### Review Article

# Legislations and Standards for Functional Livestock Products in India: An overview

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## Abstract

Potential health benefits and their scientific evidence have been described in india, and to name a few include: calcium, probiotics, whey proteins and whey peptides, from dairy products; n-3 fatty acids, from fish; conjugated linoleic acid, from some meat ; sphingolipids, Lutein and Zeaxanthin from eggs; and, the conditionally-essential nutrients L-carnitine, coenzyme Q10,  $\alpha$ -lipoic acid, choline and taurine, widely diffused in animal products. There are scientific evidences of functional foods which support the observation that functional foods from animal sources enhance human health. This over-view will lucidly place the status of functional foods in the present context in India.

Keywords: Livestock Products; Functional Food.

### Introduction

Functional foods are foods that, by virtue of their physiologically active components, provide health benefits beyond basic nutrition by mainly increasing disease refractoriness through enhancement of immunity. Besides plant origin, there are also a number of physiologically active components in animal products that need attention for their potential role in health promotion.

It is very necessary to define and categorize these new group of functional foods which would require a different approach from legislation angle and India has also recognized the importance of the issue. Accordingly we are also evolving to regulate the functional food among others in the broad food category. The effort is onerous as many foods are difficult to be put exclusively in one category as functional benefits often overlap..

Categorization and Early Definitions of Functional Foods

In general, a large number of food products can be defined as functional foods, *i.e.* foods containing specific nutrients and/ or non-nutrients, and affecting human health positively, over what is traditionally known as nutritional effects. In fact, it is very difficult to have a precise and universally accepted definition of these foods. Consequently, it has been suggested to understand the term "a functional food" as a new idea, rather than a defined product [Bellisle *et al.*, 1998; Diplock *et al.*, 1999; Roberfroid, 2000, 2002].

Accordingly, an ideal functional food was considered to be

- 1. A conventional or everyday food;
- 2. Consumed as a part of the conventional diet;
- 3. Composed of naturally occurring components;
- 4. Enhancing target function(s) beyond its nutritive value;
- 5. Reducing the risk of disease, and
- 6. Having sound, scientifically-based and verified claims.

Further, in a more practical way, a functional food is defined as:

- 1. Natural food in which one of the components (nutrient or non-nutrient) has been naturally enhanced through special growing conditions;
- 2. Food to which a component has been added to provide benefits (*e.g.* the addition of selected probiotic bacteria to improve gut health);
- 3. Food from which a component has been removed (*e.g.* the reduction of saturated fatty acids);
- 4. Food in which the nature of one or more components has been modified (*e.g.* protein hydrolysates in infant formulas);
- 5. Food in which the bioavailability of one or more components has been increased, and
- 6. Any combination of the above.

The above characteristics tried to cover all major features of functional foods and were meant to set guidelines for research and development in the field of modern human nutrition. However, with recent advent of food technology there are new food groups like neutraceuticals, foods containing prebiotics and probiotics components, novel foods, foods for special dietary purpose etc.

The designation of functional foods was first introduced in Japan, in the 1980s, and refers to processed foods containing ingredients that aid specific bodily functions in addition to being nutritious. Eventually USA and Europe also started the process of recognising legally the functional foods category. The definitions of functional foods by different agencies ranged widely as follows:

- Foods that provide health benefits beyond basic nutrition
- 2. Foods that, by virtue of physiologically active components, provide health benefits beyond basic nutrition.

3. Those in which the concentrations of one or more ingredients have been manipulated or modified to enhance their contribution to a healthful diet

According to the wide definitions, unmodified whole foods such as fish and beef represent the simplest example of a functional food, since they are rich in such physiologically active components as n-3 fatty acids and conjugated linoleic acid, respectively. Modified foods, namely those that have been enhanced with physiologically active components, from plant (phytochemicals) or animal (zoochemicals) sources, also fall within the realm of functional foods. In addition, food biotechnology is providing a range of new venues for functional food development. To avoid confusion, the emerging food spectrum is very wide but functional foods is still preferred by consumers over other commonly used terms such as neutraceuticals or designer foods. However, now public awareness about other food categories have to be created to avoid any confusion.

