## **Regulatory Procedure**

## LICENSING & OTHER REQUIREMENTS FOR MANUFACTURING, STORAGE AND SALE OF FOOD GOODS



### **Small and Medium Enterprises Development Authority**

## Ministry of Industries & Production Government of Pakistan

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### INTRODUCTION OF SMEDA

The Small and Medium Enterprise Development Authority (SMEDA) was established with the objective to provide fresh impetus to the economy through the launch of an aggressive SME development strategy. Since its inception in October 1998, SMEDA had adopted a sectoral SME development approach. A few priority sectors were selected on the criterion of SME presence. In depth research was conducted and comprehensive development plans were formulated after identification of impediments and retardants. The all-encompassing sectoral development strategy involved overhauling of the regulatory environment by taking into consideration other important aspects including finance, marketing, technology and human resource development.

After successfully qualifying in the first phase of sector development SMEDA reorganized its operations in January 2001 with the task of SME development at a broader scale and enhanced outreach in terms of SMEDA's areas of operation. Currently, SMEDA along with sectoral focus offers a range of services to SMEs including over the counter support systems, exclusive business development facilities, training and development and information dissemination through a wide range of publications. SMEDA's activities can now be classified into the three following broad areas:

- 1. Creating a Conducive Environment; includes collaboration with policy makers to devise facilitating mechanisms for SMEs by removing regulatory impediments across numerous policy areas
- 2. Cluster/Sector Development; comprises formulation and implementation of projects for SME clusters/sectors in collaboration with industry/trade associations and chambers
- 3. Enhancing Access to Business Development Services; development and provision of services to meet the business management, strategic and operational requirements of SMEs.

SMEDA has so far successfully formulated strategies for sectors, including fruits and vegetables, marble and granite, gems and jewellery, marine fisheries, leather and footwear, textiles, surgical instruments, transport and dairy. Whereas the task of SME development at a broader scale still requires more coverage and enhanced reach in terms of SMEDA's areas of operation.

Along with the sectoral focus a broad spectrum of services are now being offered to the SMEs by SMEDA, which are driven by factors like enhanced interaction amongst the stakeholders, need based sectoral research, over the counter support systems, exclusive business development facilities, training and development for SMEs and information dissemination through wide range of publications.



## ROLE OF SMEDA LEGAL SERVICES CELL

The Legal Services Cell (LSC) is a part of Business Development Division of SMEDA and plays a key role in providing an overall facilitation and support to SMEs. The LSC provides guidance based on field realities pertaining to SMEs in Pakistan and other parts of the world.

LSC believes that information dissemination among the SMEs on the existing regulatory environment is of paramount importance and it can play a pivotal role in their sustainable development.

In order to facilitate SMEs at the Micro Level LSC has developed user-friendly systems, which provide them detail description of the Laws, and Regulations including the process and steps required for compliance.

The purpose of this document is to provide SMEs either individuals or companies with information pertaining to food law which a business entity has to comply with. Entrepreneurs interested in enhancing their understanding about the procedures and rights can also use the document. For convenience of the reader's sample of various forms, instructions how fill up the forms and important addresses are also included.

### DISCLAIMER

Information in this document is provided only for general information purpose and on an "as is" basis without any warranties of any kind. Use of this information is at the user's sole risk. SMEDA assume no responsibility for the accuracy or completeness of this information and shall not be liable for any damages arising from its uses."



SMEDA Legal Services Cell

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1- Applicable Food Laws

Pure Food Ordinance, 1960 (hereinafter referred as "the Ordinance") and Pure Food Rules, 1965 (hereinafter referred as "the Rules") are the basic laws which govern the preparation and sale of foods in the Pakistan.

Before going further it will be better to ascertain what does food mean under the Ordinance? As per section 2 sub section 9 "food" means any article used as food or drink for human consumption other than drugs, and includes:

- i. any substance which is intended for use in the composition or preparation of food;
- ii. any flavoring matter or condiment;
- iii. any coloring matter intended for use in food;
- iv. chewing gum and other products of the like nature; and
- v. water in any form, including ice, intended for human consumption or for use in the composition or preparation of food.

