India

Post: New Delhi

Final Amendment for Irradiated Food Standards and Label Requirements

Report Categories:
Sanitary/Phytosanitary/Food Safety
Food and Agricultural Import Regulations and Standards - Narrative
Exporter Guide
Fresh Fruit
Vegetables
Grain and Feed
Tree Nuts
Oilseeds and Products
Fishery Products
Poultry and Products
Coffee
Food Processing Ingredients

Approved By:
Jonn Slette

Prepared By:
Radha Mani
Report Highlights:

The final amendment on standards and labeling for irradiated foods was published in the Official Gazette of India. The Food Safety and Standards Authority of India (FSSAI) notes that the final amendment includes feedback from public comments received during the comment period on the draft regulations, which were earlier published on November 23, 2015.

General Information:

DISCLAIMER: The information contained in this report was retrieved from FSSAI’s website http://www.fssai.gov.in/. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

On August 23, 2016, FSSAI notified Food Safety and Standards (Food Product Standards and Food Additives) Sixth Amendment, 2016 and the Food Safety and Standards (Packaging and Labeling) Fourth Amendment, 2016, related to standards and labeling requirements for irradiated foods. The implementation of the amendment starts from the date of its final publication in the Official Gazette, i.e., August 23, 2016. The full text of the final amendment as published in the Gazette is provided below and is also available on the website of FSSAI at: http://www.fssai.gov.in/. Please refer to GAIN report IN6006 for more details on the draft regulation published in November, 2015.

Details of Notification: F.No.1-120(1)/Standards/Irradiation/FSSAI-2015

- Publication Date on FSSAI Website: August 31, 2016
- Date of Implementation: August 23, 2016 (Publication in the Official Gazette)

Products affected: Fruits and vegetables, cereals, pulses, nuts, oilseeds, dried fruits, seafood (fresh or frozen), meat products including poultry (fresh and frozen) and eggs, seasonings, spices, condiments, dry herbs, tea, coffee, cocoa, plant products, ethnic foods, military rations, space foods, ready-to-eat, ready-to-cook and minimally processed foods, food additives, health foods, dietary supplements and nutraceuticals.

Agency in Charge: Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, GOI.
MINISTRY OF HEALTH AND FAMILY WELFARE
(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 23rd August, 2016

F. No. 1-120(2)/Standards/Irradiation/FSSAI-2015—Whereas the draft of the Food Safety and Standards (Packaging and Labelling) Amendment Regulations, 2016, were published as required under sub-section (1) of Section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F. No. 1-120(2)/Standards/Irradiation/FSSAI-2015, dated the 28th April, 2016 in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 11th May, 2016:

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (k) of sub-section (2) of Section 92 read with Section 23 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, namely:-
Regulations

1. **Short title and commencement.**—(1) These regulations may be called the Food Safety and Standards (Packaging and Labelling) Fourth Amendment Regulations, 2016.

   (2) They shall come into force on the date of their final publication in the official Gazette.

2. In the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, in regulation 2.4 -
   (a) Sub-regulation 2.4.4 relating to “Labelling of Irradiated Food” shall be omitted;
   (b) the Sub-regulation 2.4.5 relating to “Specific Labelling Requirements of other Products” shall be re-numbered as 2.4.4.

   PAWAN AGARWAL. Chief Executive Officer

   [ADVT-III/4/Exty./221]

   **Note.**— The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4, vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 and subsequently amended vide the following notification numbers:-

   (i) F. No. 4/15015/30/2011, dated the 7th June, 2013;
   (ii) F. No. P/15014/1/2011-PFA/FSSAI, dated the 27th June, 2013;
   (iii) F. No. 1-831/Sci- Pan- Noti/FSSAI-2012, dated the 17th February, 2015;
   (iv) No. 3-16/ Specified Foods/Notification(Food Labelling)/FSSAI-2014, dated 3rd May, 2016;
   (v) F. No. 1(94)2015/Notification P&L/Enf/FSSAI, dated 25th May, 2016 and
   (vi) No. 3-14P/Notification (Nutraceuticals)/FSSAI-2013, dated 13th July, 2016.