Production of Functional Foods from Animal Sources

Evidences support those foods from animal sources containing physiologically active components which possibly enhance human health (Prates and Mateus, 2002). Moreover diet is only one component of an overall lifestyle that can have an impact on health, other components which include smoking, physical activity and stress (Hasler, 1998). The field of functional foods, however, is still evolving. It is observed that claims about health benefits of functional foods must be based on sound scientific criteria (Clydesdale, 1997). It is also noted that research into functional foods will not advance public health unless the benefits of the foods are effectively communicated to the consumer.

The procedures implemented in the production of functional foods of animal origin should be based on the scientifically verified new knowledge comprising the entire food chain. Possible physiological and psychological effects of such foods on humans should be given due attention. Among the functional foods of animal origin the crucial role is played by milk products fermented with probiotic bacteria. Due to health concerns, the strategies for achieving healthier meat and meat products involve modification at the farm level and manipulation of meat raw materials. Modification at farm level includes genetic selection, diets and feeding levels and animal diet supplementation. These procedures provide changes in such meat constituents as protein, fat content, fatty acid composition and antioxidants content, e.g. vitamin E and selenium level. Most

desirable modification of meat composition includes a higher percentage of unsaturated fatty acids, especially n-3 fatty acids, including improvement of n-6: n-3 ratio, PUFA: SFA ratio and reduction in fattiness. The recent trend is also promoting the health benefits of vitamins, minerals, and bioactive chemicals already present in meat, such as Lcarnitine, taurine, creatine, choline or antioxidants, such as ubiquinone and histidyl dipeptides.

An interesting example of careful modification into functional food is with fatty acids, in particular n-3 unsaturated acids, biologically active molecules characterised by a series positive effects in the prevention and improvement of both human and animal health. Though human genome did not change since the Palaeolithic period, nutritional habits and way of life of modern people have changed significantly and subsequently led to some phenotypic changes leading to certain chronic degenerative diseases. One of the strategies for increasing the intake of n-3 unsaturated fatty acids include the increase of content of these fatty acids in feed fed to farm animals or in rearing of animals of more favourable genotype. Irrespective of the method used for increasing the intake of advantageous fatty acids, care should always be taken about the animal welfare and health, because of different basic needs of animals under stress for individual nutritive components.

## History of Food Regulations in India

India is the world's second largest producers of fruits, vegetables and animal food, but only a small amount of perishable products are processed at approximately 2-5% across various food groups in comparison to developed countries with upto 80% processing. It is observed that barriers to growth in this food sector include poor infrastructure and logistic and proper food regulation.

The multiplicity of food regulation policy makers and enforcement agencies prevailing in different sectors of the food industry contributed to considerable confusion among the consumers, producers and retailers and business and were counter-productive for the growth of the functional food and neutraceuticals industry.

By the mid-1990s there were a plethora of food processing sector laws and regulation including a number of of State as well as the Central / National laws some of which are as follows:

- 1. Export (Quality Control and Inspection) Act 1963
- Meat Food Products Order 1973

- 3. Prevention of Food Adulteration Act (PFA) 1954 rules (Ministry of Health and Family Welfare) with last amendments in 1986
- 4. Bureau of Indian Standards Act 1986
- 5. Environmental Protection Act 1986
- 6. Pollution Control Act 1986
- 7. Milk and Milk Products Order 1992
- 8. The Infant Milk Substitutes Feeding Bottles and Infant Food (Regulation of Production, Supply) Act 1992 and Rules 1993
- 9. Food Product Order 1995
- 10. Essential Commodities Act 1995 (Ministry of Food and Consumers Affairs)
- 11. Industrial license (Department of Industrial Policy & Promotion)

The recommendation of a unified legislation under a single food regulatory authority was suggested way back in 1998 which finally resulted in an integrated Indian Food Safety Standard Bill 2005, signed into law and the Indian Food Safety and Standards Act came into enforcement in 2006 with two main objectives of introducing a single statute relating to food and to provide for scientific development of the food processing industry.

