

Mr.Sandeep P.Mehtha vs State Of Kerala on 26 April, 2022

IN THE HIGH COURT OF KERALA AT ERNAKULAM
PRESENT

THE HONOURABLE MR.JUSTICE ZIYAD RAHMAN A.A.

TUESDAY, THE 26TH DAY OF APRIL 2022 / 6TH VAISAKHA, 1944

CRL.MC NO. 1279 OF 2016

[TO QUASH THE PROCEEDINGS IN C.C.NO.2007/2015 ON THE FILE OF THE
JUDICIAL FIRST CLASS MAGISTRATE COURT-1, KOZHIKODE]
PETITIONERS/ACCUSED NOS.7,3,4 & 5:

- 1 M/S. ITC LTD.,
VIRGINIA HOUSE, PLOT KOLKATHA-700071, REPRESENTED BY
ITS POWER OF ATTORNEY HOLDER MR. SATHYANATHAN, BRANCH
MANAGER, ITC LIMITED, SHENOY CHAMBERS, SHANMUGHAM ROAD,
ERNAKULAM, NO.37, J.L. NEHRU ROAD.
- 2 Y.C. DEWESHWAR (DIRECTOR), ITC LIMITED, PLOT NO.37,
VIRGINA HOUSE, J.L. NEHRU ROAD, KOLKATHA-700071.
- 3 N. ANAND (DIRECTOR),
ITC LIMITED, PLOT NO.37, VIRGINA HOUSE, J.L. NEHRU
ROAD, KOLKATHA-700071.
- 4 P.V. DHO BALE,
(DIRECTOR), ITC LIMITED, PLOT NO.37, VIRGINA HOUSE,
J.L. NEHRU ROAD, KOLKATHA-700071.

BY ADV.
SRI.M.RAMESH CHANDER (SR.)

RESPONDENTS/STATE AND COMPLAINANT:

- 1 STATE OF KERALA REPRESENTED BY ITS PUBLIC PROSECUTOR,
HIGH COURT OF KERALA, ERNAKULAM-682031.
- 2 THE FOOD SAFETY OFFICER,
MOBILE VIGILANCE SQUAD, KOZHIKODE-I. (REPRESENTED BY
FOOD SAFETY OFFICER, KOZHIKODE, NORTH CIRCLE,
KOZHIKODE-I), PIN-673001.

BY ADV. SRI.RANJIT GEORGE SR.PP

THIS CRIMINAL MISC. CASE HAVING BEEN FINALLY HEARD ON
16.02.2022, ALONG WITH CrL.MC.1453/2016, THE COURT ON 26.04.2022
PASSED THE FOLLOWING:

CRL.MC Nos.1279 & 1453 /2016 2

IN THE HIGH COURT OF KERALA AT ERNAKULAM
PRESENT

THE HONOURABLE MR.JUSTICE ZIYAD RAHMAN A.A.
TUESDAY, THE 26TH DAY OF APRIL 2022 / 6TH VAISAKHA, 1944
CRL.MC NO. 1453 OF 2016

[TO QUASH THE PROCEEDINGS IN C.C.NO.2007/2015 ON THE FILE OF
THE JUDICIAL FIRST CLASS MAGISTRATE COURT-1, KOZHIKODE]

PETITIONER/ACCUSED 1 AND 2:

- 1 MR.SANDEEP P.MEHTHA,MANAGING PARTNER, M/S. EMPEE CREDIT CORPORATION, 8/189 SILK STREET, KOZHIKODE - 673 001, RESIDING AT HOUSE NO. 2, EXHIBITION ROAD, NANDAVANAM COLONY, WEST HILL, KOZHIKODE - 673 032.
- 2 M/S. EMPEE CREDIT CORPORATION
8/189 SILK STREET, KOZHIKODE - 673001,REPRESENTED BY ITS MANAGING PARTNER SRI. SANDEEP P. MEHTHA, RESIDING AT HOUSE NO. 2, EXHIBITION ROAD, NANDAVANAM COLONY, WEST HILL, KOZHIKODE - 673 032.

BY ADV.

SRI. S.V.BALAKRISHNA IYER (SR.)

RESPONDENTS/COMPLAINANT & STATE:

- 1 STATE OF KERALA REPRESENTED BY ITS PUBLIC PROSECUTOR, HIGH COURT OF KERALA, ERNAKULAM -682 031.
- 2 THE FOOD SAFETY OFFICER
MOBILE VIGILANCE SQUAD, KOZHIKODE-673 001
(REPRESENTED BY FOOD SAFETY OFFICER, KOZHIKODE NORTH CIRCLE), KOZHIKODE-1.

