

Assessment of Processed and Raw Milk Safety using Inferential Statistics

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Abstract:

Milk safety is an important issue as consumption of unsafe milk involves health risks. From a stakeholder’s point of view, the intention of this paper is to assess processed and raw milk safety in India using inferential statistics. The paper is based on secondary data which is taken from National Milk Safety and Quality Survey, 2018 in which a total of 6432 samples of processed and raw milk were collected from 1103 different locations. At India level it is found that, point estimate of unsafe processed milk samples is 10.4% and point estimate of unsafe raw milk samples is 4.8%. State/UT wise point estimate of total unsafe milk samples vary from 0% to 33%. It is found that raw milk is significantly better when compared to processed milk at India level with respect to safety issues. It is concluded that Aflatoxin M₁ is significantly responsible for unsafe milk samples. Proportion of non-compliant samples due to Aflatoxin M₁ in processed milk is significantly greater than in raw milk. This contradicts the remark from the survey report that Aflatoxin M₁ comes in the milk through feed and fodder so further research is needed to identify cause of presence of Aflatoxin M₁.

Keywords — milk safety; compliant milk sample; non-compliant milk sample; assessment of milk safety; unsafe milk sample; unsafe processed milk sample, unsafe raw milk sample, proportion test, normal distribution, Pareto chart, Aflatoxin M₁

I. INTRODUCTION

Milk is a vital part of the diet. Not only does it fulfils our daily nutritional requirement, it also used in making some of the food products such as yogurt, cheese, ice cream, pudding, porridge, tea, coffee etc. According to the National Dairy Council, milk contains nine essential nutrients (Calcium, Protein, Potassium, Phosphorus, Vitamin D, B12, A, Riboflavin (B2), Niacin) that benefit our health. India has witnessed remarkable growth in production and consumption of milk and dairy products in recent years and this trend continues. India’s milk consumption is the highest in the world and accounts for 26% of world consumption [1]. Milk safety is an important issue as consumption of unsafe milk involves health risks such as vomiting, diarrhea, abdominal pain, fever, headache, body ache which can be recovered from, but some symptoms can become chronic or even life threatening. Food Safety and standards Authority of India (FSSAI) has carried out survey regarding milk quality and safety at national level in 2018 [2]. This survey provides baseline data for all dairy stakeholders including milk processors, researchers and regulators to know the status of milk safety and quality in India. FSSAI carried out this survey covering all states and UTs. This is a mega survey as a total of 6432 samples of raw and processed/pasteurized milk were collected from 1103 different locations and then tested for

milk quality and safety. In survey report, preliminary conclusions were drawn by computing descriptive statistics. Considering this as baseline data we have used inferential statistics, to draw conclusions about the entire population using sample data.

Milk safety problem is very common in several countries of the world because milk is highly vulnerable to bacterial contamination and hence easily spoilable [3]. Regulatory law implementation in milk and dairy industries, training of personnel, good manufacturing practices and regular monitoring is required to ensure milk safety [3]. Management system, hazard analysis and critical control point system (HACCP) in which food safety is addressed through the analysis and control of hazards throughout the food chain was proposed and applied in many countries to ensure proper safety and quality of milk [4]. Raw milk or processed milk consumption risks and benefits have been thoroughly discussed in literature and it has been recommended that milk should be heated before consumption ([5], [6]). Food safety hazards associated with consumption of raw milk were studied and it was concluded that quality of raw milk is inferior ([7], [8]). Adulteration of milk and milk products have been extensively studied in the literature and it has been concluded that governing body should periodically check these products for presence of harmful ingredients ([9], [10], [11]). Microbiological considerations regarding quality and safety of

raw milk and/or processed milk have been widely studied in the literature with recommendation of quality enhancement ([12], [13], [14]).

Statistical methods play a vital role in quality control and improvement. Applications of statistical methods in quality control and improvement have been comprehensively studied in the literature ([15], [16], [17]). In statistical context the population is the total set of subjects in which we are interested. A sample is the subset of the population for which we have data. Descriptive statistics refers to methods for summarizing the collected data. Inferential statistics refers to methods of making decisions or predictions about a population, based on data obtained from a sample of that population ([18]). Without statistical inference, we are simply living within our data. With statistical inference, we are trying to generate new knowledge ([19]).