### Dawn of a New Era in Food Safety in India

Food Safety & Standards Authority of India (FSSAI) has been set up under provisions of Food Safety and Standards Act, 2006 with mandate to inter alia lay down standards and regulate foods of livestock origin. Principles of food safety is emphasized in primary production system so that food safety concerns and traceability issues are addressed throughout entire food chain, with participation of livestock keepers and primary producers, food processors as well as marketing networks. Entire food sector is required to ensure quality, safety and suitability of food for human consumption. Livestock origin food and food products have to be free of contaminants, toxins, pathogens, pesticides and antibiotic residues, harmful additives and adulterants.

We have food legislations in name of Prevention of Food Adulteration Act, 1954, Meat Food Products Order, 1973, Milk and Milk Products Regulations, 2009 etc. subsumed under FSSA. We also have laboratory facilities for residue and microbiological analysis but use is limited to some areas. All livestock and livestock products being imported into country require import license or sanitary import permits which are issued after conducting risk analysis and examination by a Trade Investment Committee. FSSAI has been mandated by the FSS Act, 2006 for performing the following functions:

- a. Framing of Regulations to lay down the standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
- Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management systems for food businesses.
- Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.
- d. To provide scientific advice and technical support to Central and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
- e. Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
- f. Creating an information network across the country so that the public, consumers, Panchayats, etc receive rapid, reliable and objective information about food safety and issues of concern.
- g. Provide training programmes for persons who are involved or intend to get involved in food businesses.
- Contribute to the development of international technical standards for food, sanitary and phytosanitary standards.
- Promote general awareness about food safety and food standards.

### Scope of Functional Foods under FSSA

FSSAI has proposed draft regulations relating to Nutraceuticals, Functional Foods, Novel Foods and Health Supplements. These draft regulations will be finalized as soon as all the comments are received by FSSAI from all stakeholders within the stipulated time limit (sixty days from the date of publish of these draft regulations) and incorporated. After this, the final notification will be issued in the **Official Gazette of India** and the regulations shall come into force w.e.f. the subsequent 1st January or 1st July of

the year subject to a minimum 180 days from the date of final notification.

Once notified, these regulations will be called Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical purpose, Functional Foods, and Novel Food) Regulations, 2015.

The Food Industry has been asking the FSSAI for regulatory standards and these proposed guidelines are a step in the right direction. This will to a large extent remove the need for going through the product approval process. It will also help to see a higher degree of growth in the nutraceutical, supplementary and functional food industry, which is the need of the hour.

FSSAI will finalise the standard guidelines after taking into consideration the suggestions and comments of all stakeholders. Some of the main points in the proposed standards are as under:

FSSAI has defined the various categories of all such foods and has proposed that the foods may not be termed medicines. The foods have been categorised as;

- Foods containing prebiotic ingredients means foods that contain approved prebiotics and are a non-viable food component which confers a health benefit to the consumer by modulation of gut micro biota.
- 2. Foods containing Probiotic Ingredients means foods with live micro-organisms beneficial to human health, which when ingested in adequate amounts (as a single strain or as a combination of cultures) confer one or more specified/or demonstrated health benefits in human beings; and the microorganism strain used in these foods shall be deemed to possess probiotic property when it is capable of surviving passage through the digestive tract, and has the capability to adhere and proliferate in the gut and be able to confer a physiological benefit.
- 3. Foods for Special Dietary Uses (FSDU) (other than infants, and those to be taken under medical advice) (i) means and includes the foods specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain physiological or specific health conditions like low weight, obesity, diabetes, high blood pressure and foods like gluten free foods, etc and these foods may be taken without medical advice unless otherwise stated; (ii) do not include the normal foods which are merely enriched or modified with nutrients and meant for mass consumption, intended for improvement of

general health and are meant for day to day use and do not claim to be targeted to consumers with specific diseased conditions and also these not include the foods intended to replace complete diet covered under Food for Special Medical Purpose in these regulations.

