divisions of the Ministry of Health in strengthening and updating the relevant regulations as well as to provide scientific input on these products.

2. Classification of FDI

Through a series of meetings of the Committee for the Classification of Food-Drug Interface Products, the FSQD and NPCB have arrived at a system for the classification of food-drug interface products. This classification is based on multiple criteria system as follows :

2.1 If a product contains 80% or more of food ingredients, singly or in combination, and with equal to or less than 20% of biologically active ingredients of natural products with pharmacological and/or therapeutic properties, the product has to be regulated by FSQD.

2.2 If a product contains less than 80% of food-based ingredients and more than 20% of the active ingredients, such product shall be regulated by NPCB. Not withstanding this general rule, for products containing specific ingredients which possess high potencies, even if they contain less than 20% of the active ingredients, they shall be reviewed by the Committee and may be regulated by NPCB if it is found appropriate.

2.3 If the product is a 'pure' form (close to 100%) of active ingredients, e.g. vitamins, minerals, amino acids, fatty acids, fibre, enzymes, etc., the product has to be regulated by NPCB.

2.4 Products containing solely natural ingredients that are not traditionally used as food and possess medicinal value, such as alfalfa, spirulina, royal jelly, noni juice, rooibose tea, pegaga tablet and other herbal products shall be regulated by NPCB.

2.5 When there is greater uncertainty about the efficacy and safety of a product, NPCB would be the prefered authority to regulate it. This is to enable closer scrutiny of such products, to better safe guard the interest of consumers.

3. Other Criteria

The following may be used as additional criteria to assist in the classification of products:

3.1 Intended use and claims made by the product. Eventually, if a product has been decided to be regulated by FSQD, no claims shall be made, other than those permitted by the Food Regulations 1985.

3.2 Instruction for use and pharmaceutical dosage forms such as tablet, capsule.

3.3 Formulation of the product. A product with an unusual mixture of vitamins and minerals and herbs would most likely to be regulated by NPCB.

3.4 Products with unusual application or use are likely to be regulated by NPCB.

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MINISTRY OF HEALTH MALAYSIA

Guide to Classification of Food-Drug Interface Products

Standards Section
Food Safety and Quality Division

1. Introduction

Malaysians are now more health conscious and there is generally greater awareness of the importance of nutrition to overall well-being. In recent years, many consumers also rely on a variety of "dietary supplements" to improve their health. These supplements (sometimes referred to as "health foods") comprise a diverse group of products that are now freely available through a myriad of outlets.