From stakeholder's point of view, we estimate and conduct test of hypothesis with regard to proportion of unsafe milk samples at India level as well as at state/UT level considering total samples, processed milk samples and raw milk samples. The structure of this article is as follows. In section 2, we discuss National Milk Safety and Quality Survey, 2018 data collection with explanation regarding planning and execution of this survey. This section also gives analytic methods which include statistical distributions and testing of hypothesis procedures which we have used to make decisions about an entire population. Section 3 deals with descriptive statistics of the survey, identification of statistical distributions, estimation and testing of hypothesis results related to proportion of unsafe milk samples. This section also includes study of factors which are responsible for unsafe milk. The last section summarizes the investigation with some concluding remarks.

II. METHODS

A. Data Collection

Dataset is taken from National Milk Safety and Quality Survey, 2018. FSSAI carried out this survey covering all states and UTs from May 2018 to October 2018 by collecting 6432 samples from 1103 towns/cities having population above 50,000. Sampling was designed to target largely populated areas which are more prone to adulteration. Total number of samples which includes 41% samples from processed milk and remaining from raw milk. Tested milk samples grouped into two major classes as compliant and non-compliant to the FSSAI standards. Further these samples are categorised as compliant (Category A), non-compliant due to only quality issues (Category B), non-compliant due to only safety issues (Category C) and non-compliant with both quality and safety issues (Category D). Sample is treated as non-compliant (NC) with quality issues if it failed in terms of quality parameter which includes fat, SNG, sugar and maltodextrin. Sample is treated as NC with safety issues if it is 'NC for contaminants'

which includes Aflatoxin M₁, Antibiotics, pesticides and 'NC for Adulterants' which includes Urea, Detergents, Hydrogen peroxide, Neutralizers. The NC for other parameters viz. Cellulose, Glucose, Starch and Vegetable oil was not found in the collected samples. If the sample belongs to category C or D then it is treated as unsafe sample.

B. Binomial and Normal distribution

We come across with many experiments in which the outcomes can be classified only into two categories. For example the sample may be compliant or non-compliant with safety issue, the product in a lot may be defective or non-defective. Thus we are considering experiments resulting in getting either a success or failure. These labels are general and the *success* outcome not necessarily preferred result. Such experiments are called Bernoulli experiments or Bernoulli trials. A binomial experiment involves n independent and identical Bernoulli trials. If P is the probability of observing a success in each Bernoulli trial, then the number of successes X that can be observed out of these n Bernoulli trials is called as the binomial random variable. The probability of observing x successes out of these n Bernoulli trials is given by the probability mass function

$$P(X = x | n, P) = \binom{n}{x} P^x (1-P)^{n-x}, \quad x = 0, 1, 2, \dots, n.$$

The distribution of X is known as binomial distribution with parameters n and P . Mean of binomial distribution is nP and variance is $nP(1-P)$. Binomial distribution is used to estimate the proportion of individuals with a particular attribute in a large population.

We use normal probability distribution with mean $\mu = nP$ and variance is $\sigma^2 = nP(1-P)$ instead of binomial distribution when n is large. If X is normal random variable with mean μ and variance σ^2 , then X has the following probability density function

$$f(x; \mu, \sigma) = \frac{1}{\sigma\sqrt{2\pi}} e^{-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2}, \quad -\infty < x, \mu < \infty$$

$$\sigma > 0$$

The distribution of X is known as normal distribution with parameters μ and σ^2 . The curve of this distribution is bell shaped. Notation of this distribution is $N(\mu, \sigma^2)$. A random variable X is said to have standard normal distribution if $\mu = 0$ and $\sigma = 1$.

C. Point and interval estimates of population proportion P

A point estimate predicts a parameter by a single number. In case of binomial distribution, the point estimate of the population proportion (P) is the sample proportion (p) computed using x/n , where x number of successes in a sample of size n . We represent the sample proportion by p and estimator of population proportion by \hat{P} . A point estimate

(value of estimator at particular sample) alone is not sufficiently informative. An interval estimate is more useful. Confidence intervals are methods for quantifying uncertainty in our estimates. Assuming large n , 95% and 99% confidence

interval, for population proportion P is $\hat{P} \pm 1.96 \sqrt{\frac{\hat{P}(1-\hat{P})}{n}}$

and $\hat{P} \pm 2.58 \sqrt{\frac{\hat{P}(1-\hat{P})}{n}}$ respectively.