2- Licensing requirements

Section 11 of the ordinance deals with the license for manufacturing, storage and sale of food goods. Under the said section, license is required for any place to use:

- i. for the preparation, or the manufacturing, processing, blending, preserving, refrigerating, canning or bottling of any food;
- ii. for the business of a wholesale dealer in banaspati, charbi, ghee, margarine, fish-oil, mustard-oil, cotton-seed oil, or other edible oils and such food as may be prescribed.
- iii. as a creamy, dairy or bakery;
- iv. as a hotel, restaurant or eating house

To obtain license applicant shall apply in writing to the Licensing Authority (in most cases concerned District Health Officer) stating the purpose for which the place is intended to be used and shall submit block plans in triplicate showing: --

- i. the actual area so intended to be used;
- ii. the location at which the various operation connected therewith are to be carried on.



Application for the grant of license should be accompanied by a fee of rupees ten for the premises falls under the below categories:

- i. Premises for the business of whole-sale dealers in Margarine, Vanaspati, Charbini, Ghee Fish oil, Edible oils, Spices, Confectionary, Cereal Products, Soft Drinks, Aerated Water and Cold Storage.
- ii. Creamerics, Dairies, Dairy Farms, Bakeries, Hotels, Eating Houses and other small scale food manufacturing concerns.

And rupees twenty five for the premises falls under the below categories:

- i. Pasteurized milk, milk powder, condensed and evaporated milk, cheese and any other milk products
- ii. Edible oils, margarine and vanaspati
- iii. Biscuits
- iv. Canned foods
- v. Alcoholic drinks and beverages
- vi. Bottling factories
- vii. Sugar factories
- viii. Cereal products

On receipt of such applications and plans the Public Analyst concerned or the District Health Officer /Municipal Medical Officer of Health, as the case may be, shall inspect the said place and recommend the issue of the necessary license in Form 8 (attached herewith) which should be displayed in a prominent place within the licensed premises. License will only be issued if the said place conforms to the following requirements for sale or manufacture of food:

- i. The application should be accompanied by a site plan and a plan showing the building and structure;
- ii. The building for housing the plant has: -

a) floors constructed of concrete or other impervious material, smooth, provided with trapped drains, clean and in good repairs;

b) walls and ceilings have a smooth, washable light colored surface, clean and in good repair;

c) doors and windows provided with effective means to prevent the access of flies and to screen the outer-air, the doors shall be self-closing;

d) lighting on all working surfaces shall be adequate;



e) ventilation sufficient to avoid smoke and odors condensing on structures and on equipment;

f) effective means for protection from contamination from insects and rodents;

g) toilet rooms wherever provided shall bear a sign and selfclosing doors, not opening into any rooms used for handling or storing of food;

h) water-supply easily accessible, adequate and of a safe sanitary quality;

i) convenient hand-washing facilities with running water, soap and towels; and

j) cold storage facilities for perishable articles.

Licensing authority may reject the application upon non-satisfaction from the application. In such a case applicant may file appeal to the concerned government. Each such appeal shall be accompanied by a fee of Rs. 100.

3- Special Condition for Butter or Ghee factory

After getting license as specified in above paras, there are some special conditions for butter or ghee factory which have to be followed by licensee. These conditions are provided below:

- i. The licensee shall not keep Ghee or permit to be kept outside premises or on the public road or street.
- ii. No oil, margarine, vegetable products, paraffin, fat, Vasa or Charbi or other substance capable of being used for the adulteration or Ghee shall be kept on the premises.
- iii. No essences or Glouring matters likely to give resemblance to Ghee shall be kept on the premises.
- iv. The premises shall not form part of or communicate otherwise than by a Public Street with any other premises upon which is kept any of the substances provided in sub condition (ii) above.
- v. All butter brought to the premises for being manufactured into ghee shall, until actually required for such manufacture, be stored in room separate from the room or rooms in which the process of manufacturing, packing, pressing, cleaning or preparation are carried on.
- vi. All stored butter shall be kept in properly covered metal or glass or glazed ware receptacles.
- vii. The process of melting shall be carried out in properly constructed fire-place provided with a suitable flue.



