CHAPTER 2

Regulations for manufacturing traditional foods—global and regional challenges

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2.1 Descriptors and the definition of traditional foods and ethnic foods

Traditional foods (TFs) are a range of preparations or raw food commodities, the use of which is related to traditional practices experienced over centuries. Traditional foods are an integral part of the cultural heritage, history, identity, and lifestyle of a region or country (Costa et al., 2010; Trichopoulou et al., 2007). Specific eating habits also play an important role in the traditional habits of many cultures (Costa et al., 2010). Thus these foods have become part of tradition and culture. Traditional foods come with a tag of

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genuineness, minimally processed, and healthy foods. The ingredients of traditional foods are linked to local climatic and agricultural conditions that are abundantly available in addition to traditions. Due to fast-paced hectic life, lifestyle changes, and migration of rural population to nearby cities, traditional foods are rapidly disappearing from our culture (Costa et al., 2010; Trichopoulou et al., 2006). Nonetheless, there is an increased interest in traditional foods among consumers and manufacturers, as they are often perceived as having specific sensory characteristics, health benefits, and being of higher quality (Costa et al., 2010; Trichopoulou et al., 2007; Vanhonacker et al., 2010).

In most of the countries, there is currently a lack of information on the food composition of traditional foods, and it is necessary to investigate their nutrient composition by further studies (Costa et al., 2010; Trichopoulou et al., 2006). These studies are also essential for elucidating the role of such foods in the traditional dietary pattern of a population and for perpetuating the important elements of cultural inheritance (Trichopoulou et al., 2006).

Ethnic foods are regarded as unique to a particular cultural group, race, religion, nation, or heritage (Dwyer et al., 2003). "Traditional" means proven usage on the domestic market for a period that allows transmission between generations; this period is to be at least 30 years (Regulation (EU) No. 1151/2012).

A traditional food product is a product frequently consumed or associated during specific celebrations and/or seasons: for example, mass feeding during wedding and other large celebrations, in places of worship, mid-day meals served to school-going children, in institutional catering, etc. Such use does not involve prepackaging. The art and science of such TF are normally transmitted from one generation to another, and they are prepared with care in a particular way according to the gastronomic heritage, with specified processing/manipulation that is distinguished and known because of their sensory properties and associated to a certain local area, region, or country (Vanhonacker et al., 2008).

2.2 Categorization and classification of traditional food

2.2.1 Based on primary food

They may be based on primary food namely rice, wheat, pulses/lentils/legumes, cereals, corns and oats, millets, milk and milk products, vegetables and fruits, condiments and spices, oils, fats, and clarified butter. Combinations of one or more primary foods are most common to provide high sensorial and nutrition apart from promoting digestion and providing health benefits.

2.2.2 Based on process technology

A wide range of technologies is seen across categories in Asian practices. One distinctive feature enshrined perhaps by the wisdom of history of usage of TF in

temperate countries of Asia is involvement of different thermal and nonthermal processes: dehydration/roasting/sun drying/salting/processing in brine or syrup base/frying in oil/cooking in water or steam, with or without fermentation or other pretreatments to provide requisite microbial quality and desired shelf life for the required duration. These technologies are used at every household or in eateries and restaurants, at varying scales of batch sizes. Shelf life of a few hours extending to even a few years (viz. pickles) are achieved by these processes. This is in contrast to many TFs in western nations that have much less of thermal processing involved and use cold processes along with high temperatures.

