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IN THE HIGH COURT OF DELHI AT NEW DELHI

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W.P.(C) 4470/2023 & CM APPL. 17145/2023**DHARAMPAL SATYAPAL LIMITED AND ANR Petitioners**

Through: Mr. C. S. Vaidyanathan, Sr. Advocate
with Mr. Vivek Kohli, Sr. Advocate
with Mr. Nalin Talwar, Mr. Sanjai
Kumar Pathak, Mrs. Bhavya Bhatia,
Mr. Arvind Kumar Tripathi, Mrs.
Bhavya Bhatia, Mrs. Shashi Pathak,
Mr. Aashish Kaushik, Mr. Jatin
Nirwan, Ms. Divyanshi Mohan,
Advocates

versus

UNION OF INDIA THROUGH SECRETARY Respondent

Through: Mr. Anurag Ahluwalia, CGSC with
Mr. Tarveen Singh Nanda, Govt.
Pleader, for R-1/UOI
Mr. Aditya Singla, Ms. Supriya
Juneja, Ms. Saakshi Garg, Mr. Ritwik
Saha and Mr. Rahul, Advocates for
R-2/FSSAI

Reserved on: 02nd May, 2024Date of Decision: 9th July, 2024

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CORAM:**HON'BLE THE ACTING CHIEF JUSTICE****HON'BLE MS. JUSTICE MANMEET PRITAM SINGH ARORA****J U D G M E N T****MANMEET PRITAM SINGH ARORA, J:**

1. Present writ petition has been filed under Article 226 of the Constitution of India seeking a declaration that Regulation 2(i) ('impugned Regulation') of the Food Safety and Standards (Labelling and Display) Second Amendment Regulations, 2022 ('Second Amendment Regulations')



published on 11th October, 2022 be declared as illegal and violative of Articles 14, 19(1)(a) and 19(1)(g) of the Constitution of India. Petitioners also seek a declaration that the impugned Regulation is *ultra vires* the Food Safety and Standards Act, 2006 ('FSS Act').

2. Petitioners herein are aggrieved by the impugned Regulation inasmuch as vide the said Regulation, the Respondent No.2 i.e., the Food Safety and Standards Authority of India ('FSSAI'), has enhanced the size of statutory warning on Pan Masala packages to the extent of 50% of front-of-pack of the label from the erstwhile warning size of 3mm.

3. Petitioner No. 1 Company herein is a licensed manufacturer and trader of Pan Masala brands, namely, Rajnigandha, Tansen, and Mastaba. Petitioner No. 2 is a shareholder and one of the directors of the Petitioner No. 1 Company.

Submission of Counsel for parties

4. Mr. C.S. Vaidyanathan, learned senior counsel for the Petitioners stated that a conjoint reading of Sections 4, 16 and 18 of the FSS Act would indicate that the Food Authority constituted under Section 4 of the said Act, is the apex body to decide on issues relating to food safety, food standards and all other issues including labelling etc. He stated that all Regulations under the FSS Act have to be framed by the Food Authority after a thorough 'risk assessment' based on scientific material and evidence. He stated that the 'scientific opinion' is provided to the Food Authority, by the Scientific Panel and the Scientific Committee, set up under Sections 13 and 14 of the FSS Act, respectively.

4.1. He stated that thus, the structure and hierarchy of the organisation under the FSS Act would indicate that: (a) the Food Authority requests for



‘scientific opinion’ on an issue; (b) the Scientific Panel first explores the issue and provides its input; (c) thereafter, the Scientific Committee, after a review and wide consultation with all stakeholders, adopts the ‘scientific opinion’; (d) the ‘scientific opinion’ is then forwarded to the Food Authority; (e) the proposed regulations are framed by the Food Authority on the basis of the ‘scientific opinion’ and put out for a second round of public consultation; and (f) finally, after a thorough review and consideration of all comments received, the regulations are framed.

4.2. He stated that the term ‘risk’ is defined in the FSS Act and ‘risk analysis’ comprises three stages in the sequence of ‘risk assessment’, ‘risk management’ and ‘risk communication’. In this regard, he referred to sub-sections (zm), (zn), (zo), (zp) and (zq) of Section 3 of the FSS Act. He stated that thus, ‘risk analysis’ is a comprehensive process wherein every decision of the Food Authority is taken on the basis of scientific material; after discussion with the stakeholders and finally, the decision taken, along with reasons for same, is communicated to the stakeholders. He stated that the interactive and collaborative process which is informed by the scientific output is self-evident.

4.3. He stated that, however, in the present case, the impugned Regulation 2(i) was brought into force without following the aforesaid statutory process. In this regard, he relied upon the reply dated 20th February, 2023 issued by the Food Authority to an application filed by a third party under the RTI Act¹, seeking information with respect to the rationale for enhancing the size of the statutory warning to cover 50% of front-of-pack of the label. He stated that in the said reply, Food Authority has only relied upon the minutes

¹ Right to Information Act, 2005.



of the 31st Meeting of the Scientific Committee held on 15th November, 2018 and 27th Meeting of the Food Authority held on 04th February, 2019; and has failed to provide any study or report available with the Food Authority.

4.4. He stated that there is admittedly no opinion of the Scientific Panel or Scientific Committee to justify the decision to increase the size of the statutory warning from 3mm to 50% of the front-of-pack of the label. He stated that to the Petitioners' knowledge, no study was done by the Scientific Panel or Scientific Committee before proposing the said increase in the size of the statutory warning. He stated that in fact to the knowledge of the Petitioners, no study or analysis has ever been conducted by the Respondents in accordance with the procedure of FSS Act to support the content of the statutory warning qua the Pan Masala. He stated that there is no study, data or material to justify the content or the size of the statutory warning.

4.5. He stated that under the FSS Act, the standards for articles of food are to be governed and regulated by science-based standards and since in this case, there is absence of a scientific opinion, the decision of the Food Authority recommending the increase in the size of warning to 50% of front-of-pack of the label cannot stand and is liable to be struck down. He stated that revision of a Regulation expressly requires the follow-up of the entire process of the scientific opinion and interactive consultation validating the proposed revision in terms of Section 18(2)(d) of the FSS Act. In support of his contentions, he relied upon the judgment of the Supreme Court in ***Cellular Operators Association of India and Others v. Telecom Regulatory***



Authority of India and Others².

