A Surveillance and Monitoring System for Food Safety for India

(Under Food Safety and Standards Act - 2005)

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ILSI-India

March 2007

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Introduction

International Life Sciences Institute – India (ILSI-India) had organized a Seminar on "Regulatory Systems for Risk Assessment for Food Safety for Public Health" on February 9, 2007 in New Delhi, India. The objective of this Seminar was to have expert consultation on setting up an appropriate food safety surveillance system under the recently passed Food Safety and Standards Act for ensuring availability of safe food and water and thereby promoting public health. The participants in the Seminar included experts from regulatory departments, R&D institutes, food industry from India, US, Canada, Japan, and European Union and international organizations including the Food and Agriculture Organization of the United Nations. The information generated during the Seminar was further discussed at a Roundtable held on February 10 and recommendations for "National Surveillance and Monitoring System for Food Safety" were evolved.

The Roundtable was chaired by Mr. D. H. Pai Panandiker, Chairman, ILSI-Inida. The other experts who participated included the following: Mr. Ezzeddine Boutrif, Chief, Food Quality and Standards Service, FAO – Rome; Dr. P K Seth, Former Director, Industrial Toxicology Research Centre & CEO, Biotech Park; Dr. Jai Raj Behari, Scientist F & Head – Analytical Toxicology Section, Industrial Toxicology Research Centre; Dr. K. M. Appaiah, Emeritus Scientist, Central Food Technological Research Institute; Dr. P. S. Ramanathan, Director, Gharda Institute of Science and Technology; Dr. Samuel Benrejeb Godefroy, Director – Bureau of Chemical Safety, Health Products and Food Branch, Health Canada; and Dr. Raj K. Malik, Former Chief, Food Quality and Standards Service, FAO and Ex Chairman, ILSI-India.

It may be noted that ILSI-India has focused attention on food safety in the country and organized a number of seminars, conferences and training programs and brought out publications. ILSI has special consultative status with the Food and Agriculture Organization of the United Nations and Non Governmental Organization status with the World Health Organization.

The Background

Safety of food and water is a requirement of public health. Safety refers to all those hazards which make food injurious to health. These hazards arise from improper agricultural practices, poor hygiene at all stages of the food chain, lack of preventive controls in food processing operations, misuse of chemicals, contaminated inputs, or inappropriate storage and handling. Specific concerns about food hazards are chemical and microbiological contaminants, biological toxins, pesticide residues, veterinary drug residues, and allergens.

It is important that the national Food Control System is such that the consumer is protected from unsafe food. So far, the Prevention of Food Adulteration Act prescribed food standards and also established an inspection system for marketed products. But it did not seek to identify and prevent sources of contaminants. With elongated food chain, rapidly changing technologies and greater consumer awareness, it has become necessary to modernize the Food Control System.

The National Food Control System, therefore, should be effective and comprehensive with science-based food law and regulations and an institutional structure which is active and responds to the needs of food safety management. The Central, State and local authorities have complementary and interdependent roles in the implementation of the national food safety system with the ultimate objective of protecting the consumer. In particular the System must:

- ensure that only safe and wholesome foods are marketed
- take decisions based on science
- empower authorities to detect sources of contamination and take necessary action to prevent contaminated foods from reaching the consumer
- enforce compliance by farmers, manufacturers, distributors, importers, and other stakeholders
- be transparent and promote public confidence

Until now the Prevention of Food Adulteration Act offered some safety of food articles. However, the Act did not provide a holistic approach to ensure food safety. In recognition of the need to modernize the Food Control System the Food Safety and Standards Act 2005 was passed by Parliament. The Act brings together different pieces of legislation pertaining to food safety and its control under a single law and under a single authority.

I

The New Food Control System Under Food Safety And Standards Act

The Act envisages the establishment of the Food Safety and Standards Authority of India, or Food Authority for short, with a Chairman and 22 Members representing different Ministries and Departments concerned with food safety, apart from industry, consumer organizations, farmers' organizations, retailers' organizations, scientists and technologists, and the State Governments. The Food Authority will regulate and monitor the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food

The Food Authority will be assisted by a Chief Executive Officer who, along with other officers, will be responsible for administration, draw up proposals for Food Authority and implement their decisions.

