

**BHARATH COLLEGE OF SCIENCE AND MANAGEMENT  
PG AND RESEARCH DEPARTMENT OF NUTRITION AND DIETETICS**

**Subject Name: Functional food and Nutraceuticals  
Subject Code: P16FSE3  
Class: I MSc., FSMD**

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## UNIT -V

### FUNCTIONAL FOODS AND NUTRACEUTICALS

**Regulate the aspect of international and national regulatory aspect of functional foods in India**

#### **Functional Food Components**

Carotenoids  $\alpha$ -Carotene/  $\beta$ -carotene Carrots, fruits, vegetables

Lutein Green vegetables

Lycopene Tomato products

Dietary fiber Insoluble fiber

$\beta$ -Glucan Wheat bran Oats, barley Soluble fiber

Mk Psyllium Fatty acids

Long chain omega- 3 fatty acids-DHA/ EPA

Conjugated linoleic acid

Phenolics Anthocyanidins

Catechins Flavonones Flavones

Lignans Tannins

(proanthocyanidins)

Plant sterols Stanol ester

Salmon and other fish oils

Cheese, meat products

Fruits Tea Citrus Fruits/vegetables Flax, rye, vegetables

Cranberries, cranberry products, cocoa, chocolate

Corn, soy, wheat, wood oils

#### **Potential Benefits**

Neutralize free radicals, which may cause damage to cells

Reduce the risk of macular degeneration

Reduce the risk of prostate cancer Reduce risk of breast or colon cancer

Reduce risk of cardiovascular disease; protect against heart disease and some cancers; lower LDL and total cholesterol

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India has recently passed the Food Safety and Standard Act 2006, a modern integrated food law to serve as a single reference point in relation to regulation of food products including nutraceutical, dietary supplements and functional food.

**The Food Safety and Standard Act** still needs to be considerably more substantive with infrastructure and appropriate stewardship for it to match the international standards of the United States and Europe .

**Prevention:** Foods that provide health management through disease and symptom prevention fall into this category.

**Performance:** A product that provides health enhancement through improved physical and mental condition.

**Wellness:** Wellness benefits are about feeling good and finding balance.

This is a holistic approach to health care that includes the body, mind, and spirit.

**Nurturing:** Foods that can supply a sense of caring for the health and quality of life for others and the associated sense of satisfaction for the caregiver.

Marketing a product from this platform would include a focus on growth and development, aging, and healing.

**Cosmetics:** Cosmetic benefits are about looking good and enhancing self-esteem through improved physical condition and personal appearance.

## **Indian market and health**

Fast moving consumer goods companies and pharmaceutical companies are major players in the Indian nutraceutical market.

## **Regulation**

- The regulatory framework governing foods in major jurisdictions is evolving.
- Food research, product and process innovation and change in consumer behavior facilitate adaptation of food regulations.
- Increasingly, the awareness is manifested through consumption of particular foods and dietary supplements believed to contribute to good health and in some cases, to hold therapeutic value in the treatment or prevention of specific diseases.
- Many of these food products are becoming commonly known as nutraceuticals or functional foods. Nutraceuticals are products that have the characteristics of both a nutrient and a pharmaceutical.
- Taken as dietary supplements, they can modulate the symptoms of various disease conditions by providing the additional nutrients our bodies may need to maintain well-being.
- Food laws in every country are the basis of regulations of all kinds of food including health food, dietary supplements, functional food and nutraceuticals as specific guidelines/regulations are framed to regulate health food.
- Stephen DeFelice, defined “nutraceutical” as “a food or part of food that provides medical or health benefits including the prevention and treatment of disease.”

