

Regulatory aspects of nutraceuticals and functional foods in Nepal

Abstract

Nutraceuticals are garnering increased interest among people throughout the world at the present time. Although the consumption of functional foods has taken place since the Ayurvedic era, the term 'nutraceutical' has only been coined recently. With the growing nutraceutical market and its impact on population health, regulation of these food products is warranted. There are different regulatory requirements for nutraceuticals throughout the world. In Nepal, nutraceuticals are regulated by the Dietary Supplement Guideline published by the Ministry of Agriculture and Livestock Development. This Guideline aims to protect the health of the consumer and uphold service to the customer by controlling and assuring the stated composition and purity of the nutritional supplementary food, along with defining quality standards, as stated in the preamble of the Guideline. Functional foods are subdivided into six different classes; these are controlled in terms of production, sale, export and import within the territory of Nepal by this Guideline. Even though there are strict laws, unnecessary prescription of nutraceuticals for financial benefit and the sale of unauthorized herbal formulations and nutraceuticals by street vendors are still common practices. We believe the Nepalese authorities should make a greater effort to halt such practices.

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Introduction

'Nutraceutical' is a combined word firstly coined by Stephen DeFelice to describe a product that has both 'nutritional' and 'pharmaceutical' components in 1989^[1].

Dr DeFelice defined a nutraceutical as a 'food or part of a food that provides medical or health benefits including the prevention and/or treatment of a disease'^[2].

Similarly, the International Food Information Council (IFIC) defines functional foods as foods or nutritional components that may deliver a health benefit beyond fundamental nourishment.

The International Life Sciences Institute of North America (ILSI) cites a functional food as one, which, by virtue of its physiologically active constituents, provides health benefits in addition to having an elementary nutritional function. Health Canada defines a functional food as a food with a similar appearance to orthodox foods, which is eaten as part of a normal diet, but it possesses additional physiologic benefits and/or chronic disease preventative features^[3].

Although individuals and organizations define nutraceuticals in several ways, the term 'nutraceutical', used in a general sense, has no strict regulatory definition^[2, 4].

Nutraceuticals can be classified based on their chemical nature into different classes, namely: isoprenoid derivatives, phenolic substances, fatty acid-related structural lipids, carbohydrates with their derivatives, amino acid-based substances, microbes and minerals^[5].

Different functional food products that we observe in the marketplace include fortified cereals, vitamin and mineral supplements, digestive enzymes, dietary fibre, antioxidants, herbal supplements, energy drinks and tablets, foods to reduce cholesterol levels and prebiotics and probiotics, among others^[6].

Ayurvedic perspective

Traditionally in Ayurveda, the concept of a nutraceutical was covered by 'Rasayana'^[7]. According to Ayurvedic literature, Rasayanas are substances that help to improve metabolic processes such as digestion and immunomodulation, mental health and, collectively, quality of life^[8]. Consumption of Rasayanas (nutraceuticals) is believed to result in biotransformation of the tissues and prevention of senility and old-age disease. Rasayanas can be allocated to three different classes in Ayurveda, namely:

- 1) Kamyā (for 'liveliness', intellect and so on),
- 2) Naimittika (for specific illnesses) and
- 3) Ajasrika (general).

Ajasrika Rasayanas can be described as nutraceuticals an individual can consume daily to improve quality of life and to revitalize the body. Chyavanaprasha for respiratory modulation, Brahma Rasayana for mental function, Phala Ghrita for reproductive function, Shatavari Ghrita for general gynaecologic regulation, Arjuna Ksheerapaka for cardiac function and Lashuna Ksheerapaka for cardioprotective care are some examples of nutraceuticals in Ayurveda^[9].

Nutraceutical market

The nutraceutical market share is very high globally, worth an estimated \$120 billion in 2007, with annual growth of approximately 7%. A major portion of this market is the US, with China and India comprising the fastest growing market^[10]. Nutraceutical demand has demonstrated a remarkable upward trajectory in recent years worldwide^[11]. The explosive increase in demand for nutraceuticals is the result of the frequently quoted health benefits of nutraceuticals in the prevention of cardiovascular disease and cancers and

the beneficial psychological, metabolic disorder and immune-modulatory activity of nutraceuticals [12]. The FDA authorizes health claims for nutraceuticals but rigorous research – as for pharmaceutical products – to establish safety data before marketing is not mandated. This sometimes creates a considerable risk to public health, examples being some already marketed products. This also highlights the need for regulation that ensures public safety before the product is marketed [4]. The impact of the nutraceutical market on public health draws the attention of regulatory authorities in different countries to formulate laws to regulate nutraceutical products.

Table 1 outlines the regulation of functional foods in some countries/territories.

