CHAPTER II

MECHANISM OF EVOLVING AND FIXING FOOD STANDARDS

INDIA

The Department of Health & Family Welfare under the “Ministry of Health and Family Welfare” deals drug control and prevention of food adulteration.

The Central Committee for Food Standards (CCFS)

The Central Government, constitutes a committee called the Central Committee for Food standards to advise the Central Government and the State Governments on matters arising out of the administration of PFA Act and to carry out the other functions assigned to it under this Act.

The Committee shall consist of the following members, namely:-

a) the Director-General, Health Services, ex-officio, who shall be the Chairman;

b) the Director of the Central Food Laboratory or, in a case where more than one Central Food Laboratory is established, the Directors of such Laboratories, ex-officio;

c) two experts nominated by the Central Government;

d) one representative each of the Departments of Food and Agriculture in the Central Ministry of Food and Agriculture and one representative each of the Central Ministries of Commerce, Defence, Industry and Supply and Railways, nominated by the Central Government;

e) one representative each nominated by the Government of each State;


2 Ibid.
f) two representatives nominated by the Central Government to represent the Union territories;

g) one representative each, nominated by the Central Government, to represent the agricultural, commercial and industrial interests;

gg) five representatives nominated by the Central Government to represent the consumers, interests, one of whom shall be from the hotel industry;

h) one representative of the medical profession nominated by the Indian Council of Medical Research;

h) one representative nominated by the Indian Standards Institution referred to in clause (e) of Section 2 of the Indian Standards Institution (Certification Marks) Act, 1952.] (36 of 1952.)

The members of the Committee referred to in clauses (c), (d), (e), (f), (g), (gg), (h), and (i) of sub-section (2) shall, unless their seats become vacant earlier by resignation, death or otherwise, be entitled to hold office for three years and shall be eligible for renomination.

Appointment of Secretary and other staff:

1) The Central Government shall appoint a Secretary, to the Committee who shall, under the control and direction of the Committee, exercise such powers and perform such duties as may be prescribed or as may be delegated to him by the Committee.

2) The Central Government shall provide the Committee with such clerical and other staff as that Government considers necessary.

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3 Id. at 13.
4 Ibid.
5 Id. at 14.
CCFS Mechanism

In exercise of the Powers conferred by Sub-section (6) of section 3 of the Prevention of Food Adulteration Act, 1954 (37 of 1954) and after previous approval of the Central Government, the Central Committee for Food Standards (hereinafter referred to as the Committee) has made the following Bye-laws for regulating its procedure and transaction of its business, namely:

1. Short title and Commencement-
   a. These Bye-laws may be called the Central Committee for Food standards (Procedure and Transaction of Business) Bye-laws, 1986
   b. They shall come into force on the date of their publication in the Official Gazette.

2. Time and place of meetings of the Committee.
   The Committee shall meet at such time and place as the Chairman of the Committee (hereinafter referred to as the Chairman) may from time to time determine.

3. Power to call meeting of the Committee
   The Chairman may, at any time, call a meeting of the Committee and shall also do so, if a requisition for that purpose is presented to him in writing by not less than fifty per cent of the members of the Committee specifying the subject of discussion at the meeting proposed to be called.

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6 Id. at 401.
7 Ibid.
8 Ibid.
4. Notice for meeting

i. A notice of not less than twenty-one clear days in respect of every meeting of the Committee, shall be given to each of its members who is for the time being in India\(^9\).

ii. The aforesaid notice may be served on any member of the Committee either through a person or by registered post or telegram sent to each such member at his latest address intimated by him in writing to the Secretary of the Committee\(^10\).

iii. Any incidental omission to give the aforesaid notice to any of the members of the Committee shall not invalidate any decision taken or resolution passed at any such meeting of the Committee.

iv. Notwithstanding anything contained in clause (1), a meeting of the Committee may be called by the Chairman at a shorter notice of not less than seven clear days if he is of opinion that the matter to be discussed at the proposed meeting is of such a nature that it requires to be considered urgently by the Committee.

5. Quorum

a. No business shall be transacted at a meeting of the Committee unless at least one-third of its members are present.

b. If there is no quorum within half an hour from the time appointed for holding the meeting, the same shall stand adjourned till such time to the same day as the Chairman may decide.

c. Notwithstanding anything contained in clause (1), if there is no quorum at any such adjourned meeting also, members present at the meeting shall form the quorum.