- 4. Food or health supplements means the foods which are intended to supplement the normal diet of a person, and which are concentrated sources of one or more nutrients, like minerals, vitamins, proteins, mineral complexes, amino acids or enzymes, other dietary substances, plants or botanicals, substances from animal origin or other similar substances with known and established nutritional or beneficial physiological effect, and which are presented as such and are offered alone or in combination, but are not drugs as defined in the Drugs and Cosmetics Act, 1940 and the rules made thereunder.
- 5. Foods for Special Medical Purposes (FSMP) means (i) the foods intended for particular dietary uses specially processed or formulated and intended for the dietary management of patients and shall be used only under medical advice and they are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by foods for specific nutritional use, or a combination of them; (ii) include the foods specially prepared for weight reduction and intended as total replacement of normal diet.
- 6. Neutraceuticals means a naturally occurring chemical compound having a physiological benefit or provide protection against chronic disease, isolated and purified from food or nonfood source and may be prepared and marketed in the food-format of granules, powder, tablet, capsule, liquid or gel and may be packed in sachet, ampoule, bottle, etc and to be taken as measured unit quantities.
- 7. Novel Foods means the food that does not have a history of human consumption or has any other ingredient used in it which or the source from which it is derived does not have a history of human consumption as a food ingredient or foods or has ingredients obtained by new technologies or processes and includes the foods and food ingredients which have been produced by a new technology with innovative engineering

- processes, where the process gives rise to significant changes in the composition or structure or size of the foods or food ingredients which affect the nutritional value, metabolism or level of undesirable substances and not apply to any reformulation of food products produced from the existing food ingredients by altering the composition, percentage or amounts of food ingredients and additives.
- 8. Specialty Foods containing ingredients based on Ayurveda, Unani and Siddha and Traditional Health Systems of India means the foods which are shown to be safe by science based evidence and health uses referred in the authoritative texts (books of Schedule I of the Drugs and Cosmetic Act, 1940) and other Standard texts (History of evidence based use and not for curative purposes).

Besides defining the foods, FSSAI has proposed that all such foods are required to be based on sound medical and nutritional evidence backed by science. The foods may not contain any steroids and psychotropic ingredients. If the nutraceuticals contain vitamins and minerals, the quantity of the nutrients will not exceed the Recommended Daily Allowance for Indians as laid down by the Indian Council of Medical Research. The RDA is also proposed for ingredients like cow's milk, buffalo's milk, camel's milk, ghee, curd, butter, honey, gold, gold foil, silver, pearl in ayurveda, siddha and unani products,

Detailed labelling requirements have been proposed for each category of food. However, Food Business Operators (FBOs) will need to follow the packaging and labelling requirements as laid down under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011. They will also clearly mention on the label the target consumer group the food is meant for and what disease or physiological condition they address. The leaflets and all advertising will provide full and sufficient information on the nature and purpose of the foods as well as precautions if required.

The foods must also mention an upper safe level of ingredients. According to the category the labels must mention what category of food it is. For example every package of Health Supplement shall be labelled 'FOOD or HEALTH SUPPLEMENT' in addition the words 'NOT FOR MEDICINAL USE' shall be prominently written on the label. Neutraceuticals should have the term NEUTRACEUTICAL on every package and Probiotic foods will mention 'PROBIOTIC FOOD" and all categories of foods must mention that "This product is not intended to diagnose, treat, cure or prevent any disease".

On the other hand Novel Foods and ingredients used in *Ayush* foods that are not mentioned in regulations will have to go through a product approval process. The FBOs manufacturing these foods will have to furnish details about the product, ingredients used, technology and production process involved and proposed claim or declarations to be made on the label along with sufficient scientific data and documents related to safety and efficacy of the food.