4.6. He stated that Respondent No. 2 has relied upon the scientific studies referred to in the judgment of the Supreme Court in ***Union of India v. Unicorn Industries***³ which opined that Pan Masala with or without tobacco have been found to be the cause of oral cancer. He stated that, however, the scientific studies referred to in the said judgement are of the years 2007, 2010 and vintage. He stated that so also the report of the National Institute of Health and Family Welfare ('NIHFW') placed on record as Annexure R-2/2 is of the year 2011. He stated that these studies were available with the Scientific Panel and Scientific Committee when the initial Food Safety and Standards (Packaging and Labelling) Regulations, 2011 ('Regulations, 2011') and subsequent Food Safety and Standards (Labelling and Display) Regulations, 2020 ('Regulations, 2020') were published and yet, the Food Authority was satisfied that the warning size of 3mm on the pack of Pan Masala is sufficient. He stated that, therefore, the proposed change by the impugned Regulation would necessarily have to be supported by fresh material (post 2020) so as to demonstrate the inadequacy of the existing warning size of 3mm in meeting the risk management. He stated that no requisite fresh material has been shown by Respondent No. 2 in these proceedings, to justify the proposal of the impugned Regulation in the year 2022.

4.7. He stated that in fact, the Minister of State for the Ministry of Health and Family Welfare ('MoHFW') informed the Parliament on 19th November, 2019 by way of a written answer to an unstarred question that

²(2016) 7 SCC 703, para 92

³(2019) 10 SCC 575



ICMR has estimated the mortality due to cancer of mouth as 34,668, 37,212 and 39,951 in the years 2016, 2017 and 2018 respectively. He stated that, however, the Minister clarified that there is no separate data available to ascribe the above deaths due to Pan Masala consumption. He stated that, therefore, privately prepared reports without the knowledge and participation of the stakeholders cannot be accepted as the ultimate truth.

4.8. He stated that as per the Petitioners, there is no expert study, which necessitated a change from the existing Regulations, 2020 for an amendment being carried out in 2022. He stated that the process of drafting and notification of the Regulations, 2020 commenced when the draft of said Regulation was first published on 25th June, 2019⁴ and stood concluded when the Food Safety and Standards (Labelling and Display) Regulations, 2020 were notified on 17th November, 2020. He stated that in these writ proceedings, Respondent No. 2 has relied upon the meetings of the Scientific Committee held on 15th November, 2018 and the Food Authority's meeting held on 04th February, 2019 to justify the increase of the warning size to 50% of front-of-pack of the label, however, the process of Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2021 ('First Amendment Regulations') was underway during the same period and there was no proposal therein for increasing the label size to 50% in the draft of the First Amendment Regulations. He stated that, therefore, the Second Amendment Regulations proposing the impugned Regulation 2(i) is based on whims, surmises and conjectures and is liable to be struck down.

4.9. He stated that, in fact, in the 35th Meeting of the Scientific Committee

⁴Draft Food Safety and Standards (Labelling and Display) Regulations, 2019



held on 11th August, 2020, the Committee recommended continuance of the statutory warning as per existing Regulation and, therefore, the amendment proposing to increase the warning size to 50% of front-of-pack of the label is contrary to the said minutes. He stated that no explanation is forthcoming from Respondent No.2 for the contradiction between these minutes and the impugned amendment to the Regulation.

4.10. He stated that it appears from the record that the size of the warning statement was increased to 50% at the instance of one member of the Scientific Committee at the 31st Meeting dated 15th November, 2018 and thereafter, the said suggestion has been implemented without any deliberations as required under the FSS Act.

4.11. He stated that the publication of the warning statement 'Chewing of Pan Masala is injurious to health' has been in force for many years and the size of the lettering of the warning has been maintained as 3mm; and nothing has been produced by Respondent No. 2 to show as to why it is not effective. He stated that the minutes of the meeting of the Food Authority or Scientific Committee or Scientific Panel do not record why the 3mm warning statement as per existing Regulations was not sufficient to communicate the risk to the consumer. He stated on the other hand the size of the statutory warning for: (i) Betel nut or Areca nut, which is the principal ingredient of Pan Masala and (ii) Alcohol, which is admittedly acknowledged as a harmful substance; the size on the packaging is being maintained at the original size of 3mm. He stated that if the said size of 3mm is sufficient to convey the warning message to the consumers of supari and alcohol, it is absurd to hold that the same size of warning on Pan Masala packet is not sufficient for its consumers. He stated that Pan Masala is the



aggregate of its constituent ingredients including Areca nut. He stated that the prescription of different sizes of warning between Pan Masala, Areca nut (sold as an individual item) and Alcohol shows patent arbitrariness in the decision making by the Food Authority. He stated that Respondent No.2 has admitted that the increase in the size of the statutory warning for Alcohol is still under consideration and has not been enhanced. He stated that this as well shows arbitrariness and inconsistency in the stance of the Food Authority.

4.12. He stated that the doctrine of proportionality requires Respondent No. 2 to apply its mind to the various options available to it for achieving the effective communication of the statutory warning to the consumer. He stated that there is no material relied upon by Respondent No. 2 to elect to increase the warning size to 50% of front-of-pack of label from the existing letter size of 3mm. He stated that enhancing the warning size to 50% of front-of-pack of the label for the package of Pan Masala is disproportionate considering that similarly placed products such as Alcohol and Areca nut (as an individual item) continue to be sold with a warning letter size of 3mm; meaning thereby that 3mm letter size is sufficient. In this regard, he relied upon the judgment of the Supreme Court in *Anuradha Bhasin v. Union of India & Others*⁵ and *Om Kumar & Others v. Union of India*⁶.

Respondent's arguments

5. In reply to the contentions raised by the Petitioners, Mr. Aditya Singla, learned standing counsel for Respondent No. 2 stated that Section 42 (ZZZ)(3) of the Prevention of Food Adulteration Rules, 1955 ('Rules of

⁵(2020) 3 SCC 637, paras 78 to 80

⁶(2001) 2 SCC 386 paras 53, 54, 66 and 67



1955') which came into effect on 08th September, 1990 mandated that every package of Pan Masala and advertisement related thereto shall carry the warning 'Chewing of Pan Masala may be injurious to health'. He stated that the said rules were formulated under the then Prevention of Food Adulteration Act, 1954 ('Act of 1954').

5.1. He stated that the Act of 1954 and the Rules of 1955 were repealed by FSS Act w.e.f. 04th August, 2011 and thereafter, the Regulations 2011 came into effect from 05th August, 2011, wherein Regulation 2.4.4(30) prescribed that every package of Pan Masala and advertisement related thereto shall carry the warning 'Chewing of Pan Masala is injurious to health'. He stated that as is evident, the warning statement was modified and the expression 'may be' was replaced with 'is'.

5.2. He stated that subsequently, the Food Authority divided the Regulations 2011 into two sets of Regulations namely (i) the Food Safety and Standards (Packaging) Regulations, 2018; and (ii) the Food Safety and Standards (Labelling and Display) Regulations, 2020.

5.3. He stated that under the Schedule II of Regulations 2020, the Mandatory Declarations at Serial No. 1(3)(1) continue to mandate that every package containing Pan Masala and advertisement relating shall carry the warning and /or declaration that 'Chewing of Pan Masala is injurious to health'.

