FOOD SAFETY AND STANDARDS (PROHIBITION AND RESTRICTIONS ON SALES) REGULATIONS, 2011

CHAPTER 1
GENERAL

1.1: Title and commencement-

1.1.1: These regulations may be called the Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011.

1.1.2: These regulations shall come into force on or after 5th August, 2011.

1.2: Definitions-

In these regulations unless the context otherwise requires:

1. "ingredient" means any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form;

Amendment for insertion of new provision

[12][2. "Industrial trans fatty acids" means all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration. It excludes trans-fatty acids from dairy, meat, fish and their products.]

[Amendment in force from 2nd February, 2021; FBOs to comply with the provisions by 1st January, 2022]

CHAPTER 2
PROHIBITION AND RESTRICTIONS ON SALES

2.1 Sale of certain admixtures prohibited

2.1.1 Notwithstanding the provisions of 2.7 of labelling and packaging regulations no person shall either by himself or by any servant or agent sell—

(1) [4][Omitted]

(2) milk which contains any added water;

(3) ghee which contains any added matter not exclusively derived from milk fat;

(4) skimmed milk (fat abstracted) as milk;

(5) a mixture of two or more edible oils as an edible oil;

(6) vanaspati to which ghee or any other substance has been added;

(7) turmeric containing any foreign substance;

(8) mixture of coffee and any other substance except chicory;

(9) dahi or curd not prepared from boiled, pasteurised or sterilized milk;

(10) milk or a milk product specified in Food Safety and Standards (Food Products Standards and Food Additives) regulations, 2011 containing a substance not found in milk, except as provided in the regulations.

[13][(11) Any Multi source edible vegetable oil containing Mustard Oil manufactured on or after 8th June, 2021.]

Provided that the Central Government or the Food Authority may, by notification in the Official Gazette exempt any preparations made of soluble extracts of coffee from the operation of this regulation.

[1][Provided further that proprietary food articles, as defined in sub- Regulation 2.12.1of the Food safety and Standards (Food Products Standards and Foods Additives) Regulation,2011, relating to

clause (8) and (10) of sub –regulation 2.1.1 shall be exempted from the operation of these Regulations.]

Provided further that in respect of regulation 2.1.1(5), a maximum tolerance of 15.0 red units in 1 cm. Cell of Lovibond scale is permitted when oil is tested for Boudouin test without dilution that is to say by shaking vigorously for 2 minutes, 5 ml. of the sample with 5 ml. of the hydrochloric acid (specific gravity 1.19) and 0.3 ml. of 2 percent alcoholic solution of furfural and allowing to standing for 5 miutes.

Provided further that in respect of Regulation 2.1.1(5) a maximum tolerance limit of 10 red units in one cm. cell on Lovibond scale is permitted when the oil is tested for Halphen's test without dilution, that is to say, by shaking 5 ml. of the sample with 5 ml. of sulphur solution (one per cent (w/v) solution of sulphur in carbon-di-sulphide mixed with equal volume of amyl alcohol), in a closed system (test tube 250 x 25 Cm.) heating in hot water (70^0C- 80°C) for a few minutes with occasional shaking until carbon-di-sulphide is boiled off and the sample stops foaming and then placing the tube on saturated brine bath, capable of being regulated at 110^0C-115^0C for 2.5 hours

Provided also that prohibition in Regulation 2.1.1 (5) shall remain inoperative in respect of admixture of any two edible vegetable oils as one edible vegetable oil, where –

(a) the proportion by weight of any vegetable oil used in the admixture is not less than 20 per cent. by weight; and

(b) the admixture of edible vegetable oils, is processed or packed and sold, by the Department of Civil Supplies, Government of India (Directorate of Vanaspati, Vegetable Oils and Fats) or by the agencies in public, private or Joint Sector authorized by the Department, or by the National Dairy Development Board or by the State Cooperative Oilseeds Growers Federation or Regional and District Cooperative Oilseeds Growers Union set up under National Dairy Development Board's Oilseeds and Vegetable Oil Project or by the Public Sector undertakings of Central and State Governments, in sealed packages weighing not more than 15 litres under Agmark Certification Mark compulsorily and bearing the label declaration as laid down in the Regulation 2.4.(11) of Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and

(c) the quality of each edible oil used in the admixture conforms to the relevant standard prescribed by these regulations.