NOTIFICATION

   New Delhi, the 23rd August, 2016

   F. No. 1-120(1)/Standards/Irradiation/FSSAI-2015 — Whereas the draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016, were published as required by sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F. No. 1-120(1)/Standards/Irradiation/FSSAI-2015, dated the 28th April, 2016, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

   And whereas the copies of the said Gazette were made available to the public on the 11th May, 2016;

   And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

   Now, therefore, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:-

Regulations

1. **Short title and commencement.**—(1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Sixth Amendment Regulations, 2016.

   (2) They shall come into force on the date of their final publication in the official Gazette.

2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, for regulation 2.13 relating to “Irradiation of Food”, the following regulation shall be substituted, namely:
### 2.13 RADIATION PROCESSING OF FOOD

#### 2.13.1: Dose of Radiation -

1. Save as provided in clause (2) of sub-regulation 2.13.1, no food shall be processed by radiation.
2. No article of food permitted for radiation processing specified in the Table 1 and Table 2 given below shall receive the dose of radiation in excess of the quantity specified in the said Tables at the time of radiation processing.

#### Table 1: Classes of Food Products and Dose Limits for Radiation Processing

<table>
<thead>
<tr>
<th>Class</th>
<th>Food</th>
<th>Purpose</th>
<th>Dose Limit kGy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>1</td>
<td>Bulbs, stem and root tubers and rhizomes</td>
<td>Inhibit sprouting</td>
<td>0.02</td>
</tr>
<tr>
<td>2</td>
<td>Fresh fruits and vegetables (other than Class 1)</td>
<td>Delay ripening</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insect disinfection</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shelf-life extension</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quarantine application</td>
<td>0.1</td>
</tr>
<tr>
<td>3</td>
<td>Cereals and their milled products, pulses and their milled products,</td>
<td>Insect disinfection</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>nuts, oil seeds, dried fruits and their products</td>
<td>Reduction of microbial load</td>
<td>1.5</td>
</tr>
<tr>
<td>4</td>
<td>Fish, aquaculture, seafood and their products (fresh or frozen) and</td>
<td>Elimination of pathogenic microorganisms</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>crustaceans</td>
<td>Shelf-life extension</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control of human parasites</td>
<td>0.3</td>
</tr>
<tr>
<td>5</td>
<td>Meat and meat products including poultry (fresh and frozen) and</td>
<td>Elimination of pathogenic microorganisms</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>eggs</td>
<td>Shelf-life extension</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control of human parasites</td>
<td>0.3</td>
</tr>
<tr>
<td>6</td>
<td>Dry vegetables, seasonings, spices, condiments, dry herbs and their</td>
<td>Microbial decontamination</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>products, tea, coffee, cocoa and plant products</td>
<td>Insect disinfection</td>
<td>0.3</td>
</tr>
<tr>
<td>7</td>
<td>Dried foods of animal origin and their products</td>
<td>Insect disinfection</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control of moulds</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Elimination of pathogenic microorganisms</td>
<td>2.0</td>
</tr>
<tr>
<td>8</td>
<td>Ethnic foods, military rations, space foods, ready-to-eat, ready-</td>
<td>Quarantine application</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>to-cook minimally processed foods</td>
<td>Reduction of microbial load</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterilization</td>
<td>5.0</td>
</tr>
</tbody>
</table>
Table 2: Dose Limits for Radiation Processing of Allied Products

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Allied Product</th>
<th>Purpose</th>
<th>Dose Limit kGy (kiloGray)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Packaging materials for food or allied products</td>
<td>Microbial decontamination</td>
<td>5.0</td>
<td>10.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterilization</td>
<td>10.0</td>
<td>25.0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Food additives</td>
<td>Insect disinfection</td>
<td>0.25</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Microbial decontamination</td>
<td>5.0</td>
<td>10.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterilization</td>
<td>10.0</td>
<td>25.0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Health foods, dietary supplements and nutraceuticals</td>
<td>Insect disinfection</td>
<td>0.25</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Microbial decontamination</td>
<td>5.0</td>
<td>10.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterilization</td>
<td>10.0</td>
<td>25.0</td>
<td></td>
</tr>
</tbody>
</table>

(3) Routine quantitative dosimetry shall be carried out during operation and record kept of such measurements as provided under Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012.