D. Testing of hypothesis regarding population proportion P

This test is based on the normal approximation to the binomial distribution. The null and alternative hypotheses respectively of a test about population proportion P are

$$H_0 : P = P_0 \text{ and } H_1 : P \neq P_0$$

where P_0 is a specific value of P .

Under H_0 we get $Z = \frac{\hat{P} - P_0}{\sqrt{\frac{P_0(1-P_0)}{n}}} \sim N(0,1)$.

We reject H_0 at 5% level of significance if $|Z| > 1.96$. In case $H_1 : P > P_0$ or $H_1 : P < P_0$ then we reject H_0 if $|Z| > 1.64$.

E. Testing equality of two population proportions

This test is based on the normal approximation to the binomial distribution. Let P_1 be the first population proportion and P_2 be the second population proportion. Let random samples of size n_1 and n_2 drawn independently from the first and second population respectively. Now p_1 and p_2 be the respective sample proportion. The null and alternative hypothesis respectively of a equality test is $H_0 : P_1 = P_2$ and $H_1 : P_1 \neq P_2$

Under H_0 for large n_1 and n_2 we get

$$Z = \frac{\hat{P}_1 - \hat{P}_2}{\sqrt{\hat{P}(1-\hat{P})\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}} \sim N(0,1);$$

$$\text{where } \hat{P} = \frac{n_1\hat{P}_1 + n_2\hat{P}_2}{n_1 + n_2}$$

We reject H_0 at 5% level of significance if $|Z| > 1.96$. In case $H_1 : P_1 > P_2$ or $H_1 : P_1 < P_2$ then we reject H_0 if $|Z| > 1.64$.

Note: Though we have given testing procedure in section D and E considering 5% level of significance (I.o.s.) we can obtain critical value for any selected I.o.s. using normal distribution. Additionally if you use statistical software by substituting required input, then after executing testing

procedure, software output gives Z value as well as P-value, observed I.o.s. If P-value is less than selected I.o.s. then we reject H_0 .

F. Testing the homogeneity of multiple population proportions

When we have samples from k ($k > 2$) populations, we can test statistically whether there are significant differences in the proportions for these populations using contingency table approach.

$$H_0 : P_1 = P_2 = P_3 = \dots = P_k \text{ and}$$

$$H_1 : \text{At least one } P_i (i = 1, 2, \dots, k) \text{ is different}$$

The critical value for this test is obtained using Chi-square distribution with $k - 1$ degrees of freedom by choosing level of significance 5% or 1%.

Note: If H_0 is rejected, then for further analysis, if needed use Marascuillo test. This test is given below.

G. Marascuillo test procedure to compare all possible pairs of proportions

Assume we have samples of size n_i ($i = 1, 2, \dots, k$) from k populations. Initially compute the test statistics as

$$|\hat{P}_i - \hat{P}_j| (i \neq j) \text{ among all } k(k-1)/2 \text{ pairs of proportions.}$$

Considering suitable level of significance (α) compute the corresponding critical values for the Marascuillo procedure from

$$r_{ij} = \sqrt{\chi^2_{1-\alpha, k-1}} \sqrt{\frac{\hat{P}_i(1-\hat{P}_i)}{n_i} + \frac{\hat{P}_j(1-\hat{P}_j)}{n_j}}$$

where $\chi^2_{1-\alpha, k-1}$ is obtained from Chi-square distribution with $k - 1$ degrees of freedom.

III. RESULTS

H. The results of the Milk quality and Safety Survey at National level

TABLE I

SUMMARY OF TESTED SAMPLES AT INDIA LEVEL

Criteria	Processed Milk Samples	Raw Milk samples	Total
Total no. of samples	2607 (40.5)	3825 (59.5)	6432 (100)
Compliant (Cat. A)	1427 (54.7)	1902 (49.7)	3329 (51.8)
NC with only quality issues (Cat. B)	909 (34.8)	1738 (45.4)	2647 (41.2)
NC with only safety issues (Cat. C)	198 (7.6)	124 (3.2)	322 (5)
NC with both	73	61	134

quality and safety issues (Cat. D)	(2.8)	(1.6)	(2.1)
Total samples without safety issues (Cat. A&B)	2336 (89.6)	3640 (95.2)	5976 (92.9)
Total unsafe samples (Cat. C&D)	271 (10.4)	185 (4.8)	456 (7.1)

Note: Second, third & fourth columns bracketed values indicate values in percentage.