The Food Authority will set up:

(1) A Central Advisory Committee to represent interests of food industry, agriculture, consumers, food laboratories, Commissioners of Food Safety and the Chairperson of the Scientific Committee. The Chief Executive Officer will be ex-officio chairman of Central Advisory Committee.

(2) Scientific Panels consisting of independent scientific experts on food additives, pesticides and antibiotics residues, GMOs, functional foods, biological hazards, contaminants in food chain, labeling, methods of sampling and analysis, etc.

(3) A Scientific Committee consisting of chairmen of Scientific Panels and other scientists to provide scientific opinions to the Food Authority

At the State level the implementation of food safety and standards and other requirements laid down in the Act will be carried out by the Commissioner of Food Safety for the State, assisted by other officers.

The above provisions are steps in the right direction.

i.i: Requirements For An Effective Surveillance And Monitoring System

Under the Food Safety and Standards Act it is planned that the Food Authority will derive the work program from the Advisory Committee and scientific inputs from the Scientific Committee. This will enable prioritization of work and taking decisions on the basis of science. More specifically, the Food Authority will

- Set standards and limits for contaminants
- Prescribe labeling requirements
- Devise procedures
- Indicate methods of analysis
- Set out guidelines for accreditation of laboratories
- Conduct surveys
- Maintain data
- Organize training programs

A number of decisions of the Food Authority will require information and data. These decisions have to be taken with the help of natural databases of hazards in foods, testing of food for chemical and biological agents, dietary intake surveys, epidemiological surveys of consumer populations, and investigations of food borne disease outbreaks. Monitoring and surveillance data allow the identification of potential area of focus to be tabled for subsequent action by the Food Authority and the evaluation of the effectiveness of sanitary measures that have been implemented in all food safety contexts. The maximum residue levels for chemical hazards in foods are generally regarded as monitoring tools rather than health standards. ***It must be understood that monitoring or surveillance of contaminates in foods and water is a pre-requisite for monitoring risks in the population.***

At present, there are no regular programs for monitoring contaminants in food supply in the country. The Ministry of Health and Family Welfare and the Ministry of Agriculture, Government of India, have conducted occasional monitoring programs for evaluating pesticides residues, heavy metals and aflatoxin status in agricultural commodities, milk and marine products. Some evaluation of the likely intake of contaminants is possible taking daily intake of food ingredients and the content of contaminants in these ingredients by the exposed people. On the basis of this preliminary analysis, several pesticides were banned for use in agriculture and storage. However, this effort was not sufficient to provide a full picture of the country's situation, nor does it provide sufficient basis for government to make sound and long lasting measures to prevent food

contaminants from reaching the consumer. It also lacks conformity with international requirements. There is a need to develop a comprehensive and well designed national food contaminants monitoring program that takes into account the country's food safety priorities, as well as the geographic, agro climatic and population characteristics.

As a starting point, it is necessary that data currently available with research institutions like NIN, CFTRI, ITRC, ICMR, ICAR, etc. are pooled together, after proper scrutiny, to form an initial data base which can be enriched with subsequent survey results. This information may be useful to suggest science based decisions in respect of limits for contaminants, threshold limits, etc. or to initiate action at any point in the food chain which acts as a source for contamination of foods. It is however important for the food control authority that regular information (data base) is collected on the type, source(s) and extent of contaminants, etc. for use by the Scientific Committee in assessing the food safety risks.

Equally critical to the development of science based decisions adapted to the Indian context are food consumption data which need to account for the national and regional context of the population.

i.ii: International Practices: Some Examples

Regulatory agencies around the world adopt a multi-stakeholders involvement to deal with food safety matters. These stakeholders include Ministries – Agriculture, Food Processing, Health, Consumer Affairs; R & D institutions; Consumer Organizations; Analytical Laboratories – both Government and Private Sector; NGOs; Farming Community and Food Industry. The food safety committees / authority examine all aspects of chemical / microbiological contamination, conduct total diet surveys, carry out risk analysis, formulate standards and suggest appropriate action including policies. Herewith, some examples of best practices.

