Resolution no. 260 dated 18/9/1425 H. The Council of Ministers

Having reviewed the file submitted by the presidency of Council of Ministers' Diwan under number 7/B/13641 dated 15.3.1425 H, including the letter of His Highness Minister of Health no. 1153/1/26 dated 5/1/1421 H with which attached the draft law of Maternal Milk Substitutes,

And having reviewed the resolution of council of ministers no. 111/76 dated 7/2/1425 H

And having reviewed the two reports no. 160 dated 2/4/1422 h and no.229 and 23/6/1425 H as amended by the expert panel.

And having reviewed the recommendation of the General Committee of the Council of Ministers no. (509) dated 4/9/1425 H.

Resolves

Approval of "Maternal Milk Substitutes Dealing Law" as per the attached form.

Royal Decree draft has been prepared as attached herewith

Council of Ministers Head

Maternal Milk Substitute Dealing Law

Maternal Milk Substitute Dealing Law

Article 1:

The following words and Phrases shall have the meanings stated against each of them wherever they are stated herein unless otherwise required by the context:

Maternal Milk Substitutes: It is meant any substitute for the maternal milk which is composed artificially according to the applicable International Food Charter, and according to the Saudi standards, to meet the customarily food requirements up to 6 (six) months of the age which is prepared to meet the children's physiological needs including the foods which are prepared domestically.

Dealing: It is a process or more that include manufacturing, storing, promoting and sale of the products under the scope of this law.

Marketing: It is the activity through which study of promoting, distributing and selling of the product is carried out as well as the market and consumer's related research.

Label: It is a written, printed, copied, drafted or engraved on the package of the products covered by this law.

Package: It is meant any form of the product packages which are sold as customarily retail unit including the external packages.

Samples: one package or small quantities of products which are offered free of charge.

Producer: An individual, establishment or company which is operating directly or through an agent or an entity under his control or engaged with him in manufacturing of product under this system.

Marketing Employee: an individual whose tasks include marketing of the product or products covered by this law.

Supplier and distributor: An individual, establishment or company which is operating directly or indirectly in the field of wholesale or retail and marketing the products covered by this law.

Health Care Institutions: They are meant each public or private authority which has a direct or indirect relation on the field of the health care of the mothers, infants and pregnant women and all nursery homes, children care societies excluding the pharmacies and stores licensed to sell such products.

Health Care Attendant: an individual of the of health Care Institutions in charge of nutrition of the mother and child. Such covers those working in the charity and private benevolent societies working in the field of health care.

Minister: Minister of Health

Ministry: means Ministry of Health

Article Two:

This law aims to provide the safe health nutrition to the babies through protecting the natural feeding and fostering it and to warrant the proper use of the maternal milk substitutes when needed on the basis of the suitable awareness and through the suitable distribution and marketing methods and practices.

Article Three:

This law is applied to the dealing and practices associated to the following products: Mother's milk substitute, supplementary foods of milk products, other foods and drinks which are given by the bottle or through other methods when marketed or offered in any way – after being modified or without modification – for use as a partial replacement or complete replacement to the mother's milk and also feeding nipples and bottles and that they are applied to their type and availability and to the use related information.

Article Four:

All informative and educational materials – whether written, audio or visual – in respect of the child's feeding as issued by the Ministry of Health or other relative authorities – should include clear information on the following points:

A – Advantages of the natural feeding and being better than other kinds of feeding (artificial)

B – Importance of mothers' nutrition and preparing them to the natural feeding and to maintain them for the longest possible period

C – Negative effects to the natural feeding as a result of the partial feeding by the bottle. D – Health risk as entailing from the proper use of the mother's milk substitutes and

supplementary foods.

Article Five:

It is prohibited to advertise and promote in any way for the mother's milk substitute and babies' food. This prohibition includes:

A – Use of the Health Care Institutions to promote such products or advertising, offering or distributing them.

B – Furnishing he producers, suppliers, distributors and health care institutions – directly or indirectly – any sample of these products, gift, tool or system that encourage use them. C – Offering any financial gift, sample by the producers, suppliers or distributors of products to the Health attendants to promote such products.

Article Six:

As an exclusion to the provisions of article five hereof, the producers, suppliers and distributors may offer the scientific pamphlets on the babies foods – after being approved by the Ministry – to the professionals (only) working in the field of caring of the motherhood and childhood provided that the information to be limited to the scientific information and to indicate in them about the details of the natural feeding.

Article Seven:

The audio, video and read press media should cooperate effectively in the field of the awareness in a way that support the targets of this law through programs and publications provided by professionals in this field.

Article Eight:

The concerned authorities such as Ministry of Health, other health public and private sectors, Ministry of Education, Ministry of Culture and Information, Ministry of Social Affairs, Ministry of Higher Education, Ministry of Islamic Affairs, Endowment and Dawa (Call) and Guidance should contribute in the publishing the health information pertaining to this Law through their available media each according to his field.

