika Ramji and Ors. v. The State of U.P. and Ors.**, MANU/SC/0008/1956 and **Zaverbhai Amaldas v. The State of Bombay**, MANU/SC/0040/1954 : [1955]1SCR799 , were approved and the test of repugnancy was formulated thus:

"Repugnancy between two statutes may thus be ascertained on the basis of the following three principles

- (1) Whether there is direct conflict between the two provisions;
- (2) Whether Parliament intended to lay down an exhaustive code in respect of the subject matter replacing the Act of the State Legislature; and
- (3) Whether the law made by Parliament and the law made by the State Legislature occupy the same field."

**39.** Learned counsel contended that when two legislations referable to the same legislative authority are inconsistent with each other, then the later enactment is deemed to have impliedly repealed the previous one and referred to the observations of this Court in **State of Orissa v. M.A. Tulloch and Co.**, MANU/SC/0021/1963 : [1964]4SCR461 :

"The entire theory underlying implied repeals is that there is no need for the later enactment to state in express terms that an earlier enactment has been repealed by using any particular set of words or form of drafting but that if the legislative intent to supersede the earlier law is manifested by the enactment of the provisions as to effect such supersession, then there is in law a repeal notwithstanding, the absence of the word 'repeal' in the later statute. Now, if the legislative intent to supersede the earlier law is the basis upon which the doctrine of implied repeal is founded could there be any incongruity in attributing to the later legislation the same intent which Section 6 presumes where the word 'repeal' is expressly used. So far as statutory construction is concerned, it is one of the cardinal principles of the law that there is no distinction or difference between an express provision and a provision which is necessarily implied, for it is only the form that differs in the two cases and there is no difference in intention or in substance."

**40.** The learned counsel relied on **Vijay Kumar Sharma and Ors. v. State of Karnataka and Ors.**, MANU/SC/0368/1990 : [1990]1SCR614 . The observation of this Court in the majority judgment of this Court is that if the later legislation is on the same subject and the legislative intent is to occupy the whole field, then the later legislation prevails.

**41.** It is submitted that a reading of the Act 34 of 2003 clearly suggests that it is a special law intended to deal with tobacco and its product. The Prevention of Food Adulteration Act, 1954 is a general law dealing with adulteration of food articles and a tobacco product is incidentally referred to in the said law in the context of prevention of adulteration. In case of conflict between a special law and a general

law, even if both are enacted by the same legislative authority, the special law must displace the general law to the extent of inconsistency. The operation of the maxim *generalia specialibus non derogant* has been approved and applied by this Court in such situations. (See in this connection: **U.P. State Electricity Board and Ors. v. Hari Shanker Jain and Ors.** MANU/SC/0500/1978 : (1979) 1 SCR 355 **Gujarat State Cooperative Land Development Bank Ltd. v. P.R. Manded and Ors.**, MANU/SC/0508/1979 : [1979]2SCR1023 **The LIC of India v. D.J. Bahadur and Ors.**, MANU/SC/0305/1980 : (1981)ILLJ1SC **Jain Ink Manufacturing Co. v. LIC of India and Anr.**, MANU/SC/0478/1980 : [1981]1SCR498 , **Prof. Sumer Chand v. Union of India and Ors.**, MANU/SC/0561/1994 : 1993CriLJ3531 and **Allahabad Bank v. Canara Bank and Anr.**, MANU/SC/0262/2000 : [2000]2SCR1102 ).

42. Respondents contend that inasmuch as Act 34 of 2003, though passed by Parliament, and assented to by the President is not brought into force by the Central Government by notification, the question of conflict with the provisions of the Act does not arise. We need not consider this contention since Act 34 of 2003 has now been brought into force w.e.f. 1<sup>st</sup> May, 2004. In any event, as pointed out in **Pt. Rishikesh and Anr. v. Salma Begum**, MANU/SC/0743/1995 : [1995]3SCR1062 , there is distinction between "making law" and "commencement of the operation of an Act" and a situation of conflict can arise even when a law has been made and not brought into force.

#### **Articles 14 and 19 of the Constitution of India:**

43. Mr. Shanti Bhushan, learned counsel for the appellant in SLP No. 2186 of 2003. urged that the said appellant manufactures Rajnigandha pan masala which contains no tobacco. Though there might be arecanut in it, there is no trace of magnesium carbonate in the product. Assuming that traces of magnesium carbonate were to be formed during consumption of the product, along with lime, the exercise of power should have been restricted to banning pan masala containing magnesium carbonate and not wholesale banning of pan masala, irrespective of the content of magnesium carbonate. The learned counsel contended that the order made under Section 7(iv) of the Act is bad for it is an unreasonable and excessive restriction on the Fundamental Right to carry on trade or business guaranteed under Article 19(1)(g) of the Constitution of India. The learned counsel highlighted the unreasonableness by reference to the provisions of the Act and the Rules and the specific situation contemplated in Appendix B at Paragraph A.25.02.01, which gives the definition and standards of quality with reference to chewing gum and bubble gum, for which magnesium carbonate, *inter alia*, is a permitted ingredient. He therefore contends that magnesium carbonate is not per se injurious to health for otherwise it would never have been permitted in any article of food. There is no material on the basis of which it can be demonstrated that the very same magnesium carbonate would become injurious to health if it arises on account of mixing of traces of magnesium in arecanut and carbonate in lime According to the learned counsel, this is a clear case of non-application of mind, notwithstanding the medical research papers and data made available in the affidavit filed by the state Government.

44. We are unable to discern as to how the very same magnesium carbonate would become injurious as a result of combined chewing of arecanut and lime, particularly when it is not the case of the state Government that Rajnigandha pan masala itself contains magnesium carbonate. It is permissible under Article 19(6) to impose a reasonable restriction "in the interest of general public". Assuming that such a restriction can be imposed, even if by legislation intended to prohibit manufacture,

sale or storage of articles harmful or injurious to health, the restriction has to be commensurate with the danger posed. On a conspectus of the facts, we are unable to uphold the prohibition imposed by the impugned notification as a restriction which can pass the test of reasonableness under Article 19(6) of the Constitution of India for two reasons. First, there is no demonstrated danger to the public health by magnesium carbonate by consumption of Rajnigandha pan masala; secondly, even if there were, the prohibition could only have extended to pan masala containing magnesium carbonate and could not be wider than that.

**45.** Learned counsel for the appellants urge that if Section 7(iv) is construed in the manner as contended by the State, then it would become unconstitutional. It is contended that if Section 7(iv) is construed as giving the authority to ban articles of food, even though not adulterated, then the sweep of the section would go out of entry 18 of List III of the Constitution of India, ("adulteration of foodstuffs and other goods.") and intrude into the domain of entry 6 of List II ("public health and sanitation; hospitals and dispensaries") which is the exclusive domain of the state Government. If the court were to read Section 7(iv) in the manner suggested by the States, then it would be *ultra vires* the legislative competence of Parliament. It is the duty of the court to attempt to read every legislation in such manner as to uphold its constitutional validity. The learned counsel contend that in order to uphold the legislative competence of the provisions of the Act, the sweep of Section 7(iv) must be confined to the domain of 'adulteration of food stuffs and other articles' without entering into the domain of "public health". Reading down the statute in order to uphold its constitutional validity is a device well known to the constitutional courts. [See in this connection **State of Karnataka and Anr. v. Shri Ranganatha Reddy and Anr.**, MANU/SC/0062/1977 : [1978]1SCR641 **B.R. Enterprises and Ors. v. State of U.P. and Ors.**, MANU/SC/0330/1999 : (1999)9SCC700 and **State of A.P. v. National Thermal Power Corporation Ltd. and Ors.**, MANU/SC/0356/2002 : [2002]3SCR278 ].

**46.** Mr. Lalit learned counsel for the States, however, supported the findings of the division bench of the Bombay High Court that the constitutional validity of Section 7(iv) was never in danger as it could be supported on the doctrine of pith and substance. He contends that in *pith and substance* the Prevention of Food Adulteration Act, 1954 deals with the subject of adulteration, though, incidentally, by reason of Section 7(iv) it may make an incursion into the domain of "public health" which is the exclusive province of the State legislature. This contention appears to have been accepted by the impugned judgment of the High Court of Bombay. In fact, the High Court goes to the extent of saying that the power of the Food (Health) Authority under Section 7(iv) is much wider than the power of the Central Government under the Rules made under Section 23(1A)(f) on the reasoning that while the power of the Central Government under a rule made under Section 23(1A)(f) extends to the prohibition of the sale of "any substance which may be injurious to health when used as food or as an ingredient in the manufacture of any article of food" there is no such restriction under Section 7(iv) which is posited as an independent source of power. It is urged that by exercise of the power invested in the Food (Health) Authority under Clause (iv) of Section 7, any article, irrespective of whether it is used as food or as an ingredient in the manufacture of any article of food, may be prohibited as long as the prohibition is "in the interest of public health".

**47.** We find it difficult to agree with the submissions of Mr. Lalit. That all provisions of a statute have to be read harmoniously and any interpretation as to be ex

*visceribus actus*, is a trite doctrine of construction of statutes. Undoubtedly, if Section 7(iv) is read in isolation, it gives the impression that this is an independent source of power, not subject to any limitation other than the guideline "in the interest of public health". But, when the scheme of the Prevention of Food Adulteration Act is analysed in the light of its preamble and the Statement of Objects and Reasons, it becomes clear that there is no independent source of power under Section 7(iv). Had it been so, there was no need for the rule making power of the State Government under Section 24(2)(a) to define the powers and duties of the Food (Health) Authority or local authority and Local (Health) Authority under the Act. The interplay of Sections 23(1A)(f) and 24(2)(a) read with the existing rules in the different states, even after the amendment of Section 7(iv) by the Act 49 of 1964, leads us to conclude that the contention of the states in this regard cannot be accepted.

**48.** Learned counsel for the appellants contend that the impugned notification is violative of the fundamental rights guaranteed under Article 19(1)(g) as it is excessively restrictive in nature. While the notification seeks to ban pan masala which does not include tobacco, it does not at the same time ban tobacco in any form. The literature produced by the State of Maharashtra before the High Court suggested, undoubtedly, that consumption of tobacco in any form was injurious to health, but that consumption of pan masala was likely to be addictive and lead to hypermagnesia. Strangely, the States did not ban chewing tobacco or other tobacco products which contain almost cent per cent tobacco, but they banned the sale of gutka which contains only about 6 per cent of tobacco and pan masala, which contains no tobacco whatsoever, even accepting on the correctness of the material presented. Further, the literature produced by the States indicates that pan masala is addictive amongst children and, therefore, likely to be injurious to their health in the long run. Assuming this to be true, the restriction could only have been on sale to under-aged persons and not by way of a total ban. Thus, in our view, the impugned notification is violative of the fundamental right of the appellants - guaranteed under Article 19(1)(g), both because it is unreasonable and also because it is excessive in nature. A contrast with the provisions of the Act 34 of 2003 in this regard would drive home the point.

**49.** While dealing with the nature of a reasonable restriction on the fundamental rights under Article 19(1)(g), this Court observed in **Mohd. Faruk v. State of Madhya Pradesh and Ors.**, MANU/SC/0046/1969 : [1970]1SCR156 as under:

"The impugned notification, though technically within the competence of the State Government, directly infringes the fundamental right of the petitioner guaranteed by Article 19(1)(g), and may be upheld only if it be established that it seeks to impose reasonable restrictions in the interest of the general public and a less drastic restriction will not ensure the interest of the general public. The Court must in considering the validity of the impugned law imposing a prohibition on the carrying on of a business or profession, attempt an evaluation of its direct and immediate impact upon the fundamental rights of the citizens affected thereby and the larger public interest sought to be ensured in the light of the object sought to be achieved, the necessity to restrict the citizen's freedom, the inherent pernicious nature of the act prohibited or its capacity or tendency to be harmful to the general public, the possibility of achieving the object by imposing a less drastic restraint, and in the absence of exceptional situations such as the prevalence of a: state of emergency - national or local - or the necessity to maintain essential supplies, or the necessity to stop activities inherently dangerous,

the existence of a machinery to satisfy the administrative authority that no case for imposing the restriction is made out or that a less drastic restriction may ensure the object intended to be achieved."