I. Identification of Statistical Distributions

Applying probability distribution theory we note that number of unsafe samples at India level follows binomial probability distribution with $n=6432$ and $P=456/6432$. Also, as n is large we can use normal distribution instead of binomial with parameters $\mu = 456$ and $\sigma^2 = 423.6716$. On the similar lines, number of unsafe processed milk samples follows normal distribution with parameters $\mu_1 = 271$ and $\sigma_1^2 = 242.8293$ and number of unsafe raw milk samples follows normal distribution with $\mu_2 = 185$ and $\sigma_2^2 = 176.0523$.

From a comparison point of view, let us focus on estimate of proportion of unsafe milk samples at India level. Here proportion of unsafe milk samples at India level is $\hat{P} = 7.1\%=0.071$, proportion of unsafe processed milk samples is $\hat{P}_1 = 10.4\%=0.104$ and proportion of unsafe raw milk samples is $\hat{P}_2 = 4.8\%=0.048$. While noting above proportion estimates we have used estimator of P as $\hat{P} = X/n$. Using simulation technique, we have constructed sampling distributions of these proportions estimator. Fig. 1, Fig. 2 and Fig. 3 are the graphical representations of sampling distribution of \hat{P} , \hat{P}_1 and \hat{P}_2 respectively.

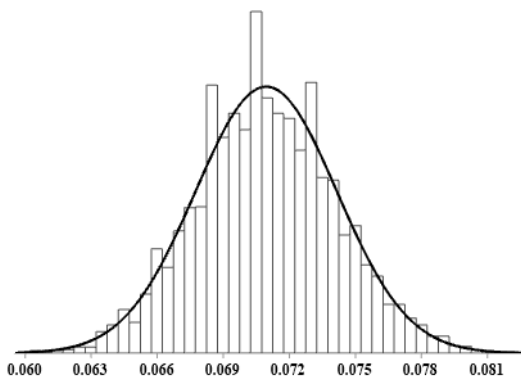


Fig. 1 Sampling distribution of \hat{P}

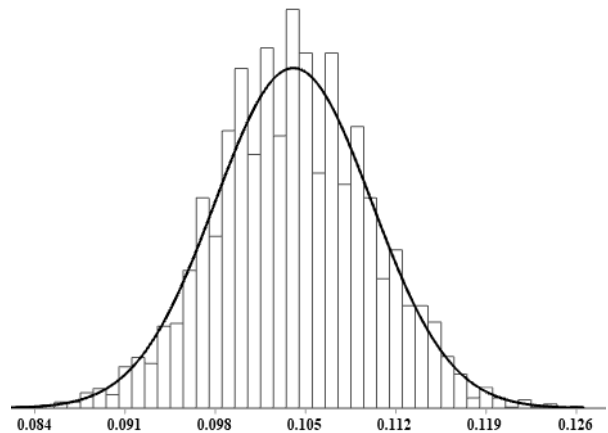


Fig. 2 Sampling distribution of \hat{P}_1

From Fig. 1, Fig. 2 and Fig. 3, it is observed that sampling distributions of \hat{P} , \hat{P}_1 and \hat{P}_2 are normal though their parameters are different. This is the validation of assumption of normality which is required in confidence interval and hypothesis testing.