# An Illustration of Neutraceuticals as Given in the Draft Chapter -IV is given below

### **Essential Composition**

The Nutraceuticals may be extracted, purified and concentrated from food or non-food source plants, microbes or animals that have a history of safe use. The Nutraceuticals may also be extracted and purified from non-food sources e.g. Amino acids and their derivatives may be prepared by bacteria grown in fermentation systems. The Neutraceuticals may contain the substances from animal origin as listed in Schedule VI which include Cow's milk, Buffalo's milk, Goat's milk, Sheep's milk, Camel's milk, curd, butter milk, clarified butter and honey.

As for a Neutraceuticals which do not have a history of safe usage in India, but such safety has been established in other countries, it may be manufactured or sold in India only after taking prior approval from the Food Authority. Application for such approval to the Food Authority shall provide documented safe history of usage of at least ten years in India or thirty years in the country of origin. The Food Authority may enlist specific neutraceuticals as approved from time to time after undertaking proper scientific evaluation.

The purity criteria for the neutraceuticals used shall be as determined and notified by the Food Authority from time to time for each of the neutraceuticals specified in the relevant Schedules and in case such standards are not prescribed, the purity criteria generally accepted by pharmacopoeias like Indian Pharmacopoeia (IP) or British Pharmacopoeia (BP) or United States Pharmacopoeia (USP) or international bodies such as CODEX Alimentarius may be referred or adopted by the Food Authority.

## Labelling

1. Labelling of Nutraceuticals shall comply with the packaging and labelling requirements as laid

- down under Food Safety and Standards (Packaging and Labelling) Regulations, 2011. No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import any package or container containing any nutraceutical, if the package or container does not bear a label containing all the particulars required by these regulations.
- 2. The labelling, presentation and advertising shall not attribute the property of preventing, treating or curing a human disease to nutraceuticals or refer to such properties and the statements relating to structure or function or for the general well-being of the body are allowed as long as they are truthful and are also supported by generally accepted scientific data and the product shall bear a statement, "This product is not intended to diagnose, treat, cure or prevent any disease".
- Every package of food containing nutraceuticals shall carry the following information on the label, namely:-
- a. The words "Nutraceutical";
- b. The common name of the nutraceutical;
- c. The amount of the active nutraceutical in the product that either has a nutritional or physiological effect where it is appropriate the quantity of nutrients shall be expressed in terms of percentages of the relevant Recommended Daily Allowances as prescribed in India by the Indian Council of Medical Research even when it is present along with a nutraceutical as an adjunct and shall bear a warning "not to exceed the stated recommended daily dose";
- d. The term "Recommended usage" shall be used on the label;
- e. Recommended usage including information concerning excessive intake of the product shall be provided on the label (e.g. Oleic acid contributes to the normal growth of fetus, but does not improve the growth of fetus with excessive intake);
- f. The term 'Not For Medicinal Use' shall be prominently written on the label;
- g. A warning in cases where a danger may exist with excess consumption;
- A warning or any other precautions to be taken while consuming, known side effects if any, contraindications and product-drug interactions, as applicable;
- i. A statement to the effect that the products shall be stored out of the reach of children;
- . The letters and numerals in every word or

statement required to be printed on the label under items (a), (b), (e) and (g) above shall be of minimum 3 mm font size.

Use of Additives in Nutraceutical formulations. -The Additives given in Schedule VIII (a) and VIII (e) of these regulations shall be permitted for use in Food Supplements.

Contaminants, Toxins and Residues.- The product shall conform to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011, as amended from time to time.

### Claims

- 1. Nutritional Claim. It shall consist of the 'Nutrient content' claim and is governed by the nutritional supplements requirements described earlier.
- 2. Health claims
- Health claim means any representation that states, suggests, or implies that a relationship exists between the constituent of that Neutraceutical and health.
- A health claim has two essential components, namely:-
- Neutraceutical ingredients; and
- A health related benefits.
- The health claims may include the following types, but not limited to- 10
- a. Nutrient function claims;
- b. Enhanced function claims;
- c. Disease risk reduction claims;
- d. Health maintenance claims;
- Immunity claims Increased Resistance (excluding vaccines);
- f. Enhanced healthy ageing; and
- Nutrient led claims excluding enhanced function or disease reduction claims.

