



PRODUCT IDENTITY AND ORGANOLEPTIC CHARACTERISTICS: UNDERSTANDING FSSAI'S RECENT REGULATORY FOCUS

Food Safety enforcement in India conventionally includes concerns such as hygiene, adulteration, unsafe food and sub-standard food. However, it has further expanded to examine whether a product is presented to consumers in a manner consistent with its prescribed identity / characteristics under the Food Safety and Standards Act, 2006 (**FSS Act**), rules and the regulations framed thereunder.

Many product standards specify what the food product should smell and taste like, thereby appearing to establish the identity of the food. This reflects the philosophy that consumers are not merely buying a composition of ingredients; they are buying a food product with a recognised identity and a set of sensory characteristics that have come to be associated with it.

Recent action by the Food Safety and Standards Authorities (**FSS Authorities**) reinforces the point that product identity is becoming an area of regulatory scrutiny alongside product safety. A Food Business Operator (**FBO**) may therefore use permitted additives, meet prescribed standards and limits, and carry an otherwise compliant label, but still face scrutiny if the finished product is misleading consumers by not reflecting the identity or organoleptic characteristics prescribed for the category under which it is sold.

This flyer explains the recent enforcement focus, its potential implications across food categories, the relevant regulatory requirements and the steps an FBO may take both as a preventive measure and when responding to regulatory action.

RECENT NOTICES ISSUED BY THE FSS AUTHORITIES TO FOOD MANUFACTURERS

One such recent action taken by the FSS Authorities includes the issuance of notices stating that certain beverages / finished products may not actually be the stated beverage. The concerns appear to be (i) flavours added to **mimic** the true, natural characteristic taste and aroma of such products; (ii) standards for such products not being fulfilled, (iii) false / inaccurate depictions of its nature/ identity, (iv) misleading consumers regarding the category. FSS Authorities have issued directions to such FBOs and sought explanations.

The regulatory question would therefore be whether a bottle sold, for e.g. “rum”, should naturally smell and taste like rum or whether it would be permissible to add flavouring substances or additives which enhance such “rum” taste and aroma. The concern seems to be that certain organoleptic characteristics of the product ought to be derived naturally from the ingredients and the manufacturing process rather than being enhanced through such additives.

Notably, this concern extends across multiple products and sectors and therefore warrants an in-depth examination. For example, even products such as spices and condiments (whole or powdered), carbonated fruit beverages, cheese, coffee and soluble coffee powder, tea etc., in addition to meeting the applicable standards for that product category, are required to have “characteristic” taste/ flavour and aroma.

WHAT IS THE REQUIREMENT UNDER FSS LAWS?

The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 (**Food Additives Regulations**) prescribe the requirement of aroma or taste characteristic of or associated with that food product,

illustratively:

2.9.4: 1. Cinnamon (Dalchini) whole means the inner bark of trunks or branches of Cinnamomum Zeylanicum Blume. It shall have characteristic odour and flavour and shall be free from foreign flavour and mustiness.

2.9.24: 1. Dried Mango Powder (Amchur)-- Means the powder obtained by grinding clean and dried mango slices having characteristic taste and flavour.

2.10.2: COFFEE

2. Soluble Coffee Powder means coffee powder, obtained from freshly roasted and ground pure coffee beans. The product shall be in the form of a free-flowing powder or shall be in the agglomerated form (granules) having colour, taste and flavour characteristic of coffee.

2.10.4: 1. Coffee - Chicory Mixture means the product prepared by mixing roasted and ground coffee and roasted and ground chicory and shall be in a sound, dry and dust free condition with no rancid or obnoxious flavour. It shall be in the form of a free-flowing powder having the colour, taste and flavour characteristic of coffee - chicory powder

DOES THIS MEAN ADDITIVES ARE NOT PERMISSIBLE AND WOULD EVERY FLAVOURED PRODUCT WOULD BE NON-COMPLIANT?

Additives are permissible if allowed for the specific product and in accordance with the standards under the Food Additives Regulations. Such permissible flavours may be natural, nature-identical and artificial flavours.