United Kingdom

The Ministry of Agriculture , Fisheries and Foods (MAFF) of the United Kingdom formed a Steering Group for Food Surveillance in 1971 to review food contamination problem, assess the need for analytical surveys of food and wherever necessary make arrangements to conduct the surveys for getting data on intake of individual components, including residues and contaminants and advise the MAFF and Health Ministries on action programs for ensuring that food intake of the population is safe and nutritious. The SGFS includes scientists from

academia, industry and health, agriculture and environmental departments of the Government. The Food Science Division of MAFF provides the secretariat. The SGFS sets out priorities for its work and carries out the work through specific working groups. The structure of SGFS is given in Appendix I.

Canada

The Bureau of Chemical Safety in Health Canada's Food Directorate is responsible for policy, standard setting, risk assessment, surveillance, research and evaluation activities with regard to chemicals in foods sold in Canada. The primary objective of the Bureau is to ensure that chemicals are not present in foods at levels that would lead to adverse health effects in the Canadians. Chemicals include food additives, food packaging materials and incidental additives, food allergens, food borne environmental contaminants, natural toxicants and process induced chemicals. Agro chemicals and veterinary drug residues are also of interest. Once delisted, they are considered as contaminants.

In Canada standard setting is based on current health risk assessment. Risk assessments require Canadian human exposure data for chemicals in food. Surveillance and monitoring enable to identify and investigate emerging issues and measure the effectiveness of risk management decisions and their implementation. Total diet studies (TDS) enable a closer representation of food consumed by Canadians and are the most cost-effective method of obtaining human exposure data. TDS forms the core of surveillance and monitoring activities in support of standard setting. Further, prevalence and monitoring activities focus on commodity based surveys and selected occurrence of chemicals in these foods. The data generated by these activities in conjunction with data developed by the Canadian Food Inspection Agency (CFIA):

- Are the source of invaluable data to support risk assessment and policy development
- Support the development of risk management strategies,
- Enable to measure the effectiveness of such strategies
- Are an excellent tool in a context for emergency preparedness
- Are evolutionary and constantly updated
- Require a National Program delivery
- Complement other data collection activities to be housed in CANLINE (Canadian Laboratory Information Network)

National Food Surveillance and Monitoring activities are pillars to ensure and maintain the safety of the Canadian food supply.

Australia and New Zealand

Food Safety Authority of Australia and New Zealand (FSANZ) and other government agencies in Australia and New Zealand monitor the food supply to ensure that it is safe, and that foods comply with standards for microbiological contaminants, pesticide residue limits and chemical contamination: FSANZ co-ordinates a BI-National Surveillance and Enforcement Strategy which involves food/health agencies in Australia and New Zealand to discuss and share information about monitoring and surveillance of the food chain in Australia and New Zealand. FSANZ acts as the central point for collection of Food surveillance data from public health units in Australia and New Zealand. This data includes the results of general compliance testing and specially targeted surveys conducted in the various jurisdictions.

USA

US Food and Drug Administration (USFDA) is the main agency in the United States for ensuring food safety. It is a science led organization with focus on public health and safe, nutritious, and properly labeled foods. It adopts a 'farm to fork' approach in ensuring food safety. Risks including chemical, microbiological, toxicological, radiological, bio-terrorism and immunological; and nutritional concerns are addressed right from the time a product is grown and harvested till it goes to consumers including serviced foods (restaurants and hospitals).

USFDA works closely with state, local, and tribal governments; other federal agencies such as US Department of Agriculture, and US Environmental Protection Agency; food industry; consumers, medical community, and international agencies such as Codex Alimentarius to ensure the safety of food products supplied globally.