5.4. He stated that it is not disputed by the Petitioners that they are already carrying the Mandatory Declaration on their packages containing Pan Masala; however, the same is only 3mm in size. He stated that the wording in the warning from 'may be' to 'is' was changed as far back as in the year 2011, and no challenge to the same has been raised till date.



5.5. He stated that the existence of the warning statement since the year 1990 and its modification in the year 2011, shows that the 'risk assessment' qua this product already exists. He stated that the exercise contemplated in the FSS Act qua 'risk', 'risk analysis', and 'risk assessment' was undertaken in the very first instance when the statutory warning was put in place at the time of the enactment of the Rules of 1955 when w.e.f. 08th September, 1990 the warning was included. He stated the substance of the warning was continued by the Regulations, 2011 and thereafter by the Regulations, 2020.

5.6. He stated the only change sought to be affected by way of the impugned Regulation is the increase in the size of the statutory warning on the packet of Pan Masala. He stated that this direction issued by the Food Authority is the 'risk management' as contemplated under Section 3(zq) of the FSS Act, considering the fact that risk assessment already exists.

5.7. He stated that the Petitioners have not placed any material on record to refute the studies referred to by the Supreme Court in *Unicorn Industries* (supra) and the report of NIHFWD dated 09th February, 2011. He stated that IARC, Lyon (WHO) have in fact, classified Areca nut as a Group-1 cancer-causing agent.

5.8. He stated that the deliberations to increase the warning size on the package of Pan Masala began in the year 2019; however, in the meantime, some other amendments were approved which were notified as the First Amendment Regulations.

5.9. He stated that the submission of the Petitioners that there is a contradiction between the amendment proposing an increase of the warning size to 50% of front-of-pack of the label and the Minutes of the Scientific Committee's 35th Meeting dated 11th August, 2020 is incorrect and



misconceived. He relied upon the Agenda of the said 35th Meeting and stated that there was a proposal before the Scientific Committee to review the warning statement and replace the existing word ‘Chewing’ with ‘Consumption’ in the said statement. He stated that the Scientific Committee recommended continuance of the warning statement as per existing Regulation and, therefore, the proposed change of replacing the word ‘Chewing’ with ‘Consumption’ was not given effect. He stated that the issue of increasing the size of the warning to 50% was not a subject matter of these meetings.

5.10. He stated that the Petitioners’ contention that the suggestion made by the Scientific Committee in its 31st Meeting held on 15th November, 2018 is without any basis or discussion is incorrect and contrary to record. He relied upon the Agenda for the said 31st Meeting and the contents of the Agenda item at serial no. 4.5 (iv) and (v) which record the scientific opinion of the Scientific Panel that the Pan Masala is not safe for human consumption and also refer to three (3) separate studies of the years 2015, 2016 and 2018, reporting the adverse effects of Pan Masala on human health. He stated that, therefore, the decision of the Scientific Committee was evidently based on studies and the scientific opinion of the Scientific Panel.

5.11. He stated that warning size has been increased as a measure of public health policy and to increase consumer awareness. He stated that the warning size is not arbitrary, unreasonable or disproportionately harsh. He stated that the same is a reasonable restriction in terms of Article 19(6) of the Constitution of India and is in the interest of the general public. He relied upon the judgment of the Supreme Court in *Unicorn Industries* (supra) to contend that the harmful effects of Areca nut and Pan Masala have been



judicially noticed by the Supreme Court in the said judgment. He stated that a proposal to increase the size of the warning on Alcohol is under consideration. He stated that the Petitioners cannot rely upon the Regulations applicable to Alcohol for challenging the impugned Regulation 2(i).

5.12. He stated that the draft notification proposing an increase in warning size to cover 50% of front-of-pack labelling of Pan Masala was issued on 06th September, 2021 to seek comments from the stakeholders. He stated, however, no representation was received from the Petitioners herein. He stated that the comments received from the stakeholders were deliberated by the Scientific Panel in its 38th Meeting dated 07th December, 2021 and it was decided to recommend it for final notification without any change. He stated that the Scientific Committee at its 40th Meeting dated 28th December, 2021 approved the final draft notification and the Food Authority also approved the final draft notification at its 38th Meeting dated 02nd March, 2022.

5.13. He stated that the Second Amendment Regulations were notified on 11th October, 2022 after getting approval from MoHFW on 04th October, 2022 and were to come into force w.e.f. 01st May, 2023. He stated that, however, representations were received by Respondent No. 2 from stakeholders requesting for an extension so as to exhaust the packaging material having the existing warning and to arrange for the new packaging material. He states that Respondent No. 2 acting upon the said representations deferred the enforcement of the impugned Regulation on three different occasions.

5.14. He stated that the enhancement of the size of the warning statement to 50% is not arbitrary, unreasonable or disproportionately harsh. He relied



upon paras 19 to 22 of Respondent No.2's counter affidavit. He stated that the intention of the Food Authority is that since the warning statement serves as a crucial public health measure it is imperative that these warning statements are made highly visible and bold on the package so that the same are noticeable to the consumer and effectively communicate the health risk associated with Pan Masala consumption. He stated that with respect to increase in the size of the warning statement on Alcohol, the said issue is being considered actively.

Analysis and findings

6. We may note, at the outset, that during the proceedings, Respondent No. 2 pointed out that the warning statement on the package that 'Chewing of Pan Masala **may be** injurious to health' was introduced in the year 1990 and was modified in the year 2011, to read as 'Chewing of Pan Masala **is** injurious to health' and continues till date. Respondent No. 2 also pointed out that the Petitioners are, in fact, already carrying the aforesaid warning statement on their package without any demur, except the same is only 3mm in size. Respondent No. 2 stated that in view of the said historical fact the challenge to the content of the warning on the allegation of non-compliance of 'risk analysis' is without any basis. At this stage, on 24th April, 2024 learned senior counsel for the Petitioners stated, on instructions, that the Petitioners are not pressing their challenge to the content of the warning statement and are willing to continue with carrying the mandatory warning statement on the package; and the present writ petition is only confined to challenging the enhancement of the warning size from 3mm to 50% of front-of-pack of the label vide impugned Regulation. For this reason, even in the written submissions, no challenge has been raised by the Petitioners to the



content of the warning statement.

With respect to compliance of statutory procedure prescribed under FSS Act by Respondent No. 2

7. The Respondent No. 2 has placed on record the relevant extracts of the Agenda(s) and Minutes of Meeting(s) of the Scientific Panel, Scientific Committee, and the Food Authority, wherein it was decided to increase the warning size to cover 50% of front-of-pack of the label.