2.2.3 Based on prepared food forms

A wide range of food preparation forms (textural matrices) create attractiveness, add rich appeal, taste, and deliver a wow-like feeling. Forms cover the following: liquids (rasam, sambar), juices (fruit/vegetable juices), semisolids (purees, gojju, chutney/sauce), solids (with gravy, without gravy, reasonably dry-like rice preparations, vegetable curries), dried vegetables and fruits (curry leaf, seasoning herbs, dried gooseberries, almonds, cashews, grapes, and other dry fruits), powders of primary foods (chutney powder, fenugreek spice mix), herbs, spices, condiments in designated mixes to be consumed with other foods, roasted (nuts, spices), roasted and ground powders (coffee with chicory, various spice mixes referred as masalas), shallow/deep or shallow fried in oils or fats (Indian breads such as chapattis, nan, roti, samosa, savories), extruded forms both for use in dehydrated and hydrated matrices (noodles and vermicelli and their variants) as well as deep fried formats (wafers, chips, sandige, and pheni), concentrated milk and milk-based sweetened forms consumed in hot state (kheer, payasams) or in cold/frozen state (jamun, rosogulla, rasamalai, and kulfi), infusions and decoctions (tea and coffee), center-filled forms (samosa, obbattu, sandesh, modak), and cooked in steam with or without fermentation (pancake, idly, puttu, dhokla).

2.2.4 Emerging forms

The last two decades have led to the use of concentrated sources of primary foods or herbs, spices, pro- and prebiotics, and enzymes instead of consuming large proportions or morsels of food. Scientific studies have demonstrated the beneficial effects of the use of these concentrated sources taken either with food or before or immediately after food. They need to be used at specified levels in predetermined quality and concentration properties either as such or as enrichment with a primary food or a TF. Demands of lifestyle and changing scenarios are narrowing the border between food forms and drug formats. New categories of such concentrated sources of nutrients or nutritionals are also adopted for delivering drug formats such as pills,

tablets, capsules, suspensions, and sweetened preparations in liquid form driven by convenience for usage and availability of unit serving sizes intended for improving compliance. These formats are intended to serve "consumers on the go." It is debatable whether 20 odd years of existence of these deserves the title of TF for such forms and concentrates.

Other forms or technologies including hybrid technologies exist in Asian nations. Examples cited earlier primarily cover India but all Asian nations would have equivalent examples to cite.

2.3 Trends in the last few decades

Traditional foods have started entering the market in a new form to suit modern trends, with long shelf life and new packing techniques. Asia has seen drastic changes in eating habits due to the influence of cross-cultural impacts, such as the blending of TF of different nations due to a desire for variety and fun in eating. Eating of TF coming from other cultures and nations either outside home or cooking and offering such foods to family and guests at home reduces cooking chores, drudgery, time and improves the convenience for both working women and men. This has led to increased use of partially processed or fully processed foods in prepackaged forms. Innovations in such foods, such as enrichment with specified nutrients, enhanced sensorial and textural properties, enhanced health benefits, and altered sweetness perception at low sugar levels are leading the trends. Packages that are microwavable and safe are emerging. The introduction of a new drug delivery format is another trend described in the preceding section. Countries such as India, Korea, Taiwan, and China are leading in providing equipment and machinery that can be partly or fully automated to produce the TF in readily packaged forms for retail distribution. Some of them are capable of operating complex steps for the effective processing of TF requiring multiple stages or processes. Newer technologies such as pasteurization, high temperature short exposure, tetra pack and Elo pack multiple laminate structure that fill and seal sterile products, nitrogen flushing, surface sterilization through ozonized or peroxide-based treatment, cryogenic processing and packing, canning, and preservation are some of the processes that assist and promote large-scale production of such prepackaged TF. Refrigerated containers, cold chain facilities, development of small-sized deep freezers, and refrigerators suitable for storing at retail levels to preserve the overall quality of packaged foods are driving these innovations. The classic example is of serving hot cooked food as part of mid-day meals packed in containers with lid in hot conditions across the cities under "Akshaya patra" (www.akshayapatra.com) in India. Foods are cooked at a central location and transported in vans or vehicles across a city to many teaching institutions for serving children as soon as it reaches the destination.