Table 1 Regulation of nutraceuticals in various countries/territories around the world

S.N.	Country Territory	Regulation
1	US	Dietary Supplement Health and Education Act of 1994 [12]
2	China	State Food and Drug Administration of China (SFDA), 2003 [13]
3	Japan	FOSHU (Food for Specified Health Uses), 1991 [14]
4	India	The Food Safety and Standards Act (FSSA), 2006 [13]
5	Europe	Functional Food Science in Europe (FUFOSE), 1996 Regulation [15]
6	Canada	Natural Health Products Directorate (NHPD), 2003 [16]
7	Nepal	Dietary Supplement Guideline, 2016 (Ministry of Agriculture and Livestock Development) [17, 18]

Regulation in Nepal

In Nepal, the control and regulation of dietary supplements is accompanied by the Dietary Supplement Guideline (2016), as

prescribed by the Food Act, 1967, under the Department of Food Technology and Quality Control in the Ministry of Agriculture and Livestock Development. This Guideline aims to protect the health of the consumer and uphold customer service by controlling and ensuring the composition and purity of products, along with defining quality standards for nutritional supplementary food, as stated in the preamble of the Guideline [17, 18]. Under this Guideline, foods are divided into the following different classes:

A. General food

This represents all the food eaten on a regular basis. It also includes spices and combinations of food that people have been consuming for a long period of time based on culture and tradition. These foods are regulated by the Food Act.

B. Foods for health, nutritional or dietary supplements

These are products that give additional nutrition to consumers, such as carbohydrates, fats, fatty acids, vitamins, minerals, protein, amino acids, enzymes from plant and animal products or their combination in the form of powders, tablets, liquids, granules, capsules or jelly that can be administered by the oral route.

C. Foods for special dietary use

Foods that are prepared by enriching different nutrients and that are targeted for physiological conditions such as overweight, low weight, diabetes, blood pressure, conditions of gluten indigestion from wheat or for any special dietary requirements. They may not require a prescription from a doctor for consumption.

D. Foods for special medicinal or therapeutic purposes

These are prescription nutritional foods that can be taken when an individual is unable to obtain sufficient nutrition from a normal

or special diet mentioned above due to an underlying physiological condition. This class also includes food prepared for weight loss and diets prepared in a particular way to replace regular food.

E. Nutraceuticals

Formulations with some physiological benefits and/or which can be used to prevent chronic disease prepared from food or other resources and prepared in powder, tablet, liquid, granule, capsule or jelly form to be taken in a specified amount.

F. Foods for special nutritional purposes

All food supplements with added nutritional value; these can be taken by patients or healthy individuals on a regular basis to improve general health, to give physiological benefit or to improve the basic health conditions of a patient.

Any individual or organization that produces and/or markets nutritional foods in Nepal can make two types of claim, as specified by this Guideline. The first is a *health claim*.

This is any statement, suggestion or implication that relates a food constituent or added nutrient to human health. It also includes functional claims made with respect to added nutrients in terms of the physical growth and general functions of the body.

In addition, it encompasses statements regarding the reduction of the likelihood of getting a disease, slowing of the growth of a disease or any health-related claim.

The second type of claim is a *nutritional claim*. This is any statement, suggestion or implication made regarding the presence of protein, fats, carbohydrates, vitamins, minerals, fibre or antioxidants in food.

With the subdivision of functional foods into six different classes, these foods are controlled

in terms of their production, sale, export and import. Any individual or organization willing to produce, import, export and/or market nutraceuticals in Nepalese territory should take the following points into account^[17]:

Functional foods must comply with the standards given by the Guideline under law and should be prepared based on food and nutrition principles verified by sufficient scientific evidence.

In addition, producers should ensure:

1. There is evidence of the formulation being prepared based on food and nutrition principles verified by sufficient scientific sources;
2. There is evidence that there is no addition of hormones, steroids and/or psychotropic ingredients;
3. The addition of at least 15% of the recommended dietary allowance (RDA) of the specific vitamin, mineral or nutritional ingredient that is the subject of the claim, not exceeding the maximum dose. For the RDA, consultation of the guidelines given by the Nepalese government, the Food and Agriculture Organization of the United Nations or the Indian Council of Medical Research can be carried out;
4. The food product is not exactly the same as its natural form and has undergone special processing. If the food product is exactly the same as its natural form; that is, no special processing has been carried out, but it can be used for a particular purpose, a claim that it is a special purpose medicine/dietary supplement cannot be made;
5. The formed formulation adheres to Nepalese or Codex Alimentarius standards;
6. The label includes the composition, instructions for use and the expiry date in a form that allows the target customer to read and understand the information.

Even after assurance of the above statements, the Department can evaluate the special

nutritional features claimed by a producer if this is deemed necessary.