50. The impugned notification fails on this test of reasonable restriction.

**Res extra commercial:**

51. Appellants next contend that the assumption of the High Court that pan masala or gutka is *res extra commercial* is wholly incorrect.

52. The concept of *res extra commercial* was expounded in the Constitutional Bench of this Court in **Khoday Distilleries Ltd. and Ors. v. State of Karnataka and Ors.**, MANU/SC/0572/1995 : (1995)1SCC574 thus:

"58. We also do not see any merit in the argument that there are more harmful substances like tobacco, the consumption of which is not prohibited and hence there is no justification for prohibiting the business in potable alcohol. What articles and goods should be allowed to be produced, possessed, sold and consumed is to be left to the judgment of the legislative and the executive wisdom. Things which are not considered harmful today, may be considered so tomorrow in the light of the fresh medical evidence. It requires research and education to convince the society of the harmful effects of the products before a consensus is reached to ban its consumption. Alcohol has since long been known all over the world to have had harmful effects on the health of the individual and the welfare of the society. Even long before the Constitution was framed, it was one of the major items on the agenda of the society to ban or at least to regulate, its consumption. That is why it found place in Article 47 of the Constitution. It is only in recent years that medical research has brought to the fore the fatal link between smoking and consumption of tobacco and cancer, cardiac diseases and deterioration and tuberculosis. There is a sizeable movement all over the world including in this country to educate people about the dangerous effect of tobacco on individual's health. The society may, in course of time, think of prohibiting its production and consumption as in the case of alcohol. There may be more such dangerous products, the harmful effects of which are today unknown. But merely because their production and consumption is not today banned, does not mean that products like alcohol which are proved harmful, should not be banned.

...

60(b) The right to practise any profession or to carry on any occupation, trade or business does not extend to practising a profession or carrying on an occupation, trade or business which is inherently vicious and pernicious, and is condemned by all civilised societies. It does not entitle citizens to carry on trade or business in activities which are immoral and criminal and in articles or goods which are obnoxious and injurious to health, safety and welfare of the general public, i.e., *res extra commercial*, (outside commerce). There cannot be business in crime."

53. Is the consumption of pan masala or gutka (containing tobacco), or for that matter tobacco itself considered so inherently or viciously dangerous to health, and, if so, is there any legislative policy to totally ban its use in the country? In the face

of Act 34 of 2003, the answer must be in the negative. It is difficult to accept the contention that the substance banned by the impugned notification is treated as *res extra commercial*. In the first place, the gamut of legislation enacted in this country which deals with tobacco does not suggest that Parliament has ever treated it as an article *res extra commercial*, nor has Parliament attempted to ban its use absolutely. The Industries (Development and Regulations) Act, 1951 merely imposed licensing regulation on tobacco products under item 38(1) of the First Schedule. The Central Sales Tax Act 1956 in Section 14(ix) prescribes the rates for Central Sales Tax. Additional Duties of Excise (Goods of Special Importance) Act, 1957 prescribes the additional duty leviable on tobacco products. The Tobacco Board Act, 1975 established a Tobacco Board for development of tobacco industries in the country. Even the latest Act, i.e. the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003, does not ban the sale of tobacco products listed in the Schedule except to minors. Further, we find that in the tariff schedule of the Central Sales Tax Act there are several entries which deal with tobacco and also pan masala. In the face of these legislative measures seeking to levy restrictions and control the manufacture and sale of tobacco and its allied products as well as pan masala, it is not possible to accept that the article itself has been treated as *res extra commercial*. The legislative policy, if any, seems to be to the contrary. In any event, whether an article is to be prohibited as *res extra commercial* is a matter of legislative policy and must arise out of an Act of legislature and not by a mere notification issued by an executive authority.

**Need to read down:**

**54.** There is also merit in the contention of the appellants that if the provisions of Section 7(iv) of the Act are not read down as conferring powers on the authority to deal with an emergent situation, the section would be conferring arbitrary powers on the authority and would be procedurally unfair. This is particularly so in the face of the statutory provision under which licences have already been granted to the manufactures of pan masala and gutka for manufacture of the articles. There is already a provision in the statutory scheme for cancellation and suspension of a licence. Without going through such procedure the power (sic) in the state authority to suddenly bring out the result of cancellation or suspension of the licence, without procedural safeguards, would certainly be arbitrary and liable to be hit by Article 14 of the Constitution of India. For this reason also, the power under Section 7(iv) needs to be read down as conferring powers on the authority only to deal with an emergent situation.

**55.** There has been some argument at the Bar as to whether the impugned notification is the result of an executive act or a legislative act. We have already indicated that, in our view, Section 7(iv) is not an independent source of power. The notification can only be issued by the authority the source of whose power must be located elsewhere. Section 7(iv) merely indicates the consequences which would flow if a valid notification is issued. It is, therefore, not necessary for us to go into the niceties between an executive and a legislative act.

**56.** Mr. Anil Divan, learned counsel appearing for one of the appellants, pointed out that the Central Sales Tax Act by Section 14(ix) recognises gutka as a legitimate article of interstate trade or interstate sale. So is pan masala recognised as such a legitimate article of interstate sale. The learned counsel relied on **Dwarka Prasad Laxmi Narain v. The State of U.P. and Ors.**, MANU/SC/0030/1954 :

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[1954]1SCR803 to contend that a law or order which confers arbitrary or uncontrolled power on the executive in the matter of regulating trade or commerce in normally available commodities must be held to be unreasonable. [See also in this connection the observations of this Court in **B.B. Rajwansi v. State of U.P. and Ors.**, MANU/SC/0036/1988 : (1988)ILLJ238SC ].

57. Learned counsel highlighted the observations of this Court in **Maneka Gandhi v. Union of India**, MANU/SC/0133/1978 : [1978]2SCR621 and contended that irrespective of whether the power to issue the impugned notification is a legislative power or an executive power, it must pass the test of fairness in procedure. Any provision of law which enables to an authority by a notification to bring to standstill a business, which is otherwise permitted by law, must be held to be arbitrary; unfair and an abridgment of the fundamental rights guaranteed under Article 14 of the Constitution. [See also in this connection **Kanti Lal Babulal v. H.C. Patel**, MANU/SC/0308/1967 : [1968]1SCR735, **Ajay Hasia and Ors. v. Khalid Mujib Sehravardi and Ors.**, MANU/SC/0498/1980 : (1981)ILLJ103SC and **Delhi Transport Corporation v. D.T.C. Mazdoor Congress and Ors.**, MANU/SC/0031/1991 : (1991)ILLJ395SC

58. It is in the light of these authorities that we are required to adjudge the constitutionality of the interpretation put on Section 7(iv).

59. Learned counsel for the States, however, urge that the impugned notification is a legislative act and not an administrative act. Thus, according to them, there is no question of giving a hearing before taking a policy decision to ban the manufacture for sale, storage, sale and distribution of pan masala and gutka.

60. We are unable to accept the contention of the States. In our view, the scheme of the Act suggests that a decision to ban an article injurious to health, when used as food or as an ingredient in the manufacture of any article of food, can only be the result of broader policy. Hence, this larger power appears to have been located only in the Central Government under Section 23(1A)(f) and not in the state Food (Health) Authority. As we have already pointed out, the power of the state Food (Health) Authority is only transitory in nature and designed to deal with local emergencies. In our considered view, the impugned notification is certainly an administrative act and not a legislative act. Inasmuch as by an executive act the manufacture for sale, storage, sale or distribution of the concerned article has been banned so as to interfere with the fundamental rights of the appellants guaranteed under Articles 14 and 19 of the Constitution of India, the impugned notification is illegal and unconstitutional.

61. We are unable to accept that the words "in the interest of public health" used in Clause (iv) of Section 7 of the Act can operate as an incantation or mantra to get over all the constitutional difficulties posited. In any event, the collocation of the words in the statutory scheme suggests not a matter of policy, but a matter of implementation of policy. For this reason also, we are of the view that the impugned notification must fail.

62. The learned Advocate General for the State of Goa contended that in the State of Goa, apart from the impugned notification dated 24<sup>th</sup> January, 2003, there is a subsequent notification dated 7<sup>th</sup> April, 2003 which is not impugned by the appellants. Reliance is placed on a judgment of the division bench of the Bombay High Court in **Vaman Raghunath Fallary & Sons and Ors. v. State of Goa and**



**Ors.**, W.P. No. 131 of 2003 decided on 3.6.2003 per Rebello and Hardas, JJ. The division bench in the said decision seems to have been overwhelmed by the material produced with regard to the hazardous nature of pan masala with tobacco and taken the view that the State Government was justified in taking a decision to ban tobacco products within the realm of such policy decision. The division bench has not addressed itself to any of the sections of the Act which decide the powers. The learned Advocate General for the State of Goa contends that matters of public health are essentially matters of policy decision, legislative or administrative, planned and executed in the greater interest of public health by the Government and the court should not interfere with such policy matters. He relied on the observations of **P.N. Krishna Lal and Ors. v. Govt. of Kerala and Anr.**, MANU/SC/1007/1995 : 1994(5)SCALE1 wherein this Court said:

"24. The *raison d'etre* of the State being the welfare of the members of the society, the whole purpose of the creation of the State would be to maintain order, health and morality by suitable legislation and proper administration. The State has the power to prohibit trade or business which are illegal, immoral or injurious to the health and welfare of the people. No one has the right to carry on any trade or occupation or business which is inherently vicious and pernicious and is condemned by all civilized societies. Equally no one could claim entitlement to carry on any trade or business or any activities which are criminal and immoral or in any articles of goods which are obnoxious and injurious to the safety and health of general public. There is no inherent right in crime. Prohibition of trade of business of noxious or dangerous substances or goods by law is in the interest of society welfare."

**63.** There is a plethora of legislation dealing with tobacco products, gutka and pan masala and the fact that licences have been issued to the appellants to manufacture the concerned articles, which does not lead to the conclusion that the trade or business in the concerned articles is an activity which is "criminal in propensity, immoral, obnoxious, injurious to the health of general public" or that the ban is a result of 'public expediency and public morality'.

#### **Is it food?**

**64.** Mr. Nagaraja, learned counsel appearing for the petitioners in writ petition No. 173 of 2003, raised a further contention that pan masala or gutka which is the subject matter of the impugned notification does not amount to food within the meaning of its definition in Section 2(v) of the Act. Section 2(v) of the Act reads as under:

"2. (v) "food" means any article used as food or drink for human consumption other than drugs and water and includes-

(a) any article which ordinarily enters into, or is used in the composition or preparation of, human food,

(b) any flavouring matter or condiments, and

(c) any other article which the Central Government may, having regard to its use, nature, substance or quality, declare, by notification in the Official Gazette, as food for the purposes of this Act."

**65.** In his submission, the expression "food" as defined in the Lexicon could only be

"a substance taken into the body to maintain life and growth". No one in his right mind would consider that pan masala or gutka would be consumed for maintenance and development of health of human being. In **P.K. Tejani v. M.R Dange**, MANU/SC/0146/1973 :1974CriLJ313 , a case arising under the Prevention of Food Adulteration Act, 1954 this Court held that the word "food" is a very general terras and applies to all that is eaten by men for nourishment and takes in also subsidiaries. Since pan masala, gutka or supari are eaten for taste and nourishment, they are all food within the meaning of Section 2(v) of the Act

**66.** The learned counsel relied on a judgment of a division bench of this Court in C.A. No. 12746-12747 of 1996 (decided on 6<sup>th</sup> November, 2003). In our view, this judgment is of no aid to us. In the first place, this judgment arises under the provisions of the Essential Commodities Act 1955, read with the Tamil Nadu Scheduled Articles (Prescription of Standards) Order, 1977 and the notification dated 9<sup>th</sup> June, 1978, issued by the Central Government which laid down certain specifications "in relation to foodstuffs". The question that arose before the Court was whether tea is 'foodstuff' within the meaning of the said legislation. The division bench of this Court came to the conclusion that 'tea' is not food as it is not understood as 'food' or 'foodstuff' either in common parlance or by the opinion of lexicographers. We are unable to derive much help from this judgment for the reason that we are not concerned with tea. It is not possible to extrapolate the reasoning of this judgment pertaining to tea into the realm of pan masala and gutka. In any event, the judgment in Tejani (supra) was a judgment of the Constitutional Bench which does not seem to have been noticed.