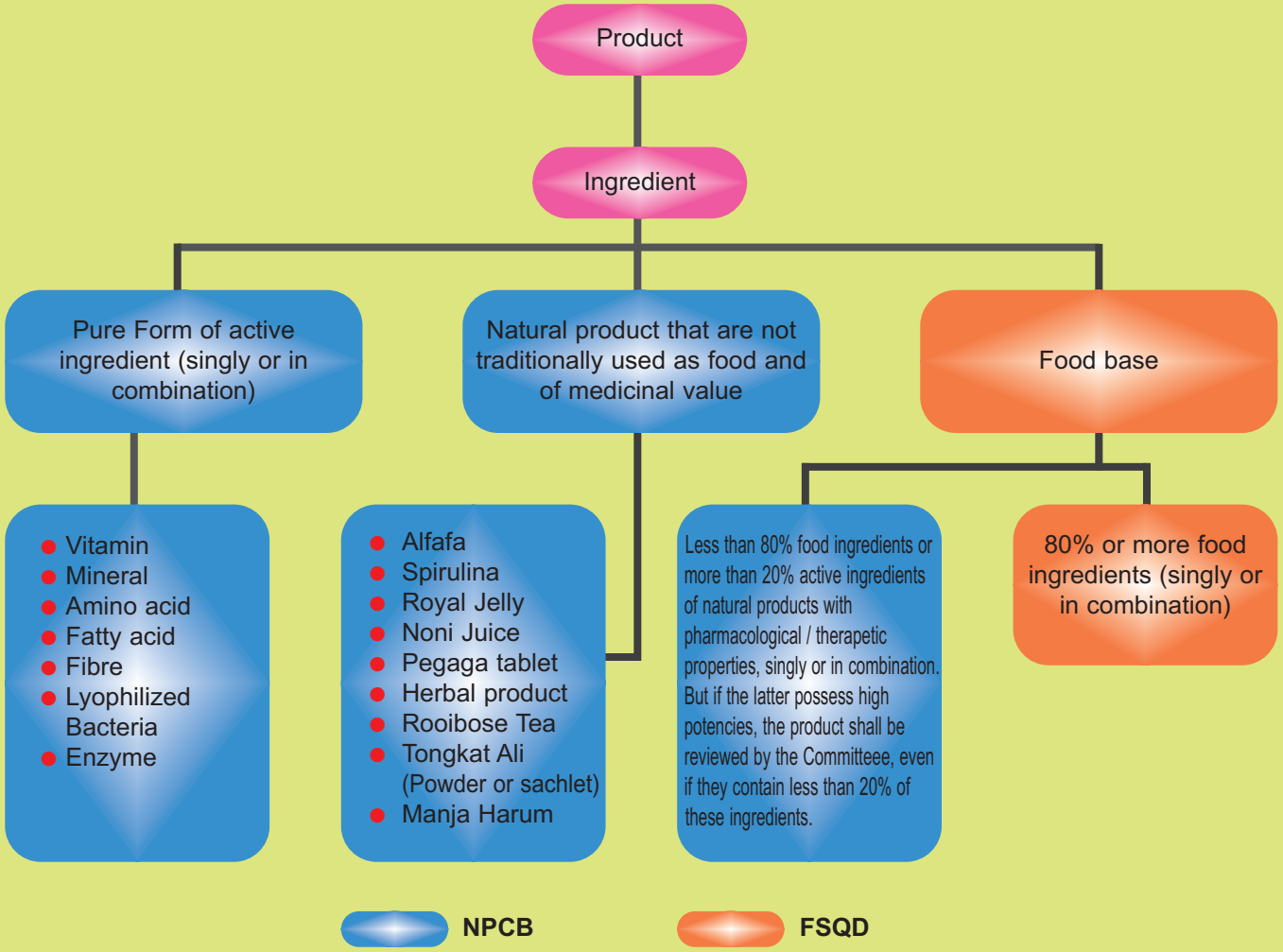
A variety of products are available in the market, supposedly for the prevention and even treatment of the chronic diseases. These products may range from foods modified to have special properties or pure form of vitamins and minerals and extracts of various botanical or animal products. These products are marketed through a variety of channels and often carry a variety of functional and health claims. It is important to monitor and regulate the marketing and sale of these products so as to protect the interest of consumers.

There are, however, various products in the market that were not clearly marketed as "food" or "drugs". These have been termed as "food-drug interface products" and include a variety of so called health products. Previously, it has been difficult to determine which authority should regulate the marketing and sale of such products, i.e. Food Safety and Quality Division (FSQD) or National Pharmaceutical Control Bureau (NPCB). This has caused difficulty to the companies intending to market such products. It is also not beneficial to the consumer as the products could be in the market and not regulated by either of the authorities.

To overcome these problems and to enable a quick decision to be made as to which authority should regulate a particular product, a committee called Committee for the Classification of Food-Drug Interface Products was formed in 2000. The committee members are from FSQD and NPCB. The main terms of reference of the committee is to assist the FSQD and NPCB in classifying an application from the industry which is not clearly a food or drug (a food-drug interface (FDI) product) in a consistent manner. Other duties include advising the two

Guide to Classification of Food-Drug Interface Products

(Guide to determining if a product is to be regulated by the FSQD / NPCB)



- If a product is more than 80% food based but contains pure forms of active ingredient (e.g: vitamins & minerals) that exceed the amounts permitted in Food Regulations 1985, the company shall be advised to reduce the amounts of these active ingredients and be regulated by FSQD.
- Intended use and claims should not be used as sole criteria for classification but can be used as additional criteria to assist in classification
- Instruction for use and pharmaceutical dosage form like tablet, capsule, should not be used as sole criteria for classification, but can be used as additional criteria in the market and not regulated by either of the authorities.