As a science-based agency, USFDA makes its decision on the basis of real risks and not perceived risks. It provides level playing field for consumers and industry. From the earlier regulatory approach of 'command and control', the USFDA has adopted outcome based approach in recent years. It has the advantages of promoting consistency and encourages innovation. It was the experience in US that the earlier 'command and control' approach impeded innovations that made food safe. The USFDA adopts acceptable approach rather than optimum approach which varies from country to country, commodity to commodity and business to business. This system allows for flexibility and

improvement in food safety as a result of advancement in technologies and products. The regulatory approach is not biased in favor of any stakeholder and stakeholders' and consumers' inputs are taken into account in the decision making process. Risk assessment forms the core of decision making. The USFDA also maintains an ongoing oversight on industry's ability to produce, label, and market safe food.

USFDA attaches a great deal of importance to effective communication with all stakeholders. Messages are simple and science-based. Policies, procedures, and practices are established to ensure that decisions are made in a consistent manner and communicated effectively to the stakeholders as improved communication is critical to the future of USFDA's food programs. USFDA considers itself as a learning agency and has an evolving food program. USFDA has an effective crisis management system and crisis management team to make sure that prompt action is initiated in case of any outbreaks.

EU

The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.

EFSA invests in food science through development, promotion and application of new and harmonized scientific approaches and methodologies for hazard and risk assessment of food and feed. EFSA's risk assessments are carried out by its Scientific Committee and nine Scientific Panels specialized in the following areas: food additives, flavorings, processing aids and materials in contact with food (AFC); additives and products or substances used in animal feed (FEEDAP); plant protection products and their residues (PPR); plant health (PLH); genetically modified organisms (GMO); dietetic products, nutrition and allergies (NDA); biological hazards (BIOHAZ); contaminants in the food chain (CONTAM); and animal health and welfare (AHAW)

The Authority also monitors specific risk factors such as BSE/TSE while the Pesticide Risk Assessment Peer Review Unit (PRAPeR) is responsible for the peer review of initial assessments carried out by rapporteur Member States on new or existing active substances used in plant protection products.

The Panels are comprised of leading independent scientists appointed for a three-year term following a public call for expressions of interest. Working Groups are created by the Panels when additional expertise in specific areas of competence is needed.

EFSA Science encourages open scientific debate on food and feed safety issues with stakeholders outside the organization. Activities in this area include open consultations on certain EFSA opinions, stakeholder colloquia where scientific issues are discussed and invitations to submit specific scientific data to EFSA.

For EFSA, the term ‘stakeholder’ describes an individual or group that is concerned or stands to be affected – directly or indirectly - by EFSA’s work in scientific risk assessment. In EFSA's work with stakeholders, a distinction is made between ‘Civil Society Stakeholders’ and ‘Institutional Stakeholders’.

EFSA’s Management Board consisting of 14 members and one representative from European Commission ensures that the Authority functions effectively and efficiently and meets the expectations of European and national institutes, stakeholders, and the public. Members of the Management Board are from countries all over Europe and are appointed on the basis of their individual expertise and competence on the various fields of interest of the Authority. None represent a government, organization, or sector. Members are required to come from an organization that represent consumers or other interests in the food chain. Members are appointed for four years and their term may be renewed once.

While EFSA is responsible for various activities of risk assessment, risk management responsibilities related to food safety remain the prerogative of the European Commission assumed mostly by Directorate General for Health Protection and Consumer Safety (DG SANCO). Risk assessment decisions are formulated in the form of various maximum levels (MLs) related to the occurrence of chemicals in foods and European directives on food safety, submitted for approval to European legislators. These directives are then passed on to various Member States’ food safety authorities (e.g., UK FSA, AFSSA, etc.) for their implementation.

The European Commission coordinates various programs of food monitoring and surveillance, which constitute one of the pillars of their Food Alert system that it administers. In EU rapid alert system is in place and Member States are required to provide information in case of serious risks associated with any product / outbreaks. The European Commission draws on the results of various research initiatives conducted by various European research teams specialized in food

safety (financed under the EU research frameworks) or conducted specifically as its request by the Joint Research Centre (JRC).