- viii. The labels used for skimming the refuse matters from the surface of the melted butter must at all times be kept in a clean state and must not be placed on the floor but on a suitable shelf or table provided for the purpose in close proximity to the fire place and such shelf or table must be maintained in a clean condition.
  - ix. The licensee shall not keep, handle or sell any butter under any condition which renders the said butter liable to contamination.
  - x. All coal, coke or firewood or liquid fuel to be used in the process of melting butter shall be kept in suitable receptacles and not loose.
- 4- Special Condition for Vanaspati, Margarine and Charbini

There are some special conditions for butter or ghee factory which have to be followed by licensee. These conditions are provided below:

- i. No substances capable of being used for the adulteration of Margarine, Vanaspati, or Charbi shall be kept in the premises.
- ii. Margarine, Vanaspati, or Charbi kept on the premises shall be conspicuously labeled marked.
- iii. The premises shall not form a part of or communicate, otherwise than by a public street, with any premises upon which is kept any of the substances capable of being used for the adulteration.

5- Special Condition for condensed milk or dried milk etc.

There are some special conditions for condensed milk or dried milk which have to be followed by licensee. These conditions are provided below:

- i. The licensee shall not keep or store on the premises any condensed or dried milk or dried skimmed milk or any preservative or any other substances capable of being used as an adulterant.
- ii. The following substances used as adulterants shall be prohibited to store in premises in which butter, ghee, etc., are made: --

| Substance | Adulterants  |
|-----------|--|
| Milk      | Skimmed milk any preservative, condensed milk, dried milk  |
| Ghee      | Vegetable products of all kinds and edible oils, hydrogenated<br>fish oil, coconut oil any other vegetable oil, fat, white oil or<br>paraffin, any mixture made of two or more of the above<br>articles. |
| Butter    | Animal, fat, margarine, edible oil, vegetable oils   |
| Tea       | Artificial tea, Phutri, Fine chaffing of wheat or bran, tea sweeping   |



| Edible oil | Ghee, Butter  |
|------------|---|
| Fats       | Ghee, Butter  |
| Coffee     | Chicory, Acetic Acid, Glacial Acid all coloring matter except |
| Vinegar    | Caramel Preservative or any mineral acids                     |
| Lime juice | Tartaric, Phosphoric or other foreign acids                   |
| Lime juice | Other than Citric Acid  |
| Aerated    | Preservatives other than those allowed under the ordinance.   |
| Water      | All coloring matters except those permitted under the rules   |
| Syrup      | Saccharine, Preservatives other than those allowed under the  |
|            | Rules.  |

6- Conditions for approval of a Plant for Pasteurization / Sterilization

No plant shall be approved for the purpose of Pasteurization / Sterilization, unless it complies with the following conditions:

- I. All type of Pasteurize / Sterilizer shall hold;
  - a) Indicating thermometer of approved accuracy
  - b) Recording thermometer pf approved temperature and time accuracy
  - c) Phosphotase test kit for determine pasteurization efficiency in field and plant laboratory
  - d) Air space thermometer
  - e) Leak-protector inlet/outlet and diversion valves
  - f) Bottle washers
  - g) Plant sanitization equipment
- II. All continuance pasteurizers / sterilizers shall have:
  - a) Indicating thermometers on pipelines
  - b) Milk flow stop, controllers and Diversion Lines
  - c) Automatic holder heaters
  - d) Recorder controllers
  - e) Automatic vat or pocket holders
  - f) Continuous flow holders
  - g) Back flow prevention devices
  - h) Automatic time/temperature/holding recorder

III. All type of Pasteurization/Sterilization plants shall: --

- a) Use "Sanitary Milk Piping" for conducting milk. The piping shall be easy to clean
- b) Use multi-use containers and equipments made of non-corrodible, non-tox material and so located as to be easily cleaned
- c) Preserve recordings of automatic equipment for at least six months



- d) Maintain vehicles for the transportation of milk
- e) Maintain well equipped and adequately staffed laboratories for the daily examination of milk
- f) Undertake to exclude the milk supply in respect of which reasonable cause exists to suspect the possibility of infection contamination

7- Special Conditions for the manufacturing of Pasteurized / Sterilized milk

According to the rule 22 (1) no person shall designate milk or milk products as "pasteurized" unless he complies with the following conditions: -

