

Certification Schemes and Marks: A New Mandate for Quality Assurance of Food and Drugs

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Available online: 1st October, 2013

ABSTRACT

Quality products are the demand of the day and the consumers have become more aware about their health and health related products. To develop a high degree of confidence about the safety and efficacy of medicines and food, specially packaged or processed food available in the market, various certifying agencies are involved. They issue quality "certificates", "marks", "logos" or "symbols" to the product after evaluating certain quality parameters developed and validated by them. Presently, one can see many certification schemes existing for drugs like "Product Certification Scheme" by Bureau of Indian Standards (BIS), "Good Manufacturing Practices (GMP) Certification Scheme" by World Health Organization (WHO), "Premium Mark" and "Standard Mark" by Department of Ayurveda, Yoga and Naturopathy, Unani, Sidha and Homeopathy, and "Fruits Product Order (FPO) Mark" and "Organic certifications" for food products. This paper shall discuss various certification schemes and marks for food and drugs across the globe and their role in assuring quality.

Key words: Organic certification, Halal, Standard Mark, Premium Mark

INTRODUCTION

In the present times, the demand for safe, effective and quality products is on the rise, especially with the increase in consumer awareness. The customer is the king today and expects full return for his money. Like consumers, manufacturers are also now very particular in providing a quality product which is safe and effective so as to gain the confidence of the customer. Therefore, quality is a matter of concern for both the manufacturers as well as the consumers in the present competitive market. The quality of the product is ensured by its quality assurance which is a mandate and can be defined as a process or procedure encompassing systemic evaluation and monitoring of different aspects [1]. This act also leads to ensure that the product is being developed in compliance with the specified quality standards [2]. Quality of a product can be assured by different frameworks which include determination of adequate technical requirements, quality audits of the products and certifications [3]. Certification is the process to assure that a specified quality or standard has been achieved. It is an evaluation and recognition process of a product meeting a set of requirements or criteria (standards) already established by the concerned authority [4]. Certifications not only act as a confidence building measure to the consumers but also help in contributing towards social responsibility and environment sustainability. They can be used as an effective tool for the marketing of the product too. Certifications can be broadly classified as either mandatory or voluntary certification.

Mandatory Certification: This certification is required by the law of the country or State for manufacture or sale of

the product in the same country or State, for example, 'Natural' and 'Organic' certification of the product is mandatory if the label claims the term organic.

Voluntary Certification: This certificate is issued by the certifying body /bodies at the request of either the vendor or manufacturer or the customer of the goods. This is not a legal requirement for a particular country or state but it takes place on voluntary basis for suitability to those standards that are declared by the manufacturer or supplier of the product, for example, certification of AYUSH products is a type of voluntary certification [5].

There exist numerous certification bodies which are authorized to issue 'certificates' and 'marks' after the process of evaluation is completed and they are assured of the quality. Certification schemes for Drugs as well as Food products are being discussed below.

Certification Schemes for Drugs: As per The Drugs and Cosmetics Act 1940, Rules 1945, Drugs can be defined as (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette

Table 1: Organic Certifications for Food








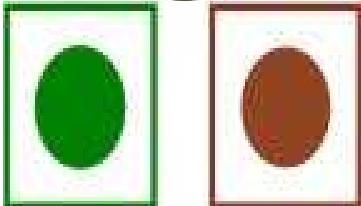
S. No.	Name	Logo	Country
1	USDA NOP		US
2	Canada Organic Logo		Canada
3	Organic Logo		EU
4	NASAA		Australia
5	India Organic		India

Table 2: Mandatory Certifications for Food Products in India

S. No.	Name	Logo	Country
1	FPO mark		India
2	AGMARK		India
3	Vegetarian and Non-Vegetarian Mark		India

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and
 (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

Though the quality of drugs is governed by pharmacopoeial standards, still there are some more agencies, which can help in assuring the quality of drug products in addition to the official requirements. Their role is being accepted by one and all because a pragmatic shift is seen towards the demand of quality products and consumers are very peculiar about their safety and efficacy. Various certification schemes which are available to ensure the same are as follows:

International Organization for Standardization (ISO) Quality Management System

There are various set of standards published by International Organization for Standardization viz., ISO 9000 series, ISO 9001 series, ISO 9004 series for the quality assurance. ISO 9001:2008 sets out the criteria for Quality Management system and is the only standard in the ISO 9000-Quality Management family that can be certified to. It has been in place for over a decade and is used by companies as a method of controlling their quality [6].

Management System Certification –Bureau of Indian Standards (BIS)

Bureau of Indian Standards also provides certification against IS/ISO 9001:2008 under its Management Systems Certification activity. BIS is the National Standards Body of India and represents India in ISO. It also provides certification against IS/ISO 9001:2000 under its Management Systems Certification activity. The scheme was launched in 1991 covering a wide range of industry as well as service sectors including food and pharmaceuticals [7].