The European branch of International Life Sciences Institute (ILSI Europe) has recently completed a Project under the European Commission's Concerted Action Program on 'Food Safety in Europe: Risk Assessment of Chemicals in Food and Diet (FOSIE)'. The objective of developing this project was to strengthen and develop science-based general understanding of risk assessment of chemicals in foods. It also identified the gaps in knowledge leading to differences in interpretation of toxicological and exposure data and research needs to reduce the gaps.

II

Recommendation For A Food Safety Surveillance And Monitoring System For India

The object of food safety surveillance and monitoring system is to ensure that the food supplied in the market is safe. In the absence of an effective system, the consumer can be exposed .to chemical and microbiological contaminants, causing a variety of food borne diseases caused by agents such as Mould, Yeast, E.Coli, Coliform, Salmonella, Stephylococus Aureus, Vibro Cholrea, etc., and chemical contaminants like pesticide residues, heavy metals, aflatoxins, etc. The effectiveness of the food safety system can be judged by the frequency and extent of such diseases. In the absence of requisite data it is not possible to assess the present state and size of the problem.

Food contaminants monitoring program requires regular testing of identified food / commodities and contaminants along the food chain and on the basis of risk ranking. This must be accomplished under the responsibility of the Food Safety Authority.

What is essential is to make arrangements for a regular surveillance of food borne diseases and a monitoring of the level of contaminants (chemical, microbiological, environmental, etc) in food to provide the basis for sound food safety measures. There are two ways in which this can be done.

- First, a full scale mechanism can be set up as part of the Food Authority.

- Second, the Food Authority can identify ***Centers of Excellence*** having expertise in different areas e.g. ITRC for toxicological data, NIN for micronutrients and macronutrients, IARI for agricultural chemicals, CFTRI for food additives, NEERI / CPCB for water and environmental contaminants, National Institute of Cholera and Enteric Diseases / National Institute of Hygiene and Public Health for Microbiological contaminants. Comprehensive dietary data, however, are not available and the information from different institutions should be coordinated by bio-statisticians.

For a start, it would be desirable to use existing institutions for regular surveillance and feedback. Even so, infrastructure will have to be built within the Food Authority to coordinate the work among all these institutions.

The Food Surveillance, Monitoring and Risk Assessment Department will have to be set under the authority of the Chief Executive Officer, and will have to consist of the following Divisions:

- **Food Surveillance and Monitoring Division should:** :
  (a) organize the collection, retrieval and analysis of information on food borne diseases throughout the country; plan and implement regular short term surveys to detect sources of food contamination - (chemical and microbial); and analyze data generated from these surveys, in collaboration with relevant institutions in the country;

  (b) Plan and implement five yearly dietary surveys (total diet surveys – TDS- as in other countries) to use in assessment of the likely intake of food borne contaminants;

  (c) Establish a data bank to help make decisions based on empirical science

  (d) Ensure that good agricultural practices, good manufacturing practices and good laboratory practices are followed by the stakeholders

- **Risk Assessment Division**:
  (a) to carry out risk assessments in line with international (FAO/WHO) guidance documents in this field;

  (b) to participate in risk management decisions concerning the control of food contaminants;

  (c) to participate in communicating risk to consumers and assist in formulating related messages.

- **Emergency Preparedness and Response Division:**
  (a) to prepare a detailed plan for emergency action in case of food borne disease outbreak;

(b) to take a leading role in organizing response to emergency situations, working in close collaboration with other government authorities concerned;

- **Capacity Building Division:**
  (a) To develop training programs, workshops, seminars and appropriate IEC materials for stakeholders.

Surveillance System, Advisory Committee and Scientific Committees will constitute the three major constituents for the decision making process for the Food Safety Authority. With inputs from the Surveillance System, prioritization of programs by the Advisory Committee and inputs from the Scientific Committee, the Food Authority will be able to take an integrated view about food safety and take appropriate decisions. **The structure of Food Control System is given in *Appendix II*.**

The following issues need to be given utmost importance:

- ***Risk Prioritization***

While the Surveillance and Monitoring System will have to address issues relating to different contaminants in food and water the products which are major sources of contaminants must receive immediate attention. Further, they should receive high priority in the collection of data, in the formulation of action programs and their implementation.