The other benefits that are not drug claims, may be allowed subject to pre-approval by Food Safety and Standards Authority of India. The Health claims must be commensurate with adequate level of documentation with valid evidence made available for review and approval by the Food Authority. The Nutrient led but inclusive of enhanced function claims and disease risk reduction claims as given

- 1. The claims shall only be nutrient led;
- 2. The claims shall be based on scientific literature adequate substantiation needed;

- 3. The claims shall be substantiated with available literature including official traditional texts plus post market data or consumer studies or cohort or retroactiveor trohoc studies based on eating pattern and health benefits, epidemiological (Indian) data, seen from well documented data;
- 4. The consensual, congruent and concurrent validity studies may be considered;
- 5. The health promotive and disease risk reduction claims shall be made only if based on evidence from literature and human data of efficacy and safety of the nutrient;
- 6. The controlled clinical trials shall not be the only options for efficacy and safety data, Nutraepidemiology also may needs to be encouraged;
- 7. The qualified structure function claims for specific organ or function which are comprehensible to consumer shall be permitted;
- 8. The implied cures of disease claims such as e.g. 'Prevents bone fragility in post menopausal women shall not be allowed:
- 9. The implied cures for disease claims via the name of the product (Example: Cancer Cure) or through pictures, vignettes or symbols (Example: ECG tracing, lipid profiles) shall not be allowed;
- 10. The structure-function claims, the case-to-case basis consumer information for specific age or gender or vulnerable population shall be given for the product;
- 11. The Food Authority may periodically review or revise the positive claims and safety guidelines or principles depending on new scientific knowledge emerging and request from stakeholders, based on recommendation of the expert body as above who may be requested to review such cases or requests from time to time.
- 12. Health claims which are product led shall be notified to the Food Authority by the manufacturer or marketer of the nutraceutical before putting the same in the market by submitting relevant documents along with a copy of the label.

Role of Department of Animal Husbandry, Dairying & Fisheries to Ensure Animal-Origin Food Safety

- A. The Prevention & Control of Infectious and Contagious Disease in Animals Act, 2009 to regulate disease transmission from one state to other with the objectives
- a. To prevent spread of economically important infectious and contagious diseases from one part of the country to another.

- b. To establish "Controlled" and "Eradicated areas" within the country in order to reduce economic losses on account of major economically important infectious and contagious diseases of livestock.
- c. To control animal diseases of public health significance on a national basis and promote import and export of animals and animal products by meeting India's international obligations.
- B. Indian Veterinary Council Act, 1984 regulates Veterinary Practice and Education.
- C. Importation of Livestock and Livestock products are regulated by the Livestock Importation Act, 1898 (Act No. 9 of 1898) as amended by the Livestock Importation (Amendment) Act, 2001 (28 of 2001)

### Risk Analysis of Imported Livestock Products

After removal of quantitative restrictions on various livestock products, the Department amended Livestock Importation Act, 1898 bringing all livestock products under its purview for purpose of regulating their imports. Accordingly, Notifications No.655 (E) dated 07.07.2001 for livestock products, No. 1043 (E) dated 16.10.2001 for fishery products and No.1175 (E) dated 27.11.2001 for Grand Parent Stock of poultry were issued making it mandatory to import all livestock products and Grand Parent Stock of Poultry against Sanitary Import Permit (SIP). On 28.03.2008 vide Notification No.794 (E), Department has further amended Notification No.655 (E) dated 07.07.2001 whereby it has categorized livestock products requiring Sanitary Import Permit (SIP), products that may be cleared on basis of 'No Objection' from Animal Quarantine and Certification Services and products which require neither SIP nor No Objection. This has been done based on the risk analysis of these products. The SIP is issued after conducting a risk analysis on basis of disease situation of exporting country vis-à-vis disease situation of this country.

Department of Animal Husbandry, Dairying & Fisheries processes proposals for import/ export/ manufacturing/ marketing of drugs and biologicals received from various State governments/ farms/ organizations. After consideration of proposals by a Committee on Trade & Investment Matters, Department's views are communicated to Directorate General of Foreign Trade (DGFT)/ Drugs Controller of India (DCI) for issue of necessary import license.