BY ADV. SRI.RANJIT GEORGE SR.PP

THIS CRIMINAL MISC. CASE HAVING BEEN FINALLY HEARD ON
16.02.2022, ALONG WITH CrI.MC.1279/2016, THE COURT ON 26.04.2022
PASSED THE FOLLOWING:

CRL.MC Nos.1279 & 1453 /2016 3

O R D E R

[CrI.MC Nos.1279/2016 & 1453/2016]

Both the above Crl.M.Cs. are filed by the accused persons in C.C.No.2007/2015 on the file of the Judicial First Class Magistrate Court-I, Kozhikode. Crl.M.C. No.1279/2016 is filed by the 7th, 3rd, 4th and 5th accused. Crl.M.C.No.1453/2016 is filed by accused Nos. 1 and 2. Crl.M.C.No.1279/2016 is treated as the leading case, and Annexures are referred in this order in the sequence as described in the said Crl.M.C.

2. The aforesaid case was registered based on Annexure-1 complaint submitted by the 2nd respondent herein under Section 42(5) of the Food Safety and Standards Act, 2006 (hereinafter referred to as 'FSS Act' alleging the violation of Sections 3(i) (zz)(v), 26(1)(2)(i), 59 of the FSS Act read with Regulation 2.3.4 of Food Safety Standards (Prohibition and Restriction of Sales) Regulation 2011.

3. The facts leading to the aforesaid case are as follows:

On 02.04.2014, at about 11 a.m., the Chief Food Safety Officer, Mobile Vigilance Squad, Kozhikode, conducted an inspection on the premises of M/s.Empee Credit Corporation, the 2nd accused herein and purchased four packets of Nicotine chewing gum (each packet contains five strips) kept for sale. A mahazar was also prepared on the spot with the signature of the accused and witnesses. Thereafter, one part of the sample taken from the aforesaid articles was forwarded to Food Analyst, Regional Analytical Laboratory (RAL), Kozhikode, for conducting a test. The Food Analyst submitted a report dated 29.04.2014 wherein it was reported that the sample contains nicotine and is, therefore, unsafe as per Section 3(10)(zz)(v) of FSS Act 2006 read with Regulation 2.3.4 of Food Safety Standards (Prohibition and Restriction of Sales) Regulation 2011. Later, a second sample was forwarded to Referral Food Testing Laboratory, Kolkata, and the said Laboratory submitted a report dated 1.5.2015; and in the said report also, the presence of nicotine in the sample was confirmed. Thereupon necessary sanctions for prosecuting the accused persons were obtained, and a complaint in this regard was submitted, which is Annexure A1. The 1st accused is the Managing Partner of the 2nd accused. The 1st accused is also the FSS licensee and the nominee of the 2nd accused. The 7th accused is a Company and manufacturer of the product in question. Accused Nos.3 to 6 are the Directors of the said Company.

4. These Crl.M.Cs. are filed by the respective petitioners praying for quashing all further proceedings pursuant to Annexure A1 complaint.

5. Heard Sri. Ramesh Chander, the learned Senior Counsel appearing for the petitioners in Crl.M.C.No.1279/2016, Sri. S.V. Balakrishna Iyer, the learned Senior Counsel appearing for the petitioners in Crl.M.C.No.1453/2016 and Sri. Ranjit George, the learned Senior Public Prosecutor for respondents 1 and 2.

6. The crucial question that arises in this case is as to whether 'nicotine chewing gum', which was manufactured as a drug on the strength of the licence issued in this regard and distributed with all

the necessary declarations on the label thereof, can be treated as food for the purpose of initiating prosecution under the FSS Act, 2006.

7. The specific contention of the petitioner's counsel is that the nicotine chewing gum is a drug manufactured by the 7th accused on the strength of Annexure A4 licence issued by the competent authority under the provisions of the Drugs and Cosmetics Act. It is discernible from Annexure A4 that the aforesaid licence is bearing No.ND/119-A, and the same was issued on 23.05.2013. The validity of the above mentioned licence was up to 22.05.2018, which would mean that as on the date of inspection, in this case, the aforesaid licence was valid. The learned Senior Counsels have pointed out that the product distributed by the 7th accused and purchased by the complainant from the 2nd accused establishment contained all necessary declarations on its label as required under the provisions of the Drugs and Cosmetics Act and Rules made thereunder. To substantiate the same, my attention was brought to the report of the Food Analyst, which forms part of Annexure A1 complaint. In the said report, the label declaration of the Company is specifically mentioned and it includes the licence obtained by the 7th accused for manufacturing the same under the provisions of the Drugs and Cosmetics Act. Necessary declarations regarding the precautions to be taken while consuming the same are also specifically mentioned therein. It is contended by the learned Senior Counsels that the nicotine chewing gum is a drug used for mitigating the addiction of nicotine and for reducing the withdrawal symptoms of the persons addicted to the same. The medical name of the same is 'Nicotine Polacrilex Gum USP 2mg', and the same was approved by the Drug Controller General of India. It is a form of Nicotine Replacement Therapy. My attention was also brought to Annexures A5 and A6 reports, wherein the usage of nicotine gum for the purpose of curtailing nicotine craving associated with quitting smoking and quitting chewing tobacco is mentioned.

