

# Pharma & Healthcare Update

January 30, 2024

## YEAR END REGULATORY UPDATE 2023: FOOD INDUSTRY IN INDIA

- The Food Safety and Standards Authority of India has taken active steps to streamline the licensing and registration regime for food business operators.
- Food business operators may now select the validity period for licenses or registrations.
- In this update we have discussed the key steps taken by the food regulatory authority to enhance ease of doing business in India while taking steps to avoid regulatory delays.

### INTRODUCTION

The last quarter of 2023 saw steady activity from the regulatory authority for the food industry in India. The Food Safety and Standards Authority of India ("FSSAI") has continued to launch initiatives aimed at increasing the ease of doing business for food business operators in the country. Notably, the FSSAI has taken steps to streamline the licensing and registration norms in the sector while providing food business operators with the opportunity of selecting the validity period for FSSAI licenses or registrations. To save time and regulatory delays, the FSSAI has also allowed labelling deficiencies to be corrected on imported food consignments with certain reservations.

Some of the key developments that have taken place in the last quarter of 2023 in the food sector are captured below.

### CERTAIN OFFENCES UNDER THE FSS ACT DECRIMINALISED

In a bid to facilitate the ease of doing business in India, the Ministry of Law and Justice notified the Jan Vishwas (Amendment of Provisions) Act, 2023 ("Jan Vishwas Act")<sup>1</sup>. The provisions relating to the Food Safety and Standards Act, 2006 ("FSS Act") came into force on November 7, 2023.<sup>2</sup>

Under the Jan Vishwas Act, the following offences have been decriminalised:

- Manufacture, import, sale, storage and distribution of unsafe food articles for human consumption where such failure or contravention does not result in injury.<sup>3</sup> Previously, the offence attracted imprisonment for up to six months and a fine of up to one lakh rupees. This has now been substituted with "imprisonment for a term which may extend to three months and also with fine which may extend to three lakh rupees".
- Providing false or misleading information in connection with a requirement or direction under the FSS Act<sup>4</sup> previously attracted imprisonment for up to three months as well as a fine of up to two lakh rupees. The Jan Vishwas Act has done away with the imprisonment term, and has increased the maximum fine to ten lakh rupees.
- The act of manufacturing, importing, selling, storing or distributing any article of food without a license<sup>5</sup> was previously punishable with imprisonment for a term extending to six months and a fine of up to five lakh rupees. As per the Jan Vishwas Act, doing so would attract a penalty which may extend to ten lakh rupees.

The Jan Vishwas Act has also clarified that the penalties stipulated shall be subject to a ten per cent increase every three years.

### FSSAI NOTIFIES RECTIFIABLE LABELLING INFORMATION FOR IMPORTED FOOD CONSIGNMENTS

The FSSAI issued an order dated November 28, 2023<sup>6</sup> ("Labelling Order") permitting all labelling deficiencies on imported food consignments to be rectified in the customs bonded warehouses. The Labelling Order has been issued by the FSSAI to facilitate the ease of doing business in India while ensuring safety of food imported into India.

As per the law, there is a requirement that all packaged food products that are made available in the Indian market bear certain declarations. The FSS (Import) Regulation, 2011<sup>7</sup> ("Import Regulations") permits the rectification of deficiencies in labelling by non-detachable methods. Previously, only the name and address of the importer, the FSSAI logo and license number, veg/non-veg and category, nature and composition of proprietary foods could be declared.

The Labelling Order now permits the rectification of all labelling deficiencies on imported food consignments with the exception of:

- Lot No./Code No./ Batch Identification

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- Date of Manufacture or packaging and Expiry/Use By/Best Before

- Country of Origin for Imported Foods.

The label rectification on such food consignments is required to be undertaken prior to visual inspection/re-inspection by the Authorised Officer or his representative. The manner prescribed for rectification of the labelling error on the food consignments is to be done by affixing a single non-detachable sticker or by any other non-detachable method to ensure consumer safety. Upon rectification of the label, the Authorised Officer shall verify the label compliance in accordance with the applicable law and such consignment would be subject to sampling and testing upon confirmation of compliance with the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011 ("**FSS Regulations**").