8. Respondent No. 2 has placed on record:- (i) the Agenda and Minutes of the 31st Meeting dated 15th November, 2018 of the Scientific Committee, which suggested increase in the warning size from 3mm to cover 50% of front-of-pack of the label, (ii) the Agenda and Minutes of the 27th Meeting dated 04th February, 2019 of the Food Authority approving the aforesaid suggestion of the Scientific Committee, (iii) the Agenda and Minutes of the 28th Meeting dated 30th April, 2019 of the Scientific Panel on Labelling and Claims/Advertisements agreeing with the recommendation of the Food Authority with respect to increase in the warning size; wherein the Scientific Panel also took into consideration the recommendations dated 06th December, 2018 made by MoHFW for increasing the said warning size, (iv) the Agenda and Minutes of the 35th Meeting dated 11th August, 2020 of the Scientific Committee, wherein the Committee approved the enhancement of the warning size to 50% and a draft notification proposing the enhanced warning size of 50% was recommended for placing before the Food Authority, and (v) the Agenda and Minutes of the 31st Meeting dated 20th October, 2020 of the Food Authority approving the draft notification for amending the regulations to increase in the size of the warning statement to 50% of front-of-pack of the label.



9. Thereafter, on 06th September, 2021, the draft of the Second Amendment Regulations was notified for seeking comments from the stakeholders. This draft amendment included the proposal to enhance the warning statement to 50% of front-of-pack of the label of Pan Masala. At this stage, it is pertinent to note that no representation or comments was filed by the Petitioners herein against the impugned Regulation.

10. Petitioners have alleged that the aforesaid Second Amendment Regulations were mooted by the Food Authority without any scientific opinion and any risk analysis. The said submission of the Petitioners is contrary to the record. The Agenda for the 31st Meeting of the Scientific Committee and more specifically, item 4.5 therein, records that the Scientific Panel on Food Additives after granting a hearing to the All India Pan Masala Manufacturers Association ('Association') in its 37th Meeting held on 18th July, 2018 and after considering three (3) separate studies of the years 2015, 2016 and 2018, highlighting adverse effects of Pan Masala on human health, had in fact, concluded that the Pan Masala is neither a food and nor safe for human consumption and recommended review of its inclusion as a food for human consumption under FSS Regulations. The Scientific Panel undertook the review of the adverse effects of Pan Masala while considering an application of the Association seeking permission for the use of Magnesium Carbonate in Pan Masala.

10.1. The Scientific Committee in its 31st Meeting dated 15th November, 2018, endorsed the opinion of the Scientific Panel on Food Additives and did not agree to the request of the Association for permitting the use of Magnesium Carbonate in Pan Masala. However, in view of the findings of the aforesaid Scientific Panel qua health hazards associated with Pan



Masala, the Scientific Committee recommended that the warning statement be changed to ‘**Consumption**⁷ of Pan Masala is injurious to health’ and the warning size should cover **50%** of front-of-pack of the label.

11. In the meantime, the Under Secretary of MoHFW also held a meeting on 06th December, 2018 of experts, medical officials, and representatives of Respondent No. 2. In this meeting, after considering the Expert Group Report of 2016 submitted to the High Court of Punjab and Haryana and the classification of Areca nut by IARC, Lyon (WHO), the MoHFW identified Areca nut, Betel Quid, and Alcohol as priority groups of cancer-causing agents. The Committee concluded that there was an urgent need to make changes in the existing regulations to especially include pack warnings on the products containing Areca nut or its produce including Arecaline with specific emphasis on the size of the warning. The relevant portion of the deliberations in these Minutes reads as under:

*“The meeting started with welcome remarks by chairman. Thereafter Sh. Rajeev Kumar briefed the members about the background. He informed that a technical committee to assess the impact of cancer causing agents (carcinogens) and to suggest preventive and corrective measures has prioritized the carcinogens along with strategies for their prevention and control. The expert group submitted the report in 2016 pursuant to court case in Hon'ble High court of Punjab & Haryana. The report was shared with stakeholders including various ministries ,ICMR and FSSAI for further necessary action as suggested by the expert group. **Areca nut, Betel Quid and Alcohol were recommended as priority groups of cancer causing agents.** The summary of report was also shared with the members.*

*The warning label of bigger size similar to tobacco may be required on **Areca nut containing packets.** Dr Ravi Mehrotra further informed that NICPR is knowledge hub for tobacco control and they have also published certain studies in this regard.*

*Dr. Sudhir Gupta informed that **Areca nut is carcinogenic and several***

⁷As against Chewing of Pan Masala is injurious to health



studies have been done. It is group-I cancer causing agent as suggested by IARC, Lyon (WHO) and expert group has put it at no. no.2 priority item for the country. Betel quid at Sl. no. 3 is Paun or similar products containing Areca nut and other substances. He further intimated that the sale of Areca nut is banned in Australia and UAE. In some countries like Indonesia the pictorial warning are used for use of Areca nut.

FSSAI informed that Areca nut is covered under foods safety act as food item. **There are regulations available for its quality but not with a view to curb its use.** Existing standards are needed to be reviewed/ revised and approved by the expert panel at FSSAI. It was informed by FSSAI that they have referred the subject matter of treatment of Areca nut and Arecoline as a carcinogen. It came out of deliberations that:

a) **Suitable changes can be made in appropriate regulations such as advertisement and claims and labelling to include pack warning on the products containing Areca nut or its produce including Arecoline. Pack warning has to be distinct, pictorial and should cover substantial portion of the pack.**

b) **Areca nut and its preparations are sold loose also. Therefore, a point of sale warning such as being used for tobacco to be considered.**

c) **Ban on advertisements of the products containing Areca nut, Arecoline or its products.**

Alcohol is also a known and identified carcinogen. At present pack warning is very small and may not be having enough effect on reduction in demand. Consumption of Alcohol is also increasing. FSSAI may revisit pack warning size by making its description bold on the front and pictorial.

The meeting ended with vote of thanks to chair.”

(Emphasis Supplied)

12. The Food Authority in its 27th Meeting held on 04th February, 2019, considered the opinion of the Scientific Panel and the Scientific Committee's dated 15th November, 2018. It approved the suggestion of the Scientific Committee to change the warning statement to '**Consumption**⁸ of Pan Masala is injurious to health' and increase the warning size to **50%** of front-of-pack of the label. The Food Authority also approved the recommendation of the Scientific Panel and the Scientific Committee to not

⁸ As against Chewing of Pan Masala is injurious to health



allow the request of the Association for the use of Magnesium Carbonate as a food additive in Pan Masala. The Food Authority, however, did not agree to suggestions for the removal of Pan Masala from FSS Regulations.

13. Therefore, the Scientific Panel on Labelling and Claims/ Advertisements in its 28th Meeting dated 30th April, 2019 considered the afore-noted minutes of the meeting and Guidelines dated 06th December, 2018 of the MoHFW as well as the decision of the Food Authority dated 04th February, 2019 approving the change in the warning statement and increase in the warning size. The Panel recorded its agreement with the recommendations of MoHFW and the Food Authority concerning increase in the size of the warning statement on the package qua Pan Masala; the Panel, however, recommended that the text of the warning statement which is already specified in the existing regulation may be continued, and it recommended that the warning statement should be specified on front-of-pack of the label. The Panel recommended that modification to the Regulations for pack warnings should be considered while finalising the draft of the Food Safety and Standards (Labelling and Display) Regulations, 2019 ('draft Regulations, 2019').