8. The specific contention of the petitioners is that since the nicotine chewing gum was manufactured and distributed as a drug on the strength of a licence issued in this regard, the same cannot be treated as food for the purpose of initiation of prosecution under FSS Act, 2006. The expression 'food' as defined under Section 3(1)(j) of the Food Safety and Standards Act, 2006 reads as follows:

"3(1)(j) "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 substances:

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

On going through the aforesaid definition, it can be seen that the drugs and medicinal products are specifically excluded from the definition of 'food'. In this case, the allegation raised is the violation of 2.3.4 of Food Safety Standards (Prohibition and Restriction of Sales) Regulation 2011 which reads as follows:

"2.3.4: 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."

From a joint reading of the definition of 'food' and the restrictions contained in Regulation 2.3.4, it can be seen that tobacco and nicotine cannot be used as an ingredient in any food products. To be precise, the product referred to in regulation 2.3.4 is to be understood based on the definition of the 'food' as contained in Section 3(1)(j) of the FSS Act, 2006. Since the aforesaid definition had a specific exclusion of drugs and medicinal products, the same cannot be treated as a 'food'. In this case, going by the complaint, it can be seen that it does not contain any averment to the effect that the nicotine chewing gum was offered as a food item by the 1st and 2nd accused. It is evident from the records that the aforesaid articles contained the necessary declaration indicating that it was a drug, and the authority to manufacture such product in the form of a licence issued by the competent authority was also specifically mentioned therein. It also contains necessary warnings on the label of the aforesaid product, which are to be taken note of while consuming. These aspects are very much evident from the contents of the report of Food Analyst. In such circumstances, the only conclusion possible is that the nicotine chewing gum, which is the subject matter of this case, is a drug that is specifically excluded from the definition of 'food'. The allegation against the petitioners in this case is regarding the sale of a food product that contained nicotine. I have already found that the product is a drug, and since the complaint does not contain any averment to the effect that the same was offered for sale as a food item, the provisions of the FSS Act cannot be made applicable in respect of the same. Therefore, the proceedings initiated against the petitioners herein on the basis of such allegation are not legally sustainable.

9. The learned Public Prosecutor contended that the petitioners could not produce any authorization to sell the aforesaid products through the 1st and 2nd respondents-licencees. The petitioners contended that the requirement of a licence under the Drugs and Cosmetics Act for selling a nicotine product is excluded by virtue of Rule 123 of the Drugs and Cosmetics Rules read with entry 33 of schedule k thereof. However, on examining the aforesaid entry in schedule k, it is seen that what is excluded is only lozenges containing up to 2mg of nicotine. Prior to the amendment brought to the aforesaid entry by virtue of GSR 1380(e) with effect from 10.11.2017, "nicotine chewing gum" was specifically included and by virtue of the said amendment, it was excluded. In such circumstances, after the aforesaid enactment with effect from 10.11.2017, an exemption from obtaining a licence for the sale of nicotine chewing gum is no longer available. Therefore, it was contended by the learned Public Prosecutor that the same amounts to a violation of the provisions. However, even if the contention of the learned Public Prosecutor is accepted, the same cannot be treated as a ground to sustain the criminal prosecution initiated against the petitioners herein at the instance of the 2nd respondent. This is because, if the violation as mentioned above is committed, that will attract only the provisions of the Drugs and Cosmetics Act and Rules/Regulations framed thereunder. There is a

separate procedure contemplated for the prosecution of the same, and such procedure can be initiated only by specified officers who are competent in this regard. The 2nd respondent is not among such officers, and his powers are confined to the provisions of the FSS Act. Therefore, unless the alleged violation makes out a case for initiating prosecution under the provisions of the FSS Act, 2006 or the Rules/Regulations framed thereunder, no prosecution can be launched at the instance of the 2nd respondent herein.

10. Another contention put forward by the learned Senior Counsel for the petitioners that accused Nos.2 to 6 therein cannot be roped in for the offence. The aforesaid contention is mainly based on the fact that the said persons are arrayed as accused persons because they are the Directors of the Company. According to the learned counsel for the petitioners, in the absence of specific pleadings in the complaint alleging that the said persons were responsible for the day to day affairs of the Company, they cannot be impleaded as accused persons. Reliance was placed on the judgments rendered by the Hon'ble Supreme Court in M/s. Pepsico India Holdings (P) Ltd. v. Food Inspector [2010 (4) KLT 706 (SC) and S.M.S. Pharmaceuticals Ltd. v. Neeta Bhalla [2005(4) KLT 209(SC)]. However, since I have already found that the offence under the provisions of the FSS Act is not attracted, I am not considering the aforesaid contention.