# Compartmentalization, Disease Free Zones and Traceability

In OIE Terrestrial Animal Health Code, compartmentalization refers to one or more establishments under a common biosecurity management system containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for purpose of international trade.

Efforts will be made to make country free from economically important transmissible diseases. Since Rinderpest, has already been eradicated from India, focus will be now on control and eradication of Foot and Mouth Disease (FMD), Pestes des Petites Ruminants (PPR) and other diseases having major impact on productivity. Foot and Mouth Disease Free Zones are in the process of being created in areas with export potential. Effort for prevention and control of various other bacterial, viral and parasitic diseases of livestock and poultry are being strengthened.

Animal health and human health are closely interlinked - more than sixty percent of the pathogens that cause diseases in humans originate from domestic or wild animals. In addition, both animals and humans are affected by, and affect, the environment in which they exist. Zoonotic pathogens may be transmitted to humans via food, through direct contact between animals and humans, or by other routes. Zoonoses control is getting momentum in country due to increased public awareness, availability of data on zoonoses, inter-sectoral collaboration and coordination among national authorities responsible for public health and animal health programmes and activities at different levels, especially after AI has opened its fangs in various SEA countries, (although, some of the States are poor on this account). World Health Organisation is actively involved in strengthening of programmes/ activities on zoonotic diseases, particularly Rabies, Japanese encephalitis, Leptospirosis, Brucellosis, Anthrax and Plague. Avian influenza has become thrust area for country, including international organizations like WHO, World Bank, Food and Agriculture Organization (FAO) of United Nations, Office International des Epizooties (OIE) etc.

# Agreement on Sanitary and Phytosanitary (SPS) Measures

India is one of the WTO members and has signed the SPS Agreement. This Agreement concerns application of sanitary and phytosanitary measures

- in other words food safety and animal and plant health regulations. For purposes of SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied:

- 1. To protect human or animal life from risks arising from additives, contaminants, toxins or diseasecausing organisms in their food;
- 2. To protect human life from plant- or animalcarried diseases;
- 3. To protect animal or plant life from pests, diseases, or disease-causing organisms;
- 4. To prevent or limit other damage to a country from entry, establishment or spread of pests.

India is a member of WTO and is following SPS measures as per guidelines. Department of Animal Husbandry, Dairying & Fisheries, Government of India is also designated as an enquiry point for SPS with respect to Animal Health and related issues.

# Way Forward

In order to improve the functional and designer livestock products, attempts can be made to develop strains of starter cultures capable of enhanced antichlolestermic characteristics, enhanced anticarcinogenic attributes, increased antagonistic influence on enterpathogenic microorganism. There is a great deal of interest in the development of new and improved strains, using modern techniques of molecular biology viz. plasmid transfer, transduction protoplast fusion, cloning and CRISPR technology for gene manipulation.

Plasmid biology of lactic acid bacteria have opened new vistas for exploring possibilities for using recombinant DNA technology and genetic engineering to improve the nutritional or therapeutic value of these products. A complete phage resistant strain can be achieved by incorporating plasmid which is inhibitory for phage absorption, penetration and DNA metabolism. Genetically engineered strains can play a vital role in manufacture of tailor made high quality fermented livestock products. Cloning of genes from lactic acid bacteria could be carried out in food grade strains of *E.coli* for which vectors & transformation systems are available. A detailed restriction endonuclease map of the citrate plasmid from Streptococcus lactis sub sp diacetylactis have been produced and various parts of molecules are cloned to define citrate permeate genes for production of diacetyl.