2.4 Basic regulations that apply to traditional food during manufacture, packing, and distribution

All TFs are made from/using primary foods approved in the national regulations. It is an accepted fact that using multiple ingredients and processing them as per traditional methods does not cause any concern for the safety of quality. This is true as long as the processes are adhered to and the processing is done in a clean and hygienic environment. Most nations do not have separate regulations for TF. All regulations that are applicable to foods apply to TF and if they are packaged for retail sale, then additional regulations that apply for packaging and labeling also apply. Nations normally have vertical standards defined and regulated for foods (primary). Using such primary foods, if a product is processed as described under categories in one of the sections discussed earlier, then national regulations have additional regulations set in place that most often cover the additives that are used for a particular TF/processed food. About two decades back, Codex Alimentarius developed horizontal standards recognizing the need for accepting and regulating processed foods. These horizontal standards specify the additives that can be used for a particular type of food mix or ready-to-eat food, or additives that are not permitted and the level of usage is specified. The term GMP is used in such horizontal standards, which means "an amount needed based on sound scientific and technological rationale." In certain instances these may also specify "lowest possible levels of usage to achieve the desired effect" for specified additives. Codex recognized that there is a need to provide technological requirements for making TFs safe in the regulations. Codex is normally adopted either in or with local adjustments by most nations. This approach, apt as it is, can be difficult for standardizing TF as the composition varies from region to region. The horizontal standards normally apply for the manufacturing of TF that are intended to be packed and distributed. However, years of experience have shown that in the case of TF prepared in large quantities (for mass serving in hotels/restaurants/ festivals/ mid-day meals), framing regulations and enforcing them are difficult and counterproductive. Instead of developing regulations, adopting safety audits, safety and risk assessments, and large-scale training and certification of workmen and premises for hygiene, hazard analysis critical control point (HACCP), good manufacturing practice (GMP), and good packaging practice are being advocated. The Indian Food Safety & Standards Act (FSSA) of the Ministry of Health & Family Welfare has adopted this approach. The Food Safety Standards Authority of India is aggressively pushing this route and building skills and competencies in the sector for processing and supply of quality and hygienic foods across the nation.

Although there are no specific standards/regulations available for TF in South Asia including India, all common regulations apply. Food Business Operators involved in

the manufacture/packing/marketing of TF in India shall comply with different Food Safety and Standards Regulations as applicable. For example:

- License as per the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 (Licensing, 2011, FSSA)
- Standards including additives and microbiological parameters as specified under the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 (Standards, 2011, FSSA)
- Labeling as per Food Safety and Standards (Packaging and Labeling) Regulation, 2011 (Labelling, 2011, FSSA)
- Safety parameters such as heavy metals and residues as per the Food Safety and Standards (contaminants, toxins, and residues) Regulation, 2011 (Contaminants, 2011, FSSA)
- Packaging as per the Food Safety and Standards (Packaging) Regulations, 2018 (Packaging, 2011, FSSA)
- Advertisement and claims as per the Food Safety and Standards (Advertising and Claims) Regulations, 2018 (Claims, 2018, FSSA)

2.5 Proprietary foods

Regulations describe and define "proprietary food" (PF) as "means an article of food that has not been standardized under these regulations, but does not include novel foods, foods for special dietary uses, foods for special medical purposes, functional foods, nutraceuticals, and health supplements." Any deviation in quality parameters of a standardized food shall not qualify the resultant product as a proprietary food. As per regulations, proprietary food shall contain only those ingredients other than additives that are either standardized or permitted for use in the preparation of food products under the Food Safety Standards and Regulations and those food or ingredients mentioned in the Indian Food Composition Table, 2017 (IFCT, 2017). It may also contain vitamins and minerals in quantities not exceeding daily Recommended Dietary Allowance of the respective micronutrient.

There are no specific standards available for TF under FSS Act, 2006 and regulations thereof. However, under the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011, standards/regulations for Proprietary Food has been specified. Furthermore, the regulations also specify food additive provision for different food categories from 1 to 16.

Proprietary food shall use only such additives and at such levels, as specified for the category or subcategory under Appendix A of these regulations, to which the food belongs. Such a category or subcategory shall be clearly mentioned on the label along with the generic name, nature, and composition of the proprietary food.