2.2: Restriction on use of certain ingredient:

2.2.1: No person in any State shall, with effect from such date as the state government concerned may by notification in the official gazette specify in this behalf, sell or offer or expose for sale, or have in his possession for the purpose of sale, under any description or for use as an ingredient in the preparation of any article of food intended for sale:—

(a) Kesari gram (Lathyrus sativus) and its products.

(b) Kesari dal (Lathyrus sativus) and its products.

(c) Kesari dal flour (Lathyrus sativus) and its products.

(d) A mixture of Kesari gram (Lathyrus sativus) and Bengal-gram (Cicer arietinum) or any other gram.

(e) A mixture of Kesari dal (Lathyrus sativus) and Bengal-gram dal (Cicer arietinum) or any other dal.

(f) A mixture of Kesari dal (Lathyrus sativus) flour and Bengal-gram (Cicer arietinum) flour or any other flour.

Explanation.—The equivalent of kesari gram in some of the Indian Languages are as follows:—

1.	Assamese	Khesari, Teora.
		Khesari, Teora, Kassur,
2.	Bengali	Batura.

		Khesari, Teora, Kassur,
3.	Bihari	Batura.
4.	English	Chikling vetch.
5.	Gujarati	Lang.
6.	Hindi	Khesari, Kessur, Kesari, Kassartiuri,Batura, Chapri, Dubia, Kansari, Kesori, Latri, Tinra, Tiuri, Kassor.
7.	Kannada	Laki Bele, Kessari Bele.
8.	Malyalam	Kesari, Lanki, Vattu.
9.	Tamil	Muku.
10.	Marathi	Lakheri, Batri, Lakhi, Lang, Mutra, Teora, Botroliki-dal, Lakh.
11.	Oriya	Khesra, Khesari, Khesari dal.
12.	Persian	Masang.
13.	Punjabi	Kisari, Chural, Karas, Karil, Kasa Kesari, Chapa.
14.	Sanskrit	Sandika, Triputi.
15.	Sindhi	Matter.
16.	Telugu	Lamka

[11][2.2.2 Notwithstanding the condition at 2.2.1 the maximum allowed limits for any incidentally occurring Khesari dal in grams /pulses shall be not more than 2% including other edible grains.]

2.3 Prohibition and Restriction on sale of certain products

2.3.1: Prohibition on sale of food articles coated with mineral oil: No person shall sell or offer or expose for sale or have in his premises for the purpose of sale under any description, food articles which have been coated with mineral oil, except where the addition of mineral oil is permitted in accordance with the standards laid down in these Regulations and Food Safety and Standards (Food Products Standards and Food Additives) regulations, 2011.

2.3.2: [9][****]

2.3.3: Food resembling but not pure honey not be marketed as honey: No person shall use the word ‘honey’ or any word, mark, illustration or device that suggests honey on the label or any package of, or in any advertisement for, any food that resembles honey but is not pure honey.

2.3.4: Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food products.

2.3.5: Prohibition of use of carbide gas in ripening of fruits: No person shall sell or offer or expose for sale or have in his premises for the purpose of sale under any description, fruits which have been artificially ripened by use of acetylene gas, commonly known as carbide gas.

[2][Provided that fruits may be artificially ripened by use of Ethylene gas at a concentration upto 100 ppm (100µl/L) depending upon the crop, variety and maturity.]

2.3.6: Sale of Fresh Fruits and Vegetables: The Fresh Fruits and Vegetables shall be free from rotting and free from coating of waxes, mineral oil and colours.

Provided that fresh fruits may be coated with bees wax (white and yellow) or carnauba wax or shellac wax at level not exceeding Good Manufacturing Practices under proper label declaration as provided in Regulation 2.4.5 (44) of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

2.3.7: Sale or use for sale of admixtures of ghee or butter prohibited: No person shall sell or have in his possession for the purpose of sale or for use as an ingredient in the preparation of an article of food for sale a mixture of ghee or butter and any substance

(1) prepared in imitation of or as a substitute for ghee or butter, or

(2) consisting of or containing any oil or fat which does not conform to the definition of ghee;

Provided that where a mixture prohibited by this regulation is required for the preparation of an article of food, such mixture shall be made only at the time of the preparation of such article of food.

