

File No. Std/SP-10/T(Formaldehyde)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi-110 002.

The

November , 2020

Subject: Direction under Section 18 (2) (d) read with Section 16 (5) of Food Safety and Standards Act, 2006 regarding re-operationalisation of Food Safety and Standards (Licensing and Registration of Food Businesses) Amendment Regulations, 2020 and Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2020 relating to limit of naturally occurring formaldehyde in freshwater and marine fish.

In exercise of the power conferred under section 92 of the Food Safety and Standards Act, 2006, FSSAI has framed draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2020 specifying the limit of naturally occurring formaldehyde in freshwater and marine fish and also hygienic and sanitary conditions to be followed while handling, processing, manufacturing, packing, storing, distributing and transporting and retail of fish and fish products under Food Safety and Standards (Licensing and Registration of Food Businesses) Amendment Regulations, 2020 and the same were operationalised initially on 10.02.2020 and re-operationalised on 21.08.2020.

2. These draft regulations are in the process of being notified and the final regulations are likely to take some more time before being notified and enforced. Meanwhile, the Authority observed that some other fish species also needs to be incorporated in the list. Hence, keeping in mind the public health interest and to ensure food safety and fair practices in food business operations, it has been decided to operationalise the revised provisions of these regulations, enclosed herewith with immediate effect.

3. This direction will supersede the earlier directions issued vide even number dated 21.08.2020 as mentioned above and will come into force with

immediate effect. The Food Business Operators shall follow these regulations and the enforcement of these regulations with immediate effect; and, in so far as schedule 4 requirement are concerned, if required, Improvement Notice under Section 32 of the Food Safety and Standards Act, 2006 may be issued to Food Business Operators and accordingly action may be taken for compliance of these requirements.

4. This issues with the approval of the Competent Authority in exercise of the power vested under Section 18 (2) (d) and 16 (5) of Food Safety and Standards Act, 2006.



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To

1. All Food Safety Commissioner.
2. All Authorized Officer, FSSAI.
3. All Central Designated Offices of FSSAI.

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI

Notice for operationalisation of Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2020 w.r.t. limit of naturally occurring formaldehyde in freshwater and marine fish.

1. The Food Safety and Standards Authority of India, hereby makes the following regulations operational with immediate effect. The Food business operators shall follow these regulations.

2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in regulation 2.6, after sub-regulations 2.6.1, following sub-regulation shall be inserted, namely:-

2.6.2. Limit of Formaldehyde-

(1) The amount of naturally occurring formaldehyde shall not exceed the limit prescribed in the column (3) for different species of fish as mentioned in the table given below:-

Table

Sl. No.	Group & Species	Max limit, mg per Kg
Group - I (Marine)		
1	<i>Rastrelligerkanagurta</i>	8.0
2	<i>Sardinellalongiceps</i>	
3	<i>Scomberomorusguttatus</i> and <i>S. commerson</i>	
4	<i>Mugilcephalus</i> and all other mullets	
5	<i>Anoxypristiscuspidata</i> and all other elasmobranchs	
6	<i>Fenneropenaeusindicus</i> , <i>Metapenaeusdobsoni</i> and all other prawns	
7	<i>Sauridatumbil</i> and all Lizard Fishes	
Group - II (Marine)		
1	<i>Chirocentrusdorab</i>	4.0
2	<i>Tylosuruscrocodilus</i> and all other half-beaks	
3	<i>Rachycentroncanadum</i> , <i>Caranxignobilis</i> , <i>Caranxsexfasciatus</i> , <i>Alepesdjedaba</i> , <i>Alepeskleinii</i> and all other carangids	
4	<i>Loligoduvaucelii</i> , <i>Loligosinghalensis</i> , <i>Loligoedulis</i> and all other squids	
5	<i>Portunuspelagicus</i> , <i>P. sanguinolentus</i> , <i>Charybdis feriatus</i> , <i>Scylla serrata</i> and all other marine crabs	
6	<i>Psettodeserumei</i> , <i>Cynoglossus bilineatus</i> , <i>Cynoglossusarel</i> , <i>Cynoglossusmacrostomus</i> and all other flat fishes	
7	<i>Etroplussuratensis</i> , <i>Scatophagusargus</i> , <i>Latescalcarifer</i> , <i>Menemaculata</i> , <i>Ariommaindicum</i> , <i>Lactariuslactarius</i> and all other perches	
8	<i>Pampusargenteus</i> , <i>Parastromateusniger</i> (all pomfrets)	
9	<i>Scrombroideslysan</i> , <i>Scomberoidestala</i> and all other leather jackets	