**67.** We are, therefore, unable to agree with the contention that pan masala or gutka does not amount to "food" within the meaning of definition in Section 2(v) of the Act. However, we do not rest our decision solely on this issue.

**Paradoxical consequence:**

**68.** There is yet another reason why we are inclined to take the view that Section 7(iv) deals with a situation of emergency with respect to the local area. A decision for banning an article of food or an article containing any ingredient of food injurious to health can only arise as a result of broadly considered policy. If such a power be conceded in favour of a local authority like the Food (Health) Authority, paradoxical results would arise. The same article could be considered injurious to public health in one local area, but not so in another. In our view, the construction of the provision of the statute must not be such as to result in such absurd or paradoxical consequences. Hence, for this reason also, we are of the view that the power of the State (Health) Authority is a limited power to be exercised locally for temporary duration.

**Width of power:**

**69.** The learned counsel for the state of Maharashtra contended that the power of the Food (Health) Authority discernible in Clause (iv) of Section 7 of the Act is an independent power and much wider than the power of the Central Government under Section 23 of the Act. He contended that while the power of the Central Government discernible from Section 23(1A)(f) is restricted only to prohibiting the manufacture or sale of articles of food or ingredients of food, the power of the state Food (Health) Authority is much wider and could extend even to articles which may not amount to food or ingredients of food, or even if they are not injurious to health, as long as the test of "in the interest of public health" is satisfied.

**70.** In our view, this is an argument of desperation. We cannot conceive of such wide ranging power vested in a local authority without there being sufficient guidelines as to the manner of deciding the policy and implementing it and elucidated in the statute itself. We may hasten to point out that even the power of Central Government for making the rules under Section 23 is subject to the condition of consultation with the Central Committee for food standards constituted under Section 23 and placing of the rules before Parliament. If the power of the Food (Health) Authority is such as contended by the learned counsel for the state of Maharashtra, then its power would range sky high without any limitation whatsoever. The authority could ban any article, irrespective of whether it is used as food or otherwise, and irrespective of whether it is injurious to health or otherwise. To take an extreme illustration, if a state Food (Health) Authority in some local area were taken it into its head that consumption of tea, coffee or milk is not 'in the interest of public health', it can issue an order of absolute prohibition irrespective of whether it is injurious to health or not. We do not think that the scheme of the Act warrants such an interpretation.

**71.** A reference of this Court's judgment in **Dineshchandra Jamnadas Gandhi v. State of Gujarat**, MANU/SC/0163/1989 : 1989CriLJ889 , makes it clear that the object and the purpose of the Prevention of Food Adulteration Act 1954 is to eliminate the danger to human life from the sale of unwholesome articles of food. This Court held that the legislation of 'Adulteration of Food Stuffs and other Goods' (entry 18 List III of the Seventh Schedule) is enacted to curb the widespread evil of food adulteration and is a legislative measure for social defence. This court indicated the object of the Prevention of Food Adulteration Act 1954, its constitutional basis and its purpose in the following observations:

"16. The object and the purpose of the Act are to eliminate the danger to human life from the sale of unwholesome articles of food. The legislation is on the topic 'Adulteration of Food Stuffs and other Goods' (entry 18 List III Seventh Schedule). It is enacted to curb the widespread evil of food adulteration and is a legislative measure for social defence. It is intended to suppress a social and economic mischief - an evil which attempts to poison, for monetary gains, the very sources of sustenance of life and the well-being of the community. The evil of adulteration of food and its effects on the health of the community are assuming alarming proportions. The offence of adulteration is a socio-economic offence. In **Municipal Corporation of Delhi v. Kacheroo Mal** MANU/SC/0171/1975 : 1976CriLJ336 , Sarkaria, J said:

The Act has been enacted to curb and remedy the widespread evil of food adulteration, and to ensure the sale of wholesome food to the people. It is well-settled that wherever possible, without unreasonable stretching or straining, *the language of such a statute should be construed in a manner which would suppress the mischief, advance the remedy, promote its object, prevent its subtle evasion and foil its artful circumvention.*

(emphasis supplied)

...

**18.** The offences under the 'Act' are really acts prohibited by the police powers of the State in the interests of public health and well-being. The prohibition is backed by the sanction of a penalty. The offences are strict

statutory offences. Intention or mental state is irrelevant. In **Good fellow v. Johnson**, (1965) 1 AER 941 referring to the nature of offences under the Food and Drugs Act 1955, it was said:

As is well known, Section 2 of the Food and Drugs Act, 1955, constitutes an absolute offence. If a person sells to the prejudice of the purchaser any food, and that includes drink, which is not of the nature or not of the substance or not of the quality demanded by the purchaser he shall be guilty of an offence. The forbidden act is the selling to the prejudice of the purchaser."

These observations make it clear that the purpose of the Act, as its title suggests, is to prevent adulteration of food. Any attempt to travel beyond these parameters must necessarily be looked at askance by the court.

**72.** There is one more facet of the impugned notification which needs consideration. Neither Section 7(iv) of the Act, nor any other provision of the Act or the Rules indicates the manner in which an order of prohibition is to be notified by the Food (Health) Authority. The manner of bringing into force the Rules made by a delegate of legislative authority would be indicated in the Act itself. There is no indication in the Act as to how the order made by the Food (Health) Authority would be brought into force. This is a pointer to the fact that the orders made by the Food (Health) Authority are only transitory and intended to deal with emergent local situations.

#### **Natural Justice:**

**73.** Learned counsel for the State of Maharashtra cited **Union of India and Anr. v. Cynamide India Ltd. and Anr.**, MANU/SC/0076/1987 : [1987]2SCR841 , where this Court observed thus:

"The third observation we wish to make is, price fixation is more in the nature of a legislative activity than any other. It is true that, with the proliferation of delegated legislation, there is a tendency for the line between legislation and administration to vanish into an illusion. Administrative, quasi-judicial decisions tend to merge in legislative activity and, conversely, legislative activity tends to fade into and present an appearance of an administrative or quasi-judicial activity. Any attempt to draw a distinct line between legislative and administrative functions, it has been said, is 'difficult in theory and impossible in practice'. Though difficult, it is necessary that the line must sometimes be drawn as different legal rights and consequences may ensue. The distinction between the two has usually been expressed as 'one between the general and the particular'. 'A legislative act is the creation and promulgation of a general rule of conduct without reference to particular cases; an administrative act is the making and issue of a specific direction or the application of a general rule to a particular case in accordance with the requirements of policy'. 'Legislation is the process of formulating a general rule of conduct without reference to particular cases and usually operating in future ; administration is the process of performing particular acts, of issuing particular orders or of making decisions which apply general rules to particular cases'. It has also been said: 'Rule-making is normally directed toward the formulation of requirements having a general application to all members of a broadly identifiable class' while, 'adjudication, on the other hand, applies to specific individuals or situations'. But, this is only a broad

distinction, not necessarily always true. Administration and administrative adjudication may also be of general application and there may be legislation of particular application only. That is not ruled out. Again, adjudication determines past and present facts and declares rights and liabilities while legislation indicates the future course of action. Adjudication is determinative of the past and the present while legislation is indicative of the future. The object of the rule, the reach of its application, the rights and obligations arising out of it, its intended effect on past, present and future events, its form, the manner of its promulgation are some factors which may help in drawing the line between legislative and non-legislative acts."

**74.** We are, however, unable to accept the contention of the learned counsel for the state of Maharashtra that, because the notification is generally intended, it is necessarily a legislative act and therefore there was no question of complying with principles of natural justice. If that were so, then every executive act could masquerade as a legislative act and escape the procedural mechanism of fair play and natural justice.

**75.** In **State of Tamil Nadu v. K. Sabanayagam and Anr.**, MANU/SC/0836/1998 : AIR1997SC4325 , this Court after referring to the aforesaid observations of Chinnappa Reddy, J. in **Cynamide** (supra), observed that even when exercising a legislative function the delegate may in a given case be required to consider the view point which may be likely to be affected by the exercise of power. This Court pointed out that conditional legislation can be broadly classified into three categories: (1) when the legislature has completed its task of enacting a statute, the entire superstructure of the legislation is ready but its future applicability to a given area is left to the subjective satisfaction of the delegate (as in **Tulsipur Sugar Co. case**, MANU/SC/0336/1980 : [1980]2SCR1111 where the delegate has to decide whether and under what circumstances a legislation which has already come into force is to be partially withdrawn from operation in a given area or in given cases so as not to be applicable to a given class of persons who are otherwise admittedly governed by the Act; (3) where the exercise of conditional legislation would depend upon satisfaction of the delegate on objective facts placed by one class of persons seeking benefit of such an exercise with a view to deprive the rival class of persons who otherwise might have already got statutory benefits under the Act and who are likely to lose the existing benefit because of exercise of such a power by the delegate. This Court emphasised that in the third type of cases the satisfaction of the delegate must necessarily be based on objective considerations and, irrespective of whether the exercise of such power is judicial or quasi-judicial function, still it has to be treated to be one which requires objective consideration of relevant factual data pressed into service by one side, which could be rebutted by the other side, who would be adversely affected if such exercise of power is undertaken by the delegate.

**76.** In our view, even if the impugned notification falls into the last of the above category of cases, whatever the material the Food (Health) Authority had, before taking a decision on articles in question, ought to have been presented to the appellants who are likely to be affected by the ban order. The principle of natural justice requires that they should have been given an opportunity of meeting such facts. This has not been done in the present case. For this reason also, the notification is bad in law.

### **Conclusion:**

**77.** As a result of the discussions, we are of the view that:

**1.** Section 7(iv) of the Act is not an independent source of power for the state authority;

**2.** The source of power of the state Food (Health) Authority is located only in the valid rules made in exercise of the power under Section 24 of the Act by the State Government, to the extent permitted thereunder;

**3.** The power of the Food (Health) Authority under the rules is only of transitory nature and intended to deal with local emergencies and can last only for short period while such emergency lasts;

**4.** The power of banning an article of food or an article used as ingredient of food, on the ground that it is injurious to health, belongs appropriately to the Central Government to be exercised in accordance with the rules made under Section 23 of the Act, particularly, Sub-section (1A)(f).

**5.** The state Food (Health) Authority has no power to prohibit the manufacture for sale, storage, sale or distribution of any article, whether used as an article or adjunct thereto or not used as food. Such a power can only arise as a result of wider policy decision and emanate from Parliamentary legislation or, at least, by exercise of the powers by the Central Government by framing rules under Section 23 of the Act;

**6.** The provisions of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 are directly in conflict with the provisions of Section 7(iv) of the Prevention of Food Adulteration Act 1954. The former Act is a special Act intended to deal with tobacco and tobacco products particularly, while the latter enactment is a general enactment. Thus, the Act 34 of 2003 being a special Act and of later origin, overrides the provisions of Section 7(iv) of the Prevention of Food Adulteration Act, 1954 with regard to the power to prohibit the sale or manufacture of tobacco products which are listed in the Schedule to the Act 34 of 2003;

**7.** The impugned notifications are ultra vires the Act and, hence, bad in law;

**8.** The impugned notifications are unconstitutional and void as abridging the fundamental rights of the appellants guaranteed under Articles 14 and 19 of the Constitution.

**78.** In the result, we allow the appeals and the writ petition and set aside the impugned judgments of the division benches of the Bombay High Court and Andhra Pradesh High Court and quash the notifications impugned as bad in law, void, illegal and unenforceable against the appellants/petitioners.

**79.** No order as to costs.

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No. H.11013/01/2021-TC  
Government of India  
Ministry of Health and Family Welfare  
(Tobacco Control Division)

Nirman Bhawan, New Delhi-110011  
Dated, the 29th December, 2021

ORDER

**Subject:** Constitution of a Committee on examination of impact of banning indigenous chewing tobacco products vis-à-vis the action taken replies on the Sixty Eighth Report of the Committee on Petitions (Sixteenth Lok Sabha) - reg.

The undersigned is directed to say that Committee on Petitions Branch, Lok Sabha Secretariat has been reviewing the issues related to representation on banning indigenous chewing tobacco products and as such had come up with the 66<sup>th</sup> Report of the Committee on Petitions (Sixteenth Lok Sabha) and Action Taken Replies were also submitted by this Ministry to the Hon'ble Committee on Petitions.