The concern is not the mere usage of flavours; rather, flavours and additives which mimic the nature of the product itself, used in a manner that artificially enhances certain organoleptic characteristics which would ordinarily be expected to develop naturally.

WHEN CAN THE USE OF FLAVOURS AND ADDITIVES BECOME A COMPLIANCE ISSUE?

The risk and consequences would depend on various factors including but not limited to: (i) whether a given product's standards prescribe requirements pertaining to characteristic taste and aroma, (ii) whether the additive is permissible or not and if permissible, whether usage is within the prescribed limits, (iii) whether the product otherwise complies with the general and/or product specific requirements pertaining to composition, (iv) whether usage of such additives impacts the quality of the product including to the extent of being sub-standard or unsafe, (v) whether the additives are appropriately disclosed on the label and therefore, whether the label is misleading.

Subject to the above factors, regulatory action could range from issuance of improvement notices or directions for compliance, sampling, site inspections or seizure of stock, and monetary penalties if found guilty of an offence.

WHAT ACTION COULD THE FSS AUTHORITIES POTENTIALLY TAKE?

- **Sampling:** FSS Laws provide for collection of samples along with mandatory procedures to be followed. This includes issuance of notice of intention to collect sample, collection of samples in the presence of witnesses, manner of collecting samples in quadruplicate and the manner of dispatch/ retention of each such sample part.

One sample is to be sent to a Food Laboratory (notified and accredited for that particular product) for analysis by a Food Analyst (qualified and notified), two are retained for potential future testing requirements and the fourth is available for the FBO to send to an accredited laboratory for testing. The report of the Food Analyst may be challenged by the FBO in appeal. At this point, one of the retained samples is sent to a Referral Laboratory for testing, whose report will be final.

- **Seizure:** The FSS Authorities have been provided with the power to enter, inspect, search and seize any article of food/ adulterant (or documents) in case there is a reasonable doubt that there has been contravention of FSS Laws or commission of an offence. Noteworthy, the provisions of Code of Criminal Procedure, 1973 (now Bharatiya Nagrik Suraksha Sanhita, 2023) pertaining to search, seizure, summons, investigation and prosecution are applicable to actions of the Food Safety Officer (FSO) under this Act.

- **Improvement notices and directions:** FSS Authorities may also issue “Improvement Notices” if there is a reasonable doubt of non-compliance. A finding of non-compliance may ultimately lead to suspension or cancellation of license, which is appealable before the Commissioner of Food Safety whose decision is final. FBOs are required to be granted an opportunity to be heard at various stages.

The FSS Authorities may also provide directions for compliance or corrective action in certain cases. Failure to comply with such directions may lead to the imposition of a monetary penalty.

- **Enforcement action affecting stock /sale or production:** In serious cases mostly involving grave violations, supply of unsafe food, public health risk or repeated non-compliances, regulatory action may additionally be taken which might affect existing stock or future production. Such actions may include:
 - Discontinuance or modification of processes pursuant to directions
 - Product Recall
 - Prohibition Order in case of conviction of an offence and satisfaction of the court regarding existing health risk, against a process/ treatment, use of premises/ equipment etc., as prescribed
 - Emergency prohibition notice and subsequent order in case of health risk with respect to any food business, until satisfaction of sufficient measures being taken. The Designated Officer may also prohibit the sale of any food article which is in contravention of FSS Laws.

WHAT IS THE RISK IN CASE THERE IS AN OFFENCE ESTABLISHED?

FSS Laws have prescribed liability pertaining to offences on the basis of role in the supply chain, i.e. manufacturing, storage, sale, distribution etc. The broad nature of offences is categorized as follows:

- If the general and product specific standards/ requirements are otherwise complied with, but artificial flavour is used to add/ enhance what is supposed to be its natural taste and aroma, this may be considered as **misbranded food**, based on the facts and the representations made.
- If the additives used are not within permissible limits or there is non-compliance with the general standards and requirements, this may be considered as **sub-standard**.
- In case the additives added are not only impermissible but also cause deterioration in the nature, substance or quality to render it injurious to health, it may be considered as **unsafe food**.
- Penalties are also prescribed in case of failure to sell food of the substance or quality demanded and failure to comply with the directions of the FSO.