\(^9\) Ibid.
\(^10\) Id. at 402.
6. **Chairman to preside at meetings of the Committee**

a. The Chairman of the Committee shall, when present, preside at all meetings of the Committee.

b. If for any reason, the Chairman is not present in a meeting any other member duly authorised by the Chairman shall preside at the meeting of the Committee\(^{11}\).

7. **Adjournment of meeting**

a. The Chairman may, with the consent of the members present at any meeting of the Committee, adjourn the meeting from time to time\(^{12}\).

b. No business other than the business included in the agenda for that meeting shall be transacted at any such adjourned meeting except with the consent of the Chairman\(^{13}\).

8. **Voting**

a. Each member of the Committee shall have one vote.

b. All matters submitted for consideration at a meeting of the Committee shall be decided by a majority of the members present and voting at such meeting; and in case of equality of votes on an issue, the Chairman or the person presiding at the said meeting shall have second or casting vote\(^{14}\).

9. **Transaction of business by circulation of papers**

a. Any business, which in the opinion of the Chairman, is necessary for the Committee to transact before the next meeting of the Committee, may be transacted by circulation of papers sent to all the members of the Committee.

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\(^{11}\) *Ibid.*


\(^{13}\) *Id. at 403.*

\(^{14}\) *Ibid.*
Committee, for the time being in India, in the manner and at the latest address as is specified in clause (2) of bye-law 4, and any decision taken or resolution passed by a majority of the members through such circulation shall be as effectual and binding as if it has been taken or, as the case may be passed at a meeting of the Committee.\textsuperscript{15}

b. When any papers mentioned in clause (1) are sent to the members by circulation, a period of not less than 30 clear days shall be communicated to all the members of the Committee.

\textbf{10. Record of business}

A record of all business transacted by the Committee, shall be maintained including the issue of the minutes. The said minutes duly approved by the Chairman shall be circulated to all the members, for their approval or comments within 30 days of the date of which the minutes are issued. Comments received on the minutes, if any, should be put at the next meeting of the Committee for confirmation of the said minutes. It also comprises of one representative nominated by the Indian Standards Institution.\textsuperscript{16}

\textbf{Bureau of Indian Standards}

Bureau of Indian Standards (BIS) is formulating need-based Indian Standards in line with the national priorities as a time bound programme. The Bureau has taken a decision to harmonize national standards with regional and international standards in order to facilitate adoption of international standards by all segments of business and industry.\textsuperscript{17}

\textsuperscript{15} Ibid.
\textsuperscript{16} Ibid.
\textsuperscript{17} http://www.bis.org.in/bs/bsrules.htm
The progress on activities relating to formulation of Indian Standards:-

1) Establishment of Standards –

a. The Bureau establishes Indian Standards in relation to any article or process and amends, revises or cancels the standards so established as may be necessary, by a process of consultation with consumers, manufacturers, technologists, scientists and officials through duly constituted committees. The procedure employed in establishing the standard is designed such that concerned interests, in addition to the members of the Committees of the Bureau, have the opportunity to communicate their views.

b. All standards, their revisions, amendments and cancellations are established by notification in the Official Gazette.\(^\text{18}\)

2) Technical Committees –

a. For the purpose of formulation of Indian Standards in respect of articles or processes, technical committees of experts may be constituted. Such committees may include Division Councils, Sectional Committees, Subcommittees and Panels.\(^\text{19}\)

b. Division Councils, Sectional Committees and Sub-committees are reconstituted once every three years.

3) Division Councils –

Division Councils are set up by the Bureau in defined areas of industries and technologies for formulation of standards. These include concerned officers of the Bureau and representatives of various interests such as consumers, regulatory and other Government bodies, industry, scientists, technologists and testing organizations. These may also include consultants. An officer of the Bureau shall be the Member Secretary.\(^\text{20}\)


\(^{19}\) *Ibid.*

Major functions of Division Council are as follows:-

1. To advise on the subject areas to be taken up for formulation of standards in their respective areas keeping in view the national needs and priorities;

2. To set up Sectional Committees within their areas, define their scopes, appoint their Chairmen and members and coordinate their activities;

3. To approve proposals for work, decide which proposals should be taken up and direct the Sectional Committee(s) concerned to undertake the approved work and to determine the priority to be assigned to the work.