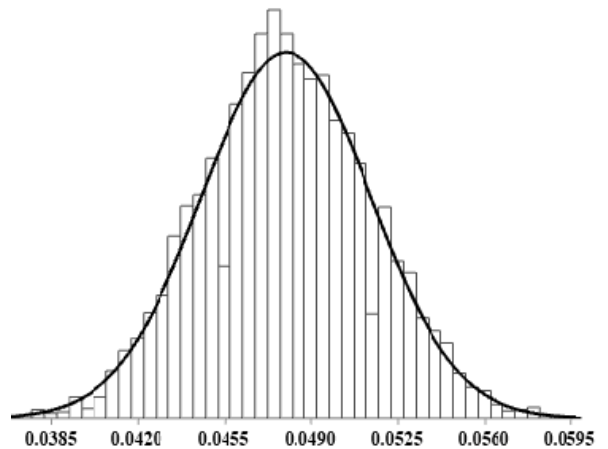


Fig. 3 Sampling distribution of \hat{P}_2

J. Confidence interval for proportion of unsafe milk samples

We have already noted that proportion of unsafe milk samples at India level is $\hat{P} = 0.071$, proportion of unsafe processed milk samples is $\hat{P}_1 = 0.104$ and proportion of unsafe raw milk samples is $\hat{P}_2 = 0.048$. These are the point estimates for proportion of unsafe samples at India level. To quantify uncertainty in these estimates, referring procedure mentioned in section C we below note 95% confidence intervals for proportion of unsafe samples.

- 1) 95% confidence interval for proportion unsafe milk samples at India level is (0.0646, 0.0771)

This interval is interpreted as we are 95% confident that the true proportion of unsafe milk samples is between 0.0646 and 0.0771. In other words confidence interval gives range of plausible values (0.0646 to 0.0771) of true proportion of unsafe milk samples with 95% confidence coefficient.

2)95% confidence interval for proportion of unsafe processed milk samples at India level is (0.0922, 0.1156)

3)95% confidence interval for proportion of unsafe raw milk samples at India level is (0.0415, 0.0551)

Note: From 2) and 3) it is clear that consumer risk is more of purchasing processed milk than raw milk regarding milk safety issue.

K. Testing of hypothesis regarding proportion of unsafe samples

Hypothesis tests uses data collected from sample to test specified hypothesis.

1)Consider one of the leading national level paper headlines, “FSSAI Milk Survey: 7 per cent milk samples found unfit for consumption”. Stakeholder’s point of view, we are going to test this claim considering processed milk.

$$H_0 : P_1 = 0.07 \text{ and } H_1 : P_1 > 0.07$$

Here P_1 is the proportion of unsafe processed milk samples and 0.07 is the specified value of P_1 . Referring procedure mentioned in section D calculated value of test statistic Z is 6.79. At 5% level of significance null hypothesis is rejected and alternative hypothesis is accepted. So here conclusion is proportion of unsafe processed milk samples is larger than 7%. Answer to the question how large?, is given by the confidence interval.

2)Considering milk safety issue, it is recommended that raw milk is unsafe to consume directly. But this survey data contradicts this claim. Let us consider P_1 proportion of unsafe processed milk samples and P_2 proportion of unsafe raw milk samples. Let us test the following claim.

$$H_0 : P_1 = P_2 \text{ and } H_1 : P_1 > P_2$$

Referring procedure mentioned in section E calculated value of test statistic Z is 8.53. At 5% level of significance null hypothesis is rejected, that is there is significant difference between P_1 and P_2 and alternative hypothesis is accepted. So here, conclusion is raw milk is better when compared to processed milk at India level with respect to milk safety.

L. Summary of tested samples at States/UTs level and testing of homogeneity

We have divided all states/UTs in three classes considering total samples. First class includes fourteen states/UTs that have 0% unsafe samples. Second class includes seven states/UTs that have percentage of unsafe samples greater than 0% and less than 5%. Third class includes fifteen states/UTs

that have percentage of unsafe samples larger than 5%, where urgent vigilance is necessary. Class wise names of state/UT are given in the Table II.

TABLE II
 CLASS-WISE NAMES OF STATES/UTS

Class	% of unsafe samples	Name of the States/UTs
1	Zero	Andaman & Nicobar, Arunchal Pradesh, Assam, Dadra & Nagar Haveli, Daman & Diu, Goa, Jammu & Kashmir, Jharkhand, Lakshadweep, Manipur, Megalaya, Puducherry, Sikkim, Tripura
2	Larger than zero and ≤ 5	Andhra Pradesh (AP) , Bihar (BR), Gujarat (GJ), Karnataka (KA), Maharashtra (MH), Uttar Pradesh (UP), West Bengal (WB)
3	More than Five	Rajasthan (RJ), Chhattisgarh (CG), Haryana (HR), Himachal Pradesh (HP), Telangana (TS), Madhya Pradesh (MP), Uttarakhand (UK), Odisha (OR), Punjab (PB), Delhi (DL), Mizoram (MZ), Tamil Nadu (TN), Kerala (KL), Chandigarh (CH), Nagaland (NL).