## **Overview of regulations**

- By the mid-1990s the food processing sector laws were framed in a veritable grid of regulation including a multitude of state laws as well as the following national laws: • Export (Quality Control and Inspection) Act 1963 • Solvent Extracted Oil Control Order 1967 •
- The Insecticide Act 1968 •
- Meat Food Products Order 1973 •
- Prevention of Food Adulteration Act (PFA) 1954 rules (Ministry of Health and Family Welfare) with last amendments in 1986 •
- Bureau of Indian Standards Act 1986 • Environmental Protection Act 1986 •
- Pollution Control Act 1986 •
- Milk and Milk Products Order 1992 •
- The Infant Milk Substitutes Feeding Bottles and Infant Food (Regulation of Production, Supply) Act 1992 and Rules 1993 •
- Food Product Order 1995 •
- Agriculture Produce Act •
- Essential Commodities Act 1995 (Ministry of Food and Consumers Affairs) •
- Industrial license •
- Vegetable Oil Product Control order 1998 In 1998, the Prime Minister's council on trade and industry appointed a subjective group on food and agriculture industries, which recommended a unified legislation under a single food regulatory authority.
- Public experts and members of the Standing Committee of Parliament encouraged the convergence of current 19.4
- Regulation 333 food laws with single regulatory authorities accountable for public health and food safety in India.
  
- **The Indian Food Safety and Standard Act** came into enforcement in 2006 with two main objectives: to introduce a single statute relating to food and to provide for scientific development of the food processing industry.

- Food Safety and Standard Act 2006 The Food Safety and Standard Act 2006 aims to establish a single reference point for all matters relating to Food Safety and Standards, by moving from multilevel, multidepartmental control to a single line of command.
- It incorporates the salient provisions of the Prevention of Food Adulteration Act 1954 and is based on international legislations, Instrumentalities and the Codex Alimentarius Commission [12].
- The Food Safety and Standards Act 2006 consolidates the eight laws governing the food sector and establishes the Food Safety and Standards Authority (FSSA) to regulate the sector and other allied committees.
- FSSA will be aided by several scientific panels and a central advisory committee to lay down standards for food safety.
- These standards will include specifications for ingredients, contaminants, pesticide residue, biological hazards, labels and others.
- U.S. Nutraceutical Market The US has been the largest Nutraceutical market so far and almost fully mature. Between 2012 & 2016 it grew from \$ 50 Bn to \$ 65 Bn, a compounded growth of 10% annually;
- The US market comprises of Functional Food & Beverages (65%) and Dietary Supplements (35%); Fast approaching maturity in the dietary supplements segment, while functional food and beverages are quickly catching up;
- US Consumers are extremely health conscious and demand specific ingredients in the nutraceutical products they consume, resulting in a need for customization of nutraceuticals for each target group.
- Currently, companies in the US are looking to diversify their products and are leaning more and more towards natural nutraceutical ingredients in their product offering, mainly

due to the increasing consumer demand for allnatural, non-modified functional ingredients [4] .

### **Nutrition Content Claim:**

- A nutritional claim suggests a food has beneficial nutritional properties, such as “low fat”, “no added sugar” and “high in fiber”.
- A Claim is a statement that suggests a relationship between food and health. For instance a Food can "help lower cholesterol", "help reinforce the body's natural defenses" or "enhance learning ability" Reduction of Disease Claim:
- Any claims states or implies that the consumption of dietary supplements or one of its constituents significantly reduce the risk factor in the development of human disease. Structure/Function Claim: Structure claim is a statement on label of a food or dietary supplement about how that product affects the human body structure. Regulatory

### **Requirements in India:**

- Product Evaluation: Examination of each active ingredients & additive. Various steps in the product evaluation include: Developing extracts of documents•
- Sample collection (in the presence of witnesses)• Sample dispatch to the concerned authority (different• processes for bulk package and single package) Food analysis•
- If analysis is not complete within the stipulated period of• time, further action plan by the designated officer Adjudication proceedings (holding enquiry, appeal• procedure, hearing, etc.)