10	<i>Megalaspiscordyla</i> (horse mackerels)		
11	<i>Amphioctopusneglectus, Amphioctopusmembranaceus</i> and all other octopus		
12	<i>Anodontostoma chacunda, Escualosa thoracata, Megalops cyprinoides, Stolephorus commersonii, S. indicus, Thryssa malabarica, T. mystax, Tenualosailisha, Sardinellaalbella, S. fimbriata, S. melanura, S. gibbosa</i> and all other clupeoids and anchovies		
13	<i>Arius subrostratus, Plicofollis layardi, P. dussumieri</i> and all other marine catfishes		
14	<i>Epinephelus diacanthus, Epinephelus epistictus, E. areolatus, E. chlorostigma, E. radiatus, E. bleekeri, E. longispinis</i> and all other groupers/rock cods		
15	<i>Gerres setifer, Leiognathus equulus, L. insidiator</i> and all other silver bellies/biddies		
16	<i>Johnius dussumieri, J. elongatus, Otolithes ruber</i> and all other croakers		
17	<i>Auxisthazard, Thunnusalbacaes, Katsuwonus pelamis</i> and all other tunas & bonitos		
18	<i>Lutjanus argentimaculatus, L. quinquelineatus, L. fulviflamma, L. Lutjanus, Pristipomoides sieboldii</i> and all other snappers		
19	<i>Nemipterus randalii, N. japonicus</i> and all other threadfin breams		
20	<i>Priacanthushamrur</i> (Bullseyes)		
21	<i>Sphyaena jello, Sphyaena obtusata</i> and all other barracudas		
22	<i>Sepia, elliptica, Sepia pharaonis, Sepiellainermis</i> and all Cuttlefishes		
23	<i>Thenus orientalis</i> and all other Lobsters		
24	<i>Lethrinus nebulosus</i> and all other Pigface breams		
25	<i>Muraenesox cinereus</i> and all other Eels		
26	<i>Trichiurus lepturus</i> and all other Ribbon fishes		
27	<i>Upeneus vittatus</i> and all other Goat fishes		
28	<i>Litopenaeus vannamei</i> and all other aquacultured shrimps		
Group - III (Freshwater fishes)			
1	All major-, exotic- and minor carps (<i>Catla catla, Labeo rohita, Cirrhinus mrigala, Cyprinus carpio, Labeo calbasu, Puntius sarana</i>)		4.0
2	All other freshwater fishes (<i>Oreochromis niloticus, O. mossambicus, Glassogobius giuris, Xenentodon cancila</i>)		
3	All freshwater catfishes (<i>Ompok bimaculatus, Heteropneustes fossilis, Wallago attu, Mystus gulio, Pangasianodon hypophthalmus, Horabagrus brachysoma</i>)		
4	All other freshwater fishes, crustaceans and molluscs not covered above		

Note- The above limits are subjected to revision on the basis of data collected over different seasons and geographical locations and upon analysis and recommendation by the scientific panel, as and when required.

(2) For fish and fish products of marine origin other than those mentioned in the table at Group I and II, the limit of naturally occurring formaldehyde shall not be more than 100 ppm.

Notice for operationalisation of Kind of Businesses (KoB) and their eligibility criteria for Registration/License and hygienic and sanitary practices to be followed by food business operators engaged in manufacture, processing, storing, transporting and retailing of fish and fish products as a part of schedule 1 and 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 respectively.

The Food Safety and Standards Authority of India, hereby makes the following regulations operational with immediate effect. The Food business operators engaged in manufacture, processing, storing, transporting and retailing of fish and fish products shall follow these revised regulations. These are basic food safety measures to be followed by FBOs. Any non-compliance may be addressed by issuing Improvement Notice under Section 32 of the Food Safety and Standards Act, 2006 for further compliance with immediate effect.

I. List of Kind of Businesses (KoB) and their eligibility criteria for Registration/License

1.MANUFACTURING/PROCESSING

(103) Fish and Fish Products

Registration – Not applicable

State License – Up to 150 MT per year

Central License – More than 150 MT per year

2. STORAGE, TRANSPORT AND TRADE

(301) Storage

(302) Transporter

(303) Wholesaler/Distributor/Supplier/ Marketer/ Merchant Exporter

Registration – Not applicable

State License – All

Central License – units of Multi-state Chain

(321) Transporter having single vehicle

Registration - Annual Turnover up to Rs. 12 Lacs

For annual turnover above Rs. 12 Lacs, the applicable category shall be appropriate category under 302.

3. RETAIL

(401) Meat Retail shop (Poultry/fish/animal)

Registration – Not Applicable

State License – All

Central License – Units of Multi-State Chain

(422) Fish retail vendors

Registration– Annual Turnover up to Rs. 12 Lacs

For annual turnover above Rs. 12 Lacs, the applicable category shall be appropriate category under 401.