Any individual or organization that wants to import or export functional foods to or from Nepal should follow the specified procedure as mentioned by the Department. After obtaining a recommendation letter from the Ministry of Agriculture and Livestock Development, those wishing to import nutraceuticals should register the product at the Department by submitting all the necessary documents.

Any product that is banned in any country for any reason cannot be imported and marketed in Nepal.

The right to import products that are not banned in other countries and fulfil the above requirements is only given to authorized dealers of the production company.

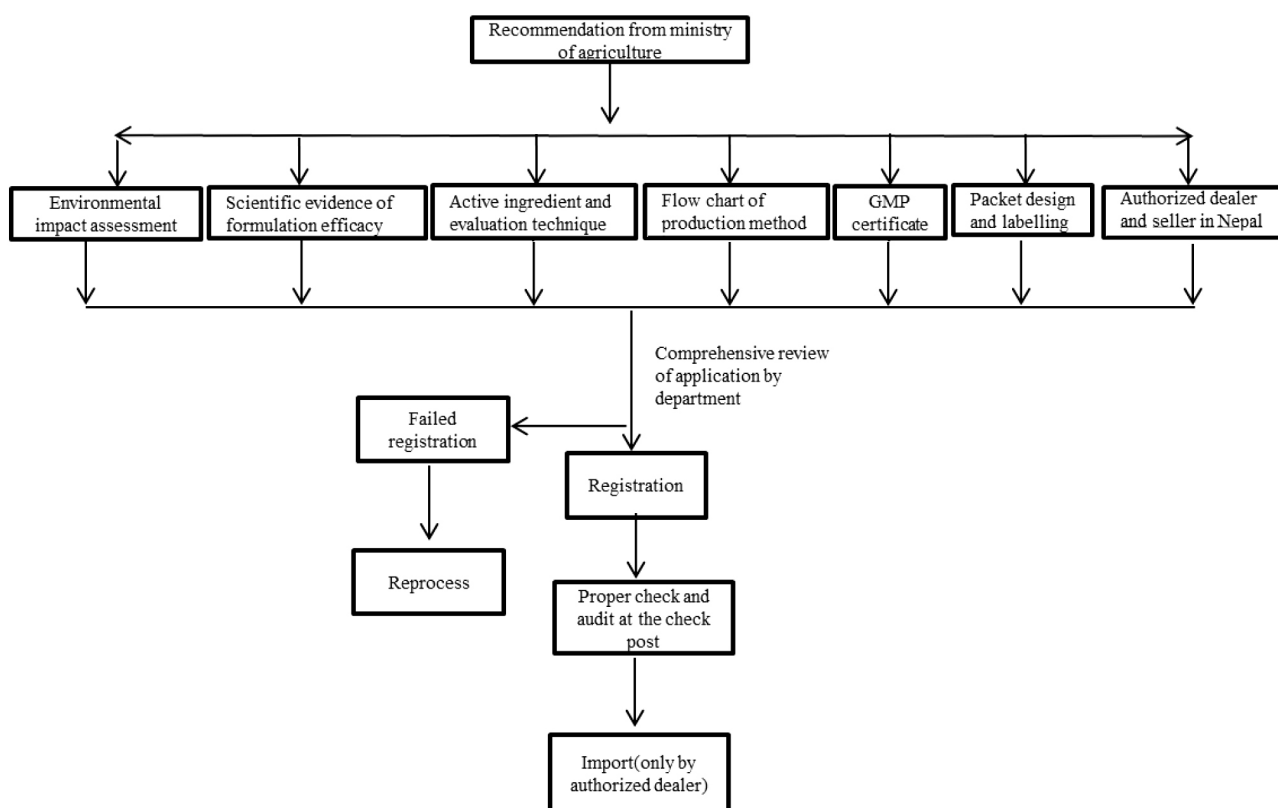
For export or import of a product out of or into Nepal, the Export-Import Inspection and Quality Certification System in Nepal (2063 BS), under the Ministry of Agriculture and Livestock Development, should be followed [17, 19].

Fig. 1 explains the detailed procedure for the import of nutraceuticals to Nepal.

The importer should provide a sample of the product that they wish to import to the Department and if the Department sees it as necessary, it will send that sample to a laboratory in Nepal and a foreign country for evaluation.

The cost incurred by that evaluation should be covered by the importer of the goods. If the Department feels it is necessary, more documents can be requested before permission to import is granted [17].

Figure 1 Flow chart of the procedure for the import of nutraceuticals to Nepal [18]



Moreover, for the production of nutraceuticals in Nepal, the manufacturing company must provide the following:

- GMP certificate;
- Scientific evidence of formulation efficacy;
- Details of the active ingredient(s) with their assay method(s);
- Flow chart of the production process;
- Packaging design;
- Availability of laboratory for quality checks;
- Availability of a sufficient workforce for quality production;
- Other documents if deemed necessary.