### **Licenses:**

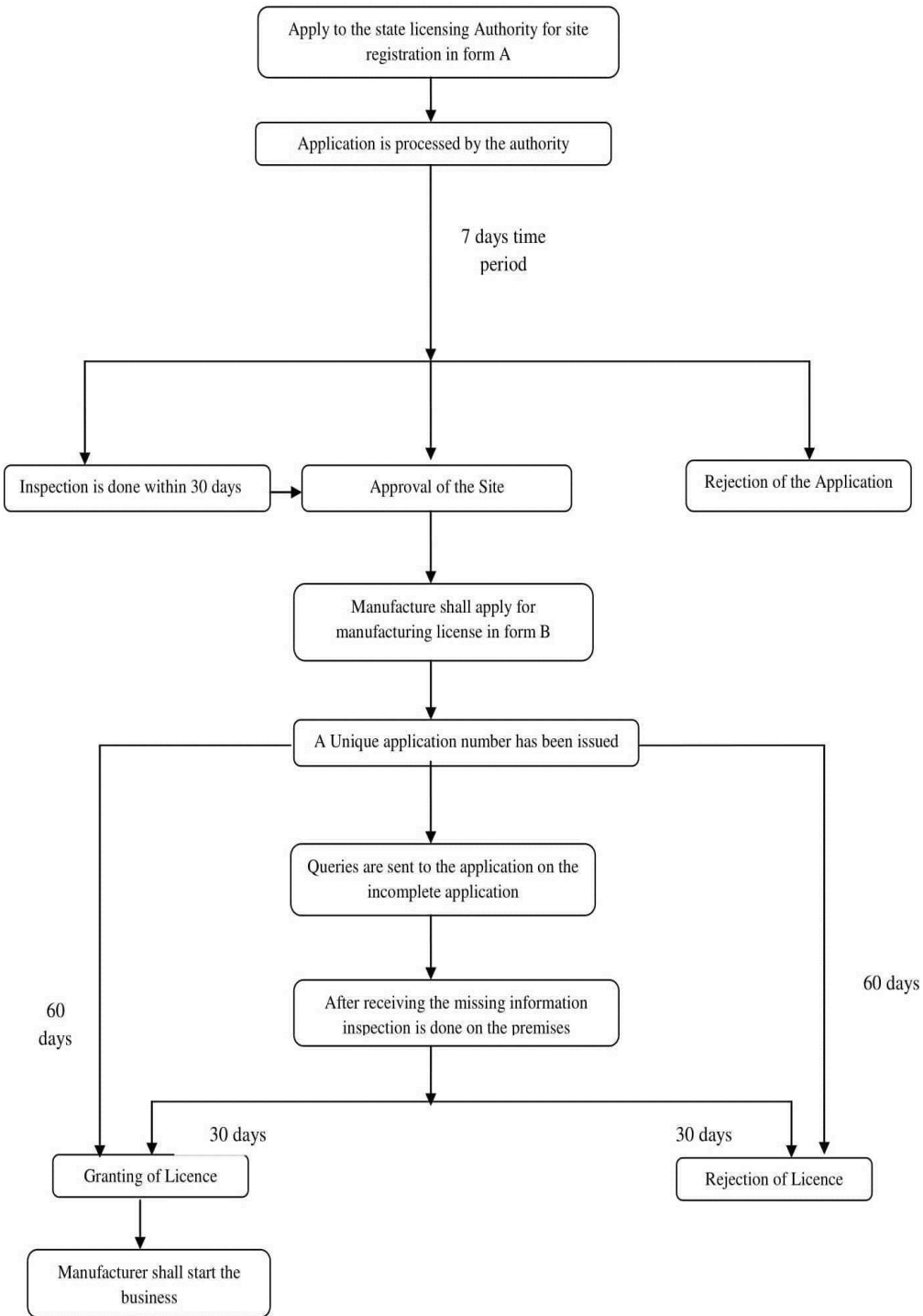
- To get Product registered in India, number of licenses (almost 4 - 5) might be required which include: Import licensing• Manufacturing licensing•

- Marketing licensing and
- Other state and national level clearances/licenses required
- from the regulatory side, which need to be taken care of before launching these products in India.