14. In view of the aforesaid recommendations of the Scientific Panel, the issue of substituting the word 'Chewing' with 'Consumption' in the warning statement was placed for re-consideration before the Scientific Committee in its 35th Meeting held on 11th August, 2020. The draft notification proposing an amendment to increase the warning size to cover 50% of front-of-pack of the label with the existing warning statement was also placed for approval. The Scientific Committee after taking note of the aforesaid recommendations of the (a) Scientific Panel on Food Additives, (b)



Scientific Panel on Labelling and Claims/Advertisements and (c) the Food Authority recommended continuance of the warning statement in its existing form i.e., ‘Chewing of Pan Masala is injurious to health’ with a modification that the warning size to cover 50% of front-of-pack of the label.

14.1. We may note here that the Scientific Committee in its 31st Meeting dated 15th November, 2018 had initially suggested a modified warning statement ‘**Consumption**⁹ of Pan Masala is injurious to health’; however, in its 35th Meeting dated 11th August, 2020 it recalled the said suggestion in view of the recommendation of the Scientific Panel on Labelling and Claims/Advertisements in its 28th Meeting dated 30th April, 2019 to continue with the existing text of the warning statement.

15. In the aforesaid changing scenario, when the matter was placed before the Food Authority in its 31st Meeting held on 20th October, 2020 it approved the draft notification (as approved by the Scientific Committee on 15th November, 2018) proposing amendment to the Regulations, 2020 to propose warning statement to cover 50% of front-of-pack of the label, without changing the content of the warning statement.

15.1. We may note here that the Food Authority in its 27th Meeting dated 04th February, 2019 had initially approved a modified warning statement ‘**Consumption**¹⁰ of Pan Masala is injurious to health’, however, in its 31st Meeting dated 20th October, 2020 it recalled the earlier approval in view of the recommendation of the Scientific Committee made in its 35th Meeting dated 11th August, 2020.

16. The aforesaid facts show that the decision of the Food Authority to

⁹ As against Chewing of Pan Masala is injurious to health.

¹⁰ As against Chewing of Pan Masala is injurious to health



increase the warning size on front-of-pack of the label to 50% is based on concerted deliberations of the Scientific Panel on Additives, Scientific Committee, Scientific Panel on Labelling and Claims/Advertisements, the guidelines issued by MoHFW and expert studies/reports, which led to the conclusion that due to the use of Areca nut in Pan Masala it is extremely hazardous to the consumer; and, therefore, there is a necessity to enhance the communication of the warning through labelling for public awareness. Hence, the submission of the Petitioners that the recommendation for enhancing the warning size to 50% of front-of-pack of the label was a consequence of a random suggestion by a member of the Scientific Committee at its meeting held on 15th November, 2018 is fallacious, incorrect and contrary to the record.

17. It is admitted that on 06th September, 2021 the draft of the Food Safety and Standards (Labelling and Display) Second Amendment Regulations, 2022 was notified for seeking comments from the stakeholders in compliance with Section 18(2)(d) of the FSS Act. We may note here that it is admitted that the Petitioners herein did not make any representation with respect to the proposed amendment in response to the said draft notification inviting comments from the stakeholders. Petitioners admit knowledge of the notice inviting objections; however, the petition is silent as regards the inaction of the Petitioners to participate in the consultations.

18. Respondent has placed on record, the minutes of the 38th Meeting of the Scientific Panel on Labelling and Claims/Advertisements dated 07th December, 2021, which deliberated on the comments, received from stakeholders and thereafter, recommended the final notification without any change. Respondent has also placed on record the minutes of the 40th of the



Scientific Committee Meeting dated 28th December, 2021, which approved the final notification and finally, the minutes of the 38th Meeting of the Food Authority dated 02nd March, 2022 approving the final notification after considering the above. It is only thereafter, that the Second Amendment Regulations were notified on 11th October, 2022 after getting approval from MoHFW on 04th October, 2022.

19. The afore-noted facts disclose that the Food Authority, before framing the impugned Regulation, took into account scientific opinion provided by the Scientific Committee and concerned Scientific Panel, which was based on the scientific evidence of expert studies including the report of WHO¹¹; and it was after transparent public consultation that the Food Authority notified the impugned Regulation for the protection of the interest of the consumers in accordance with Sections 16 and 18 of the FSS Act.

20. In fact, the Petitioners having elected to remain outside the consultation process despite the notification inviting comments to the draft Regulations raises question about its locus to maintain this challenge. The reliance placed on the judgment of *Cellular Operators* (Supra) is not attracted in the facts of this case, since the Food Authority undertook consultation with the stake holders in a transparent manner and the Petitioners themselves elected not to participate in the said process.

21. In view of the afore-noted facts, the arguments advanced by the learned senior counsel for Petitioners with regard to impugned Regulation being *ultra vires* the FSS Act are without any merits.

With respect to non-inclusion of the statutory warning of 50% on front-of-pack of label in the draft Regulations dated 25th June 2019, notified as Regulations 2020 on 17th

¹¹ World Health Organization



November, 2020

22. The timeline of 15th November, 2018 to 20th October, 2020 shows that labelling of Pan Masala i.e., the issue of increase in warning size to 50% was actively under consideration, however, it was recognised within the Food Authority as a sensitive¹² issue; and the decision to increase the size of warning attained finality on 20th October, 2020, which is much after the draft Regulations, 2019 had been notified for inviting objections and suggestions on 25th June, 2019 and its adoption as the Regulations, 2020. Therefore, the contention of the Petitioners that the proposal to amend Regulations, 2020 to bring in the impugned amendment in the year 2022 is without any expert study or necessity is misconceived and contrary to record. The record of the Food Authority duly explains the time taken for proposing the impugned Regulation vide the Second Amendment. Even otherwise, given the fact that impugned Regulation has been brought on the statute book in the interest of public health, the delay in proposing an amendment is no ground for challenging the same.