2.3.8: Restriction on sale of ghee having less Reichert value than that specified for the area where such ghee is sold.

(1) The ghee having less Reichert value and a different standard for Butyro-refractometer reading at 40^0 C than that specified for the area in which it is imported for sale or storage shall not be sold or stored in that area except under the 'AGMARK' seal:

Provided that such ghee may be (i) sold lose, after opening the 'AGMARK' sealed container, in quantities not exceeding two kilograms at a time, and (ii) used in the preparation of confectionery (including sweetmeats).

(2) A person selling:—

(i) ghee in such manner as specified in Regulation 2.3.8 (1) and

(ii) confectionery (including sweetmeats) in the preparation of which such ghee is used, shall give a declaration, in the Form A, to the Food Safety Officer when a sample thereof is taken by him for analysis under Section 47 of the Act and also to a purchaser desiring to have the sample analysed under Section 40 of the Act.

(iii) If on analysis such sample is found to be conforming to the standards of quality prescribed for the area where it is alleged to have been produced, the ghee shall not be deemed to be adulterated by reason only that it does not conform to the standards of quality prescribed for the area where it is sold.

2.3.9: [9][****]

2.3.10: [9][****]

2.3.11: Condition for sale of flavoured tea: Flavoured tea shall be sold or offered for sale only by those manufacturers who are registered with Tea Board. Registration number shall be mentioned on the label. It shall be sold only in packed conditions with label declaration as provided in the Regulation 2.4.5 (23) of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

[6][2.3.12: Restriction on sale of common salt.- No person shall sell or offer or expose for sale or have in his premises for the purpose of sale, common salt for direct human consumption or for use as an ingredient in a food product unless the same is iodized:

Provided that common salt may be sold or exposed for sale or stored for sale for iodization, iron fortification, animal use, preservation not meant for direct consumption, for infant food products, manufacturing medicines and industrial use under proper label declarations, as specified in the provisions of regulation 2.4.4 of Food Safety and Standards (Packaging and labelling) Regulations, 2011.]

2.3.13: Use of flesh of naturally dead animals or fowls prohibited.

No person shall sell or use as an ingredient in the preparation of any article of food intended for sale, the flesh of any animal or fowl which has died on account of natural causes.

2.3.14: Restrictions relating to conditions for sale

(1) No person shall store, expose for sale or permit the sale of any insecticide in the same premises where articles of food are stored, manufactured or exposed for sale:

Provided that nothing in this regulation shall apply to the approved household insecticides which have been registered as such under the Insecticides Act 1968 (46 of 1968).

Explanation.—For the purpose of this regulation, the word 'insecticide' has the same meaning as assigned to it in the Insecticides Act, 1968 (46 of 1968).

(2) No person shall sell or serve food in any "commercial establishment" in plastic articles used in catering and cutlery, unless the plastic material used in catering and cutlery articles, conform to the

food grade plastic, specified in these regulations.

Explanation:- For the purpose of the Regulation 2.3.14 (2), "commercial establishment" means any establishment, called by whatever name, being run\ managed by any person or by any authority of the Government\ Semi-Government or by any corporate\ registered body which deals in the business of selling or serving food.

(3) Iron fortified common salt shall be sold only in high density polyethylene bag (HDPE) (14 mesh, density 100 kg/m^3, unlaminated) package which shall bear the lable as specified in the Regulation 2.4.5 (21 & 42) of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

(4) No person shall manufacture, sell, store or exhibit for sale, an infant milk food, infant formula and milk cereal based weaning food, processed cereal based weaning food and follow up formula except under Bureau of Indian Standards Certification Mark.

(5) Condensed milk sweetened, condensed skimmed milk sweetened, milk powder, skimmed milk powder, partly skimmed milk powder and partly skimmed sweetened condensed milk shall not be sold except under Indian Standards Institution Certification Mark.

(6) Every package of cheese (hard), surface treated with Natamycin, shall bear the label as specified in the Regulation 2.4.5 (33) of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

(7) No person shall sell protein rich atta and protein rich maida except in packed condition mentioning the names of ingredients on the label.

