

**File No. 19(2)2018/FSA/RCD/FSSAI**  
**Food Safety and Standards Authority of India**

(A Statutory Authority established under the Food Safety & Standards Act, 2006)

Regulatory Compliance Division

FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the **24 Sep, 2019**

**Clarification**

**Subject: Clarification on order on the subject mandating food safety audit of Food Businesses holding Central license and falling under high risk categories under the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 dated 13.08.2019 -reg**

In continuation to the order dated 13.08.2019, the following clarifications are being issued following lot of queries raised by auditing agencies and food businesses:

| S. No | Query                                                                                                                                                  | Clarification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.    | When does the order come into effect?                                                                                                                  | The order comes into effect from the date of issue i.e. 13.08.2019.<br><b>However, the food business directed for mandatory audits should get the first audit of their premises by 31<sup>st</sup> Dec 2019.</b>                                                                                                                                                                                                                                                                                   |
| 2.    | Whether the complete chain (manufacturing, storage, transport, packaging etc) involved in these product categories should get mandatory auditing done? | It is important that the complete chain from manufacturing, transport, storage etc follow good hygienic practices, however, in the initial stage only the food businesses involved in manufacturing and processing sector under the product categories mentioned in the order dt 13.08.2019 should get their premises mandatorily audited.<br>Further, the Head Offices wherein no food related activities are being done but are holding Central License are also not being mandated for audits . |
| 3.    | Can an audit agency, audit a food business that they have already Certified or provided training?                                                      | No, as per section 12(1) of Food Safety and Standards (Food Safety Auditing) Regulations, 2018 an agency or its auditor should not have provided any training, guidance, food safety certification or consultancy or not carried out internal audits to the food business or its parent or subsidiary for last two years.                                                                                                                                                                          |

2. All Food Businesses are hereby directed to comply with the contents of the order dated 13.08.2019 read with these above clarifications. This issues with the approval of the Competent Authority.

Yours sincerely

  
(Dr. Shobhit Jain)

Executive Director (Compliance Strategy)

To,

- (i) All Food Business Operators
- (ii) All Commissioners of Food Safety/ All Central Licensing Authorities
- (iii) All Auditing agencies recognised under FSS (Food Safety Auditing) Regulations, 2018.

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FDA Bhawan, Kotla Road, New Delhi-110 002

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Dated, the **13** August, 2019

**ORDER**

**Subject: Mandating food safety audit of Food Businesses holding Central license and falling under high risk categories of food businesses under the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 -reg**

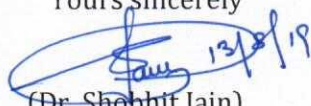
In pursuance of Part III, Section 8(1) of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 notified w.e.f 28.08.2018, the food authority herewith directs that the food business holding Central License and falling under the following 06 categories of businesses as per FLRS shall be subject to mandatory food safety auditing:

| Product ID | Product                                                                             |
|------------|-------------------------------------------------------------------------------------|
| 1          | Dairy products & analogues, excluding products of food category 2.0                 |
| 8          | Meat and meat products including poultry                                            |
| 9          | Fish and fish products, including molluscs, crustaceans, and echinoderms            |
| 10         | Eggs and egg products                                                               |
| 13         | Foodstuffs intended for particular nutritional uses (Food for infant nutrition etc) |
| 16         | Prepared Foods (catering etc)                                                       |

2. Further, as per Part III, Section 8(3) of the Food Safety and Standards (Food Safety Auditing) Regulations, 2018, the food businesses subject to mandatory food safety auditing (falling under above categories) shall get its business audited by a recognized auditing agency at intervals specified by the Food authority. The list of recognized audit agencies with their scope of audits is at Annex A. The audit frequency prescribed by the authority is at Annex B. An auditor manual with these details and list of agencies can also be downloaded from the link-  
<https://www.fssai.gov.in/cms/third-party-audit.php>

3. All Food Businesses are hereby directed to comply with the contents of this order. This issues with the approval of the Competent Authority.

Yours sincerely

  
(Dr. Shobhit Jain)

Executive Director (Compliance Strategy)

To,

- (i) All Food Business Operators
- (ii) All Central Licensing Authorities
- (iii) All Commissioners of Food Safety
- (iv) All Auditing agencies recognised under FSS (Food Safety Auditing) Regulations, 2018.