II. Specific considerations for fish retail vendors:

Fish retail vendors may be grouped into two major categories:

- a. Stationary street vendors - Those operating on fixed locations such as fish retail shops in the market or petty shops at the road side.
- b. Moving street food vendors - Those who move from one place to another carrying their wares by hand or on the head or in wheeled transport such as bicycles, push carts and wagons.

(A) To ensure hygiene and safety of fish being sold by the moving street food vendors, the following best practices shall be followed:

1. They shall commence their business in areas not subjected to regular and frequent flooding, and shall be free from undesirable odour, smoke, dust, pest, and other contaminants.
2. In case more than one type of fish is being sold, care shall be taken to avoid cross-contamination.
3. Water used for cleaning the fish/utensil shall be clean and microbiologically safe.
4. Ice used for chilling of fish shall be produced from clean and microbiologically safe water.
5. The equipment such as knives etc. shall be of food grade material so as to enable easy cleaning, maintain hygiene and to avoid contamination. They shall be durable, resistant to corrosion and capable of withstanding repeated exposure to normal cleaning and disinfection.
6. The chopping block shall be of food-grade synthetic material, which does not contaminate the fish and fish products. If the block is of wooden it shall be of hardwood trunk, must be free of splits, cracks and holes and must be maintained in a hygienic condition and shall not contaminate the fish and fish products.
7. Fish and fish products shall only be procured from reliable and traceable vendors. The quality of fish and fish products shall be checked for organoleptic tests like texture, colour, odour, etc. Products exhibiting signs of decomposition shall be rejected.
8. The fish and fish products shall not contain any preservative including formaldehyde which is not permitted under these regulations.
9. Clean, disinfected fish holding crates shall be used for storage and transportation of fish. It is ideal to use a different colour crates for waste disposal.
10. Cleaning and disinfection shall be done preferably with hot water or 50 ppm chlorinated water.
11. Fish laid down for sale shall not come into direct contact with floor.
12. They shall have waste and garbage collection bins with lids which shall be effectively cleaned and sanitized. The garbage bins shall be lined with garbage collection bags and shall have lids to be kept closed so that they do not provide a breeding ground for pests.
13. Fish and fish products handlers shall undergo a medical examination by a registered medical practitioner annually to ensure that they are free from any infectious and other communicable diseases.
14. Every person engaged in a fish and fish product handling shall keep their finger nails trimmed and shall wash his hands frequently and thoroughly with a suitable hand cleaner with potable water. Hands shall always be washed before commencement of work, immediately after using the toilets, after handling contaminated material and whenever else necessary.
15. Fish and fish products handlers shall wear clean clothing and head wears and if possible disposable gloves.
16. Fish and fish products handlers shall not chew/smoke tobacco, gums, any other such item.

17. All personnel handling fish in the markets shall be trained in all aspects of food safety and hygienic fish handling practices.

(B) In addition to the above mentioned practices, the stationary street vendors shall follow the following best practices:

1. A sign board indicating the type of fish and fish products sold shall be displayed prominently.
2. The surfaces of walls, partitions and floors of retail area shall be made of impervious materials for easy cleaning and sanitation and to avoid accumulation / absorption of dust, blood / fish material, microbial / fungal growth.
3. Doors, windows and floors shall be constructed for effective cleaning & sanitation to avoid accumulation / absorption of dust, blood / fish particles, microbial / fungal growth
4. Fish vending tables/wares for display and sale of fish shall be easy to clean, maintain and made of smooth, non-absorbent materials. It must be inert to the food, to detergents and disinfectants under normal operating conditions.
5. Vending table / platform/ wares shall have proper drainage facility and proper slope towards drain.
6. There shall be an adequate supply and storage of clean and microbiologically safe water.
7. Fish handlers shall have access to hand washing and toilet facilities.
8. Facility shall ensure there are no pest infestations which may cause food safety threat. Regular pest control treatments have to be adopted.
9. The temperature at the point of receiving and during storage shall be between 0-4 °C. However, in case of frozen products it shall be -18°C.
10. For retailing frozen fish and fish products, the facility shall have deep freezers capable of maintaining product temperature of -18°C or lesser. In case of fresh or chilled product, storage must be below 4°C.
11. Product shall be stacked to allow proper air circulation.
12. A proper product rotation system shall be established. This system could be based on first-in, first-out usage, production date or "best before" date on labels, sensory quality of the lot, etc., as appropriate.
13. Raw product shall be stored on shelves below cooked product to avoid cross-contamination from drip.
14. Ready-to-eat items and molluscan shellfish shall be separated from each other and from raw food products in a chilled display.
15. Product temperature shall be maintained in cabinet self-service display cases of packaged products.
16. Each commodity in a display shall have its own container and serving utensils to avoid cross-contamination
17. Eating and chewing of tobacco, gums, any other items, smoking and spitting shall be prohibited in any part of retail facility. It is recommended to display sign boards like 'No Smoking' and 'No Spitting'.