2. In this regard, to examine the matter comprehensively, a Committee with the following members is constituted:

- i. Additional Secretary (Health), MoHFW - Chairperson
- ii. Representative from NITI Aayog
- iii. Representative from Ministry of Law and Justice
- iv. Representative from Department of Agriculture & Farmers Welfare
- v. Representative from Food Safety and Standards Authority of India - Convenor
- vi. Representative from Directorate General of Health Services
- vii. Representative from Department of Health Research

CEO - on leave

Head Reg.

dl  
4/11/22

Head (Legal)

The Committee may co-opt any expert/official for deliberation on the issue as may be deemed fit.

3. The Terms of References of the Committee would be:

- i. To identify administrative and legal issues regarding definition of "food" as defined under the Food Safety and Standards (FSS) Act, 2006, keeping in view the various judicial pronouncement regarding chewing tobacco, khaini, zarda, gutkha, and chewing tobacco products in any other form.
- ii. In view of the issues identified, to determine whether any amendment is required in the definition of "Food" under Food Safety and Standards (FSS) Act, 2006.
- iii. If any such amendment is not required, is there any need to issue any clarification regarding the definition of "food", with regard to tobacco products.

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3/13



iv. Whether a complete ban on all forms of tobacco products is advisable? And if so, the feasibility of its implementation.

4. The Committee shall submit its report within two months.
5. Food Regulations Division and Tobacco Control Division shall provide all the necessary information to the Committee, as may be required.
6. This issues with the approval of the competent authority.

*Pulakesh Kumar*  
29/12/21

(Dr. Pulakesh Kumar)  
Deputy Secretary to Govt. of India  
Tel: 23062744

To  
All the Members of the Committee

Copy to:

1. Dr. V. K. Paul, Member (NITI Aayog), with a request to nominate a senior level officer for the said Committee.
2. Secretary (Ministry of Law and Justice), with a request to nominate senior level officer for the said Committee.
3. Secretary (Department of Agriculture & Farmers' Welfare), with a request to nominate senior level officer for the said Committee.
4. CEO, FSSAI with a request to nominate senior level officer for the said Committee.
5. DGHS, Ministry of Health & Family Welfare with a request to nominate senior level officer for the said Committee.
6. Secretary DHR, Ministry of Health & Family Welfare with a request to nominate senior level officer for the said Committee.

Copy for information to:

1. PS to Hon'ble Union Minister of Health & Family Welfare
2. Shri G.C. Dobhal, Additional Director, Committee on Petitions Branch, Lok Sabha Secretariat, Parliament House Annex, New Delhi-110001
3. Advisor, Parliament Section, MoHFW
4. Sr. PPS to Secretary (Health & Family Welfare), MoHFW
5. Sr. PPS to Additional Secretary (Health), MoHFW
6. Sr. PPS to Additional Secretary & Mission Director, MoHFW

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First meeting of the Committee on examination of impact of banning indigenous chewing tobacco products

The first meeting of the committee held at 3.00 pm on 28.4.2022 in the office of AS (Health), and DG, NACO, Chandralok Building, Janpath, New Delhi. The list of the officers who attended the meeting are at annexure. The ToRs of the Committee are indicated below:

- (i) To identify administrative and legal issues regarding definition of 'food' as defined under the Food Safety and Standards (FSS) Act, 2006, keeping in view the various judicial pronouncement regarding chewing tobacco, khaini, zarda, gutkha and chewing tobacco products in any other form.
- (ii) In view of the issues identified, to determine whether any amendment is required in the definition of 'Food' under Food Safety and Standards (FSS) Act, 2006.
- (iii) If any such amendment is not required, is there any need to issue any clarification regarding definition of 'food', with a regard to tobacco products.
- (iv) Whether a complete ban on forms of tobacco products is advisable? And if so, the feasibility of its implementation.

2. Welcoming the Members, Shri Alok Saxena, Chairman of the Committee elaborated upon the ToRs and stated that the Committee would confine its report/recommendations to ToRs.

3. The definition of 'food' as in PFA Act, 1954 and FSS Act, 2006 was discussed and it was stated that both the Acts did not mention specifically the tobacco and /or tobacco products. However, there was a provision in PFA Rules, 1954, added in the year 2006 as Rule 44J, which stated that 'Tobacco and Nicotine' shall not be added to any food product. Neither the PFA Act nor FSS Act did mention the 'Chewing tobacco' or any other tobacco product. The Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 provide for corresponding provision of 44J in Regulations 2.3.4 with ditto provision.

4. Various judicial pronouncements of Hon'ble High Courts and Supreme Court were discussed and it was noted that the High Courts have taken conflicting position as to whether 'Tobacco' / 'Tobacco products' would be within the definition of 'food' both under PFA Act as well as FSS Act. Some Courts have taken the position that COTPA being special Act would prevail over FSS Act as far as tobacco & tobacco products were concerned while other courts have decided that since FSS Act is of later origin and due to section 89 it would have precedence over COTPA. It was also noted that Supreme Court was seized of the matter in Ankur Gutkha and large number of other transferred cases lying pending adjudication in that court.

5. In their order dated 23.09.2016, the Hon'ble Supreme Court has asked States/ UTs to comply with Regulation 2.3.4 of Food Products Standards (Prohibition and Restrictions on Sales) Regulations, 2011 and file affidavits in this regard. Committee observed that the pure form of

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tobacco does not seem to be regulated under FSS Act, which is the domain of COTPA. Since quite a few tobacco products are specifically mentioned in Schedule II of COTPA, it would appear the COTPA, is the only enactment to regulate these. The Committee however observed the ambit of both Acts, FSS Act as well as COTPA being different, both can run parallel to each other and there is need of harmonious construction of these enactments.

6. The Committee however noted that till Supreme Court finally delivers their judgment on the issue, it does not seem appropriate to suggest any legislative changes.

7. The Chairman observed that to make the deliberations of the Committee more meaningful, it would be necessary that Shri L. Swasticharan (DGHS) and Dr. Pulkesh (DS, Tobacco Division) are present in the next meeting. The Legal Division was asked to prepare a statement of all leading cases on the subject and the summary of decisions. Next meeting would be held based on convenience of Dr. Pulkesh and Shri Swasticharan.

The meeting ended with the vote of thanks to the Chair.

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W.S.

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First Meeting of the Committee held at 3.00 pm on 28.04.2022

Attendance

1	Shri Alok Saxena	Additional Secretary (Health)	Chairman
2	Shri Mahendra Khandelwal	Joint Secretary & Sr. Govt. Advocate (Dept. of Legal Affairs)	Member
3	Dr. R. S. Dhaliwal	ICMR	Member
4	Dr. K. Madan Gopal	NITI Aayog	Member
5	Shri Raj Singh	Head (Legal), FSSAI	Member
6	Ms. Pooja Gupta	NTCP, MOH	
7	Ms. Srikala	Tobacco Council Division, MOH	
8	Ms. Smita Singh	AD- Legal, FSSAI	

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Second meeting of the Committee on examination of impact of banning indigenous chewing tobacco products

The second meeting of the committee held at 11.00 am on 17.05.2022 in the office of AS (Health), and DG, NACO, Chandralok Building, Janpath, New Delhi. The list of the officers who attended the meeting are at annexure. Shri Alok Saxena, AS (Health) and DG, NACO could not be available in the meeting as he was asked to attend urgent meeting with the Hon'ble Minister of Health & Family Welfare in Nirman Bhawan, New Delhi. Shri Raj Singh, Head (Legal), PSSAI was requested by the participants to chair the meeting.

Head (Legal), PSSAI made a presentation on all major juridical pronouncement of various High Courts and Supreme Courts since the regime of Prevention of Food Adulteration Act, 1954. The cases included (i) Pyarali K. Tejani vs Mahadeo Ramchandra Dange WP/29/1973 SC, (ii) Khedan Lal & Sons v. State of UP WP 4613/1975 High Court of Allahabad, (iii) State of Tamil Nadu Vs. R. Krishnamurthy AIR 1980 SC 538, (iv) Manohar Lal v. State of UP Criminal Revision No. 318 of 1982 (High Court of Allahabad), (v) Godawat Pan Masala v. Union of India AIR2004SC4057, (vi) Ankur Gutka v. Asthama Care Society & Ors SLP 16308/2007. Order dated 7.12.2010 SC, (vii) Central Areca Nut Marketing Corporation v. UOI TFR Case-1/2010 SC. Order dated 23.9.2016, (viii) Dhariwal Industries Limited and Ors. Vs. The State of Maharashtra Writ Petition No. 1631 of 2012 (Bombay High Court), (ix) Omkar Agency and Ors. Vs. The Food Safety and Standards Authority of India and Ors. CWJ 3805/2015 High Court of Patna, (x) Sanjay Anjay Stores and Ors. v. The Union of India and Ors (2017) Calcutta High Court, (xi) Muhammad Yamin Naeem Mohammad and Ors. v. The State of Maharashtra and Ors. Criminal Writ Petition No. 543/2020, and (xii) Kamadhenu Traders vs. The State of Telangana and Ors. W.P. Nos. 19928/2021 Telangana High Court (A batch of 128 WP's dismissed).

The ToRs were deliberated at length. Dr. Swasticharan of DGHS pointed out about the economic burden in the health sector and huge machinery involved in treatment of patients suffering from cancer and other diseases directly caused by the use of tobacco in either form, singly or in combination in both smoking and non-smoking. He pointed out about the detailed study, which had been carried out by a Committee of National Institute of Health & Family Welfare, set up in sequel to the orders dated 07.12.2010 of the Hon'ble Supreme Court in the matter of Ankur Gutka v. Asthama Care Society & Ors SLP 16308/2007 and the report of the Committee was duly apprised to the Court.

It was apprised that in Godawat Pan Masala case, the Supreme Court though held that the State Govt. did not have power to impose ban on Gutkha, Pan Masala with Tobacco, chewing tobacco etc. under the PFA Act, 1954 and PFA Rules, 1955, and it was the power vested only with the Central Govt. The Court, nonetheless, held that these products are 'food' within the definition of

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food under these enactments. It was after this judgments that PFA Rules, 1955 were amended to incorporate Rule 44J in the PFA Rules, 1955 which reads: *'Product not to contain any substance which may be injurious to health: Tobacco and Nicotine shall not be used as ingredients in any food products.'* The corresponding provision has been made part of Prohibition and Restrictions on Sales Regulations, 2011 as Regulation 2.3.4.

The Committee noted that the Ministry of Health & Family Welfare has taken consistent position whether in Courts or Parliament that tobacco when eaten in any form is 'food' and amenable to regulation under formerly PFA Act and presently FSS Act, 2006. The COTPA, 2003 though a special Act enacted by the same Central Legislature, the Parliament, COTPA is primarily to prohibit advertising and regulation of production, supply and distribution of cigarettes and tobacco products. FSS Act on the other hand is an Act for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto. Despite tobacco not being specifically included in the definition of 'food' under FSS Act, it cannot escape the regulation within the ambit of FSS Act and Rules/Regulations if tobacco is eaten in any form which as the varied judicial pronouncements have held the same as food since it is ingested into body through mouth and is taken for nourishment and/ or taste. Therefore, the Committee felt that the COTPA as well as FSS Act do not run counter to each other but in fact seem complementary to each other and may go parallel to each other.

The Committee took the view that based on the definition of 'food' and considering various judicial pronouncements on tobacco products, the administrative and legal issues be identified considering the discussions of the Committee. Head (Legal), FSSAI was requested to draft a report in consultation with Shri Khandelwal, Joint Secretary, Ministry of Law and the same could be placed in the next meeting of the Committee for consideration/ finalization.

The meeting ended with the vote of thanks to the Chair.

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P.S.