4. To advise on matters relating to research and development needed for the establishment of standards or their revisions;

5. To study the work of international organizations and their committees in standards formulation as related to the area of work of the Division Council and recommend on the extent and manner of participation in standardization activities at the international level;

6. To advise on implementation of established standards;

7. To receive and deal with activity reports and to make recommendations thereon to the Bureau concerning matters in which the decision of the Bureau is necessary;

8. To carry out such tasks as may be specifically referred to it by the Bureau/Standards Advisory Committee.\(^{21}\)

4) Sectional Committees, Sub-committees and Panels –

a. Sectional Committees are appointed by Divisional Councils.

b. Sectional Committees, sub-committees and panels may co-opt experts to assist them in their work.

\(^{21}\) Ibid.
5) Terms and conditions for engaging Consultants –

The terms and conditions for engaging consultants in the work of the Division Councils and other technical committees and in the work relating to establishment of standards are decided by the Executive Committee.

Procedure for establishment of Indian standards

- Proposals to the Bureau for establishing a standard or revising, amending or canceling an established standard
- Work of formulation of standards is undertaken
- Division council assign the task to appropriate technical committee or appoint a new technical Committee
- Draft Standards
- In case of urgent or non-controversial matter wide circulation may be waived.
- Draft Standards widely circulated amongst concerned for critical review.
- Finalize the draft by Technical committee
- Draft submission to the Chairman of Division council
- Final Standards

Any Ministry of central, state or union territory, consumer organizations etc may submit proposals.

After Division Council Concerned is satisfied in terms of necessity for the standardization.

After approval from Sectional Committee or its Chairman

22 Ibid.
All established standards are reviewed periodically, at least once in five years, to determine the need for revision or withdrawal. Proposals for revising or amending published standards shall be considered by the Technical Committee concerned.

The Director General, have the power to issue amendments of the corrigenda type meant to correct errors and omissions in established Indian Standards, without reference to the concerned Technical Committee or the Division Council and report to the concerned Technical Committee.

The Director General also have the power to tentatively modify such of the provisions of an Indian Standard as in his view are necessary for expeditious fulfillment of any of the objectives of the Act.

Withdrawal of an established Indian Standard is decided upon by the Chairman of the respective Division Council on the recommendation of the Sectional Committee concerned.23

**BIS Organisation Structure**

The Bureau is a body corporate consisting of members representing the Government, industry, consumers, scientific and research institutions and other relevant interest groups with Minister in charge of the Ministry/Department having administrative control of the Bureau as its President and Minister of State or a Deputy Minister, if any, as Vice-President. The Secretary in the administrative Ministry/Department and Director General of the Bureau are ex-officio members of Bureau. The Bureau is assisted in its functions by Executive Committee and the Advisory Committees on finance, certification, standards formulation, laboratories, planning & development, legal and consumer policy24.

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CODEX ALIMENTARIUS

The Codex Alimentarius (food code) is the seminal global reference point for food standards.25 The Codex Alimentarius Commission develops food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. Article 1 states the purpose of the Commission, and sets out its terms of reference and objectives. It states that the Commission is responsible for making proposals to, and shall be consulted by, the Directors-General of the FAO and the WHO on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

a. protecting the health of consumers and ensuring fair practices in the food trade;

b. promoting co-ordination of all food standards work undertaken by international governmental and non-governmental organisations;

c. determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organisations;

d. finalising standards elaborated under (c) above and, after acceptance by governments, publishing them in a Codex Alimentarius either as regional or worldwide standards, together with international standards already finalised by other bodies under (b) above, wherever this is practicable;

e. amending published standards, after appropriate survey in the light of developments.

Codex standards may be fully accepted, accepted with minor deviations, or accepted by ‘free distribution’ by the member countries. The FAO and the WHO


26 Id. at 153.
provide assistance to developing countries to ensure that they have the technical and administrative infrastructure in place to enable them to adopt Codex standards. Such assistance includes convening expert meetings to advise the Codex Alimentarius Commission on relevant issues, conducting workshops and training courses, strengthening analysis and inspection capabilities, and assisting in the establishment of food control agencies.