**Health and label claims: “**

- Health claims” means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health.
- This includes: India specific labeling and packaging requirements
- Packaging of the consignment composition of the consignment and approach to market the same
- Need for sample material and declaration for registration
- Label content and claim
- Structure - function claim
- Registration Process in India [8





- **Indian Council of Medical Research (ICMR)**, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest and largest medical research bodies in the world. The ICMR is funded by the Government of India through the Department of Health Research, Ministry of Health and Family Welfare.<sup>[1][2]</sup>
- ICMR's 26 national institutes address themselves to research on specific health topics like tuberculosis, leprosy, cholera and diarrhoeal diseases, viral diseases including AIDS, malaria, kala-azar, vector control, nutrition, food & drug toxicology, reproduction, immuno-haematology, oncology, medical statistics, etc.
- Its 6 regional medical research centres address themselves to regional health problems, and also aim to strengthen or generate research capabilities in different geographic areas of the country.<sup>[2]</sup>
- The council's research priorities coincide with National health priorities nutritional disorders such as control and management of communicable diseases, fertility control, maternal and child health, control of , developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; mental health research and drug research (including traditional remedies).
- These efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population.<sup>[2]</sup>

## ICMR

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- National Institute of Nutrition, Hyderabad (NIN), Hyderabad
- National Centre for Laboratory Animal Science, (NCLAS) Hyderabad
- Food and Drug Toxicology Research Centre, (FDTRC) Hyderabad
- National Animal Resource Facility for Biomedical Research, (NARF-BR) Hyderabad
- National Institute for Research in Tuberculosis (NIRT), Chennai
- National Institute of Epidemiology (NIE), Chennai

- National Institute of Cancer Prevention and Research (NICPR), Noida
- National Institute of Malaria Research (NIMR), Delhi
- Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna
- National Institute for Research in Reproductive Health (NIRRH), Mumbai
- National Institute of Virology (NIV), Pune
- National Institute of Traditional Medicine (NITM), Belagavi
- Microbial Containment Complex (MCC), Pune
- National AIDS Research Institute (NARI), Pune
- National Institute of Occupational Health, Ahmedabad
- National Institute of Pathology (NIP), Delhi
- National Institute of Medical Statistics (NIMS), Delhi
- Vector Control Research Centre (VCRC), Puducherry
- National Institute of Cholera and Enteric Diseases (NICED), Kolkata
- National Institute for Research in Tribal Health (NIRTH), Jabalpur
- National Center for Disease Informatics and Research (NCDIR), Bengaluru
- Bhopal Memorial Hospital and Research Center, (BMHRC), Bhopal
- National Institute for Research in Environmental Health (NIREH), Bhopal
- National JALMA institute for Leprosy & Other Mycobacterial Diseases, Agra
- Centre for Research in Medical Entomology (CRME), Madurai
- National Institute of Immunohaematology (NIIH), Mumbai
- Enterovirus Research Centre (ERC), Mumbai
- Genetic Research Centre, Mumbai
- National Institute for Implementation Research on Non-Communicable Diseases (NIIRNCD), Jodhpur
- Regional Medical Research Center, Port Blair
- Regional Medical Research Center, Bhubaneswar
- Regional Medical Research Centre, Dibrugarh
- ICMR Virus Unit, Kolkata
- Institute of Reproductive Medicine, Kolkata

## **Research frontiers in functional foods**

- From cancer fighters to heart boosters, the next generation of food products are far more than just tasty meals. A leading research manager provides perspective on the fast-rising trend toward functional foods and the dramatic potential it holds for western Canadian agriculture.
- The functional food and nutraceutical industry is one of the fastest-growing areas of opportunity in food production, and western Canadian agriculture is well-positioned to cash in, says Kelley Fitzpatrick, Marketing and Research Development Manager at the Richardson Centre for Functional Foods and Nutraceuticals at the University of Manitoba.
- "Interest by the general public is growing worldwide in the prospect that food and food products can promote and maintain health," says Fitzpatrick. "Currently, Canada accounts for three percent of the global market, but there's major opportunity for that to grow. The Canadian nutraceutical and functional food industry has garnered a great deal of attention in recent years from several sectors, and several crops grown in the Prairies have been identified as excellent candidates for value-added processing as functional foods."
- Current world consumption of nutraceuticals and functional foods is estimated to be between \$70 and \$250 billion annually, depending upon the product categories that are included in the statistics, she says. Predictions are that the value of the functional foods and nutraceuticals industry will expand ten-fold over the next decade, growing three-to-four times the rate of the conventional food industry.