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Second Meeting of the Committee held at 11.00 pm on 17.05.2022

Attendance

1	Shri Alok Saxena	Additional Secretary (Health)	Chairman
2	Shri Mahendra Khandelwal	Joint Secretary & Sr. Govt Advocate (Dept of Legal Affairs)	Member
3	Dr. R. S. Dhaliwal	ICMR	Member
4	Dr. K. Madan Gopal	NITI Aayog	Member
5	Shri Raj Singh	Head (Legal), FSSAI	Member
6	Dr. L. Swasticharan	DGHS	Member
7	Ms. Srikala	Tobacco Council Division, MOH	
8	Ms. Smita Singh	AD- Legal, FSSAI	
	Ms. Pooja Gupta	NTCP, MOH	

Third meeting of the Committee on examination of impact of banning indigenous chewing tobacco products held on 23.05.2022

The third meeting of the committee held at 11.00 am on 23.05.2022 in the office of AS (Health), and DG, NACO, Chandralok Building, Janpath, New Delhi. Besides Shri Alok Saxena, AS (Health) and DG, NACO (as Chair), Shri Raj Singh, Head (Legal), FSSAI, Shri M. Khandelwal, Joint Secretary, Ministry of Law and Dr. Madan Gopal of Niti Aayog, were present.

The draft Report had already been shared with the O/o AS (Health). The hard copies of the Report were circulated to all the Members present and they were requested to go through the same and offer their comments/ suggestions. Shri Raj Singh, Head (Legal), FSSAI, briefly summarized the structure, contours and the contents of the Report. It was stated that the Report is comprised in four Chapters, Chapter I throws light on the definition of 'food' under PFA, FSS Act and the CODEX. The aims and objectives of PFA, FSS Act and COTPA to be also part of Chapter I. Chapter II comprises of various decisions of High Courts and the Supreme Court on Food Law. Chapter III contains the pending litigations in Supreme Court on Food Law. It also contains various interim orders and directions in the pending cases. The recommendations of the Committee are part of Chapter IV.

The Committee finalized the Report as drafted by Shri Raj Singh, Head (Legal), FSSAI with some changes in the Chapter IV. It was decided that after carrying out the changes as suggested, the Report may be emailed to the Chairman.

The meeting ended with the vote of thanks to the Chair.

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## Estimates of Area, Production and Yield of Tobacco

State	Area (000 Hectares)					(Production 000 tonnes)					Yield (Kg/ha.)				
	2016-17	2017-18	2018-19	2019-20	2020-21	2016-17	2017-18	2018-19	2019-20	2020-21	2016-17	2017-18	2018-19	2019-20	2020-21
Andhra Pradesh	78.00	83.00	88.00	85.00	61.00	177.00	180.00	140.00	185.00	145.55	2269	2169	1591	2176	2385
Assam	0.23	0.15	0.14	0.11	0.10	0.12	0.07	0.07	0.06	0.05	507	473	511	545	530
Bihar	10.05	10.89	10.81	10.27	10.33	17.69	19.13	18.93	18.03	18.12	1761	1756	1751	1756	1754
Gujarat	167.00	174.00	177.41	162.26	170.45	375.00	519.00	331.56	382.65	396.19	2246	2983	1869	2358	2324
Karnataka	90.00	95.00	83.70	90.00	71.00	65.00	89.00	71.57	83.00	58.86	722	937	855	922	829
Kerala	0.01	0.01	NA	0.01	0.01	0.02	0.02	NA	0.02	0.01	1500	1600	NA	1800	1883
Maharashtra	0.80	1.00	0.46	0.45	0.59	1.10	1.00	0.80	0.83	1.19	1375	1000	1739	1844	2015
Meghalaya	0.80	0.80	0.80	0.80	0.81	0.79	0.79	0.80	0.80	0.81	988	991	993	994	993
Mizoram	0.22	0.34	0.34	0.30	0.29	0.20	0.28	0.42	0.46	0.43	914	828	1229	1533	1464
Odisha	0.60	0.31	NA	0.13	0.07	0.36	0.18	NA	0.09	0.05	600	NA	NA	692	714
Rajasthan	0.45	0.35	0.24	0.15	0.34	0.85	0.48	0.84	0.50	0.70	1895	1387	3583	3428	2059
Tamilnadu	1.80	3.79	2.11	1.66	1.77	2.74	5.78	3.22	2.53	2.70	1522	1525	1526	1524	1525
Telangana	7.00	4.00	4.00	3.00	1.00	19.00	13.00	12.00	9.00	1.85	2714	3250	3000	3000	1845
Uttar Pradesh	27.00	23.00	26.00	35.00	25.00	119.00	105.00	56.00	98.00	109.03	4407	4565	2154	2800	4361
West Bengal	15.68	13.99	14.69	15.15	14.41	26.65	17.67	21.87	20.46	19.74	1700	1264	1488	1350	1370
All India	399.63	410.62	408.70	404.29	357.16	805.51	951.40	658.07	801.42	755.25	2016	2317	1610	1982	2115

NA: Not available.

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ANNEXURE - VICONFIDENTIAL

MINUTES OF THE SEVENTEENTH SITTING OF THE COMMITTEE ON PETITIONS  
(SEVENTEENTH LOK SABHA)

The Committee met on Thursday, 24 June, 2021 from 1200 hrs. to 1430 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Dr. Virendra Kumar - Chairperson

MEMBERS

2. Shri Anto Antony
3. Shri Dr. Sukanta Majumdar
4. Prof. Sanjay Sadashivrao Mandlik
5. Dr. Bharati Pravin Pawar
6. Shri Brijendra Singh
7. Shri Sushil Kumar Singh
8. Shri Manoj Tiwari
9. Shri Prabhubhai Nagarbhai Vasava
10. Shri Rajan Vichare

SECRETARIAT

1. Shri T.G. Chandrashekhar - Joint Secretary
2. Shri Raju Srivastava - Director
3. Shri G. C. Dobhal - Additional Director

SPECIAL INVITEE

[Representatives of Smokeless Tobacco Federation (India)]

1. Shri Sanjay Bechan - Representationist
2. Shri Manoj Gupta
3. Shri Vivek Kohli

WITNESSES

MINISTRY OF HEALTH AND FAMILY WELFARE  
(DEPARTMENT OF HEALTH AND FAMILY WELFARE)

- |    |                          |   |   |
|----|--------------------------|---|---|
| 1. | Shri Rajesh Bhushan      | - | Secretary   |
| 2. | Shri Vikas Sheel         | - | Additional Secretary                                      |
| 3. | Shri Mandeep K. Bhandari | - | Joint Secretary (Food Regulation)                         |
| 4. | Shri Sunil Bakshi        | - | Head (Regulations/Codex/International Cooperation), FSSAI |
| 5. | Shri Rakesh Kumar        | - | Director (Science & Standards), FSSAI                     |

2. At the outset, the Hon'ble Chairperson welcomed the Members to the sitting of the Committee.

*[The representatives of Smokeless Tobacco Federation (India) were, then, ushered in]*

3. After welcoming the representationist and other representatives of the Smokeless Tobacco Federation (India), the Chairperson drew their attention to Direction 55(1) of the Directions by the Speaker regarding confidentiality of the proceedings of the Committee and invited them to express their views on their representation regarding proposed amendments to the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 and its impact on banning indigenous chewing tobacco. The main issues that were put forth by the representationists, before the Committee, were as follows:-

- (i) The Ministry of Health and Family Welfare (Tobacco Control Division) vide F. No. P.16011/04/2020 - TC (Part) dated 1 January 2021 placed the draft Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Amendment Bill, 2020 [COTPA Amendment Bill] in the public domain on 1 January, 2021 for eliciting the comments/views of public.
- (ii) On 13 January, 2015, a similar draft COTPA Amendment Bill was placed in the public domain by the Ministry of Health and Family Welfare (Tobacco Control Division) vide F. No. Z-21020/03/2014-PH-I [FTS-111238] for soliciting comments/views of the stakeholders including the general public. However, later on, the draft Bill was revoked by the Ministry for reasons best known to them.

- (iii) The COTPA Amendment Bill, which was published in 2015, *inter alia* contained stringent provision(s) in regard to regulation of cigarettes and tobacco/nicotine such as mandatory disclosure of the constituents and emission of each cigarette, whereas, in the COTPA Amendment Bill of 2020, such provision(s) is/are missing and the same has now been focused on the regulation of only chewing tobacco, as if tobacco/nicotine is found only in the chewing tobacco and not in the cigarettes.
- (iv) It is an undeniable fact that tobacco/nicotine, in all its forms, is harmful for human health and there has been innumerable cases of untimely death due to their consumption. Hence, there is a dire need to regulate all forms of tobacco/nicotine products and to put a ban on all these products, if necessary. However, from the opinion of the Ministry, it appears that only 'smokeless tobacco', i.e., chewing tobacco could be banned and not the 'smoking tobacco', i.e., cigarettes, etc.
- (v) There are the following four Acts/Rules/Regulations which are relevant in dealing with the subject:-
- (a) Food Safety and Standards Act, 2006;
  - (b) Food Safety and Standards Rules, 2011;
  - (c) Food Safety and Standards (Prohibition & Restrictions on Sales) Regulations, 2011; and
  - (d) Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 or COTPA, 2003.
- (vi) There is no explicit mention of either 'tobacco' or 'nicotine' in the principal Food Act or Rules, however, in spite of this, the Ministry intends to proscribe chewing tobacco by way of bringing it under the category of 'Food Products' by way of subordinate legislation in the form of regulations. It is a fact that chewing tobacco products are sold in the country as 'tobacco products' with 85 per cent warning on their labels as mandated by the Government and not as 'food'.
- (vii) The Acts related to tobacco which have been enacted world-wide, have taken into account the ill-effects of smoke emitted therefrom on the children, women and old age persons, which are the vulnerable groups. However, despite the fact that the practice of chewing tobacco which is prevalent in the Indian sub-continent since ages, the harmful effects on human health besides protection of environment, etc., have not been considered as the 'focal point' while formulating laws on tobacco in the country.

- (viii) With a view to regulating various products containing tobacco/nicotine, the Cigarettes and other Tobacco Products Act (COTPA) was enacted in the year 2003. However, it is unfortunate that since then, nothing on scientific basis has been done by the Government for 'standardisation' of tobacco by specifying the nicotine and tar contents in the tobacco products despite the fact that for 'regulation' of any product, the first and foremost thing is its 'standardisation'.
- (ix) As per the Bureau of Indian Standards (BIS), specific standards with respect to chewing and smoking tobacco have been prescribed. However, until now, the Ministry of Health & Family Welfare have not been able to adopt and implement the same.
- (x) COTPA, in itself, is a composite legislation, wherein, provisions for regulation on production and sale of tobacco products already exist. In such a situation, it is unjustifiable to 'pick and choose' a particular tobacco product, either for surreptitiously taking it outside the purview of COTPA or for including the same through the circuitous route of Subordinate Legislation.
- (xi) The exiting version of the COTPA Amendment Bill is also contrary to the recommendations given by the two Parliamentary Committees of 16<sup>th</sup> Lok Sabha, i.e., the Committee on Petitions and the Committee on Subordinate Legislation.
- (xii) While considering a strict regulation or a ban on all form of tobacco products *per se*, viz., 'smokeless tobacco' and 'smoking tobacco', its repercussions on millions of tobacco farmers, traders/businessmen and other stakeholders should also be taken into account. A complete ban on all tobacco products may also result into smuggling/illegal trade and other unlawful activities.
- (xiii) The issue of banning 'smokeless tobacco' is already pending before the Supreme Court. In an affidavit filed before the Supreme Court, the Ministry of Health and Family Welfare had acknowledged that 'smoking tobacco' is, at least, ten times more harmful than 'smokeless tobacco'. In spite of that, in the COTPA Amendment Bill 2020, the focus is only on 'smokeless tobacco', which is not only a regressive and illogical hypothesis but would also have a cascading impact on source of livelihood of millions of tobacco farmers, traders/businessmen, etc., and on the revenue of the Government, as well.