**Annex B****I. The Audit Frequency prescribed by the authority for conducting the food safety audits is as follows:**

| Product ID | Product                                                                                                                                                                         | Audit Score Range | Audit Frequency   |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| 1          | Dairy products and analogues, excluding products of food category 2.0                                                                                                           | Score: 81-100%    | Once in 12 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 09 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 2          | Fats and oils, and fat emulsion                                                                                                                                                 | Score: 81-100%    | Once in 18 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 12 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 3          | Edible ices, including sherbet and sorbe                                                                                                                                        | Score: 81-100%    | Once in 18 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 12 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 4          | Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds                                        | Score: 81-100%    | Once in 18 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 12 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 5          | Confectionery                                                                                                                                                                   | Score: 81-100%    | Once in 18 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 12 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 6          | Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 7.0 | Score: 81-100%    | Once in 18 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 12 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 7          | Bakery products                                                                                                                                                                 | Score: 81-100%    | Once in 18 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 12 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 8          | Meat and meat products including poultry                                                                                                                                        | Score: 81-100%    | Once in 12 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 09 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |
| 9          | Fish and fish products, including molluscs, crustaceans, and echinoderms                                                                                                        | Score: 81-100%    | Once in 12 months |
|            |                                                                                                                                                                                 | Score: 51 – 80 %  | Once in 09 months |
|            |                                                                                                                                                                                 | Score: < 50 %     | Once in 06 months |

|    |                                                                                         |                 |                   |
|----|-----------------------------------------------------------------------------------------|-----------------|-------------------|
| 10 | Eggs and egg products                                                                   | Score: 81-100%  | Once in 12 months |
|    |                                                                                         | Score:51 – 80 % | Once in 09 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 11 | Sweeteners, including honey                                                             | Score: 81-100%  | Once in 18 months |
|    |                                                                                         | Score:51 – 80 % | Once in 12 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 12 | Salts, spices, soups, sauces, salads and protein products                               | Score: 81-100%  | Once in 18 months |
|    |                                                                                         | Score:51 – 80 % | Once in 12 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 13 | Foodstuffs intended for particular nutritional uses (eg. Food for infant nutrition etc) | Score: 81-100%  | Once in 12 months |
|    |                                                                                         | Score:51 – 80 % | Once in 09 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 14 | Beverages, excluding dairy products                                                     | Score: 81-100%  | Once in 18 months |
|    |                                                                                         | Score:51 – 80 % | Once in 12 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 15 | Ready-to-eat savouries                                                                  | Score: 81-100%  | Once in 18 months |
|    |                                                                                         | Score:51 – 80 % | Once in 12 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 16 | Prepared Foods (catering etc)                                                           | Score: 81-100%  | Once in 12 months |
|    |                                                                                         | Score:51 – 80 % | Once in 09 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |
| 99 | Substances added to food                                                                | Score: 81-100%  | Once in 18 months |
|    |                                                                                         | Score:51 – 80 % | Once in 12 months |
|    |                                                                                         | Score:< 50 %    | Once in 06 months |

## II. The Audit Duration prescribed by the Authority for conducting the food safety audits:

### 1. Manufacturing

| Food handlers<br><br>(Parameter 1) | No. of production lines/<br>Product group in FBO/<br>No. of HACCP study<br>(Parameter 2) | On Site Man-days ** |
|------------------------------------|------------------------------------------------------------------------------------------|---------------------|
| 0-50                               | 1                                                                                        | 0.5                 |
| 51-100                             | 1-2                                                                                      | 1                   |
| 101-300                            | 4                                                                                        | 1.5                 |
| 301-600                            | 6                                                                                        | 2                   |
| 601-1000                           | 8                                                                                        | 2.5                 |
| >1000                              | 10+                                                                                      | 3                   |

**Note:** For calculating the number of man-days, the parameter with the higher number of man-days shall be taken into consideration.

**For eg:** If the number of food handlers is 80(i.e <100) and the number of production lines is 4 then the number of man-days will be 1.5 man-days ( i.e. maximum of 1 and 1.5 man-days).

**2. Catering/QSR/ Restaurants**

| <b>Food handlers</b> | <b>On Site Man-days **</b> |
|----------------------|----------------------------|
| 0-25                 | 0.5                        |
| 26-50                | 1                          |
| 51-100               | 1.5                        |
| More than 100        | 2                          |

**3. Food Retail/ Warehouse/ Storage**

| <b>Area (Sq. ft)</b> | <b>On Site Man-days **</b> |
|----------------------|----------------------------|
| <15,000              | 0.5                        |
| 15001-50,000         | 1                          |
| >50,000              | 1.5                        |

**\*\* All these are ON-SITE audit man-days prescribed and do not include reporting time.**