(8) No person shall sell sal-seed fat for any other purpose except for bakery and confectionery and it shall be refined and shall bear the label declaration as specified in the Regulation 2.4.5 (19) of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

(9) No person shall sell confectionery weighing more than 500 gms. except in packed condition and confectionery sold in pieces shall be kept in glass or other suitable containers.

Explanation.—for the purposes of regulation 2.3.14 (9) "Confectionery, shall mean sugar boiled confectionery, lozenges and chewing gum and bubble gum";

(10) All edible oils, except coconut oil, olive oil, imported in crude, raw or unrefined form shall be subjected to the process of refining before sale for human consumption. Such oil shall bear a label declaration as laid down in the Regulation 2.4.2 of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

[13][(11) The Multi Source Edible Vegetable Oil shall not be sold in loose form. It shall be sold in sealed package weighing not more than 15 Kilograms. The container having Multi Source Edible Vegetable Oil shall be tamper proof. It shall also not be sold under the common or generic name of the oil used in the blend but shall be sold as – Multi Source Edible Vegetable Oil. The sealed package shall be sold or offered for sale only under AGMARK certification mark bearing the label declarations as provided in the Regulations besides other labelling requirements under the Regulation.]

(12) Coloured and flavoured table margarine shall only be sold in a sealed package weighing not more than 500 gms, with a label declaring addition of colour and flavour as required under these regulations.

(13) The fat spread shall not be sold in loose form. It shall be sold in sealed packages weighing not more than 500 gms. The word 'butter' shall not be associated while labelling the product. The sealed package shall be sold or offered for sale only under AGMARK Certification mark bearing the label declaration as provided under Regulation 2.4.2 of Food Safety and Standards (Packaging and Labelling) regulations, 2011 beside other labelling requirements under these regulations.

(14) No person shall sell compounded asafoetida exceeding one kilogram in weight except in a sealed container with a label.

(15) No person shall sell powdered spices and condiments except 'under packed conditions.

Explanation:— For the purpose of regulation 2.3.14 (15) "Spices and Condiments" means the spices and condiments as specified in 2.9 of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

(16) The katha prepared by bhatti method shall be conspicuously marked as "Bhatti Katha"

(17) No person shall manufacture, sell or exhibit for sale packaged drinking water except under the Bureau of Indian Standards Certification Mark.

(18) No person shall manufacture, sell or exhibit for sale mineral water except under the Bureau of Indian Standards Certification Mark";

Explanation:— For the purpose of regulation 2.3.14 (18), the expression "mineral water" shall have the same meaning as assigned to it in the Regulation 2.10.7 of Food Safety and Standards (Food Products Standards and Food Additive) Regulations, 2011.

(19) No person shall sell any food product wherein artificial sweetener is permitted under these regulations, except under packed condition and as per the labelling requirements prescribed under the regulation 2.4.5 (24, 25, 26, 28 & 29) of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

[8][Provided that if such product is sold through a vending machine, the food business operator shall display on the vending machine prominently and cause it to be labelled on the cup or container in which the product is served in respect of artificial sweetener as per the labelling requirements specified under regulation 2.4.4 (24, 25, 26, 28 and 29) of Food safety and Standards (Packaging and labelling) Regulations, 2011.

Explanation.- For the purpose of this proviso, vending machine does not include those which serve pre-packaged beverages and food.]

(20) Conditions for sale of irradiated food.- All irradiated food shall be sold in pre-packed conditions only. The type of packaging material used for irradiated food for sale or for stock for sale or for exhibition for sale or for storage for sale shall conform to the packaging and labelling requirements specified in the regulation 2.4.4 of Food Safety and Standards (Packaging and Labelling) regulations, 2011.

Amendment for insertion of new provision

[12][(21) Food Products in which edible oils and fats are used as an ingredient shall not contain industrial trans fatty acids more than 2% by mass of the total oils/fats present in the product, on and from 01st January, 2022.]