The procedures for preparing standards are well defined, open and transparent. In essence they involve:

The submission of a proposal for a standard to be developed by a national government or a subsidiary committee of the Commission. This is usually followed by a discussion paper that outlines what the proposed standard is expected to achieve, and then a project proposal that indicates the time frame for the work and its relative priority.

i. A decision by the Commission or the Executive Committee that a standard be developed as proposed. “Criteria for the Establishment of Work Priorities” exist to assist the Commission or Executive Committee in their decision-making and in selecting the subsidiary body to be responsible for steering the standard through its development. If necessary, a new subsidiary body - usually a specialized task force - may be created.

ii. The preparation of a proposed draft standard is arranged by the Commission Secretariat and circulated to member governments for comment.

iii. Comments are considered by the subsidiary body that has been allocated responsibility for the development of the proposed draft standard, and this subsidiary body may present the text to the Commission as a draft standard. The draft may also be referred to the Codex Committees responsible for

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27 Id. at 152.
29 Ibid.
labeling, hygiene, additives, contaminants or methods of analysis for endorsement of any special advice in these areas.

iv. Most standards take a number of years to develop. Once adopted by the Commission, a Codex standard is added to the Codex Alimentarius. The Commission keeps abreast of the changes. Maintaining the scientific basis for consumer protection, the standards for new food products are developed.

The procedure for revision or consolidation follows that used for the initial preparation of standards.

Under its Rules of Procedure, the Commission has established two kinds of subsidiary bodies:

1) Codex Committees, which prepare draft standards for submission to the Commission;

2) Co-ordinating Committees, through which regions or groups of countries coordinate food standards activities in the region, including the development of regional standards.

In addition, General Subject committees are formed. General Subject Committees develop all-embracing concepts and principles applying to foods in general, specific foods or groups of foods; endorse or review relevant provisions in Codex commodity standards; and, based on the advice of expert scientific bodies, develop major recommendations pertaining to consumer’s health and safety. Five of the General Subject Committees have the responsibility of ensuring that specific provisions in Codex commodity standards are in conformity with the Commission’s main general standards and guidelines in their particular areas of competence. They are:

1) Committee on Food Additives and Contaminants.

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30 Id. at 16.
31 Ibid.
2) Committee on Food Hygiene
3) Committee on Food Labeling
4) Committee on Methods of Analysis and Sampling.
5) Committee on Nutrition and Foods for Special Dietary Uses

These Committees may also develop standards, maximum limits for additives and contaminants, codes of practice or other guidelines for either general application or in specific cases where the development of a complete commodity standard is not required.

The Committee on Pesticide Residues and the Committee on Residues of Veterinary Drugs in Foods prepare MRLs for these two categories of chemicals used in agricultural production. The MRLs are based on scientific advice regarding the safety of the residues that remain after the substances are used in accordance with defined good agricultural or veterinary practices.\(^\text{32}\)

**Commodity Committees**

The responsibility for developing standards for specific foods or classes of food lies with the Commodity Committees.

There are currently five Commodity Committees:

1) Committee on Fats and Oils.
2) Committee on Fish and Fishery Products.
3) Committee on Fresh Fruits and Vegetables.
4) Committee on Milk and Milk Products.
5) Committee on Processed Fruits and Vegetables.\(^\text{33}\)

\(^{32}\) Ibid.
\(^{33}\) Ibid.
The following Commodity Committees work through correspondence or are in recess:

1) Committee on Cereals, Pulses and Legumes.
2) Committee on Cocoa Products and Chocolate.
3) Committee on Meat Hygiene.
4) Committee on Natural Mineral Waters.
5) Committee on Sugars.
6) Committee on Vegetable Proteins.

The overall process of developing the food standard may be described as below:

Before a decision is made to undertake the development of a new standard or other text, a project proposal is prepared and discussed at Committee level.

**The Codex Step procedure**

**STEP 1**

The project proposal is reviewed by the Executive Committee and compared against the criteria and priorities established by the Commission.

**STEPS 2, 3 AND 4**

A draft text is prepared (Step 2) and circulated to member countries and all interested parties for comment (Step 3). The draft and the comments are reviewed at Committee level (Step 4) and, if necessary, a new draft is prepared.\(^{34}\)

**STEP 5**

The Commission reviews the progress made and agrees that the draft should go to finalization. After this stage, the draft is also endorsed by the relevant General Subject Committees so that it is consistent with Codex general standards.

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\(^{34}\) *Id.* at 17.
STEPS 6 AND 7

The approved draft is sent again to governments and interested parties for comment and finalized by the relevant Committee. The draft is submitted to the Commission for adoption.

STEP 8

Following a final round of comments, the Commission adopts the draft as a formal Ccex text. The standard, guideline or other text is then published by the Codex Secretariat.

THE CODEX STANDARDS PROCESS

Getting Started Critical Review Elaboration Approval & Adoption

Initial Proposal optional

Discussion Paper

Project Proposal

Criteria & Priorities Proceed?