Product Certification Scheme: This Scheme of BIS aims at providing Third Party Guarantee of quality, safety and

reliability of products to the ultimate customer. Presence of ISI certification mark known as Standard Mark on a product is an assurance of conformity to the specifications. The conformity is ensured by regular surveillance of the licensee's performance by surprise inspections and testing of samples, drawn both from the market and factory [9].

World Health Organization (Who) Certification Scheme for the Quality of Pharmaceuticals Moving in International Commerce

For the assurance about the status and quality of pharmaceutical products, requirements for “Good Practices in Manufacture and quality control of drugs (GMP)” and “WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce” were adopted by World Health Assembly in 1969, in resolution WHA 22.50 [8]. Under the provisions of this Scheme, three types of certificates can be requested: Certificate of Pharmaceutical Product (Product Certificate) which is a confidential document and is issued by the exporting country only with the permission of applicant/product license holder.

Statement of Licensing Status of Pharmaceutical Product which assures that a license has been granted for the product for use in exporting country.

Batch Certificate which is issued by the manufacturer of the drug product. In case of some biological products, it is issued by the competent authority of the exporting country [10].

Good Manufacturing Practices (GMP) Certification






The Good Manufacturing Practice (GMP) is a system that assures quality by ensuring that the product is being manufactured according to the quality standards. The first International Standards for GMP were developed by the World Health Organization (WHO) during 1967-69. In India, statutory status was given to GMP in 1988 and was incorporated as Schedule ‘M’ under Drugs and Cosmetics Rules 1945 but implemented only in 2005 [11].

WHO GMP covers all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. Many countries have

Table 3: AYUSH Logos under Voluntary Certification Scheme for AYUSH Products

S.No.	Name of the Mark	Logo
1	AYUSH Standard Mark	
2	AYUSH Premium Mark	

Table 4: Halal Logos in Different Countries

S.No.	Country	Logo
1	India	
2	South East Asia Region	
3	Singapore	
4	Australia	
5	Canada	

formulated their own requirements for GMP based on WHO GMP [12].

Certification Schemes and Marks for Food: Food market has experienced a boom in both the supply and demand of processed and packaged foods in the recent past. Therefore it becomes essential that the consumers are delivered safe and quality products. Though, the product quality systems guarantee the product quality but safety being credence attribute, different certification schemes are implemented at national and international levels to ensure the safety of the products [13]. Various certification schemes and marks for food products are as follows:

Organic Certification: There is a worldwide demand for organic food and people want to eat healthy food grown without pesticides and fertilizers. To gain the confidence that the food produced is free from pesticides and fertilizers and grown using natural and organic manure, there exists various “Organic Certifications” for producers of organic food and agricultural products. It is pertinent to inform that one cannot use the term organic legally without getting certification. Organic certification is mandatory all over the world and each country has its different organic logo which it permits to put on the label after issuing the certification (Table 1). The Organic Certifications for food are as follows:

USDA Organic: US Department of Agriculture has defined four organic labeling categories under which the organic product is certified. The labeling categories 100% organic, organic (at least 95% organic ingredients) must display the organic seal and certifying agent’s name and address on the product label. The category ‘made with organic ingredients’ (not less than 70% organic ingredients) must display the logo of the certifying agent but not the organic seal. According to this standard, products made with less than 70% of organic content may not display either the seal or the certifying agent’s name and address [14].

Organic Certification Canada: All the agricultural products represented as organic are legally required to be certified under the organic certification program of Canada, whether it may be for the import, export or marketing with in the territory of the country. It is also essential that the certified products must bear the federal organic logo too [15].

Organic Certification in Europe: The organic legislation in Europe came into existence after the implementation of EU-Eco Regulation 1992 and the certification functions are performed on the national level, for example, Soil Association (UK), AB-agriculture biologique, Agrocerc and Ecocert (France), Association sans but lucrative

(ASBL) (Belgium). In 2002, European Commission launched a European wide organic label and in 2009 a new organic logo was designed with an objective to remove the translation problems due to different languages in different member states and thus no words are presented on the label. Organic label is mandatory for the organic food and for a transition period both national and new organic logo are allowed to be used on the organic food products [16]. NASSA Australia: NASSA is a food certification body and a product can be labeled as “organic” only if it contains 95% of the ingredients certified as organic and if 70% of the constituents are organic then “made with organic” label can be used [14].

India Organic: India Organic is a trademark owned by Government of India. A license is granted under National Standards for Organic Production (NSOP) to use the logo. Agricultural and Processed Food Products Export Development Authority (APEDA) accredits the certification bodies as per the accreditation programme involved in the National Programme for Organic Production (NPOP) implemented by Government of India. The NPOP conformity assessment procedures of accreditation are recognized by European Commission, Switzerland and US as equivalent to their country standards. Therefore, the certified organic products marked with India Organic logo are accepted by the importing countries [17].

Mandatory Food Certifications in India: The mandatory food certifications in India are ‘FPO’ certification for processed fruit products, ‘AGMARK’ for Agricultural products and Vegetarian (green dot in a green square) and Non-vegetarian mark (brown dot in a brown square). All these marks are enlisted in Table 2.