**"It's becoming increasingly clear that people prefer to get their health benefits from the kitchen cabinet rather than the medicine cabinet," says Fitzpatrick. "This is a growing trend worldwide. The Canadian agricultural community needs to determine where we fit and where our potential lies within this trend. Once identified, we can then really push the button to develop these products and capture the full market advantage of the unique health-enhancing properties of our crops." **The new world of functional foods and nutraceuticals****

- A functional food is a food that is similar in appearance to conventional foods and is consumed as part of a usual diet, but also has demonstrated physiological benefits and/or reduces the risk of chronic disease beyond nutritional functions, says Fitzpatrick.
- "Basically, many foods could be considered functional. We're interested in those foods that have inherent health qualities or those in which we can enhance natural constituents - essentially we would like to be able to make a health claim based on scientific identification of efficacy."
- "Among specific functional food products, one of the best known is oat based Cheerios cereal, which in the U.S. carries a health claim that it can help reduce the risk of coronary disease through the consumption of soluble fibre. On the more tailored side, another high-profile product is calcium-fortified Tropicana orange juice, which markets the health benefits of added calcium."
- Similar in appeal to functional foods are nutraceuticals, she says. A nutraceutical is a product produced from foods but sold in pill, powder, potion or other medicinal form not generally associated with food, but demonstrated to have a physiological benefit or to provide protection against chronic disease.
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- "In Canada, we now have a brand new regulatory area called 'natural health products' (NHPs), which encompasses nutraceuticals," she says. "This recognizes that while nutraceuticals aren't the same as foods, they aren't the same as drugs either. They're a unique health product that deserves their own recognition."
- One example of a natural health product with potential for our producers is barley beta-glucans sold as dietary supplements. "Beta-glucans are a component of barley known to

help lower blood cholesterol. They represent significant sales in pill form in the U.S." Another example is herbs and botanicals used in numerous nutraceutical products.

### **Biomarker to indicate the efficacy of functional ingredients**

- Background
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- Introduction—biomarkers in nutrition research
  - Dietary and health biomarkers have been addressed in several recent reviews [1,2,3,4,5,6,7]. These reviews cover various applications of biomarkers in food, nutrition, and health research as well as aspects of their identification, measurement, and validation. The definition of the term “biomarker” varies considerably.
  - While definitions in these papers cover specific aspects of food intake or health effects, biomarkers are more generally defined as “chemical or biological test results in an analysed biological material related to a certain exposure, susceptibility, or biological effect” [6].
  - In the Ontobee subsection on Chemical Entities of Biological Interest (ChEBI) [8], a biomarker is defined as “A substance used as an indicator of a biological state,” clearly reflecting biomarkers as a subcategory of “indicators.”
  - “Indicators” are, in turn, defined as “anything used in a scientific experiment to indicate the presence of a substance or quality, change in a body, etc.”
  - The ChEBI ontology therefore reflects experimental science and measurement of chemical substances as prerequisites for the use of the term, “biomarker.”
  - However, in nutrition research, there is widespread use of observational studies and of markers that cannot be characterized as a substance, e.g., blood pressure, waist circumference, or a host antibody response.