Furthermore, the labelling requirements for the product as defined by the Department are as follows:

- Name of the product and the group it falls into with respect to the classification of functional foods;
- Amount of all added vitamins and nutrients claimed to be present in the product;
- The label must include text stating that 'this product is not for medical treatment of the disease' or similar;
- The dose and mode of administration must be stated properly so that the target customer can read and understand it;
- Warning(s) (if any);
- Nutritional claim(s);
- Expiry date of the product.

Conclusion

In this way, functional foods are regulated using a completely different guideline for assurance of the quality of the product in the Nepalese market^[17]. Even though there are strict laws, unnecessary prescription of nutraceuticals for financial benefit and the sale of unauthorized herbal formulations and nutraceuticals by street vendors is still common. We believe the Nepalese government should make a greater effort to halt such practices.

References

1. Brower V (1998) Nutraceuticals: poised for a healthy slice of the healthcare market? *Nat Biotechnol* 16(8):728–731
2. Kalra EK (2003) Nutraceutical – definition and introduction. *AAPS Pharm Sci* 5(3):27–28
3. Ramesh CK, Jamuna KS (2012) Concepts and trends of functional foods: a review. *Int J Pharm Res Dev* 4(6):273–290
4. Zeisel SH (1999) Regulation of "nutraceuticals". *Science* 285(5435):1853–1855
5. Keservani RK, Kesharwani RK, Vyas N, Jain S, Raghuvanshi R, Sharma AK (2010) Nutraceutical and functional food as future food: a review. *Pharm Lett* 2(1):106–116
6. Chauhan B, Kumar G, Kalam N, Ansari SH (2013) Current concepts and prospects of herbal nutraceutical: a review. *J Adv Pharm Technol Res* 4(1):4–8
7. Tiwari V, Morya GC (2018) A conceptual study on nutraceuticals in Ayurvedic perspectives WSR to Rasayana. *J Glob Biosci* 7:5350–5357
8. Deshmukh KS (2017) Ksheerpaka kalpana – nutraceutical in Ayurveda. *Int Ayurveda Publ* 2(5):657–664
9. Rani Y, Sharma NK (2005) Nutraceuticals: Ayurveda perspective. *Acta Horti* 680:131–136
10. Ahmad MF, Ashraf SA, Ahmad FA, Ansari JA, Siddiquee MRA (2011) Nutraceutical market and its regulation. *Am J Food Technol* 6(5):342–347
11. Ajjawi I, Shintani D (2004) Engineered plants with elevated vitamin E: a nutraceutical success story. *Trends Biotechnol* 22(3):104–107
12. Kottke MK (1998) Scientific and regulatory aspects of nutraceutical products in the United States. *Drug Dev Ind Pharm* 24(12):1177–1195
13. Singh J, Sinha S (2012) Classification, regulatory acts and applications of nutraceuticals for health. *Int J Pharm Biol Sci* 2(1):177–187
14. Shimizu T (2003) Health claims on functional foods: the Japanese regulations and an international comparison. *Nutr Res Rev* 16(2):241–252
15. European Parliament and Council (1997) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. *Off J Eur Communities* 40:1–6

16. Fitzpatrick K (2005) Regulatory issues related to functional foods and natural health products in Canada. In: Hasler CM (ed) Regulation of functional foods and nutraceuticals: a global perspective, 1st edn. Blackwell Publishing, Iowa, pp 213–226
17. Department of Food Technology and Quality Control, Ministry of Agriculture and Livestock Development, Government of Nepal (2016) Dietary Supplement Guideline. Available from: http://dftqc.gov.np/downloadfile/supplement_1575441578.pdf (accessed 12 July 2020)
18. Department of Food Technology and Quality Control, Ministry of Agriculture and Livestock Development, Government of Nepal (1967) Food Act, 1967. Available from: <http://nnfsp.gov.np/PublicationFiles/fa11d36f-b393-49f8-b449-5f7dfbaa774d.pdf> (accessed 12 July 2020)
19. Department of Food Technology and Quality Control, Ministry of Agriculture and Livestock Development, Government of Nepal (2063 BS). Directives on Export-Import Inspection and Quality Certification System in Nepal. Available from: [http://www.spsenquiry.gov.np/downloadfile/PDMO_Text_of_Notification_NNPL5_Exp_Imp_Dir_for_Food_\(1\)_1559802882_1589278835.pdf](http://www.spsenquiry.gov.np/downloadfile/PDMO_Text_of_Notification_NNPL5_Exp_Imp_Dir_for_Food_(1)_1559802882_1589278835.pdf) (accessed 12 July 2020)