Fig. 4 shows Class 3 States/UTs, where percentage of unsafe samples is more than 5%.

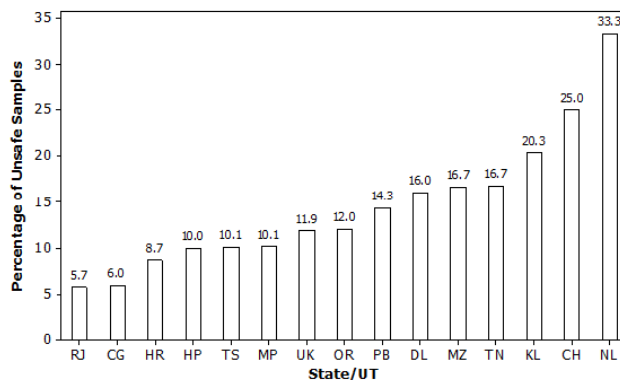


Fig. 4 Class 3 States/UTs with % of unsafe samples

Homogeneity of multiple population proportions (states/UTs where proportion of unsafe samples is larger than 5%) is tested using contingency table approach [20]. Using R program, calculated value of test statistic is 51.1548 and tabulated value from chi-square distribution at 5% level of significance is 23.6848. Thus homogeneity is rejected at 5% level of significance.

M. Testing of processed milk verses raw milk at state/UT level

Let us consider P_1 proportion of unsafe processed milk samples and P_2 proportion of unsafe raw milk samples. Look at the following hypotheses.

$$H_0 : P_1 = P_2 \text{ and } H_1 : P_1 > P_2$$

Estimated values of P_1 , P_2 , calculated value of test statistic Z for each state/UT of class 2 and 3 is given in the Table III with conclusion. Referring procedure mentioned in section E, Z-value computed and hence conclusion is noted.

TABLE III
COMPARISON OF PROCESSED MILK WITH RAW MILK REGARDING SAFETY OF MILK

State/UT	\hat{P}_1	\hat{P}_2	Z-Value	Conclusion
AP	0.0251	0.0206	0.27	H_0 not rejected
BR	0.0185	0.0059	0.98	H_0 not rejected
CH	0.5000	0.0833	2.11	H_0 rejected
CG	0.1923	0.0000	3.44	H_0 rejected
GJ	0.0530	0.0349	0.86	H_0 not rejected
HR	0.1176	0.0787	0.72	H_0 not rejected
HP	0.0000	0.1818	-1.35	H_0 not rejected
KA	0.0454	0.0180	1.48	H_0 not rejected
KL	0.2788	0.1084	2.88	H_0 rejected
MP	0.1029	0.1011	0.04	H_0 not rejected
MH	0.0555	0.0360	1.19	H_0 not rejected
MZ	0.0000	0.2500	-0.77	H_0 not rejected
NL	0.3333	0.3333	0.00	H_0 not rejected
DL	0.2010	0.0441	3.03	H_0 rejected
OR	0.1226	0.1162	0.14	H_0 not rejected
PB	0.3170	0.0987	3.57	H_0 rejected
RJ	0.1052	0.0420	2.06	H_0 rejected
TN	0.2123	0.1158	3.03	H_0 rejected
TS	0.1538	0.0680	2.14	H_0 rejected
UP	0.1098	0.0274	4.51	H_0 rejected
UK	0.1428	0.0967	0.55	H_0 not rejected
WB	0.0416	0.0038	2.90	H_0 rejected

It is very interesting to note that there is no significant difference between processed milk and raw milk with reference to milk safety in all states and UTs except CH, CG, KL, DL, PB, RJ, TN, TS, UP and WB. In the ten states/UTs (CH, CG, KL, DL, PB, RJ, TN, TS, UP and WB) raw milk is significantly better as compared to processed milk with regard to safety issues.