All the above offences lead to the imposition of varied monetary penalties. However, if the same is held to be unsafe food, there can be additional consequences of imprisonment. While adjudging the quantum of penalty, due regard shall be given to factors including amount of gain/unfair advantage, loss caused/likely to be caused to any person due to contravention, repetitive nature of contravention, whether done without knowledge etc.

WHAT ARE THE REMEDIES AVAILABLE IN CASE AN ADVERSE ORDER IS PASSED AGAINST THE FBO?

The Act has provided that where inquiry proceedings are initiated and an order is passed accordingly, an appeal lies to the established Food Safety Appellate Tribunal, or the “designated” Food Safety Appellate Tribunal in certain states where it is not separately established (e.g., Karnataka Appellate Tribunal). A further appeal against the order of such Tribunal or order of a special court (pertaining to offences resulting in grievous injury or death of consumers) lies to the respective High Court.

WHAT WOULD BE THE LIABILITY OF PERSONNEL/ DIRECTORS OF FBOs?

FSS Laws provide for additional liability on the person who was in charge of and responsible for conduct of business of the FBO/Company. Where the FBO has various brands, units or establishments, then the concerned Head or nominated person-in-charge would be considered liable in respect of such unit/brand/ establishment.

However, if such person proves that the offence was committed without his knowledge or that due diligence was undertaken to prevent the commission of such offence, then liability may be avoided. Conversely, if proved that the offence was committed with the consent / connivance of, or is attributable to the neglect of any director, manager or other personnel, such management/personnel would be proceeded against and punished.

WHAT STEPS COULD FBOS TAKE TO SAFEGUARD THEIR POSITION?

FBOS can undertake the following compliances:

- Ensure usage of only permissible additives and within the applicable limits in its manufacturing processes
- Ensure taste and aroma to be consistent with product identity/ characteristics where prescribed and required
- Maintain evidence and reports to substantiate usage of permissible additives, manufacturing process, compliance with requirements and standards, labels and claims, etc., and maintain batch test reports (rendered prior to its release)
- Ensure batch traceability and preserve distribution records, complaint records and recall-readiness documents, if and when required
- Train plant, quality, regulatory and sales teams on requirements (procedural and otherwise) prescribed under FSS Laws especially at the time of search, inspection, sampling and seizure
- FBOS may choose to nominate persons-in-charge to avoid multiple notices or involvement of all personnel and must ensure the same is updated based on actual operational control
- Strategize and take appropriate action at each stage while keeping in mind the facts and also the shelf life of the product, including for e.g., whether the fourth sample should be sent for testing, or whether the FBO should independently send a sample of the same batch for testing
- Ensure checks are undertaken at each stage of enforcement action which may be mandatorily prescribed under FSS Laws, including but not limited to:
 - Mandatory procedures for sampling are complied with
 - Report is received by the FBO and upon receipt, checking whether the report is in the prescribed format and specifies the prescribed details, whether testing was undertaken by a notified and NABL accredited laboratory (including specifically for the product and parameter), whether report was signed by a qualified and notified Food Analyst, etc.
 - To exercise statutory rights and opportunities of appeal and hearing as and when required, including filing an appeal against the Analysis Report and sending of sample to Referral Laboratory, filing appeals to the Food Safety Appellate Tribunal, etc.
 - Where an adverse Referral Laboratory report is issued subsequently, the FBO may check to ensure that the scope is not exceeded beyond 'confirming' the Analysis report findings, ensure consistency or similarity between the remaining parameters in both reports, ensure testing is undertaken within the prescribed timeline and before expiry of the product at all stages, etc.
 - Check statutory timelines and whether proceedings are initiated only upon fulfilment of prescribed pre-conditions.

We trust you will find this an interesting read. For any queries or comments on this update, please feel free to contact us at insights@elp-in.com or write to our authors:

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