There is a dire need to develop safety standards for the entire range of dietary supplements and nutraceuticals that are currently not under the regulatory classification of either drugs or foods. Domestic and multinational companies are looking for a share in the projected \$500 million Indian nutraceuticals market, which is growing at 40% annually [Jacobs K, 2008]. The United States and Europe are slated to be the emerging markets for nutraceutical exports from India, because an existing large market base for the neutraceuticals, novel and speciality foods is already in place in these places and consumers are looking for better and healthier options to prevent lifestyle-related diseases [Mehta AG, 2008]. However, most of the large companies have not ventured into neutraceuticals or dietary supplements due to regulatory confusion and lack of adequate awareness. Thus, with adequate awareness creation there is a huge scope for functional food production in India.

#### References

- Bellisle F., Diplock A.T., Hornstra G., Kolezko B., Roberfroid M.B., Salminen S. and Saris W.H.M. Functional food science in Europe. Brit. J. Nutr., 1998;80 (Suppl. 1):1-193.
- Clydesdale, F.M. A proposal for the establishment of scientific criteria for health claims for functional foods, Nutr. Rev. 1997;55(12):413-422.
- Diplock A.T., Aggett P. J., Ashwell M., Bornet F., Fern E.B., Roberfroid M.B. Scientific concepts of functional foods in Europe: Consensus document. Brit. J. Nutr., 1999;81(Supl. 1):1-27.
- Government of India. Ministry of Health & Family Welfare: Draft of the Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical purpose, Functional Foods, and Novel Food) Regulations, 2015. http://fssai.gov.in/Portals/0/ Pdf/Draft\_Regulation\_on\_Nutraceuticals\_WTO\_ 23\_07\_2015.pdf.
- Gupta S. and Savalia C.V. Application of biotechnology to improve livestock products, Vet. World, 2012;5(10):634-638.
- Hasler, C.M. (1998): Functional foods: Their role in disease prevention and health promotion, Food Technology 1998;52(2):57-62.
- Jacobs K. INDIA: Nutraceutical Market sees 40% growth, Just- Food. In book: Nutraceutical and Functional Food Regulations in the United States and Around the World (Second Edition), Elsevier Academic Press., 2008 June 17; chapter 19.p.327-342.
- Keservani R. K., Sharma A.K., Ahmad F. and Baig Mirza E. In book: Nutraceutical and Functional Food Regulations in the United States and Around the World (Second Edition), Nutraceutical and Functional Food Regulations in India, Edited by Bagchi D,

- Department of Pharmacological and Pharmaceutical Sciences, University of Houston College of Pharmacy, Houston, TX, USA, Publisher: Elsevier Academic Press., Chapter 19.pp.327-342.
- Marenjak1, T. S., I. Delaš, I. Štokoviæ, N. Poljièak-Milas (2008): Production Strategy Of Functional Foods Of Animal Origin, srpanj - kolovoz br. 2008;10(4): 307-314.
- 10. Mehta AG. Untapped wealth of nutraceutical exports. The Hindu Business Line; In book: *Nutraceutical and Functional Food Regulations in the United States and Around the World* (Second Edition), Elsevier Academic Press.,2008; Chapter 189.pp.327-342.
- 11. Mestr Eprates J.A. and M.R.P. Cristina Mateus. Functional foods from animal sources and their physiologically active components Revue Méd. Vét., 2002;153(3):155-160.

- 12. Pawe M. Pisulewski, Renata B. Kostogrys. Functional Properties Of Foods Of Animal Origin And The Methods Of Their Assessment. Pol. J. Food Nutr. Sci. 2003;12/53, SI 1:65–73.
- 13. Prates, J.A.M. and C.M.R.P., Mateus (2002): Functional foods from animal sources and their physiologically active components, Revue Méd.Vét. 2002;153(3):155-160.
- 14. Roberfroid M. Concepts and strategy of functional food science: the European perspective. Am. J. Clin. Nutr., 2000;71:1660–1664.
- 15. Roberfroid M.B. *Global view on functional foods:* European perspectives. Brit. J. Nutr., 2002;88( Suppl. 2):S133–S138.
- 16. Vass N., Czegledi L, Javor A. Significance of Functional Foods of Animal Origin in Human Healt, Lucrări stiinNifice Zootehnie si Biotehnologii, 2008;41(2).