With respect to availability of fresh Scientific studies prior to proposing the impugned Regulation

23. Respondent No. 2 has placed on record the agenda item no. 7 for the 28th meeting of the Scientific Panel on Labelling and Claims/Advertisements dated 30th April, 2019. The said agenda item refers to a meeting held in the MoHFW on 06th December, 2018 to discuss the issues related to the Areca nut and guidelines for its prevention and control. It refers to a report of 2016 prepared by an Expert Group i.e., a technical committee for assessing the impact of cancer-causing agents (carcinogens) and submitted to MoHFW. It

¹² Refer to the Agenda No. 2.2(3) of the 35th Scientific Committee Meeting



records that the said report of the Expert Group was submitted to the High Court of Punjab and Haryana and shared with stakeholders including Food Authority for taking necessary action as suggested in the report. It records that Areca nut, Betel Quid, and Alcohol have been recommended by the Expert Group as the priority group of cancer-causing agents. The Agenda notes that Areca nut is carcinogenic and has been identified as a Group-1 cancer-causing agent by the International Agency for Research on Cancer ('IARC'), Lyon (WHO) and the Expert Group and has put it at No.2 priority item for India. The Agenda notes that the sale of Areca nut is banned in Australia and UAE¹³ and in some countries like Indonesia; a pictorial warning is used for the use of Areca nut. In this background, the Agenda item in para 3(a) proposed consideration of suitable changes on the products using Areca nut or its produce including Arecaline in the appropriate labelling regulations with respect to pack warning to cover a substantial portion of the pack and proposed inclusion of pictorial warning as well.

23.1. The aforesaid Agenda records that Areca nut has been classified by IARC, WHO as a Group-1 cancer-causing agent. In this regard, it would be relevant to note that IARC has classified carcinogenic agents into four groups based on the existing scientific evidence for its carcinogenicity¹⁴, summary whereof reads as under:

“Group 1: "Carcinogenic to humans" There is enough evidence to conclude that it can cause cancer in humans.

Group 2A: "Probably carcinogenic to humans" There is strong evidence that it can cause cancer in humans, but at present it is not conclusive.

Group 2B: "Possibly carcinogenic to humans" There is some evidence that it can cause cancer in humans but at present it is far from conclusive.

¹³ United Arab Emirates

¹⁴ <https://monographs.iarc.who.int/agents-classified-by-the-iarc/>



Group 3: "Unclassifiable as to carcinogenicity in humans" There is no evidence at present that it causes cancer in humans.

Group 4: "Probably not carcinogenic to humans" There is strong evidence that it does not cause cancer in humans."

(Emphasis Supplied)

23.2. Petitioners have not disputed the IARC classification of Areca nut as a Group-1 cancer-causing agent.

24. Respondent No. 2 has also placed on record the Minutes of the 28th Meeting of the Scientific Panel on labelling held on 30th April, 2019¹⁵. The Scientific Panel took note of the recommendations and guidelines issued by MoHFW on 06th December, 2018 as well as the decision of the Food Authority in its 27th Meeting dated 04th February, 2019 recommending that the statutory warning covers 50% of front-of-pack of the label. The Panel took note of the report of WHO classifying Areca nut as a carcinogen and the alerts issued in USA¹⁶ by both FDA¹⁷ and the CDC¹⁸ on the health risks associated with Areca nut chewing. The Scientific Panel, therefore, agreed with the recommendations made by MoHFW and Food Authority on labelling and recommended that a warning should be specified on front-of-pack of the label.

25. In fact, the Panel opined that the MoHFW recommendation for a distinct pictorial warning on the pack, and point of sale warning for Areca nut and its products may be considered at later stages.

26. In view of the information placed before the Scientific Panel as is evident from the contents of the Agenda and the Minutes of the 28th Meeting

¹⁵ The extract of the Minutes have been placed on record as Annexure R-2/6 to the counter affidavit of Respondent No. 2. The Minutes record the date of the Meeting as 30th April, 2018, which is admittedly a typographical error and the correct date is 30th April, 2019.

¹⁶ United States of America

¹⁷ Food and Drug Administration, USA

¹⁸ Centres for Disease Control and Prevention, USA



of the Scientific Panel held on 30th April, 2019, the contention of the Petitioners that there was no scientific studies before the Scientific Panel for recommending the 50% size of the pack warning, is without any merits.

27. In addition, as noted above, the recommendation for increasing the statutory warning size to 50% was first made by the Scientific Committee at its 31st Meeting on 15th November, 2018, on the basis of the Scientific opinion of the Scientific Panel on Food Additives, which panel after considering the studies of the year 2015, 2016 and 2018 had, in fact, concluded that Pan Masala is not safe for human consumption.

28. The scientific opinion of the Scientific Committee dated 15th November, 2018 and the Scientific Panel for Labelling and Claims/Advertisements dated 30th April, 2019 which led to the formulation of impugned Regulation are based on scientific studies and expert reports from 2015 to 2018 as well as the IARC, WHO, which findings of the expert reports and classification by IARC, WHO, remained unchanged till date. We may note here that the 2015 expert study referred to in the agenda of 31st Scientific Committee Meeting held on 15th November, 2018 was by the Department of Head and Neck Surgery, Tata Memorial Hospital, Mumbai. This study titled “A review on harmful effects of pan masala” has been extensively referred to by the Supreme Court in *Unicorn Industries* (Supra)¹⁹ and has been relied upon to conclude that the consumption of Pan Masala is hazardous to health. Therefore, in the absence of any change in the opinion of the experts on the hazardous nature of Pan Masala of public health, the challenge of the Petitioners to the vintage of the reports is without any merit.

¹⁹ At para 28 to 32 of the judgment.



With respect to the issue of non-availability of space on the package for the Trademark

29. The writ petition also seeks to challenge the enhancement of the size of the warning statement to 50% of front-of-pack of the label on the grounds that it takes away the right of the Petitioners under the Trademarks Act, 1999 and Copyright Act, 1957 as the space on the package will be constricted. However, this ground was neither pressed during arguments nor raised in the written submissions. In our considered opinion, the Petitioners have space available on the package for displaying its trademark or brand name and the display of the warning statement on 50% of front-of-pack of the label does not affect their ability to display their trademark or brand name. In any event, keeping in view the object of protecting and promoting public health sought to be achieved by Respondent No. 2, the constriction of space, if any, in displaying the trademark is not a ground for striking down the impugned Regulation keeping in view the public health concern.

Public Health trumps Private Interest

30. The Supreme Court in catena of judgments has held that private interests must cave in, to the extent required, when the public interest is so explicitly defined and there is an immediate and compelling necessity. In this regard, it would be relevant to refer to the judgment of the Supreme Court in *Sayyed Ratanbhai Sayeed v. Shirdi Nagar Panchayat*²⁰, wherein it has been held as under:

“58. The emerging situation is one where private interest is pitted against public interest. The notion of public interest synonymises collective welfare of the people and public institutions and is generally informed with the dictates of public trust doctrine — res communis i.e. by everyone in common. Perceptionally health, law and order, peace, security and a clean environment are some of the areas of public and collective good where

²⁰(2016) 4 SCC 631



private rights being in conflict therewith has to take a back seat. In the words of Cicero “the good of the people is the chief law”.