- While discriminating between the terms “indicators” and “biomarkers” may be useful in some areas of research, the overlap in their definitions and use make this distinction less useful in nutrition research underlining the need for a specific ontology for nutritional science.
  - The distinction between different categories of biomarkers has been underlined in several reviews in the area. Jenab et al. [2] subdivides them into recovery, predictive, concentration, and replacement biomarkers, based on their biokinetics and intended use.
  - As already mentioned, another classification divides them into exposure, effect, and susceptibility biomarkers, thereby focusing only on their use.
  - These classifications may cause ambiguity and a unifying classification scheme may therefore be needed. This is particularly important since the discovery of new biomarkers and their validation is clearly needed to advance nutritional science as outlined in several recent reviews of this area [4, 7, 9].
  - Biomarker validation is particularly important in order to improve the quality of nutritional studies.
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- However, the reliability of a biomarker may depend on the application, biological sample, sample collection strategy (time, frequency), and study design.
  - A clear distinction of validation criteria for the different classes of biomarkers is therefore needed.
  - Excellent tools and guidance exist for producing systematic reviews and meta-analyses such as the Cochrane handbook [10]. In addition, the PRISMA Statement [11, 12] has been developed to assist researchers in conducting systematic reviews of randomized trials and interventions.

- When it comes to biomarkers used as tools for measuring food intake or assessing nutritional status, there is a need for another paradigm because several of the steps described for the current procedures do not apply.
- Also, when it comes to sharing all of this information in databases and associated online tools, there is a need to build upon several of the tools already mentioned. These include ontologies for the subject area, a classification scheme for biomarkers, validation tools, and high quality reviews of the current state of knowledge, see Fig. 1.
- As a project launched under the JPI-HDHL, the FoodBALL consortium aims to close some of these gaps through a series of reviews in this thematic issue of the journal.

