

Voluntary Report – Voluntary - Public Distribution

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Report Name: FSSAI Publishes Sampling Plan for Fortified Salt

Country: India

Post: New Delhi

Report Category: FAIRS Subject Report, Sanitary/Phytosanitary/Food Safety, Exporter Guide

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Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published a 'sampling plan for fortified salt' amendment. This amendment is part of the Food Safety and Standards (Fortification of Foods) Regulation which has been in effect since July 1, 2019.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standard Authority of India's (FSSAI) website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs, USDA and/or the U.S. Government make no claim of accuracy or authenticity.

On November 25, 2019, FSSAI published a sampling plan for fortified salt to prevent non-compliance of iodine and iron content in stray samples of salt by food business operators. The sampling plan will enable the food safety officer to analyze salt samples for compliance and prevent any complaint by food business operators.

Background: After the publication of the Food Safety and Standards (Fortification of Foods) Regulations in 2018, the industry sought an exemption on the enforcement of the upper level of iodine content in iodized and iron fortified iodized salt (included in Schedule-I, sub-regulation 1 of the Food Safety and Standards (Fortification of Foods) Regulations, 2018). Based on the feedback from salt stakeholders, an exemption was granted by FSSAI to the industry, but with the sampling plan in place, the exemption is removed. End background.

The full text of the Direction as well as the sampling plan for salt is pasted below and is also available on FSSAI's website: <http://www.fssai.gov.in/>



F. No. Stds/Fortification regulations/Directions/FSSAI-2019
Food Safety and Standards Authority of India
(A Statutory body under Ministry of Health and Family Welfare)
(Regulatory Compliance Division)

FDA Bhavan, Kotla Road,
New Delhi-110 002
Dated, the 25th November, 2019

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding 'Sampling plan for Salt' for the purpose of enforcement of FSS (Fortification of Foods) Regulations, 2018.

Reference is drawn to the notification no. 11/03/Reg/Fortification/2014 dated 02.08.2018 regarding Food Safety and Standards (Fortification of foods) Regulations, 2018. All the provisions of these regulations have come into force for compliance by the food business operators w.e.f. 01st July, 2019.

2. Several representations were received from salt manufacturers associations at FSSAI seeking exemption for enforcement of the upper level of iodine content in iodized and iron fortified iodized salt mentioned under Schedule-I, Sub-regulation 1 of Food Safety and Standards (Fortification of Foods) Regulations, 2018.
3. The concerns raised by the salt manufacturers were placed in the Scientific Panel, wherein it was recommended to frame guidelines on sampling and enforcement of salt samples in order to prevent any harassment of FBOs in cases of non-compliance of stray samples. Accordingly, a sampling plan for salt is attached herewith, which shall be used invariably by the Food Safety officer for analysing salt samples.
4. This issues with the approval of the Competent Authority.

Yours Sincerely


(Dr. Shobhit Jain)

Executive Director (Compliance Strategy)

SAMPLING PLAN FOR SALT

This plan is for production and/or bulk storage area only.

A. General Guidelines for Sampling:

- 1) A single sample for laboratory analysis shall be of minimum 500 g each.
- 2) Precaution is required to avoid contact of samples with moisture or moist areas.
- 3) The glass bottles (preferably amber colored) or PET jars be used for sending the sample to laboratory to avoid deterioration of iodine due to light.
- 4) FSO will make sure that the samples are coded properly and the label (if any) is masked in such a way to hide the identity of the FBO.
- 5) If needed, the FSO may take the help of laboratory personnel while picking up the samples; however, the responsibility of sampling shall lie with the FSO only.
- 6) FSO shall decide whether to pick samples from production line or from the stacked area.

B. Procedure for Sampling:-

I. FOR PRODUCTION LINE:-

Scenario-1 : Picking samples in production line when the FSO has no time constraint.

Step-1: Ascertain the number of bags that are made in a day/shift in the manufacturing unit on production line.

Step-2: Determination of sample size

By using the following formula, calculate the number of bags that shall be drawn as part of sampling -

$$\frac{(\sqrt{n} + 1)}{2} = x$$

[Example : 2000 bags of say 25 Kg each].
where, **n is the total number of bags produced in a day/ shift**, determine the number of bags to be selected (x). [Example: $(\sqrt{2000} + 1) \div 2 = 22.86$ rounded off to 23 i.e “x” will **23 bags**]

Step-3: Determination of sampling interval (i.e. the interval at which the bags to be sampled, are to be selected)

Divide total number of bags by the value of “x” [i.e., $n \div x$].

In above example, $2000 \div 23 = 86.95$, which is rounded of to next digit i.e. 87. This means pick up every 87th bag (i.e., 87th, 174th, 261st, 348th etc) from the production line and keep them aside till you reach the 2000th bag.

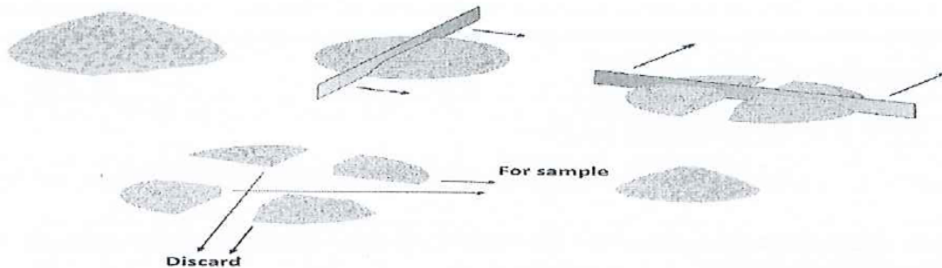
Step-4: Preparation of Laboratory Sample:-

For sending samples to laboratory for analysis the follow the following process for preparation of laboratory samples:

- (a) From the number of bags picked as, we need to get 4 samples of minimum 500 g each. For this, using a trier (see the picture below) sample 1 kg each from each bag of salt (it will be about 23 Kgs, as per the above example). Remaining material may be left with/ returned to the manufacturer or bulk storage facility itself.