59. The Latin maxim *Salus Populi Suprema Lex* connotes that health, safety and welfare of the public is the supreme in law. Herbert Broom, in his celebrated publication, *A Selection of Legal Maxims* has elaborated the essence thereof as hereunder:

“This phrase is based on the implied agreement of every member of the society that his own individual welfare shall, in cases of necessity, yield to that of the community; and that his property, liberty and life shall, under certain circumstances, be placed in jeopardy or even sacrificed for the public good.”

(Emphasis Supplied)

31. A similar issue with regard to the increase in the size of statutory warnings on Tobacco products has already been dealt with by the Supreme Court. The *vires* of Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2014 prescribing 85% warning size with pictorial content was challenged by the sellers of cigarettes and other tobacco products before the High Court of Karnataka. The Division Bench of the High Court of Karnataka in WP No. 53876 of 2015 had struck down the said Amending Rules of 2014 vide judgment dated 15th December, 2017. However, in the SLP(C) No. 37348 of 2017, titled ***Health for Millions Trust v. Union of India and Others***, challenging the judgment dated 15th December, 2017, Union of India sought a stay of the said judgment, which was opposed by the sellers. The Supreme Court after a detailed hearing directed a stay on the said judgment of the High Court of Karnataka vide order dated 08th January, 2018²¹ as it was of the considered opinion that the health of the citizen has primacy and the consumer should be aware of that which can affect or deteriorate their health condition. As a consequence, the Amending Rules of 2014 are in force. The operative portion of the order

²¹ (2018) 14 SCC 152



reads as under:

*“9. Considering the rivalised submission advanced at the Bar and keeping in view the Objects and Reasons of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 and the measures taken by the State, we think it appropriate to direct stay of operation of the judgment and order passed by the High Court of Karnataka. **Though a very structural submission has been advanced by the learned counsel for the respondents that it will affect their business, we have remained unimpressed by the said proponent as we are inclined to think that health of a citizen has primacy and he or she should be aware of that which can affect or deteriorate the condition of health. We may hasten to add that deterioration may be a milder word and, therefore, in all possibility the expression “destruction of health” is apposite.**”*

(Emphasis Supplied)

32. In the present case, the impugned Regulation has been introduced in the interest of the larger public health, to raise awareness among consumers about the risk associated with chewing Pan Masala. The Petitioners’ challenge to the impugned Regulation seems to be driven by its self-interest in safeguarding the sale of its Pan Masala brands, which might be affected if they comply with the impugned Regulation. The harm and deleterious effects of Pan Masala have already been judicially noticed by the Supreme Court in *Unicorn Industries* (supra), wherein the relevant observations reads as under: -

“27. Judicial notice can be taken of the fact that by various scientific studies on betel quid and substitutes, tobacco and their substitutes i.e. pan masala with tobacco and without tobacco, these products have been found to be one of the main causes for oral cancer...

...

*32. **It could thus be seen that, by scientific research conducted by experts in the field, it has been found that the consumption of pan masala with tobacco as well as pan masala sans tobacco is hazardous to health. It has further been found that, the percentage of teenagers consuming the hazardous product was very high and as such exposing a large chunk of young population of this country to the risk of oral cancer. Taking into***



consideration this aspect, if the State has decided to withdraw the exemption granted for manufacture of such products, we fail to understand as to how it can be said to be not in the public interest.

(Emphasis Supplied)

33. The perusal of the expert Reports and guidelines dated 6th December, 2018 of the MoHFW, in fact, shows that though there is a worldwide recommendation for banning the product of Pan Masala, yet the Food Authority has for the present only taken the limited step of increasing the warning size. The resistance of the Petitioners to the increase in the warning size while accepting the existence of the health hazard of the Pan Masala, as evidenced by the expert studies, shows that the Petitioners are only seeking to subserve their personal interest without having regard for the public health.

34. In view of the aforesaid, this Court is of the opinion that the impugned Regulation gives effect to the legislative intent of safeguarding the larger public interest which is paramount and as held by the Supreme Court in *Unicorn Industries* (Supra), the larger public interest of public health would outweigh the individual loss to the manufacturer/licensee like the Petitioners herein. The reliance placed by the Petitioners on the judgments of *Anuradha Bhasin* (Supra) and *Om Kumar* (Supra) is, therefore, not applicable in the facts of this case.

Article 14 - Petitioners' Claim for Negative Equality

35. The Petitioners have contended that Respondent No. 2 has acted in an arbitrary and discriminatory manner by enhancing the statutory health warning size to 50% of front-of-pack of the label of Pan Masala, while the statutory health warning size for Alcohol is still maintained at its original



size of 3 mm. It is a well-settled principle of law that there cannot be any concept of negative inequality. The Supreme Court in the matter of *Basawaraj v. Special Land Acquisition Officer*²², has held as under:

“8. It is a settled legal proposition that Article 14 of the Constitution is not meant to perpetuate illegality or fraud, even by extending the wrong decisions made in other cases. The said provision does not envisage negative equality but has only a positive aspect. Thus, if some other similarly situated persons have been granted some relief/benefit inadvertently or by mistake, such an order does not confer any legal right on others to get the same relief as well. If a wrong is committed in an earlier case, it cannot be perpetuated.”

(Emphasis Supplied)

36. In view of the aforesaid, this Court is of the opinion that the Petitioners are not entitled to claim parity with the size of 3mm for statutory health warning on Alcohol bottles, being maintained by Respondent No. 2, for its Pan Masala product. At this stage, it would be apposite to note the submission made by Respondent No. 2 that a decision to increase the size of the statutory health warning on Alcohol bottles is being actively considered by the Respondent No. 2. We are also of the opinion that the Petitioners claim for parity with other products [more specifically Alcohol], which falls under the purview of Respondent No. 2 is unjustified.

Whether the impugned Regulation meet the test of proportionality?

37. The concept and contours of the doctrine of proportionality have already been dealt with by the Supreme Court of India in *K.S. Puttaswamy v. Union of India*²³, wherein it was held that there are four sub-components of proportionality that need to be satisfied. In this regard, the relevant portion of the aforesaid judgment reads as under: -

²²(2013) 14 SCC 81

²³(2019) 1 SCC 1



“319. ...This discussion brings out that following four sub-components of proportionality need to be satisfied:

319.1. A measure restricting a right must have a legitimate goal (legitimate goal stage).

319.2. It must be a suitable means of furthering this goal (suitability or rational connection stage).

319.3. There must not be any less restrictive but equally effective alternative (necessity stage).

319.4. The measure must not have a disproportionate impact on the right holder (balancing stage).”

(Emphasis Supplied)

38. The Statement of Objects and Reasons of the FSS Act indicates that the Food Authority had been established to fix food standards and regulate the manufacturing, import, distribution and sale of food, to ensure safe and wholesome food for the people and to meet the changing needs of the Indian food industry and international trade, as well as to guarantee improved consumer safety through the use of Food Safety Management Systems and standards that are based on transparency and science.