*[The representationist and other representatives of the Smokeless Tobacco Federation (India), then, withdrew]*

*[Thereafter, the representatives of the Ministry of Health and Family Welfare were ushered in]*

4. After welcoming the representatives of the Ministry of Health and Family Welfare, the Chairperson read out Direction 55(1) of the Directions by the Speaker regarding confidentiality of the proceedings of the Committee. The Chairperson, thereafter, on behalf of the Committee, appreciated the efforts made by the Ministry of Health & Family Welfare during the difficult times of Covid-19 pandemic. The Committee, then, sought clarifications from the representatives of the Ministry of Health and Family Welfare on various aspects relating to the proposed amendments to the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 and its impact on banning the indigenous chewing tobacco products *vis-a-vis* the action taken replies on the Sixty-Eighth Report of the Committee on Petitions (16th Lok Sabha), as under:-

- (i) In the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) (Amendment) Bill 2015 [COTPA (Amendment) Bill], sub-section 5 was substituted by a new 'sub-section' by making it mandatory for all person manufacturing or producing cigarettes to disclose the 'constituents' and 'emission' of each cigarette. However, this 'sub-section' has been omitted from the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) (Amendment) Bill 2020.
- (ii) In the COTPA (Amendment) Bill 2015, the words "nicotine and tar contents" which were substituted with the words "constituents and emissions" have also been omitted in the COTPA (Amendment) Bill 2020 by the Ministry of Health and Family Welfare.
- (iii) In the COTPA (Amendment) Bill 2015, the Ministry had appended a detailed 'Notes on Clauses'. However, in the Amendment Bill 2020, this has not been appended.
- (iv) In the Food Safety and Standards Act 2006 and Rules made thereunder, whether there is any reference of tobacco, nicotine, etc., even in the definition of 'Food'?
- (v) The Food Safety and Standards (Prohibition and Restriction on Sales), Regulation was notified in the year 2011. Since the Food Safety and Standards Act and the Rules made thereunder were already in place in the year(s) 2006 and 2011 respectively, what was the need to notify the said Regulations by specifically bringing in an unconnected Regulation, namely, 2.3.4 which specifies that 'tobacco' and 'nicotine' shall not be used as ingredient in any food product?

(19)

- (vi) Notwithstanding the fact that in Regulation 2.3.4 of the Food Safety and Standards (Prohibition and Restriction on Sales), Regulation 2011, it has been provided that "*Product not to contain any substance which may be injurious to health and that 'tobacco' and 'nicotine' shall not be used as ingredient in any food product*", a hypothesis has been made by categorizing the tobacco products into two categories, i.e., 'smokeless tobacco' and 'smoking tobacco' along with a conceptualization that 'smoking tobacco' cannot be brought under the definition of 'food' as anything which is eaten through mouth or chewed can only be 'food'.
- (vii) If the Food Safety and Standards (Prohibition and Restriction on Sales), Regulation 2011 explicitly provide that 'tobacco' and 'nicotine' shall not be used as ingredient in any food product, why 'smoking tobacco' has been excluded while making an interpretation of the definition of 'food'?
- (viii) Whether the representatives of the Ministry of Health and Family Welfare had endorsed similar views before the Committee on Petitions during the Sixteenth Lok Sabha on the basis of which the Committee had formulated its sixty-eighth Report in Lok Sabha in the year 2019?
- (ix) Whether it is a fact that while categorizing the tobacco products into two categories, viz., 'smokeless' and 'smoking', the Ministry of Health and Family Welfare has ignored that both of these products are 'nicotine delivery devices' and a health hazard and instead put their emphasis on the 'mode/method of consumption' due to which it was conceived that 'smokeless tobacco' comes within the definition of 'food' and could be proscribed and 'smoking tobacco' does not come under the definition of 'food' and, therefore, could be regulated under the provisions contained in the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003?
- (x) If the Ministry of Health and Family Welfare consider that tobacco in any form and quantity is harmful, what were the reasons that the Ministry have not made any effort to amend the Food Safety and Standards Act 2006 and Rules made thereunder and instead brought out Regulation in the year 2011 containing a 'one-line' provision to the effect that 'nicotine' and 'tobacco' shall not be used as ingredient in any food products?

5. The representatives of Ministry of Health and Family Welfare, thereafter, put forth their comments/views, as under:-

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- (i) India is amongst 181 ratifying countries under the Framework Convention on Tobacco Control (FCTC), which is an International Framework for tobacco control, and has the responsibility to regulate the consumption of tobacco at public places and to ensure public health.
- (ii) There is no intention of the Ministry of Health & Family Welfare to exclusively ban 'smokeless tobacco' or in other words, the chewing tobacco. The objective is only to regulate the consumption of tobacco so that large number of people should not be addicted to it.
- (iii) Presently, tobacco is sold in the country as *beedi* or *tendu leafs*, in dried forms, which is legal and there is no ban on it. However, there is prohibition and restrictions on sale of products when tobacco or nicotine is mixed with any other food item as per provision of the Food Safety and Standards (Prohibition & Restrictions on Sales) Regulations, 2011 (Regulation 2.3.4) formulated under the Food Safety and Standards Act, 2006 which *inter alia* stipulates that- "*tobacco and nicotine shall not be used as ingredients in any food products.*"
- (iv) Pursuant to placing of COTPA Amendment Bill 2020 in the public domain on 1 January, 2021, the Ministry of Health & Family Welfare received around 89,000 objections through electronic mode viz., e-mails, etc., besides, more than 2 lakhs representations, letters, etc., in physical form by bringing out various grievances and suggestions on the subject. The Ministry of Health & Family Welfare are, presently, considering all the inputs received from various stakeholders and after considering all these inputs and also suggestions given by the Committee on Petitions, Lok Sabha, the said Bill would be finalised and introduced in the Parliament. After finalising the draft Bill, the Ministry would also inform the Committee on Petitions and seek appropriate guidance/suggestions from the Committee prior to bringing the said Bill before the Parliament.
- (v) Under the Food Safety and Standards Act, 2006, there are provisions for formulating Rules as well as Regulations. The Regulations which *inter alia* contain the standards of food products come under the purview of FSSAI, whereas, the Rules which *inter alia* specify qualification, experiences and responsibilities of the Designated Officers come under the purview of the Ministry of Health & Family Welfare or the Government of India.
- (vi) In terms of section 3(1)(j) of the Food Safety and Standards Act, 2006, which *inter alia* states that 'Food' means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption. In other words, any substance whether processed, partially processed or unprocessed



which intended for human consumption, i.e., through ingestion (which goes through alimentary canal), is to be categorized as 'Food' and therefore, something which is inhaled (*which goes through lungs*) cannot be considered as 'Food'. There has been no change in this definition since the enactment of this Act in 2006, and at present, *pan masala*, *gutkha* and *zarda* are considered to be food products. However, whether this definition of 'Food' is illogical as it emphasizes on the 'mode of consumption' and not the 'element of harm' would have to be re-examined by the Ministry of Health & Family Welfare and the matter would also be discussed with the Committee on Petitions, Lok Sabha.

- (vii) The Regulation 2.3.4 under the Food Safety and Standards Act, 2006, on the one hand, states that "*tobacco and nicotine shall not be used as ingredients in any food products*" and on the other hand, the two forms of tobacco use, i.e., smoking and smokeless have been dealt with differently on the basis of difference in 'nicotine delivery mechanism', this self-devised categorization has also been agitated/contended in various legal fora including the High Courts and the Supreme Court.
- (viii) Imposing a blanket ban on all forms of tobacco product(s), i.e., 'smokeless' and 'smoking tobacco' is to be considered by the Ministry of Health and Family Welfare cautiously after taking into consideration various complexities as discussed above as also its implications and ramifications in view of the fact that such a decision would also give rise to illegal trade and/or black marketing.
- (ix) Although, strict regulation on tobacco products could also be an option, the most important aspect which is connected with the livelihood and employment of farmers, traders, etc., who are neither socially prosperous nor financially opulent would also be taken into account while finalising the COTPA Amendment Bill. The objective of the Bill is to achieve reduction in the supply and demand of tobacco products as it is an undeniable fact that their consumption is harmful to human health irrespective of their 'forms' and 'mode of consumption'.

6. After hearing the views of the representatives of the Smokeless Tobacco Federation (India) and the representatives of the Ministry of Health & Family Welfare (Department of Health & Family Welfare), the Committee expressed their views, as follows:-

- (i) The classification of food product should not solely on the basis on the interpretation of definition of 'Food' as provided under the Food Safety and Standards Act, 2006. The classification of tobacco products into 'smokeless tobacco' and 'smoking tobacco' is unjustifiable as it based on their mode of consumption which does not eliminate its harmful effects on human health.

- (ii) There should not be any inconsistency in interpreting the definition of 'Food' from the Principal Act, i.e., the Food Safety and Standards Act, 2006 *vis-a-vis* Rules and Regulations made thereunder. There is a need for harmonization of definition of 'Food' in all the extant Acts/Rules/Regulations.
- (iii) The Ministry of Health and Family Welfare should fix responsibility of the officials who have deliberately attempted to twist the focal point of the COTPA Amendment Bill of 2015, while formulating the similar Bill of 2020, wherein, stringent provision(s) in regard to declaration of constituents and emission of cigarettes have been omitted along with devising a classification of 'smokeless' and 'smoking tobacco' which does not find mention in the relevant Act, Rules and Regulations.
- (iv) Since there is no explicit mention of 'tobacco' and/or 'nicotine' in the Food Safety and Standards Act 2006 and Rules made thereunder, the Ministry should refrain from misinterpreting Regulation 2.3.4 of Regulation 2011 for including 'tobacco' and that too, 'smokeless tobacco' as 'food' in view of the fact that 'tobacco' could not be mixed with 'tobacco'. It appears that due to some 'vested interests', the illogical interpretation of 'smoking' and 'smokeless' tobacco products and pronouncing that only 'smokeless tobacco' comes under the 'category of food' has been made out. The origin and reasons for such illogical interpretation could be known by handing over the investigation to the Central Bureau of Investigation.
- (v) The Ministry of Health & Family Welfare should consider all possible impact on the stakeholders taking into account their past experience as to whether complete ban on all forms of tobacco products could be effectively implemented or not?
- (vi) Since millions of people are involved in tobacco farming and its related business, in the event of imposing a complete ban on all forms of tobacco products, whether the Ministry of Health and Family Welfare have prepared any concrete and implementable Action Plan to provide them with alternate employment opportunities.
- (vii) In case of a complete ban on all forms of tobacco products, the Ministry of Health and Family Welfare should ensure that it may not lead to illegal trade of tobacco products and the resultant loss of revenue to the Government.
- (viii) There should not be an unjustified and biased classification of tobacco products, while effecting any legislation on strict regulation on the manufacturing and sale of all tobacco products.

- (ix) All such issues have to be considered taking into account long term ramifications and implications in terms of social and financial aspects such as employment and livelihood of millions of farmers and traders involved in tobacco farming and business.
- (x) There is a need to carry out a comprehensive study on the ill effects of tobacco products, i.e., 'smokeless tobacco' and 'smoking tobacco' on human health.
- (xi) As the instant issue relates to the public health at large, therefore, the Ministry of Health and Family Welfare, while taking into account the views/opinion of all the stakeholders, should take utmost care before taking any decision in the matter.
- (xii) The clarifications sought by the Members of the Committee which could not be responded to by the representatives of the Ministry of Health & Family Welfare should be furnished to the Committee Secretariat within a week's time.
- (xiii) After receipt of replies from the Ministry of Health and Family Welfare, the Committee on Petitions, Lok Sabha would decide as to whether the matter would further be deliberated upon with the representatives of the Ministry by convening another sitting of the Committee.

*[The witnesses, then, withdrew]*

7.           XXXX       XXXX       XXXX       XXXX

8.       A copy of the verbatim record of the proceedings of the sitting of the Committee has been kept.

XXXX - Not related with the Report.

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CONFIDENTIAL

MINUTES OF THE NINETEENTH SITTING OF THE COMMITTEE ON PETITIONS  
(SEVENTEENTH LOK SABHA)

The Committee met on Wednesday, 22 December, 2021 from 1500 hrs. to 1710 hrs. in Committee Room No.139, Parliament House Annexe, New Delhi.

**PRESENT**

Shri Harish Dwivedi - Chairperson

**MEMBERS**

2. Shri Anto Antony
3. Shri Brijendra Singh
4. Shri Sushil Kumar Singh
5. Shri Manoj Kumar Tiwari
6. Shri Prabhubhai Nagarbhai Vasava

**SECRETARIAT**

1. Shri T.G. Chandrashekhar - Joint Secretary
2. Shri Raju Srivastava - Director
3. Shri G. C. Dobhal - Additional Director

**WITNESSES**

**MINISTRY OF HEALTH AND FAMILY WELFARE  
(DEPARTMENT OF HEALTH AND FAMILY WELFARE)**

1. Shri Rajesh Bhushan - Secretary
2. Shri Arun Singhal - CEO, FSSAI
3. Shri Vikas Sheel - Additional Secretary
4. Shri Mandeep K. Bhandari - Joint Secretary
4. Shri Sunil Bakshi - Head Regulations, FSSAI

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4.	XXXX	XXXX	XXXX	XXXX
5.	XXXX	XXXX	XXXX	XXXX

*[The witnesses, then, withdrew]*

*[The representatives of the Ministry of Health and Family Welfare (Department of Health and Family Welfare) were ushered in]*

6. After welcoming the representatives of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), the Chairperson read out Direction 55(1) of the Directions by the Speaker regarding confidentiality of the proceedings of the Committee.