The principal contaminants are chemical and microbiological. The latter accounts for the majority of diseases – roughly 70%.

The priority chemical contaminants to be monitored are pesticides and insecticides residues, veterinary drug residues, natural toxins, heavy metals and additives including colors.

Epidemiological/food borne disease surveillance data should be analyzed to Identify the major bacteria, viruses and parasites which contaminate food supply so that these may be targeted in the monitoring program.

Risk Prioritization

Microbiological	*Chemical*
Pathogens	Food Additives
Viruses	Environmental Contaminants
Bacteria	Agriculture Chemicals: Pesticide Residues, Veterinary Drug Residues

Exposure to contamination is generally high in respect of primary products. Some of the products to monitor are water, street foods, serviced foods, confectionery and sweets, spices, meat and marine products, and chilled and frozen foods. As far as drinking water is concerned, public health policy has revolved around controlling only bacterial pathogens. Prevalence data as well as quantification of health risks on account of presence of viruses and parasites have not been addressed.

Foods prepared at home are less risk prone. However, with changing societal trends new risks have emerged in respect of foods served in food outlets, particularly by street hawkers.

- ***Harmonization of Standards***

FAO and WHO have developed guidelines for food safety risk analysis covering chemicals, biological and other agents in food. The guidelines consist of risk analysis with its three components viz. risk assessment, risk management and risk communication. Risk assessment comprises hazard identification, hazard characterization, exposure assessment and risk characterization. The risk assessment of biological agents includes similar components as in chemical hazards. Codex is in the process of developing Guiding Principles for Food Safety Risk Analysis for use by national food safety authorities. It is important to harmonize national procedures with Codex standards and guidelines to facilitate international trade, apart from ensuring safety and quality of foods.

The WTO Agreement also underlines that the safety of food in international trade should be based on risk analysis with the SPS Agreement covering measures to protect human health, animal health and plant health while ensuring under TBT Agreement that product standards and technical regulations do not create unnecessary obstacles to trade. These Agreements presume Codex standards as benchmark of safety and quality.

➢ ***Capacity Building***

There are three specific capacity gaps viz.

- Lack of personnel with appropriate technical qualifications and expertise
- Inadequate skills of personnel already deployed
- Lack of well equipped laboratories for food analysis

A food safety and analytical quality control laboratory should have the state of the art facilities and capability to carry out food compositional analysis, food contaminants/toxicants analysis, food additives analysis, vitamins and minerals analysis, microbiological analysis, and so on. These analyses require well qualified and expert food analysts and modern equipment.

At present Public Analyst's laboratories are used for testing food samples and the Central Food Laboratories are used as reference laboratories. There are only four Central Food Laboratories. More reference laboratories may need to be set up or some of the existing institutions can be identified for carrying out the work in addition to the private sector laboratories. The reference laboratories may be identified as centers of excellence for different aspects of food safety such as chemical contaminants and microbiological contaminants It is important to lay down the requirements for reference laboratories in term of equipment, staff, and accreditation from national and international institutions.

At present there is acute dearth of technical personnel, particularly analytical chemists. Training programs for in-house chemists and new entrants should be organized, to start with, with the assistance of FAO. Such programs can be arranged by ILSI-India also.

The institutional framework for food analysis should be such as to create confidence among the consuming public. This has become particularly important in view of the high profile media attention.

➢ ***Immediate Steps***

The implementation of the Food Safety and Standards Act will take another few months. This lead time should be used to take steps which will enable the Food Authority to function effectively right from the start.

Two steps can be immediately taken:

- **First,** since information is a precondition to taking any decision, the authorities should collect and collate information relating to diets, food contaminants, etc, available with research organizations, both national and international. ILSI-India can be one of the channels to be utilized for this purpose. The immediate problems that need to be addressed are drinking water and street foods which presumably are major sources of contamination and consequently disease. Hence information relating to chemical and microbiological contaminants in these products should be gathered on a priority basis.