39. MoHFW in its Meeting held on 06th December, 2018 discussed issues relating to Areca nut and formulated guidelines for its prevention and control. The meeting was attended by experts and senior medical officials wherein it was recommended that warning label of bigger size similar to tobacco may be required on Areca nut containing packets. It was recommended that suitable changes be made in the labelling regulations to ensure that the pack warning is distinct and covers a substantial portion of the pack. Pertinently, at this point of time the warning size as per the then existing Regulation was 3mm; however, the members attending this meeting opined that there was an urgent need to change the pack warning. Since, the minutes refer to (and recommend) warning size similar to tobacco it would be relevant to note that under the Cigarettes and Other Tobacco Products



(Packaging and Labelling) Amendment Rules, 2014, the law mandates that the specified health warning shall cover at least 85% of the principal display area of the package of which 60% shall cover pictorial health warning and 25% shall cover textual health warning.

40. In this regard, we may also refer to the WHO Framework Convention on Tobacco Control²⁴ ('WHO FCTC'). The said convention came into force on 14th September, 2005 and has been ratified by India. Article 11 of the said convention deals with the packaging and labelling of the tobacco products. The said Article 11 obliges the signatory states to ensure that the warning covers 50% or more, but not less than 30% of the principal display area. The Conference of the Parties ('COP') is the governing body of the WHO FCTC and is comprised of all the parties to the convention. The Guidelines²⁵ on implementation on Article 11 were adopted at COP-3 and in these Guidelines, the purpose of large warning sizes has been explained as under:

“DEVELOPING EFFECTIVE PACKAGING AND LABELLING REQUIREMENTS

Well-designed health warnings and messages are part of a range of effective measures to communicate health risks and to reduce tobacco use. Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text-only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption. Larger picture warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people. Other elements that enhance effectiveness include locating health warnings and

²⁴<https://fctc.who.int/publications/i/item/9241591013>

²⁵[https://fctc.who.int/docs/librariesprovider12/default-document-library/who-fctc-summary.pdf?sfvrsn=1e770ac7_29&download=true#:~:text=The%20WHO%20Framework%20Convention%20on%20Tobacco%20Control%20\(WHO%20FCTC\)%20is,globalization%20of%20the%20tobacco%20epidemic](https://fctc.who.int/docs/librariesprovider12/default-document-library/who-fctc-summary.pdf?sfvrsn=1e770ac7_29&download=true#:~:text=The%20WHO%20Framework%20Convention%20on%20Tobacco%20Control%20(WHO%20FCTC)%20is,globalization%20of%20the%20tobacco%20epidemic)



messages on principal display areas, and at the top of these principal display areas; the use of colour rather than just black and white; requiring that multiple health warnings and messages appear concurrently; and periodic revision of health warnings and messages.

...

...

Size

Article 11.1(b)(iv) of the Convention specifies that health warnings and messages on tobacco product packaging and labelling should be 50% or more, but no less than 30%, of the principal display areas. Given the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible. The text of health warnings and messages should be in bold print in an easily legible font size and in a specified style and colour(s) that enhance overall visibility and legibility. If a border is required, Parties should consider excluding the space dedicated to framing health warnings and messages from the size of the health warning or message itself when calculating the percentage of display area occupied by them, that is to say the space dedicated to the frame should be added to the total percentage of space occupied by the health warnings and messages and not included within it.”

41. We have referred to Article 11 of WHO FCTC and the Guidelines issued for its implementation, to highlight the established practice followed for issuing large size warnings of carcinogenic products to ensure effective communication of the health risks to the consumers. In the case of tobacco products as noted above the Government has elected to prescribe a warning size of 85% on the package and has, therefore, recognised that large size warnings are necessary for communicating the health risks to the consumer. In contrast, the Food Authority has prescribed a warning size of 50% on the Pan Masala packet and the prescription of this size is not disproportionate and is in fact, appropriate considering the object sought to be achieved by the Regulator and for instructive purposes; the Guidelines issued by the COP for Article 11 are relevant and reads as under:



“Article 11

Packaging and labelling of tobacco products

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra-light”, or “mild”; and

(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:

- (i) shall be approved by the competent national authority,
- (ii) shall be rotating,
- (iii) shall be large, clear, visible and legible,
- (iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,
- (v) may be in the form of or include pictures or pictograms.

2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.

4. For the purposes of this Article, the term “outside packaging and labelling” in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.”



42. As submitted by Respondent No. 2 that the intention of Food Authority in introducing the impugned Regulation is that the statutory health warning statement serves as a crucial public health measure and it would be suitable that the warning statements are made highly visible, so that the same is noticeable to the consumers. Thus, the increase in size of warning statements from 3mm to 50% of front-of-pack of label is an effective alternative and does not disproportionately impact the rights of the Petitioners. Having these parameters in mind, this Court is of the opinion that the impugned Regulation meets the test of proportionality.

43. Mr. Vivek Kohli, learned senior counsel for the Petitioners while concluding the arguments had submitted that in the event the petition is dismissed, the Petitioner No. 1 be granted sufficient time to undertake compliance of the packaging of its product with the impugned Regulation. This submission of the Petitioners is without any merit as the Respondent No. 2 in its Note of arguments has submitted that though initially, the impugned Regulation was to come in force w.e.f. 01st May, 2023, on consideration of the request for extension received from the stakeholders to enable them to exhaust their existing packaging material of its product and implement the changes in the packaging, the enforcement date has been deferred on three occasions with the last extension expiring on 30th April, 2024. The relevant extract of the note of arguments of Respondent No. 2 in this regard reads as under:

“11. ...representation has been received from association requesting an extension of the aforementioned "Note" amendment so as to exhaust the packaging material having the existing warning and to arrange for the new packaging material”:



<i>Extended on:</i>	<i>For a Period of:</i>
22.05.2023	Three months w.e.f. 01.05.2023
01.08.2023	Three months w.e.f. 01.08.2023
07.12.2023	Six Months w.e.f. 01.11.2023

44. In our view, the Petitioners herein therefore were granted sufficient time by Respondent No. 2 itself between 01st May, 2023 until 30th April, 2024 to change the packaging of its product and comply with the impugned Regulation w.e.f. 01st May, 2024. Moreover, the present writ petition was filed on 06th April, 2023 and there was no interim stay granted in favour of the Petitioners and, therefore, they have no justification for not complying with the impugned Regulation upon its coming into effect as on 01st May, 2024. In view of our findings on the *vires* of the impugned Regulation, we are not inclined to grant any further time to the Petitioner for permitting transition of the packaging of its product.

45. In view of the foregoing discussion, the present writ petition stands dismissed along with pending application. No order as to the cost.

MANMEET PRITAM SINGH ARORA, J

ACTING CHIEF JUSTICE

JULY 09 , 2024/msh/rhc/aa/MG/AKT