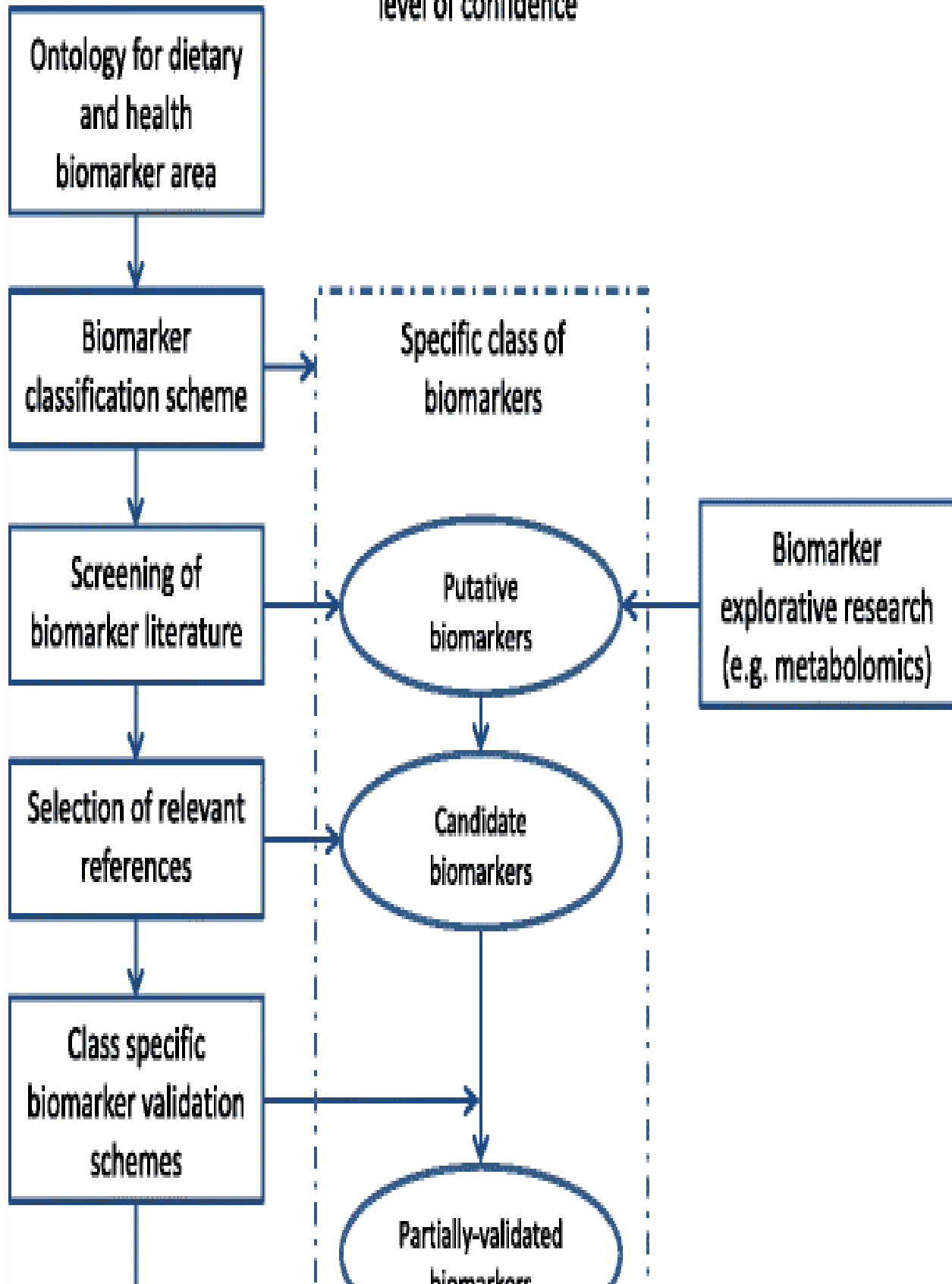




Theoretical framework

Experimental research

Terminology for biomarker  
level of confidence



Class /subclass terms (literals)	Definition and subclass terms
<ul style="list-style-type: none"> <li>▼ ● Nutrition (or nutritional science or dietetics)</li> <li>▶ ● Diet</li> <li>▼ ● Food</li> <li>▼ ● Food group</li> <li>▶ ● Food component</li> <li>▼ ● Food compound</li> <li>▼ ● Nutrient <ul style="list-style-type: none"> <li>▶ ● Essential nutrient</li> <li>▼ ● Non-nutrient <ul style="list-style-type: none"> <li>▼ ● Bioactive food compound <ul style="list-style-type: none"> <li>▶ ● Food toxicant</li> </ul> </li> </ul> </li> </ul> </li> </ul>	<p>The study of the effects of diets, foods or food components on the metabolism, health, behaviour, performance and disease prevention in humans or animals.</p> <p>The combination of foods consumed by an individual or a group within a certain time period.</p> <p>Any material or substance that can be ingested by an animal or human for nutrition</p> <p>Collection of foods with similar origin, production method, or characteristics, e.g. fruit, dairy, or alcoholic beverages. Subclasses include all the single foods within</p> <p>A subdivision or fraction of a food, defined by the production or processing of the food. Subgroups include 1) production raw materials, including ingredients and additives used to produce the food, and 2) food processing fractions (products and waste products)</p> <p>Any substance that is distributed in foods or in food components. Subclasses include nutrients and non-nutrients</p> <p>A food compound needed to maintain a living organism</p> <p>A nutrient that cannot be made by the body and must, therefore, be consumed from food</p> <p>Any food compound that is not currently defined as a nutrient</p> <p>A food compound with a documented biological activity in a defined biological system; may be a nutrient or a non-nutrient. May have beneficial health actions or be a food toxicant.</p> <p>Bioactive food compound with the main potential to cause harm to a living organism.</p>
<ul style="list-style-type: none"> <li>▼ ● Biomarker <ul style="list-style-type: none"> <li>▶ ● Exposure (intake) biomarker</li> <li>▶ ● Effect biomarker</li> <li>▶ ● Susceptibility biomarker</li> </ul> </li> </ul>	<p>An objective measurement to assess the exposure (including food intake), effect, or susceptibility of the human organism (or an animal etc.).</p> <p>An exposure (syn. intake) biomarker reflects the level of extrinsic variables that humans are exposed to, such as diets or food compounds, including nutrients and non-nutrients.</p> <p>An effect biomarker reflects the functional response of the human body to an exposure.</p> <p>Measurable indicator including genetic or acquired host factors and intrinsic factors, influencing the response of an individual to a (dietary) exposure.</p>