2.13.2: Requirement for Radiation Processing:

(1) Approval of facilities - No irradiation facility shall be used for the treatment of food unless such facility -

(i) has been approved and licensed under the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012.

(ii) complies with the conditions for approval, operation, license and process control prescribed under the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012.

(iii) carries out irradiation in accordance with the provisions of the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012 and a certificate of irradiation indicating the dose of irradiation and the purpose of irradiation is provided by the facility.

2.13.3: Restrictions on Radiation Processing of Food -

(1) The radiation processing shall conform to the dose limit, the radiation source, and the conditions specified for each type or category of food for processing by radiation, under the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012.

(2) The food which has been processed by radiation shall be identified in such a way so as to prevent its being subjected to re-irradiation.

(3) The radiation processing shall be carried out by personnel having the minimum qualifications and training as prescribed for the purpose under the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012.

(4) The food once irradiated shall not be re-irradiated unless specifically so permitted under these regulations.

2.13.4: Record of Radiation Processing of Food -

Any treatment of food by radiation shall be recorded by facility as specified under the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012.

2.13.5: Standards of Radiation Processed Food -

The Radiation processed food shall comply with all the provisions of the Food Safety and Standards Act and the Regulations made thereunder specifying standards of such food.
2.13.6: Storage and Sale of Radiation Processed Food -

Save as otherwise provided in these regulations, no person shall irradiate for sale, store for sale, or transport for sale irradiated food.

2.13.7: Restriction on Sale of Radiation Processed Food -

The Radiation processed food shall be offered for sale only in pre-packaged conditions.

2.13.8: Labelling of Radiation Processed Food -

(1) The label of a food, which has been treated with ionizing radiation, shall carry a written statement indicating the treatment in close proximity to the name of the food.

(2) All packages of radiation processed food shall bear the Radura logo in green colour and following declaration, namely:

<table>
<thead>
<tr>
<th>PROCESSED BY RADIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Radura Logo]</td>
</tr>
<tr>
<td>Name of the Product:</td>
</tr>
<tr>
<td>Purpose of Radiation Processing:</td>
</tr>
<tr>
<td>Operating License No.:</td>
</tr>
<tr>
<td>Batch Identification No. (BIN) (as provided by facility):</td>
</tr>
<tr>
<td>Date of Processing:</td>
</tr>
</tbody>
</table>

PAWAN AGARWAL, Chief Executive Officer
[ADVT.-III/4/Exty./221]

Note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4, vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 and subsequently amended vide the following notification numbers:-

(i) F. No. 4/15015/30/2011, dated the 7th June, 2013;
(iii) F. No. 5/15015/30/2012, dated the 12th July, 2013;
(iv) F. No. P.15025/262/13-PA/FSSAI dated the 5th December, 2014;
(v) F. No. 1-83F/SciPan-Noti/FSSAI-2012 dated the 17th February, 2015;
(vi) F. No. 4/15015/30/2011, dated the 4th August, 2015;
(vii) F. No P. 15025/263/13-PA/FSSAI, dated the 4th November, 2015;
(viii) F. No. P.15025/264/13-PA/FSSAI, dated the 4th November, 2015;
(ix) F. No. 7/15015/30/2012, dated the 13th November, 2015;
(x) F. No P. 15025/208/2013-PA/FSSAI, dated the 13th November, 2015;
(xi) F. No P.15025/261/2013-PA/FSSAI, dated the 13th November, 2015;
(xii) F. No. 1-10(1)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013, dated the 11th January, 2016;
(xiii) No. 3-16/Specified Foods/Notification(Food Additive)/FSSAI-2014, dated the 3rd May, 2016;
(xiv) F. No. 15-03/EnFSSAI/2014, dated 14th June, 2016;
(xv) No. 3-14/F/Notification (Nutraceuticals)/FSSAI-2013, dated 13th July, 2016 and
(xvi) F. No. 1-12/Standards/SP(Sweets, Confectionery)/FSSAI-2015, dated 15th July, 2016.

[Digitally signed by RAJ KUMAR
Date: 2016.03.29
Time: 07:50]