- i. The milk has been retained at a temperature of not less than  $143^{\circ}F$  for at least 15 seconds continuously and has been cooled immediately to a temperature of not more than  $40^{\circ}F$  in a plant approved for the purpose
- ii. The milk has been retained at such temperature for such period as specified by the Director General of health, Pakistan
- iii. The milk shows efficient pasteurization as evidenced by satisfactory negative phosphotase test
- iv. The milk does not show a coliform count exceeding 10 per milliliter, at any time after pasteurization and before delivery to the consumer

According to the rule 22 (2), no person shall designate milk as "Sterilized" unless he complies with the following conditions: -

- i. The milk has been filtered or clarified and homogenized
- ii. The milk has been heated to and maintained at such a temperature, not less than 212°F for such a period as to ensure that it will comply with prescribed Turbidity Test.
- iii. The milk has been treated as above in such a manner that on completion of the treatment, the receptacle was sealed with an air tight seal.
- iv. The processing has been done in a plaint approved for the purpose in a licensed premise.
- v. The milk shows efficient sterilization at any processing and before delivery to the consumer as evidenced by a satisfactory Turbidity Test.



### 8- Special Conditions for Milk & Dairy Products

No person shall offer or keep in possession for sale or deliver for sale or supply to an person: -

- i. Impure or unwholesome milk or milk drawn from animals affected with any disease of livestock whether contagious, infectious or otherwise capable of causing the milk to become unwholesome.
- ii. Milk drawn from animals within thirty days before or ten days after pasteurization, or for butter, curd or cheese making.
- 9- Labeling and Packaging requirements of Pre-Packed Food

Under the ordinance and rules, there are also some requirements / conditions for labeling and packaging of pre-packed food which have to be followed. According to rule 13 (1) no person shall sell by retail or display for sale by retail , any pre-packed food, unless there appears on a label marked on or securely attended to the wrapper or container a true statement which:

- i. shall be clearly legible and shall appear conspicuously and in a prominent position on the label and if the food is pre-packed in more than one wrapper or container, the label shall be marked on or attached to the innermost wrapper or container and if it is not clearly legible through the outermost wrapper or container a label bearing a like statement shall be marked on or securely attached to or be clearly legible through, the outermost wrapper or container. For the purpose of this clause a plain immediate wrapping which under ordinary conditions of use would not be moved from the next outer wrapper or container shall not be counted as a wrapper or container.
- ii. shall specify the name of either the packer or the labeler of the food and an address at which such person carries on business.
- iii. shall also specify;
  - in he case of food consisting of one ingredients, the appropriate designation of the ingredients;

• in the case of food made of two or more ingredients, the common or usual name (if any) of the food and the appropriate designation of each ingredient and unless the quality or proportion of each ingredient is specified, the ingredients shall be specified in the order of the proportion in which they were used, the ingredients used in the greatest proportion (by weight) being specified first.



Provided that: -

• it shall not be necessary to state that the food contains water

• where a food contains an ingredient which is made from two or more constituents, the appropriate designation of these constituents shall be so specified that it shall not be necessary to specify the appropriate designation of that ingredient. For the purpose of this clause "appropriate designation" means a name or description, which shall indicate to a prospective purchaser the true nature of the ingredient or constituent to which it is applied.

• shall specify the minimum quantity of the food in the wrapper or container expressed in terms either of net weight or of measure:

Provided that in any case where the weight of wrapper or container is usually permitted to be in the weight purported to be sold, it shall be sufficient compliance with this paragraph if the statement specifies the minimum weight of the food with its wrapper or container.

10- Provisions regarding Unsound Food and Food Injurious to Health

According to the ordinance and rules there under, no person shall, directly or indirectly, himself or by any other person: --

- i. prepare, manufacture, keep or store for sale, sell or offer to sell any food which is unsound, unwholesome injurious to health or unfit for human consumption; or
- ii. import or export any food in such manner or in such condition as renders it or is likely to render it injurious to health.