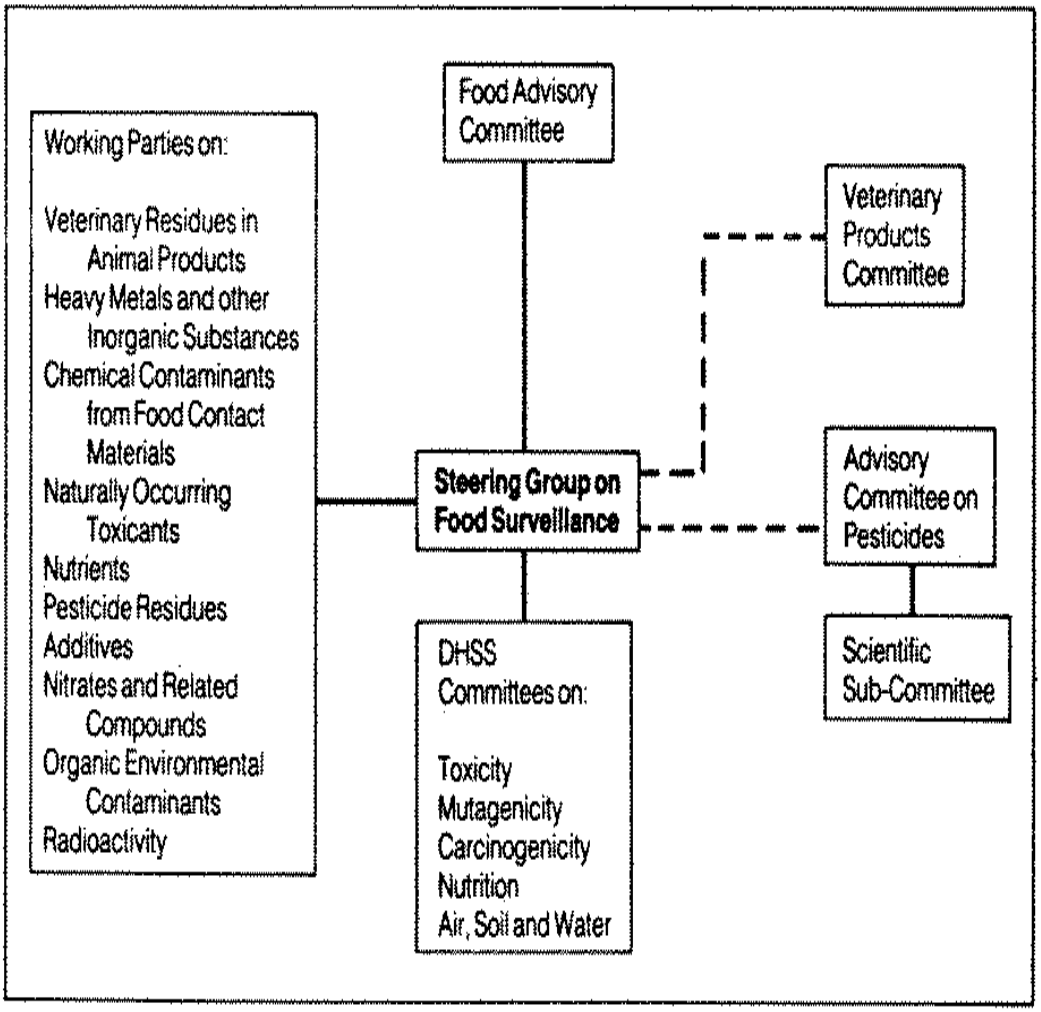
- **Second,** a Committee of Analysts should be appointed to suggest:

  (a) Availability of well qualified persons to carry out risk analysis and the devise training programs for them and

  (b) Identify the gaps in Central and State laboratories to bring them up to world standards

Appendix I

Structure of Steering Group on Food Surveillance in United Kingdom



The committee structure of the Steering Group and its relation to other committees

Appendix II

Suggested Structure Of Food Control System Under Food Safety And Standards Act Of India