N. Factors responsible for unsafe samples.

It is observed that contaminant Aflatoxin M_1 is majorly responsible for unsafe samples. This is shown through Pareto Chart for raw and processed milk in Fig. 5. Total unsafe processed milk samples are 271. Out of 271, 227 failed due to Aflatoxin M_1 , 40 failed due to Antibiotics and 5 failed due to other adulterants. The total number of individual failures does not match to total number of unsafe samples because one sample failed for more than one factor. Total number of

unsafe raw milk samples is 185. Out of 185, 141 failed due to Aflatoxin M_1 , 37 failed due to Antibiotics and 8 failed due to other adulterants. The total number of individual failures does not match to total number unsafe samples because one sample failed for more than one factor.

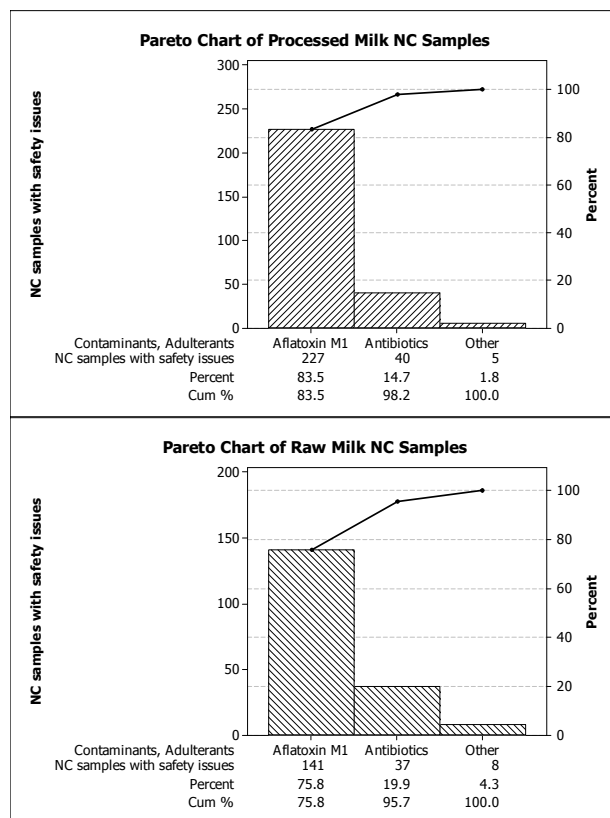


Fig.5 Pareto Chart of Milk Non-compliance samples

Let us consider Q_1 proportion of unsafe processed milk samples and Q_2 proportion of unsafe raw milk samples due to Aflatoxin M_1 . Look at the following hypotheses.

$$H_0 : Q_1 = Q_2 \text{ and } H_1 : Q_1 > Q_2$$

Referring procedure mentioned in section E calculated value of test statistic Z is 7.96. At 5% level of significance null hypothesis rejected and alternative is accepted. So proportion of unsafe processed milk samples is significantly large than unsafe raw milk samples due to Aflatoxin M_1 .

IV. CONCLUSIONS

From a stakeholder’s point of view the intention of this paper is to assess processed and raw milk safety in India as well as various states/UTs using inferential statistics. The paper is based on secondary data which is taken from National Milk Safety and Quality Survey, 2018. Initially we have found sampling distributions of estimators of proportion of total

unsafe samples (\hat{P}), proportion of unsafe processed milk samples (\hat{P}_1) and proportion of unsafe raw milk samples (\hat{P}_2). All the sampling distributions are normal though their parameters are different. Confidence intervals (95%) for P , P_1 and P_2 are constructed which are (0.0646, 0.0771), (0.0922, 0.1156) and (0.0415, 0.0551) respectively. In literature, it is recommended that raw milk is not safe to consume directly. But this survey data contradicts this claim because at India level it is found that raw milk is better as compared to processed milk. Overall proportion of unsafe samples at states/UTs level varies from (0, 0.33). There are 15 states/UTs where proportion of unsafe samples larger than 5%. So keeping in mind safety of milk there is urgent need to improve this situation. It is found that there is no state/UT where processed milk is better than raw milk. It is observed that contaminant Aflatoxin M_1 is majorly responsible for unsafe samples. Through statistical tests it is observed that proportion of non-compliant samples due to Aflatoxin M_1 in processed milk is much greater than in raw milk. This contradicts the remark from the survey report that Aflatoxin M_1 comes in the milk through feed and fodder. This claims that further research is needed to identify its cause. The limitations of this survey are that samples are from small town/villages and milk products are not considered while collecting data.

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