- (b) Spread sample uniformly and divide it into four quadrant i.e, 1,2,3 & 4 of about 5-6 kg each. Mix either 1&3 or 2&4. From one of the mixed part, draw 4 samples of 500 gm each.



- (c) These 4 samples of 500g each, which will form the statutory samples that will be analysed in a notified laboratory.

Out of these 4 samples, one will be sent to the notified laboratory, one will be sent to the laboratory of FBO's choice (if the FBO so desires) and two counter samples will be deposited with Designated Officer.

Scenario-2 : Picking samples in production line when the FSO has time constraint.

If the FSO has a limited time to devote, samples are to be picked from the production line, the operations are fairly controlled, the production line is operating in a standardised manner, **then** the FSO shall divide the number of bags that are made in a day/shift (as the case may be) in the manufacturing unit with the number of production hours, multiplied by the number of hours he decides to sample, to arrive at the sampling population.

For example, if 2000 bags are made in 8 hours of shift on a standardised and controlled production line, and FSO decides to devote 2 hours for sampling then, the sampling population will be $= (2000/8) \times 2 = 500$.

After the above calculation of the population size, the FSO shall follow the Step-2 to 4 of the Scenario-1.

II. FOR BULK STORAGE POINTS:-

Scenario – 3: Picking of samples from stacked bags containing unit packs.

Step-1: Ascertain the number of bags stacked, identity details of the stack selected for sampling and number of unit packs in a single bag to ensure the homogeneity of stack. Then

number the bags starting from 1 to m, start from bottom row from left to right and then move up as shown in a representative picture below –



Step-2: Determination of sample size

By using the following formula, calculate the number of bags that shall be drawn as part of sampling -

$$\frac{(\sqrt{n} + 1)}{2} = x$$

[Example : 2000 bulk packs of say 25 Kg each].
where, **n** is the total number of bags, determine the number of bags to be picked (x).

[Example: $(\sqrt{2000} + 1) \div 2 = 22.86$ rounded off to 23 i.e “x” will **23 bags**]

Step-3: Determination of sampling interval (i.e. the interval at which the bags to be sampled, are to be selected)

Divide total number of bags by the value of “x” [i.e., $n \div x$].

In above example, $2000 \div 23 = 86.95$, which is rounded of to next digit i.e., 87. Pick up every 87th bag (i.e., 87th, 174th, 261st, 348th etc) from the stack.

Step-4. Preparation of Laboratory Sample:-

For sending samples to laboratory for analysis the follow the following process for preparation of laboratory samples:

Case-I: Bags containing unit packs of smaller size:

From the bags picked up, we need to select 4 unit packs of minimum 500 g each. For determination of sampling interval, the number of selected bags in Scenario-1, 2 & 3 shall be divided by 4.

In the above example, the same will be $23 \text{ bags} \div 4 = 5.75$, rounded off to 6.

Accordingly, arrange all the slected bags in a series and pick up a unit pack from every 6th bag from the series.

In above example, a unit packs will be picked each from 6th, 12th, 18th and 23rd (last bag in this case) bag for sending the same for analysis.

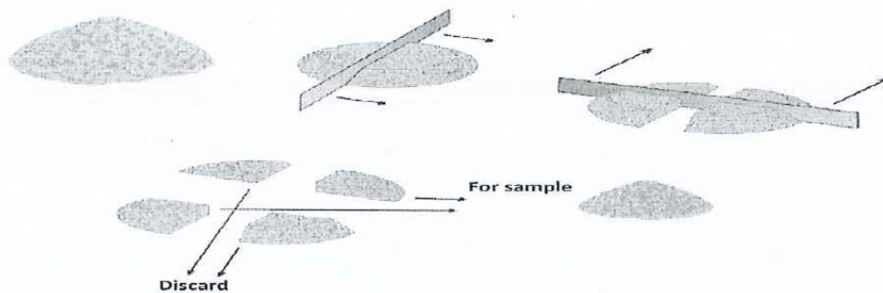
From these 4 unit packs, one will be sent to the notified laboratory, one will be sent to the laboratory of FBO's choice (if the FBO so desires) and two counter samples will be deposited with the Designated Officer concerned.

Case-II: In case of bulk bags of large size have loose salt.

- (a) From the number of bulk bags picked as, we need to get 4 samples of minimum 500 g each. For this, using a trier (see the picture below) sample 1 kg each from each bag of salt (it will be about 23 Kgs, as per the above example). Remaining material may be left with the manufacturer or bulk storage facility itself.



- (b) Spread sample uniformly and divide it into four quadrant i.e, 1,2,3 & 4 of about 5-6 kg each. Mix either 1&3 or 2&4. From one of the mixed part, draw 4 samples of 500 gm each.



- (c) These 4 samples of 500g each, which will form the statutory samples that will be analysed in a notified laboratory.

Out of these 4 samples, one will be sent to the notified laboratory, one will be sent to the laboratory of FBO's choice (if the FBO so desires) and two counter samples will be deposited with Designated Officer.

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Attachments:

No Attachments.