For the purpose of determining the unsound and food injurious to health, any article of food shall be considered as injurious to health and unfit for human consumption, if;

- i. it is putrefied or decayed or emits a bad smell; or
- ii. it is infested with insects; or
- iii. it has evidence of filth or of rodent excretion or hair; or
- iv. it contains chemical known to be toxic; or
- v. contains bacteria which are likely to cause food poisoning; or
- vi. it contains the following metals and metalloids in excess of the tolerance shown against each: --



| Aluminum<br>Antimony            | Maximum 250 parts per Million<br>Maximum 2.0 parts per Million |
|---------------------------------|--|
| Arsenic Liquid<br>Arsenic Solid | Maximum 0.1 parts per Million<br>Maximum 2 parts per Million   |
| Boron                           | Maximum 80 parts per Million                                   |
| Cadmium                         | Maximum 6 parts per Million                                    |
| Zinc                            | Maximum 100 parts per Million                                  |
| Copper                          | Maximum 10 parts per Million                                   |
| Tin                             | Maximum 100 parts per Million                                  |
| Flouring                        | Maximum 1.5 parts per Million                                  |
| Silver                          | Maximum 1 parts per Million                                    |
| Lead Liquid                     | Maximum 2 parts per Million                                    |
| Lead Solid                      | Maximum 20 parts per Million                                   |

vii. it contains in acidity in excess of the limit prescribed in appendix II to the rules when not conforming to the standards shown against it.

11- Provisions regarding Coloring matter in Food

According to the rules, color should not be used in the food in contravention to the following provisions:

| Color Index No. | Color Index name | Common Name       | Chemical Class  |
|-----------------|------------------|-------------------|-----------------|
| (a) 730.5       | Food Blue        | 1 Indigo Carmine  | Indigoid        |
| (b) 42090       | Food Blue        | 2 Brilliant Blue  | Triarylmethance |
|                 |                  | FCS               |                 |
| (c) 69800       | Food Blue        | 4 Indianthrone    | Anthraquinone   |
| (d) 42051       | Food Blue        | 5 Patent Blue V   | Triarylmethance |
| (e) 42640       | Food Violet      | 2 Voilet 6B       | Ditto           |
| (f) 42580       | Food Violet      | 3 Voilet BNP      | Ditto           |
| (g) 42085       | Food Green       | 1 Sulpho Green    | Ditto           |
|                 |                  | 2BA               |                 |
| (h) 42095       | Food Green       | 2 Acid Brilliant  | Ditto           |
|                 |                  | Green ASF         |                 |
| (i) 15985       | Food Green       | 3 A.F. Green No.3 | Ditto           |
| (j) 15985       | Food Yellow      | 3 Sunet Yellow    | Monoazo         |
|                 |                  | F.C.F.            |                 |
| (k) 19140       | Food Yellow      | 4 Tartrazine      | Ditto           |
| (L)             | Food Brown       | 1 Brown F.K.      | Disazo          |
| (m)             | Food Brown       | 2 Chocolate       | Monoazo         |

i. No coaltar dyes or mixtures thereof except the following shall be used in the preparation of any food: --



|           |            | Brown F.B.          |          |
|-----------|------------|---------------------|----------|
| (n) 2285  | Food Brown | 3 Chocolate         | Disazo   |
|           |            | Brown H.T.          |          |
| (o) 14700 | Food Red   | 1 Ponceau SX        | Monoazo  |
| (p) 16185 | Food Red   | 9 Amarnath          | Ditto    |
| (q) 45430 | Food Red   | 14 Erythrosine B.S. | Xarthene |
| (r) 28440 | Food Black | 1 Black P.N.        | Disazo   |

- ii. The maximum limit of permissible color which may be added to any food shall be one grain per pound of food as consumed.
- iii. The following natural coloring matters may be used in or upon any article of food: --

| <br>Caramel     |
|-----------------|
| <br>Cartotenes  |
| <br>Cochineal   |
| <br>Lactoflavin |
| <br>Saffron     |
| <br><br>        |

- iv. Inogranic coloring matters or pigments shall not be added to any article of food.
- v. The use of artificial or synthetic coloring matters in raw food stuffs which are consumed after cooking in the usual way is prohibited.
- vi. No person shall sell a coaltar color or a mixture of coaltar colors unless the label on the package carries: --
  - The common and the color index names of the coaltar color(s)
  - The lot number of coaltar color
  - The words "Food Color"
- vii. Use of permitted coaltar dyes in or upon any food other than those shown below is prohibited: --
  - Ice-cream
  - Dairy products except milk, dahi, butter ghee, chana, condensed milk, cream and baby food
  - Smoked fish
  - Egg preparation
  - Sweets including pastry and confectionary
  - Fruit products
  - Non-alcoholic beverages except tea, cocoa and coffee
  - Custard powder
  - Jelly Crystals