## FSSAI PROVIDES OPTION FOR SELECTING THE VALIDITY PERIOD FOR LICENSE

The FSSAI vide order dated November 8, 2023<sup>7</sup> ("**Modification Order**") seeks to partially modify the previous order issued on the instant renewal of license/registration dated January 11, 2023 ("**Instant Renewal Order**"). The FSSAI vide the Instant Renewal Order undertook to streamline the process of licensing/registration and renewal by encouraging instant approvals for such applications for ease of doing business in India.

Prior to the Instant Renewal Order, the documents submitted by the food business operator at the time of renewal were to be scrutinised, which increased the timelines for renewal. The Instant Renewal Order did away with the scrutiny requirement, subject to the condition that there are no other changes to the existing details. However, the renewal of license was permitted for 1 year only while the registration could be renewed for a period of 1-5 years basis the application submitted and fee paid by the FBO.

The Modification Order has extended the option to select the period of validity while applying for new license/registration or applying for renewal to 1-5 years in the application submitted by the FBOs. The option to select the period of validity between 1-5 years was only available for renewal of registration prior to the Modification Order. The Modification Order has been brought into effect from November 8, 2023.

## FSSAI RE-OPERATIONALISES LICENSING AND REGISTRATION NORMS RELATED TO E-COMMERCE FOOD BUSINESSES

The FSSAI issued a direction dated October 20, 2023 re-operationalising the draft Food Safety and Standards (Licensing and Registration of Food Business) Amendment Regulations, 2021 ("**E-Commerce Regulations**")<sup>8</sup> issued under the Food Safety and Standards Act, 2006 ("**FSS Act**").

The FSSAI had approved a draft amendment to the regulations in 2017 which was operationalised from February 2018. The draft E-Commerce Regulations in November 2020, which provide for the licensing and registration of e-commerce food business operators, were released for public comments in 2020 and are under the process of finalization. In the interim, the FSSAI has been issuing directions for the operationalisation of the E-Commerce Regulations. At present, food business operators are expected to follow the regulations, but the enforcement shall only commence once the draft is finalised and notified.

## CONCLUSION

The developments from the second half of 2023 in the food industry indicate the FSSAI's intent to ease business operations and regulatory processes while providing FBOs with the opportunity to select validity period for new licenses as well as renewal of registrations. The licensing regulations are under the process of finalisation and are likely to be notified in the new year.

– Varsha Rajesh, Tanya Kukade, Eshika Phadke and Dr. Milind Antani

You can direct your queries or comments to the authors.

<sup>1</sup> Accessible at: <https://egazette.gov.in/WriteReadData/2023/248047.pdf>

<sup>2</sup> Accessible at: [https://egazette.gov.in/\(S\(xh2r1namsviuggvb21s1rt2y\)\)/ViewPDF.aspx](https://egazette.gov.in/(S(xh2r1namsviuggvb21s1rt2y))/ViewPDF.aspx)

<sup>3</sup> Section 59(i) of the FSS Act

<sup>4</sup> Section 61

<sup>5</sup> Section 63

<sup>6</sup> Accessible at: [https://www.fssai.gov.in/upload/advisories/2023/11/6565a92ca991a1abel%20rectification%20order\\_28.11.2023.pdf](https://www.fssai.gov.in/upload/advisories/2023/11/6565a92ca991a1abel%20rectification%20order_28.11.2023.pdf)

<sup>7</sup> Accessible at: [https://www.fssai.gov.in/upload/advisories/2023/11/654cca7d1465fFSSAI%20Order\\_Revising%20the%20option%20for%20selecting%20the%20validity%20period.pdf](https://www.fssai.gov.in/upload/advisories/2023/11/654cca7d1465fFSSAI%20Order_Revising%20the%20option%20for%20selecting%20the%20validity%20period.pdf)

<sup>8</sup> Accessible at: [https://www.fssai.gov.in/upload/uploadfiles/files/L-and-R%20oper%20content\\_merged.pdf](https://www.fssai.gov.in/upload/uploadfiles/files/L-and-R%20oper%20content_merged.pdf)

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