Consultation with governments and interested parties and committee Debate

Mid-term review

Endorsement*

Final Standard, guideline, etc.

Committee Level

Executive Committee

Committees & Task Force

Commission

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35 Id. at 16.
EUROPEAN UNION

European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) was set up in January 2002, following a series of food crisis in the late 1990s, as an independent source of scientific advice and communication on risks associated with the food chain. EFSA was created as part of a comprehensive programme to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply.\(^{36}\)

In the European food safety system, risk assessment is done independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions.\(^{37}\)

EFSA’s remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA’s most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge.

EFSA’s goal is to become globally recognized as the European reference body for risk assessment on food and feed safety, animal health and welfare, nutrition, plant protection and plant health.

EFSA’s independent scientific advice underpins the European food safety system. Thanks to this system, European consumers are among the best protected and best informed in the world as regards risks in the food chain.\(^{38}\)

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\(^{37}\) Largo N. Palli, “The European Food Safety Authority at a glance” (2009).

\(^{38}\) Ibid.
Role of EFSA

EFSA’s role is to assess and communicate on all risks associated with the food chain. Since EFSA’s advice serves to inform the policies and decisions of risk managers, a large part of EFSA’s work is undertaken in response to specific requests for scientific advice. Requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States. EFSA also undertakes scientific work on its own initiative, so-called self-tasking.

Accordingly, EFSA’s advice frequently supports the risk management and policy-making processes. These may involve the process of adopting or revising European legislation on food or food safety, deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and policies for instance in the field of nutrition. EFSA is not involved in these management processes, but its independent advice gives them a solid scientific foundation.

Through its risk communications activities EFSA seeks to raise awareness and further explain the implications of its scientific work. EFSA aims to provide appropriate, consistent, accurate and timely communications on food safety issues to all stakeholders and the public at large, based on the Authority’s risk assessments and scientific expertise

Structure of EFSA

EFSA, which has legal personality, consists of a management board, an executive director and his staff, an advisory forum, and a scientific committee and scientific panels. The management board comprises 14 members appointed by the Council in consultation with the European Parliament, from a list drawn up by the Commission, as well as a representative of the Commission.

40 Supra not 25 at 187.
EFSA is made up of four distinct bodies:

The Management Board is responsible for ensuring that the authority functions well and efficiently. It adopts the authority’s draft budget and work programmes, monitors their implementation, and approves internal rules and regulations. It also appoints the Executive Director and members of the Scientific Committee and Panels.

The Executive Director is the legal representative of the Authority and reports on its activities to the Management Board. The Executive Director is appointed for a period of five years (renewable) and is responsible for the day-to-day management of the authority and for all staff matters\(^{41}\).

The Advisory Forum is composed of representatives of national food-safety or similar authorities from all 27 member states, as well as observers from Norway, Iceland and Switzerland and a representative of the European Commission. Chaired by the Executive Director, the Forum is at the heart of the authority’s collaborative approach to risk assessment across Europe. It advises on the work programme and on emerging risks and provides for effective sharing of information on food safety and risk assessment.

EFSA’s scientific opinions are provided by the Scientific Committee and nine scientific panels, each of which is responsible for a specific area of risk assessment. The Scientific Committee co-ordinates the work of the groups and addresses multi-sectoral issues of concern to all the panels (such as the methodology used to assess exposure)\(^{42}\).

**Risk Assessment**

The European Food Safety Authority (EFSA) was established to assess risks associated with the food chain, its main mandate. EFSA’s risk assessment work contributes to improving food safety in Europe and to building public confidence in the food supply.

\(^{41}\) EFSA, Largo N. Palli, International Conference on "Identity, Quality and Safety of Mediterranean Food Products", 25 June (2007).

\(^{42}\) Ibid.
Risk assessment is a specialized field of applied science that involves reviewing scientific data and studies in order to evaluate risks associated with certain hazards.\(^{43}\)

In its first five years EFSA delivered over 450 scientific opinions on a wide variety of risk issues. These included Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE), the safety of food additives such as aspartame, allergenic food ingredients, genetically modified organisms (GMOs), wild and farmed fish, pesticides, and animal health issues including Avian Influenza.