III. specific requirements for establishment engaged in handling, processing, manufacturing, packing, store, distribution and transportation of fish and fish products:

In addition to Part-II of Schedule 4, as operationalized vide direction F. No. 1(80) 2016/Enf-II Info/FSSAI(Pt.) dated 28th August, 2019, following are specific requirements.

1. Internal Structure and fittings

All interior structures (including floors, walls, ceilings, doors, windows, partitions, overhead fixtures, working surface that come into direct contact with fish and fish products, such as stairs, elevators, etc.) shall be constructed of materials that are corrosion-resistant, light-coloured, durable, impervious to minimize the build-up of fish slime, blood, scales and guts and to reduce the risk of physical contamination, with no toxic effect in intended use, shall be unable to provide pest harbourage and be easy for cleaning and disinfection.

2. Equipment and containers

2.1 Conveying equipment for live and dressed products shall be constructed of suitable corrosion-resistant material that doesn't transmit toxic substances and shall not cause mechanical injuries.

2.2 Cooling chambers for storage of fish and fish products shall be equipped with temperature recorder and with/without automatic air temperature controllers in the chamber as well as with temperature recording devices.

3. Procurement of raw materials and ingredients

3.1 Both the raw material and ingredients shall, wherever feasible, be procured from registered, or approved supplier. Raw material shall be washed or cleaned as necessary to remove soil or other contaminants using clean and microbiologically safe water. Other raw material or ingredient or any other material used in fish and fish products shall not be accepted by a food business operator, if it is known to contain chemical, physical or microbiological contaminants. It is recommended that temperature of fish and fish products at the time of delivery shall be in the range of 0°C to +4.0°C. In case of frozen products, receiving temperature shall be -18°C or below.

3.2 Shrimps shall be procured from registered farmers and use only approved aquaculture inputs.

3.3 Fish shall free from fishy, sour, or ammonia-like odour and the eyes shall be clear and shiny.

3.4 Whole fish shall have firm flesh and red gills with no odour. The flesh shall spring back when pressed. Fresh fillets shall have firm flesh and red blood lines, or red flesh if fresh tuna.

3.5 Fish fillets shall display no discoloration, darkening, or drying around the edges.

3.6 Shrimp, scallop, and lobster flesh shall be clear with a pearl-like colour and little or no odour.

4. Food and packaging materials storage including warehousing

4.1 It is recommended that temperature of fish and fish products at the time of storage shall be in the range of 0°C to +4.0°C for fresh/chilled/refrigerated and -18 °C or below for frozen. Too long storage time and severe fluctuation shall be avoided. Where the product is susceptible to temperature abuse and / or weather damage, covered bays shall be provided for loading and unloading.

5. Processing

5.1 Fin fish and shellfish shall be handled and conveyed with care during processing operations to avoid physical damage such as puncture and mutilation. Food contact surfaces shall be made of food grade material.

5.2 Personnel shall put on clean protective clothing and wash their hands before entering processing area.

5.3 Ice used in cooling and holding raw material shall not be mixed with ice used to store processed and packed products.

5.4 Wherever steam is used directly on food during processing, the steam shall be generated from clean and microbiologically safe water.

6. Packaging

6.1 Avoid packages with signs of frost or ice crystals, which may mean the fish has been stored a long time or thawed and refrozen.

6.2 Avoid packages where the "frozen" fish flesh is not hard. The fish shall not be flexible.

6.3 Packaging used for storing ice cooled fish and fish products shall ensure the drainage of the melt water.

6.4 The packaging of fish and fish products shall ensure safety of fish and fish products and shall not alter the organoleptic properties before the expiration date.

7. Food Transportation

7.1 Transportation facility for fish and fish products shall have chilling equipment either to maintain a temperature at or below 4 °C (OR) maintain a temperature at or below -18 °C, as appropriate.

7.2 Contamination, exposure to extreme temperatures and the drying effects of the sun or wind shall be avoided.

7.3 Free flow of chilled air should be made around the load when fitted with mechanical refrigeration means.

7.4 Inner surfaces of transport vehicles shall be smooth and easy to wash and disinfect.

7.5 Cargo compartments of transport vehicles and containers shall be subjected to regular washing and disinfection with a frequency necessary to prevent cargo compartments of transport vehicles and containers from becoming sources of contamination (dirtying) of products

8. Quality control

8.1 fresh fish shall not contain any food additives including formaldehyde, contaminants and natural or synthetic hormonal substances. Fish products shall contain permitted ingredients and comply with the relevant regulations.

8.2 Biological water resources catchments and food products of aquaculture of animal origin shall be examined for parasites (parasitic affections).

8.3 The fish and fish products shall not contain any preservative including formaldehyde which is not permitted under these regulations.