7. Before taking oral evidence of the representatives of the Ministry of Health & Family Welfare (Department of Health & Family Welfare) on the representations of S/Shri R. P. Patel and Sanjay Bechan regarding proposed amendments to the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 and its impact on banning indigenous chewing tobacco products *vis-a-vis* the action taken replies on the Sixty Eighth Report of the Committee on Petitions (16th Lok Sabha), the Committee while recapitulating the issues/points and various legal aspects discussed with the representatives of the Ministry during the earlier sitting of the Committee held on 24 June, 2021 under the Chairmanship of Dr. Virendra Kumar who has now been appointed as the Minister of Social Justice and Empowerment, expressed their views and sought further clarifications, as under:-

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- (i) The sitting of the Committee held on 24 June, 2021, under the Chairmanship of Dr. Virendra Kumar, lasted for more than 2 hours and 30 minutes and during the said sitting, various members expected meaningful and legally tenable replies/clarifications from the representatives of the Committee.
- (ii) The Committee on Petitions, which was created prior to independence, i.e., on 20 February, 1924, have invariably selected petitions/representations that are of wider public interests and thereafter, examined the issues raised therein entirely from a legal perspective and by adopting a neutral and welfare-oriented approach. The outcome of such examination by the Committee often persuaded the Ministry concerned to review their earlier policy formulations. On the other hand, when the Committee realised that some vested interests have outweighed the wider public interests and the cardinal principal of law of natural justice, the Committee even do not hesitate to recommend initiating an inquiry by the Central Bureau of Investigation.
- (iii) During the earlier sitting of the Committee on the said subject, some pertinent questions were put forward before the representatives of the Ministry and the Committee expected that that the Ministry would undertake some course correction and tobacco as well as all the related products, which are harmful for human consumption as it causes cancer and other life threatening disease would either be 'proscribed' or 'regulated' in such a manner that this habit would eventually come to an end and at the same time, the millions of people who are involved in cultivation of tobacco would also not become unemployed/jobless.
- (iv) Keeping the above hypothesis in view, during the earlier sitting, the Committee urged the representatives of the Ministry to review their formulations and in case, some related Act or Rules require amendment, the same could be taken up by the Ministry in the right earnest. However, it is unfortunate that no out-of-box proposal was put forward by the Ministry *vide* their communication dated 26 July, 2021. The Committee, therefore, again forwarded a detailed List of Points to the Ministry for giving clarifications on various aspects relating to the subject under examination. However, the Committee found that the replies submitted by the Ministry were mere repetition of their earlier submissions.

8. Pursuant to the replies furnished by the Ministry of Health & Family Welfare *vide* their Office Memorandum No. H-11013/01/2021-TC dated 17 December, 2021, the Committee categorized the various aspects connected with the subject into four parts, viz., (i) Contradiction in the definition of 'Food' as contained in the relevant Act and the interpretation made by the Ministry; (ii) Judgements/orders given by various Courts; (iii) Further consequential action on the

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Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Bill, 2020; and (iv) Possible resolution to the issues/aspects connected with the subject under examination, and thereafter, expressed their views and sought further clarifications, as under:-

- (i) The Ministry of Health & Family Welfare *vide* their replies dated 25 June, 2018 to the List of Points forwarded by the Committee, had *inter alia* submitted before the Committee that under the definition of 'Food' under Section 3(j) of the FSS Act, 2006, gutkha, zarda, khaini, etc., have been included. However, when the Committee expressed that in Section 3(j) *ibid*, there is no such explicit mention of these products, the representatives of the Ministry immediately changed their version and informed the Committee that during the year 2011, Food Safety and Standards (Prohibition and Restriction on Sales) Regulations was issued by them, wherein, under Section 2.3.4, it was mentioned that "Tobacco and nicotine shall not be used as ingredients in any food products". However, when the Committee further disputed that in tune with the provisions of Section 2.3.4 of the Regulations *ibid*, all the tobacco products could, therefore, be proscribed, the representatives of the Ministry again changed their stance and submitted before the Committee that tobacco products are of two types, i.e., 'smoking tobacco' viz., cigarettes, bidis, etc., and 'smokeless/chewing tobacco' viz., Gutkha, Zarda, Khaini, etc. The definition of 'food' under Section 3(i) of the FSS Act, 2006 is very wide. Therefore, smokeless tobacco products such as Gutkha, Zarda, Khaini and any other similar processed/flavoured chewing tobacco products are all food products under the definition of the word 'food' under the FSS Act, 2006. On the other hand, 'smoking tobacco' cannot be brought under the definition of 'food' as anything which is eaten through mouth or chewed can only be 'food'. When the Committee further disputed that in Section 2.3.4 of the Regulations *ibid*, no such explicit mention has been made, the representatives of the Ministry stressed that the relevant assumption is based on their interpretation. The Committee, thereafter, brought to the attention of the representatives of the Ministry of the fact that such types of contradiction has led to various court cases and therefore, would it not be feasible to include the said interpretation by amending the FSS Act of 2006 so that the Parliament would also get an opportunity to discuss their interpretation and classification of tobacco as 'smoking tobacco' and 'smokeless/chewing tobacco'? On this, no response was forthcoming from the representatives of the Ministry of Health & Family Welfare.
- (ii) The Committee emphasised that 'tobacco' and 'nicotine' are harmful for human consumption in view of the fact that it causes cancer and other terminal disease. On this count, the Committee would appreciate if all the tobacco products are proscribed in the country. However, proscribing a specific category of tobacco

product and on the other hand, regulating another specific category of tobacco product on the basis of 'mode of consumption', i.e., one which is 'eaten/chewed' and the other which is 'smoked' is not a legally tenable proposition and calls for a dispassionate review by the Ministry of Health & Family Welfare.

- (iii) The Ministry of Health & Family Welfare, in their replies to the List of Points forwarded by the Committee have frequently quoted the Godawat Pan Masala case of 2004 and R. Krishnamurthy case of 1979 to emphasise before the Committee that the Hon'ble Supreme Court had concurred that 'tobacco', 'supari', 'pan masala' and 'gutkha' come under the definition of 'food'. However, when the Committee undertook an intensive study of relevant judgements of Hon'ble Supreme Court, they found that in the Godawat Pan Masala case, the Hon'ble Supreme Court had held 'pan masala' and 'gutkha' as 'food' and there is absolutely no mention of 'chewing tobacco' and 'supari' in the said judgement/order. On the other hand, the Krishnamurthy Case and the judgement/order of Hon'ble Supreme Court relates to 'Gingelly Oil' and has no relation whatsoever to tobacco, supari, pan masala and gutkha. The Committee, therefore, expressed that giving misleading information to a Parliamentary Committee invariably comes under the category of 'breach of privilege'.
- (iv) The Ministry of Health & Family Welfare have selectively quoted various judgements/orders of the Hon'ble High Courts/Hon'ble Supreme Court in their replies furnished to the Committee and have not made any reference of judgment(s)/order(s) of Calcutta High Court (2014), Gauhati High Court (2014) and Patna High Court (2015), whereby, Regulation 2.3.4 of Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011 was interpreted or the orders of the Government of Assam for proscribing the 'chewing tobacco' were nullified. The Committee, therefore, urged the representatives of the Ministry to examine this issue, devoid of any pre-conceived notions, so that the all tobacco products, be it, smoking tobacco or smokeless/chewing tobacco, should be treated at par for arriving at a justifiable conclusion, either to proscribe all products that contain 'tobacco' and/or 'nicotine' or to regulate these products under COTPA.
- (v) Keeping in view the placing of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Bill, 2020 in public domain for eliciting the comments/views of public and the deletion of some important clauses relating to 'indication of nicotine and tar contents', etc., vis-a-vis the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Bill of 2015, the Committee *vide*

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their communication dated 17 March, 2021 had urged the Ministry of Health & Family Welfare to keep the finalisation of said Bill in abeyance so that all the connected aspects could be holistically deliberated upon by the Committee in wider public interests. On this, the Ministry of Health & Family Welfare informed the Committee that since a large number of comments/views have been received from public, they need more time to examine these issues and thereafter, put up their final proposal for consideration of the Committee.

- (vi) On this issue, the Committee concurred with the view point put forward by the representatives of the Ministry of Health & Family Welfare and also urged them to keep the Committee apprised of the final formulations of the said exercise so that the Committee could also get an opportunity to clarify their doubts in wider public interests.
- (vii) Keeping in view the recurring inconsistencies in the replies furnished by the representatives of the Ministry of Health & Family Welfare and their successive deposition, the Committee suggested that with a view to achieving clarity on various issues, the Ministry should constitute a 'Special Committee', consisting of 2-3 Senior Officials of the Government of India, who have not been associated with this subject at any point of time, to review the case in its entirety with an objective and independent perspective. The said Special Committee would be required to submit their report to the Committee within a month's time. The Committee would, then, undertake a final discussion with the representatives of the Ministry of Health & Family Welfare and present the report to Parliament.

9. Thereafter, the Committee heard the representatives of the Ministry of Health & Family Welfare. The major issues put forth before the Committee by these witnesses, were as follows:-

- (i) The Ministry of Health & Welfare would constitute a 'Special Committee' consisting of 2-3 Senior Officials of the Government of India, who have never been associated with any of these issues at any point of time, to look into the various facets of the case with an independent perspective. The said 'Special Committee' would formulate a report, taking into account the public health related issues, legal implications, chronological analysis of the orders/judgments pronounced by various High Courts and Supreme Court, etc., and submit the same to the Committee.
- (ii) Apart from examining legal and administrative aspects of the case, the 'Special Committee' would also undertake a study on the matter of policy decision on issues of livelihood of farmers and economic repercussions.

- (iii) Since the Ministry are already pre-occupied with various health-related issues connected with Covid-19 pandemic, it would be appreciable if the Committee consider giving two month's time to the said 'Special Committee' to submit its report to them.
- (iv) Gutkha is a product, wherein, pan masala is mixed with tobacco. Therefore, there is a ban on 'Gutkha', whereas, there is no ban on 'tobacco'. Today also, any consumer has the freedom to purchase pan masala and tobacco separately and consume it by mixing both of them. There is *per se* no ban on 'tobacco' and/or 'pan masala'.
- (v) Section 2.3.4 of Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011 only provides that 'nicotine' or 'tobacco' should not be mixed in any food product. There is no provision in Section 2.3.4 of the Regulation *ibid* that restricts selling of pan masala and tobacco separately. The policy is only confined to regulation, *i.e.*, as to how tobacco could be sold. As a matter of fact, tobacco could be sold separately and should not be pre-mixed with pan masala and to this extent only, it comes under Section 2.3.4 of the Regulation of 2011.

10. On the aspect of time limit for submission of the report by the said 'Special Committee', the Committee agreed to the proposal that the 'Special Committee' could submit their report to the Committee on Petitions, Lok Sabha within a period of two months, *i.e.*, on or before 22 February, 2022.

*[The witnesses, then, withdrew]*

11.        XXXX        XXXX        XXXX        XXXX

12.        XXXX        XXXX        XXXX        XXXX

13. A copy of the verbatim record of the proceedings of the sitting of the Committee has been kept.

The Committee, then, adjourned.

XXXX - Not related with the Report.

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**MINUTES OF THE TWENTY FOURTH SITTING OF THE COMMITTEE ON PETITIONS  
(SEVENTEENTH LOK SABHA)**

The Committee met on Monday, 17 October, 2022 from 1200 hrs. to 1500 hrs. in Committee Room 2, Parliament House Annexe (Extension), New Delhi.