- Soup powder
- Luncheon meat
- Processed or preserved vegetables
- Flavoring agents

### 12- Register for manufacture and wholesale business

As per section 12 of the ordinance, every occupier of a place used for the preparation or manufacture for purposes of trade of any article of food and every wholesale dealer or his agent who stores any such article shall keep and maintain a register and such register shall be open to inspection by the inspector. The said register shall be kept and maintained in the Form shown below: -

 (i) Front Page ... Name and address of applicant Address of premises
Number and date of license
Operation carried on

(ii) Subsequent page: --

Disposal

. . . . . . . . . . . . . . . . . . . .

1) There any many food articles provided in appendix II of the rules which articles when not conforming to the standards shown against it shall be deemed to be not of the nature substance of quality. So all the persons dealing in food articles are advised to go through appendix II of the rules.



### FORM 8 (FORM OF LICENSE UNDER SECTION (11) (THIS LICENSE IS NOT TRANSFERABLE)

### Fee is not refundable

#### No.....of 19

License for using premises for carrying on the business of .....

| Pursuant to the provisions of section 11                                   | of the West Pakistan Pure Food      |  |
|--|-------------------------------------|--|
| Ordinance, 1960, Mr is   | hereby licensed for the period from |  |
| To 31 <sup>st</sup> December, 19   | To use a place for the purpose      |  |
| of being the room or shop  | or place measuring                  |  |
| square feet being part of the premises No subject to the restrictions laid |                                     |  |
| down in the rules and the conditions stated b                              | pelow:                              |  |

- 1. This license is valid only for the premises above specified, that is, for the number of rooms, godowns, or space mentioned therein and as shown in the block plan attached with the license, and if the licensee at anytime during the period of this license desires to use any additional room or godown or space for the purpose aforesaid, he must obtain previous sanction from the Food Authority for doing so.
- 2. If the licensee vacates or gives up the possession of the premises during the period of this license, he shall forthwith inform, in writing, the Licensing Authority that he is about to do so.
- 3. The Licensee shall cause the built up portion of premises to have the following: -
  - a) Floors constructed of concrete or other imperious material, smooth, properly drained and drains provided with traps clean and in good repairs.
  - b) Walls and ceilings having smooth, washable light colored surface, clean and good repair.
  - c) Doors and windows provided with effective means to prevent the access of files and to screen the outer air, the doors shall be self-closing.
  - d) Lighting on all working surfaces shall be adequate.
  - e) Ventilation sufficient to avoid smoke off odours accumulating in structures and on equipment.
  - f) Effective means for protection and contamination from insects and rodents.



- g) Toilet rooms wherever provided shall bear a sign and selfclosing doors not opening into any room used for handling or storing of food.
- h) Water supply which is easily accessible adequate, and of a safe sanitary quality.
- i) Convenient hand washing facilities with water, soap and clean towels
- 4. The licensee shall cause the open and un-built portion of the premises and their surroundings to be kept at all times in a clean and sanitary condition and shall not permit construction of any latrine, cesspool, cow shed, stable, manure heap or other unsanitary heap or other unsanitary place within the premises which in the opinion of the Food Authority renders it undesirable that the premises should be used for business aforesaid.
- 5. The licensee shall not use or permit to be used any portion of the premises for dwelling or cooking purposes.
- 6. The licensee shall keep and maintain a Register required by section 12 of the Ordinance in the Form prescribed in rule 32 and shall keep it all times for inspection of the officers authorized.
- 7. The licensee shall at all times adopt and cause to be maintained in good order and efficient action upon the said premises all such appliances or means as the local authority may from time to time require for the purpose of minimizing danger to life and properly or preventing, abating or minimizing any nuisance annoyance or inconvenience to the neighborhood or to the public from the use of which the premises are put.
- 8. The licensee shall provide on the premises and maintain in good repair and use metal sanitary dust bins of approved pattern and size for the deposit of all trade refuse and sweepings and make proper arrangements for the disposal of their contents daily.