Article Nine:

The Health Care Institutions may not employ the staff of the producers of the maternal milk substitutes, suppliers nor distributors nor employing their staff in the field of the motherhood and childhood care. Further, the staff of such institutions and their staff may not be employed by those producers, suppliers nor distributors.

Article Ten:

Without prejudice to the Saudi standards pertaining to the maternal milk substitutes, a label should be fixed on each packet in a clear way that, easy to read and understand and difficult to remove, provided to include the following particulars:

1—Phrase which indicates that the natural breast feeding is advantageous and to be written in a clear and visible way preceded by **N.B.** and that such phrase is to specify the competent authority in the Ministry.

2—Particulars and information on the right way of preparation and warning on the health risks that may result form improper preparation and that the label or the package should not bear any pictures nor photos of children nor any other signs or texts that give impression that it is better than the natural feeding.

3—Statement which indicates to be used only upon necessity under doctor's or professional's advice in the field of baby feeding provided to include the proper way of use.

4—Statement should show the following:

- A—list of ingredients.
- B—Nutritional composition.
- C—Required storage conditions.
- D—Batch number, production date and expiry date in straight and clear way.

Article Eleven:

The maternal Milk Substitutes and supplementary foods should be in conformity with the Saudi standards and to write on the package the suitable years of age to use.

Article Twelve:

The Health Care Institutions should take the suitable arrangements to encourage and protect the natural feeding through giving advice, information and training to health attendants working in this field.

Article Thirteen:

The Health Care Institutions should not accept any free of charge or discounted samples of the baby milk or foods to minimize the spread of the maternal milk substitutes.

Article Fourteen:

The Social Care Homes of Orphans may accept samples of the children milk and foods.

Article Fifteen:

The Health attendants in charge of mothers' nutrition should encourage the natural feeding and to be well aware of their work requirements and to be qualified to provide the relative information, advice and training when necessary.

Article Sixteen:

The Health attendants in charge of mother's nutrition and their family members should not accept any material or non material gift that may be offered to them by the producers, suppliers and distributors of the mother milk substitutes and supplementary foods.

Article Eighteen:

The health attendants and pharmacists only are allowed to explain how to give the mother milk substitutes which are prepared or manufactured domestically, provided the same is to be limited to the mothers and family members in need of them and the provided information is to include clear explanation on the improper use of such products.

Article Nineteen:

A committee or more is to be formed under a ministerial resolution and such committee to include:

A - A representative for the Ministry of Justice to be nominated by the Minister of Justice

B - A representative for the Ministry of Ministry to be nominated by the Minister of Health

C - A representative for the Ministry of Commerce & Industry to be nominated by the Minister of Commerce & Industry

One member or more at least should be legal official advisor, this committee will resolve the disputes arising from the violations of this law and to issue the necessary decisions and that the Minister will be the authority that approves the committee's decision. The Executive Regulation will specify the membership duration in this committee and how to implement the same and that the remuneration so the committee members will be determined under a resolution passed by the Council of Ministers as recommended by the Minister.

Article Twenty:

Without prejudice to any penalty stipulated by any other laws, whoever breaches any provision hereof (individual, establishment or company) manufacturers, imports or distributes the maternal milk substitutes will be punished by a penalty or more of the following:

- A Warning
- B Fine varying from SR5.000 as a minimum to SR 150.000 as a maximum
- C Closure of the violating firm for at most 180 days.

Article Twenty One:

Without prejudice to any other severer penalty stipulated by any other laws, whoever breaches any provision hereof of the private health care institutions or nay of their employees will be punished by a penalty or more of the following:

- A Warning
- B Fine varying from SR5.000 as a minimum to SR 100.000 as a maximum.
- C Closure of the violating firm for at most 60 days.

Article Twenty Two:

If the committee has found that the violation requires to apply fine higher than the amount specified under articles 20 & 21 hereof or cancellation of license, then the committee has to raise the subject to the Minister to forward the dispute to the Grievances Board to resolve what is seen necessary.

Article Twenty Three:

Decision or award passed by the committee may be challenged before the Grievances Board within sixty days of informing such decision to the party to the violating party.

Article Twenty Four:

Under an award passed by the Grievances Board, the penalty sentence may be published in one or more local paper at the violator's expense.

Article Twenty Five:

A staff who breaches the violations of articles (5, 9, 12, 15, 16, 17 and 18) hereof will be punished according to the provisions of the Staff Disciplinary Code.

Article Twenty Six:

The Minister shall, in coordination with the Minister of Commerce and Industry, the Exe4cutive Regulations and Decisions for this law within ninety days of being issued in the official gazette.

Article Twenty Seven:

This law cancels all other materials conflicting with it.

Article Twenty Eight:

This law is to be published in the official gazette and to be effective 90 days after publishing it.