11. In this case, I have already found that no offence under the provisions of the FSS Act, 2006 or the Rules/Regulations made thereunder are made out. In such circumstances, the prosecution initiated against the petitioners herein are clear abuse of the process of law. Accordingly, these CrI.MCs. are allowed, and Annexure A1 complaint and all further proceedings in C.C.No.2007/2015 pending before the Judicial First Class Magistrate Court-I, Kozhikode are hereby quashed.

Sd/-

ZIYAD RAHMAN A.A. JUDGE pkk PETITIONERS' ANNEXURES:

ANNEXURE A1 TRUE COPY OF THE COMPLAINT DATED 20TH OCTOBER 2015 FILED BY THE RESPONDENT NO 2 BEFORE THE JUDICIAL FIRST CLASS MAGISTRATE- 1, KOZHIKODE ANNEXURE A2 TRUE COPY OF THE MAHAZAR DATED 02 APRIL ANNEXURE A3 TRUE COPY OF THE REPORT OF THE FOOD ANALYST DATED 29 APRIL 2014 ISSUED IN FORM VII A ANNEXURE A4 TRUE COPY OF THE DRUG MANUFACTURING LICENCE DATED 23 MAY 2013 ISSUED BY JOINT COMMISSIONER (NAGPUR DIVISION), FOOD AND DRUG ADMINISTRATION ,M.S.NAGPUR ANNEXURE A5 TRUE COPY OF THE REPORT OF THE 48TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 24 TH JULY ,2015 AT NEW DELHI ANNEXURE A6 TRUE COPY OF THE TOBACCO DEPENDENCE TREATMENT GUIDELINES ANNEXURE A7 TRUE COPY OF THE 18TH LIST OF THE WHO MODEL LIST OF ESSENTIAL MEDICINES ANNEXURE A8 TRUE COPY OF THE LETTER ADDRESSED BY THE FOOD SAFETY COMMISSIONER DATED 10.06.2014 ANNEXURE A9 TRUE COPY OF THE LETTER DATED 27 JUNE 2014 OF ASSISTANT COMMISSIONER (INTELLIGENCE),MOBILE VIGILANCE SQUAD,KOZHIKODE PETITIONERS'

ANNEXURES:

ANNEXURE A1 PHOTOCOPY OF THE COMPLAINT DATED 20 OCTOBER 2015 FILED BY THE RESPONDENT NO.2 BEFORE THE JUDICIAL FIRST CLASS MAGISTRATE-I, KOZHIKODE.

ANNEXURE A2 TRUE COPY OF THE MAHAZAR DATED 02 APRIL 2014.

ANNEXURE A3 TRUE COPY OF THE REPORT OF THE FOOD ANALYST DATED 29 APRIL 2014, ISSUED IN FORM VII A. ANNEXURE A4 TRUE COPY OF THE DRUG MANUFACTURING LICENSE DATED 23 MAY 2013 ISSUED BY JOINT COMMISSIONER (NAGPUR DIVISION), FOOD AND DRUG ADMINISTRATION, M.S. NAGPUR.

ANNEXURE A5 TRUE COPY OF THE NOTIFICATION AMENDING SCHEDULE K OF DRUGS AND COSMETICS RULES, 1945, AND INCLUDING NICOTINE POLACRILEX GUM IN ENTRY 33.

ANNEXURE A6 TRUE COPY OF THE "LIST OF APPROVED DRUGS FROM 01.01.2009 TO 31.12.2009" PUBLISHED BY THE CENTRAL DRUGS STANDARD ORGANIZATION, MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA ANNEXURE A7 TRUE COPY OF THE TOBACCO DEPENDENCE TREATMENT GUIDELINES ANNEXURE A8 TRUE COPY OF THE 18TH LIST OF THE WHO MODEL LIST OF ESSENTIAL MEDICINES ANNEXURE A9 TRUE COPY OF THE LABEL ON THE PACKET OF KwikNic NICOTINE POLACRILEX GUM USP-2 MG ANNEXURE A10 TRUE COPY OF THE LABEL ON THE PACKET OF NICOTINE POLACRILEX GUM USP-2 MG MANUFACTURED BY OTHER MANUFACTURES.

ANNEXURE A11 TRUE COPY OF THE LETTER DATED 05 MAY 2014 ADDRESSED BY THE DESIGNATED OFFICER (FOOD SAFETY), KOTTAPARAMBHA, KOZHIKODE TO THE PETITIONER NO.1 ANNEXURE A12 TRUE COPY OF THE REPLY DATED 30 MAY 2014 OF THE PETITIONER NO.1 ADDRESSED TO THE DESIGNATED OFFICER (FOOD SAFETY), KOTTAPARAMBHA, KOZHIKODE.

//TRUE COPY// SD/- P.S. TO JUDGE