Proprietary food shall comply with the microbiological requirements as specified in Appendix B of these regulations. If no microbiological standards are specified for any foods or food categories in Appendix B of these regulations, proprietary foods falling under such food categories shall not contain any pathogenic microorganism at a level that may render the food product unsafe.

The food business operator shall be fully responsible for the safety of the proprietary food with respect to human consumption, as such foods have a composition that has no specific standards in the regulations. As it is rather difficult to obtain intellectual property rights (patents), many marketers adopt this approach to make some changes in the formulations or format of the TF and classify them under PF and try to use it for marketing propositions as unique selling points.

2.6 International standards: Codex

The general standard for food additives (Codex STAN 192-19956) provides information on the food additive provisions that are acceptable for use in foods conforming to the food category 1−16. The broad categories include dairy products and analogs; fats and oils, and fat emulsions; fruits and vegetables, cereals and cereal products, bakery wares, meat, fish, snacks, prepared foods, etc. The packaged traditional food also needs to comply with the same based on the category in which it is falling. In case of prepared foods (category 16) that are not included in the other food categories (01−15), the additives in accordance with GMP (Table 3 of Codex STAN 192-1995, i.e., additives permitted for use in food in general) may be used under the conditions of good manufacturing practice (GMP) as outlined (Additives. GMP, CODEX 1995).

All Asian nations have equivalent/similar regulations for primary foods, TF and PF. All primary foods and additives used in TF need to comply with the regulations. For most of these, content claims of the ingredients and their nutritive values are permitted and normally health benefit claims are not made.

2.7 Labeling

Although normally there are no regulations that specify labeling requirements for TF that are served in hotels/restaurants/ festivals, there are detailed regulatory requirements for labeling of TF packed and supplied over retail. New developments in India are leading to asking the suppliers of TF in hotels/restaurants to label the vessels in which they are kept with basic information like calories per 100 g, and few other nutrient levels that can caution consumers and guide them to eat right (especially for sugar, salt, or fat content). The suppliers are being educated on these aspects to support healthy eating.

For all other packaged TF intended for retail selling distribution

There are detailed specific labeling requirements specified in the regulations as listed in the earlier section.

Mandatory requirements:

- Name of food and a descriptor for consumer understanding of the type of food.
- Composition in descending order of proportions of the ingredients, except those ingredients that are less than 1.0% of the composition can be given in any order.
- Presence of added permitted preservatives, colors, flavors, stabilizers, and any other additives.
- Serving sizes.
- Nutrition information giving the nutritional value (calories, contents of carbohydrate, protein, fat, trans fat, vitamins, and minerals, if added, and any other constituents important for health, such as soluble and insoluble fiber, added sugars, etc). These need to be given either per 100 g or per serving size. Those of the nutrients that come under RDA, the proportion of RDA contributed by the product per serving size or per 100 g, need to be given in the table.
- Directions for making and use.
- Storage conditions.
- Date of packing or manufacturing and best before use date.
- Other mandatory requirements like contents/weight or volume /number on the pack, price for sale, manufacturer's address and license number, consumer care number or an email ID for consumers to contact for any feedback, etc.
- The term "Proprietary Food."
- A special symbol as specified to indicate the nonvegetarian or vegetarian nature of the TF.

Nonmandatory requirements:

- Any cautionary statements
- Any advisories
- Allergen cautions
- Special instructions of any nature.

All Asian nations have equivalent/similar regulations for the labeling of TF and PF, though there may be variation in the way the nutritional composition is declared. Although some regulations specify for declarations similar to India, other representations like using traffic signal or giving sugar/salt/fat contents in the different pictorial depictions are also used. This is for easy understanding by the consumer so that he/she can decide which of these nutrients are above or at par or below recommended levels.