**PRESENT**

Shri Harish Dwivedi - Chairperson

**MEMBERS**

2. Shri Hanuman Beniwal
3. Shri Arvind Sawant
4. Shri Brijendra Singh
5. Shri Manoj Kumar Tiwari

**SECRETARIAT**

1. Shri Raju Srivastava - Director
2. Shri Harish Kumar Sethi - Under Secretary

**WITNESSES**

**MINISTRY OF HEALTH & FAMILY WELFARE  
(DEPARTMENT OF HEALTH & FAMILY WELFARE)**

1. Shri Rajesh Bhushan - Secretary
2. Shri Alok Saxena - Additional Secretary
3. Ms. V. Hekali Zhimomi - Additional Secretary

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2. At the outset, the Hon'ble Chairperson welcomed the Members to the sitting of the Committee.

[The representatives of the Ministry of Health & Family Welfare (Department of Health & Family Welfare) were ushered in]

3. After welcoming the representatives of the Ministry of Health & Family Welfare (Department of Health & Family Welfare), the Chairperson read out Direction 55(1) of the Directions by the Speaker regarding confidentiality of the proceedings of the Committee.

4. At the outset, the Committee, while recapitulating the issues/points discussed with the representatives of the Ministry of Health & Family Welfare (Department of Health & Family Welfare) during the last sitting of the Committee held on 22 December, 2021 on the representations of S/Shri R. P. Patel and Sanjay Bechan regarding proposed amendments to the Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade & Commerce, Production, Supply and Distribution) Act, 2003 and its impact on banning indigenous chewing tobacco products *vis-a-vis* the action taken replies on the Sixty Eighth Report of the Committee on Petitions (16th Lok Sabha), sought clarifications, as under:-

- (i) During the discussion held with the representatives of the Ministry of Health & Welfare on 22 December, 2021, it was assured that the Ministry would constitute a 'Special Committee' consisting of 2-3 Senior Officials of the Government of India, who have never been associated with any of these issues at any point of time, to look into the various facets of the case including its legal and administrative aspects besides undertaking a study on the policy decision on issues of livelihood of farmers and its economic repercussions. The said 'Special Committee' would formulate a report, taking into account the public health related issues, legal implications, chronological analysis of the orders/judgments pronounced by various High Courts as well as the Supreme Court, etc., and submit the same to the Committee within a period of two months, i.e., on or before 22 February, 2022.
- (ii) The Ministry of Health & Welfare (Tobacco Control Division), however submitted Volume-I of the Report of the Expert Committee on 24 May, 2022 and informed that the Final Report would be submitted shortly.
- (iii) The Committee, in their sitting held on 13 July, 2022, undergone detailed deliberations on the findings contained in Volume-I of the Report of the Expert Committee. Pursuant to this, the Committee on Petitions were in agreement with the views expressed by the said Expert Committee *inter alia* to the effect that banning of tobacco and tobacco products is an issue which has huge implications and a decision impinge on livelihood of large number of people. A conscious decision would, therefore, need to be taken, balancing the interests of all and would therefore, require large scale consultations with stake-holders including

farmers, industry, States and concerned Ministries Departments in the Government of India.

- (iv) The Committee also endorsed the clarification made by the Expert Committee vis-a-vis their earlier submissions made by the Ministry of Health & Family Welfare, on the following aspect(s):-

*"...Under the FSS Act 2006, tobacco is neither excluded nor included in the definition of food. In the Prevention of Food Adulteration Rules, 1955, Rule 44(j) was inserted in the year 2006 which reads-*

*'44(j) Product not to contain any substance which may be injurious to health Tobacco and Nicotine shall not be used as ingredients in any food products'..*

*It may be noted that though Rule 44(j) was not originally in the PFA Rules, it was added subsequently in the year 2006, probably because the State Food Authorities could legitimately issue orders banning food products found mixed with tobacco and/or nicotine'....*

*The Prevention of Food Adulteration Act and Rules were superseded by the Food Safety and Standards Act 2006 and various regulations which were notified and come into force we.f., 5 August 2011. One of the principal regulations is the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011. Regulations 2.3.4 of Food Safety and Standards (PRS) Regulations, 2011 corresponds with Rule 44(j) of PFA Rules..."*

- (v) On this aspect, the Committee has always been of the considered view that in case, 'Tobacco' and 'Nicotine' are used as ingredients in any food product(s), the same should not be sold in the market as a food product under any circumstances. Therefore, in order to make the said proviso explicit and devoid of ambiguity, the Committee felt that Regulation 2.3.4 of the Food Safety and Standards Regulations, 2011 needs to be amended, as under:-

*"Product not to contain any substance which may be injurious to health.*

*Tobacco and Nicotine shall not be used as ingredients in any food products as otherwise all such items shall be included as 'tobacco products' and regulated through relevant Rules, Regulations, etc."*

- (vi) While emphasizing that the viability of aforementioned amendment in the Regulation *ibid* be expeditiously explored and the same should also form part of the final Report (Volume II), the Committee urged the Ministry of Health & Family Welfare to submit the final Report (Volume II), within a period of one month, *i.e.*, by 16 August, 2022. This was communicated to the Ministry *vide* Lok Sabha Secretariat O.M. dated by 15 July, 2022.
- (vii) The Ministry of Health & Family Welfare (Tobacco Control Division), thereafter, furnished the Final Report (Volume-II) of the Expert Committee *vide* their communication dated 14 October, 2022.
- (viii) The main contents of the Volume-I of the Report of the Expert Committee consisted of 26 pages, whereas the Annexures consisted of around 200 pages which contained mainly the communications of various individuals/organisations and the copies of orders of the Supreme Court. Upon plain reading of the said Report, it could be gathered that 'smoking tobacco' has been depicted as a less harmful product *vis-à-vis* 'smokeless/chewing tobacco'.
- (ix) Volume-II of the Report of the Expert Committee consisted of 9 pages only, thereby making a cumulative total of merely 35 pages. It is perturbing to note that the Expert Committee took almost 10 months for formulating such a Report.
- (x) Based on the inconclusive findings contained in the Report of the Expert Committee, the Committee, therefore, unanimously expressed their unwillingness to accept the same.

5. The Committee, thereafter, referred to the judgment dated 27.09.2022 of the High Court of Delhi which *inter alia* quashed the impugned ban on chewing tobacco products and drew attention of the representatives of the Ministry to the following aspects:-

- (i) As regards Regulation 2.3.4 of the Regulation, 2011, the Delhi High Court in paragraph 195 of the above said judgment, has *inter alia* observed that the executive power of the State is not to act as an independent law-making agency and its function is only to fill up the gaps. It is settled that the power to make the laws lies with the Legislature and not with the Executive. The Executive has to merely implement the policies/laws made by the Legislature.
- (ii) In paragraph 211 of the above said judgment, it has been *inter alia* stated that the Acts in question, *i.e.*, FSSA and COTPA, occupy different fields, *i.e.*, the former applies to the 'food industry' while the latter applies to the 'tobacco industry'.

Hence, in the considered view of this Court, the FSSA does not impliedly repeal the provisions of the COTPA.

- (iii) In paragraph 219, the Delhi High Court has *inter alia* observed that Regulation 2.3.4 *ibid* merely lays down general principle for food safety and cannot, in any manner, be read to construe that "tobacco" is "food" within the meaning of the FSSA.
- (iv) In paragraph 229, the Delhi High Court has stated that it is apparent that the classification/distinction between 'smokeless' and 'smoking' tobacco has no connection with the object sought to be achieved by the impugned Notifications. In fact, the said discrimination which is being promoted by the impugned Notifications encourages smoking tobacco over smokeless tobacco, thereby being not only clearly discriminatory but also in violation of Article 14 of the Constitution.
- (v) In paragraph 230, the Delhi High Court has further stated that the impugned Notifications have purportedly being issued in the garb of Regulation 2.3.4 which bars the usage of tobacco and nicotine in any food article.
- (vi) In paragraph 234, the Delhi High Court has *inter alia* observed that it is clear that compliance of the ban imposed on manufacturing and sale of 'Gutkha' and 'Pan Masala' with tobacco and/or nicotine has to be ensured. Nevertheless, the essence of Regulation 2.3.4 is to prohibit use of tobacco and nicotine as ingredients in any food products and not prohibit the manufacture and sale of tobacco and/or nicotine *per se*.
- (vii) In paragraph 236, the Delhi High Court has clearly stated that tobacco, in any form, not only 'smokeless' but also 'smoking', is injurious to public health.
- (viii) In paragraph 238(c), the Delhi High Court has asserted that it has never been the intention of the Parliament to impose an absolute ban on manufacture, sale, distribution and storage of tobacco and/or tobacco products. However, the intention of the Parliament is to regulate the trade and commerce of tobacco and tobacco products in accordance with the COTPA, a Central Act which deals with tobacco industry. Further, in paragraph 238(e), the Court explicitly stated that tobacco cannot be construed as "food" within the meaning of the provisions of FSSA. Also, in paragraph 238(f), the Court has contended that the impugned Notifications for banning tobacco products have been issued without following the general principles laid down under various provision(s) of the FSSA, which is a clear abuse of the powers conferred upon under the FSSA.

(ix) As regards Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, the Committee have been deliberating on its provisions in their earlier sittings on the subject. Besides, the Ministry were also asked to furnish the clarifications on the inconsistencies in the COTPA (Amendment) Bill. However, the Ministry have not yet furnished their clarification. In this backdrop, the Committee enquired as to whether the Ministry are contemplating to introduce amendments in respect to following aspects:-

- (a) Since the 'powers to amend' have been retained by the Ministry themselves, how it could be ensured that after amendment in the COTPA Act, smoking tobacco would not be given concession *vis-a-vis* smokeless/chewing tobacco over the time?
- (b) If COTPA has to be considered as the Principal Act, whether other relevant Act(s) would be in consonance with the provision(s) of the Act *ibid*? If not, how such consistency could be ensured in future?
- (c) Whether the clause(s) relating to fixing standards for 'nicotine and tar contents' in tobacco products as well as powers to conduct test(s) would be included in the COTPA (Amendment) Bill?

6. Thereafter, the Committee heard the representatives of the Ministry of Health & Family Welfare. The major issues put forth before the Committee by these witnesses, were as follows:-

- (i) As per the directions of the Committee on Petitions, the Ministry of Health & Family Welfare had constituted an 'Expert Committee' consisting of Senior Officials of the Government of India, who have never been associated with any of these issues at any point of time, to look into the various facets of the case with an independent perspective, which was not an Internal Committee of the Ministry. The said 'Expert Committee' consisted of representatives from the CGHS, NITI Aayog, AIIMS, Department of Agriculture & Farmers' Welfare, Department of Legal Affairs, Non Communicable Diseases Division (ICMR) and FSSAI.
- (ii) The Ministry of Health & Family Welfare had already asked the said 'Expert Committee' to examine and give their opinion on the alternate formulation in regard to Regulation 2.3.4 of the Food Safety and Standards Regulations, 2011 as suggested by the Committee on Petitions *vide* Lok Sabha Secretariat O.M. dated 15 July, 2022.

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- (iii) The Ministry has been waiting for the final judgment of the Areca Nut Case (tagged with 70 other related cases), wherein, the question as to whether tobacco is a food product or not is expected to be resolved, which is pending in the Supreme Court since 2016-17. Besides, the Ministry is not in favour of challenging the recent judgement of the High Court of Delhi and at the same time.
- (iv) As regards formulation and enactment of any Subordinate Legislation, the final decision is taken by the highest level. The Competent Authority has already been briefed about the alternate formulation in regard to Regulation 2.3.4, in question and a formal meeting for discussing the matter would be held soon.
- (v) The Ministry fully endorses the views of the Committee that consumption of 'tobacco', in any form is harmful for public health and does not want to discriminate the same on the basis of its form which is evident from the mandatory graphic warning on the packets of 'smoking tobacco' as well as 'smokeless/ chewing tobacco'.

*[The witnesses, then, withdrew]*

7.	XXXX	XXXX	XXXX	XXXX
8.	XXXX	XXXX	XXXX	XXXX
9.	XXXX	XXXX	XXXX	XXXX
10.	XXXX	XXXX	XXXX	XXXX

11. A copy of the verbatim record of the proceedings of the sitting of the Committee has been kept.

The Committee, then, adjourned.

XXXX - Not related with the Report.