Fruits Product Order (FPO) Mark: FPO (Fruits Product Order) is a mandatory mark in India for all processed fruit products. It is issued by Ministry of Food Processing Industries, Govt. of India and ensures quality and safety of the product by ensuring that the product is manufactured in a food safe environment [18].

AGMARK: AGMARK is a mandatory mark for agricultural products marketed in India. It is a statutory mark and is enforced legally under Agricultural Produce (Grading and Marking) Act, 1937. Certifying agency is Directorate of Marketing and Inspection, Govt. of India and covers different commodities like pulses, cereals, semi processed food products, fruits and Vegetables etc [19].

Vegetarian and Non-Vegetarian mark: Vegetarian and Non-vegetarian mark is mandatory in India for packed food products. It is required to clearly demarcate between vegetarian and non-vegetarian products. Green dot symbolizes completely vegetarian products and non-vegetarian products are marked with a brown dot [20].

Voluntary Certification Scheme for AYUSH Products
AYUSH products are regulated under Drugs and Cosmetics Act, 1940. Under this Act, the Department of Ayurveda, Yoga and Naturopathy, Unani, Sidha and Homeopathy (AYUSH) has introduced a scheme “Voluntary Certification Scheme for AYUSH Products” in collaboration with Quality Council of India (QCI) in which Department of AYUSH shall be the Scheme owner and

QCI will manage the scheme on behalf of Department of AYUSH. National Accreditation Board for Certification Bodies (NABCB) accredits the certifying bodies which further certify the manufacturing units. The manufacturing units meeting the standards are allowed to use the relevant AYUSH mark. This scheme is available for herbal products only. Based on the criteria of certifications, there are two types of marks (Table 3) available under this scheme-

AYUSH Standard Mark: It is based on the compliance to the domestic regulatory requirements i.e. the regulatory requirements prescribed in Drugs and Cosmetics Act 1940.
AYUSH Premium Mark

It is based on:

- GMP requirements Based on WHO Guidelines and
- Compliance to the regulatory requirements of the importing country provided they are more stringent than the former criteria [21].

Halal Certification for Food And Drugs: Halal is an Arabic word mentioned in Quran, the holy book of Muslims, which means lawful or permitted by Allah in the Muslim law Shariah [22]. The products considered as Halal are Milk (from cows, buffalos, sheep, camels, and goats), Honey, Fish, fresh or naturally frozen vegetables, fresh or dried fruits, legumes, grains, plants which are not intoxicant, animals such as sheep, goats, cows but they must be *Zabiha* i.e., slaughtered according to Islamic rites [23]. Opposite of Halal is Haram which means unlawful or prohibited. Pork, alcohol, blood, carcasses of dead animals is explicitly forbidden from Halal certification. Many things can be easily identified as Halal or Haram. However, there are certain things which are difficult to classify because of the ingredients they contain, these are referred as *Mashbooh* i.e., doubtful. For example, food additives such as gelatin, enzymes, emulsifiers, etc can either have animals as their source of origin or plants. If the source is from animal, it should be *Zabiha*. The ingredients which are from animal origin or are produced with the aid of some animal material and are not in accordance with Shariah law must be avoided [24]. Halal certification is not limited to food products; it also covers all matters of daily life such as non-alcohol beverage, raw materials needed in food processing, traditional herbal products, cosmetics and personal care products, pharmaceutical and health care products etc [25]. Halal certification for medicines is as important as for food products because there are many drug products available in the market which contain ingredients like gelatin, alcohol, porcine etc. The origin of these ingredients in the products is always enigmatic to the patients especially from the Muslim population and usually the patient is unaware of what they are purchasing is Halal or Haram. Therefore, Halal certification of medicines is of great importance not only in differentiating between Halal and Haram products but also in ensuring the permissible consumption of the drugs [26]. Halal certification by a competent authority assures the consumer that the product is manufactured or produced according to Shariah law and has not in the course of preparation, processing or storage been in contact with or close proximity to any food that

fails to satisfy with the Islamic law. Halal deals with good quality, safe, nutritive and hygienic product, thus are not only accepted domestically but also have a worldwide demand. It is an important marketing tool for markets that permit only Halal products especially in Muslim countries. Halal product are not only preferred by Muslims but by non-Muslim consumers too. Muslim consumers have a great confidence while purchasing these products because certification is recognition that the products meet the rigorous standards in production and hygiene and are permissible under Islamic law [27]. Products are certified as “Halal” by different certification agencies in different countries and Halal logos in some countries are tabulated in Table 4.

CONCLUSION

Certification from a competent authority builds consumer confidence and clears all suspicions and doubts about the product. It is a reliable testimony to state that the product has confirmed to the established standards. Thus, we can conclude that certification of the products assures the consumers about the safety and quality of the product they are using. Besides the quality and safety, consumers are also concerned about the performance of the product and are also willing to buy the products which are produced in an environmentally and socially responsible way. Overall, the certification marks have a positive impact on the consumer psyche. The work has brought to the fore the existence, importance and need of different types of certifications that will certify the product quality and safety so as the consumer could believe in what they are paying for is safe and effective.

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