2.8 Good manufacturing practice aspects during manufacture

Manufacturers/repackers in India need to conform to the general hygienic and sanitary practices specified under Schedule 4 of the Food Safety and Standards (Licensing and

Registration of Food Businesses) Regulations, 2011. These are the basic-compulsory requirements for ensuring the safety of the food manufactured in any premise, and manufacturers need to continuously try to improve the sanitary and hygienic conditions at the premises with a goal of attaining HACCP standards. Details of these are not covered.

2.9 Traditional food for infants, children, and geriatrics

Most Asian nations have adopted fully or appropriately to the Codex regulations and Standards for Infant Foods of all categories (complete foods, complementary foods, weaning foods, cereal-based or noncereal-based, and other types). These provide detailed descriptions, usage, ages for infants and children, directions for use and compositions with minimum and maximum levels for various vitamins, minerals, amino acids, and other ingredients (like probiotics). Most of the categories are primarily aimed at formulated products with milk or cereals. These regulations do not necessarily cover or give guidance for TF intended to be manufactured and supplied for infants and children. Recognizing this, Indian Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2017 framed standards for "Foods for Infant based on traditional food ingredients" that is in the draft stage (Infant Foods Regulations, 2017, FSSA). Foods for infants based on traditional food ingredients are products known to be prepared at home for feeding infants traditionally and have a long history of safe use. These need to be and can be processed and provided in packaged forms with specified best before use dates. These are either "Ready to Use" or to be reconstituted with a medium such as milk, water, curd/yogurt, or any other medium appropriate for an infant. Some such TF products have long been offered in some UK and European markets and India should be no exception, as it has a rich history of traditional documented knowledge. Regulations for TF for geriatric use are not common and are an area for the development of both the products and the regulations.

2.10 Developing scenario

Competition, recognition of a nation's tradition and knowledge, promoting a nation's business interests, providing personalized nutrition, age-specific/disease-specific nutrition products, products that can provide disease risk reduction, preventive healthcare foods, supplements/nutraceuticals, foods driven by ones metabolomic characteristics, *Prakruti* led nutrition/foods from Ayurveda, or Yin & Yang led nutrition/foods from traditional Chinese medicine, and parenteral nutrition are expected to develop and get into the market even before regulators would have thought about them. The challenge will be to decide whether to regulate or to train and educate the concerned business and technologists and manufacturers. This space will be driven by consumer's

movement worldwide, slowly but steadily from "Illness centric (drug approach) to Wellness centric (food approach)." Challenges will be to all players in the sector. With the ever-increasing cost of innovations, there would be focus to offer TF with a history of safety and usage in packaged forms.

The regulations among Asian nations for TF are by and large on the same lines. This has made transborder trade easier. Exporters/importers of packaged TF across nations need to check specifically for compliance to local laws related to the additives used (colors, flavors, stabilizers, preservatives if any, contaminants, and their levels) before exporting consignments. There is a large variation in the contaminants to be tested and their acceptable levels, among each nation. For example, the heavy metal residues and contaminants, not only vary in the number needing testing and control, but also for the same heavy metal the acceptable levels vary, and their specified methods of analysis differ. Labeling requirements vary significantly and some nations do not permit correction by way of affixing sticker labels at the port of entry. Regulations that call for bilingual or labeling in local languages add another element of challenge. This puts a lot of challenges to manufacturers who for logistic reasons want to keep the same packaging materials and configurations across nations. However, the local production of TF for serving in hotels and restaurants, across nations may not face many challenges. Challenge for such a business would be in the event when some essential ingredients are not approved in the importing nation; therefore, regulatory approvals must be in place before starting a business, so that import of such ingredients does not face problems.

A systematic study of traditional foods and their documentation is necessary (in English as well as in regional languages). Traditional foods recipe cards containing detailed information about the recipe, ingredients, preparation process, and contents of selected nutrients need to be developed. This will help to promote them to consumers and the industry. They can be used by individuals for cooking, by schools to promote traditional foods to pupils, or by the food industry for the development of traditional products. This type of documentation has already been undertaken by Europe (Elisabeth et al., 2005).

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