[Amendment in force from 2nd February, 2021; FBOs to comply with the provisions by 1st January, 2022]

2.3.15: Special provisions relating to sale of vegetable oil and fat

(1) No person shall sell or expose for sale, or distribute, or offer for sale, or dispatch, or deliver to any person for the purpose of sale any edible oil –

(a) Which does not conform to the standards of quality as provided in the Food Safety and Standards Act, 2006 (34 of 2006) and rules/regulations made there under; and

(b) Which is not packed in a container, marked and labelled in the manner as specified in FSSAI regulations

Provided that the State Government may, in the public interest, for reasons to be recorded in writing, in specific circumstances and for a specific period by a notification in the Official Gazette, exempt any edible oil from the provisions of this Act.

(2) No vegetable oil shall contain any harmful colouring, flavouring or any other matter deleterious to health;

(3)[5][Vanaspati, interesterified vegetable oil or fat, bakery shortening, bakery and industrial Margarine, table Margarine and fat spreads shall be prepared from any of the edible vegetable oils whose standards are specified in sub-regulation 2.2 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 or from any other edible vegetable oil with prior approval of the Food Authority.]

(4) No colour shall be added to hydrogenated vegetable oil unless so authorized by Food Authority, but in no event any colour resembling the colour of ghee shall be added. If any flavour is used, it shall

be distinct from that of ghee, in accordance with a list of permissible flavours and such quantities as may be prescribed by the Food Authority

(5) No anti-oxidant, synergist, emulsifier or any other such substance other than those permitted by these regulations be added to any vegetable oil except with the prior sanction of the Food Authority.

(6) Restriction on the use of solvent.

No solvent other than n-Hexane (Food Grade) shall be used in the extraction of cocoa butter, oils and fats and edible soya flour.

The quantity solvent mentioned in the column (1) of the Table below, in the food mentioned in column (2) of the said Table, shall not exceed the tolerance limits prescribed in column (3) of the said Table:

Name of Solvent	Article of food	Tolerance limits mg/kg (ppm)
Hexane (Food Grade)	(a) Refined solvent extracted cocoa butter	5.00
	(b) Refined solvent extracted oils and fats	5.00
	(c) solvent extracted edible soya flour	10.00

[7][(7) Restriction on the use of diacetyl as flavouring substance in oils and fats.]

[10][(8). The Total Polar Compounds in unused or fresh vegetable oil or fat shall not be more than 15% and used vegetable oil or fat having developed Total Polar Compounds more than 25% shall not be used.]

FORM A

(Refer Regulation 2.3.8 (2))

Declaration

I/ We on behalf of ..... solemnly declare that the ghee sold by me / us/ on behalf of ...../ ghee used by me / us / on behalf of ..... in the preparation of .... .Confectionary (including sweetmeats) is / was from a tin containing ..... origin and having “AGMARK” seal. The said ghee of tin pertains to batch number..... from Shri/ Shrimati/ Kumari/ Sarvsri ..... on the ..... as per invoice / cash/ credit memo. No..... Dated.....

Signature of Trader/ Traders

Date.....

Place.....

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

1. F.No. 4/15015/30/2011, dated 8th February, 2013;

2. F.No. Stds/F&VP/Notification (02)/FSSAI-2016, dated 23rd August, 2016;

3. F.No. Stds/O&F/Notification(2)/FSSAI-2016, dated 23rd August, 2016;

4. F.No. A-1 (1)/Standards/MMP/2012, dated 12th October, 2017;

5. F. No. Stds/O&F/Notification (8)/FSSAI-2017, dated 31st July, 2018;

6. F.No. Stds/Salt/Misc/01/FSSAI-2016 (pt-1), dated 25th June, 2019;

7. No. Stds/Additives-2/Notification/FSSAI/2018, dated 25th June, 2019;

8. No. stds/Additive-3/notification/FSSAI/2018, dated 21st july, 2020.

9. F. No. Stds/Agmark-BIS/02/FSSAI-2018, dated 20th October, 2020.

10. No. Stds/O&F/Notification(12)/FSSAI-2019, dated 26th October, 2020.

11. F.No.Reg/Stds-Khesari dal/FSSAI-2020, dated 12th January, 2021.

12. F. No. Stds/O&F/Notification(13)/FSSAI-2019, dated 2nd February, 2021.

13. No. Stds/SP-15/T[T(IMST)], dated 8th March, 2021.