EFSA also undertakes scientific work on its own initiative, so-called self-tasking, particularly in fields such as emerging risks where scientific knowledge and approaches are continually evolving. EFSA’s work includes harmonization of risk assessment methodologies. One example is the development of a harmonised approach to compare the risks posed by substances with the potential to cause cancer, and provided advice on the biosafety of antibiotic resistant marker genes.\(^{44}\)

The Authority also has an important role in collecting and analysing scientific data to ensure European risk assessment is supported by the most complete scientific information available. It does this by working with the EU Member States to gather, share and analyse EU-wide data, as well as launching public consultations and calls for data to gather information from external sources.\(^{45}\)

EFSA’S risk assessments are carried out by its Scientific Committee and Scientific panels.

The Scientific Panels are responsible for providing the scientific opinions of the Authority and other advice as appropriate, each within their own spheres of competence. Each Scientific Committee comprises no more than nineteen members, the number of members being determined by the EC in view of the


\(^{44}\) Ibid.

\(^{45}\) Ibid.
expertise required. Members are scientific experts in one or more of the relevant fields of competence of the Committee in question. The Scientific Committees have an advisory role, being consulted where required by Community law and where the EC decides to consult them in relation to consumer health and food safety. In more detailed terms, the Scientific Committees’ roles are as follows:\(^{46}\):

- to examine critically risk assessments made by scientists belonging to member state organizations
- to develop new risk assessment procedures relating to areas such as, for example, food-borne diseases and the transmissibility of animal diseases to humans
- to prepare scientific opinions designed to enable the EC to evaluate the scientific basis of the recommendations, standards and guidelines prepared in international forums
- to evaluate the scientific principles on which Community health standards are based, taking into account the risk assessment techniques developed by the international organisations concerned\(^{47}\).

The competence of the Scientific Panels and the respective expertise sought through this call are as follows:

1. The Panel on food additives, flavourings, processing aids and materials in contact with food (AFC Panel) deals with questions of safety in the use of food additives, flavourings, processing aids, food enzymes and materials in contact with food; with associated subjects concerning the safety of other deliberately added substances to food and with questions related to the safety of processes. Further details can be found at [http://www.efsa.eu.int/science/afc/catindex_en.html](http://www.efsa.eu.int/science/afc/catindex_en.html)


\(^{47}\) Ibid.
Expertise required: toxicology and risk assessment, chemistry, biochemistry, food consumption and exposure assessment, safety and bioavailability of nutrient sources, food technology and microbiology, within the area of the panel as described above.48

2. The Panel on animal health and welfare (AHAW Panel) deals with questions on all aspects of animal health and animal welfare, primarily relating to food producing animals including fish. Further details can be found at http://www.efsa.eu.int/science/ahaw/catindex_en.html

Expertise required: veterinary medicine, risk assessment in animal health and welfare, bacteriology, virology, parasitology, epidemiology, pathology, zootechnics, animal production, immunology, animal behaviour, ethology, physiology.

3. The Panel on biological hazards (BIOHAZ Panel) deals with questions on biological hazards relating to food safety and food-borne disease, including food-borne zoonoses and transmissible spongiform encephalopathies, microbiology, food hygiene and associated waste management.

Further details can be found at: http://www.efsa.eu.int/science/biohaz_en.html

Expertise required: food microbiology, food technology, food hygiene, microbiological risk assessment, quantitative risk assessment, public health, veterinary public health, animal health, virology, parasitology, zoonoses, epidemiology, meat inspection, transmissible spongiform encephalopathies, neuropathology, TSE exposure assessment, TSE testing, epidemiology.49

4. The Panel on contaminants in the food chain (CONTAM Panel) deals with questions on contaminants in food and feed, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues

49 Ibid.
of non-authorised substances not covered by another panel. Further details can be found at: http://www.efsa.eu.int/science/contam_en.html

Expertise required: toxicology, risk assessment, chemistry, food consumption and exposure assessment, epidemiology, analytical and environmental chemistry, biochemistry, food technology, natural toxicants, veterinary toxicology, animal nutrition, toxicokinetics (modelling and metabolism).

5. The Panel on additives and products or substances used in animal feed (FEEDAP Panel) deals with questions on safety for the animal, the consumer of products of animal origin, the user and the environment and with the efficacy of additives, products or substances intended for use in animal nutrition.

Further details can be found at: http://www.efsa.eu.int/science/feedap_en.html

Expertise required: animal nutrition, toxicology, biochemistry, microbiology, metabolism and residues of feed additives, exposure assessment, environmental assessment of feed additives, animal production, feed technology.\(^{50}\)

6. The Panel on genetically modified organisms (GMO Panel) deals with questions on genetically modified organisms (plants, micro-organisms and animals) as defined in Directive 2001/18/EC. The GMO Panel assesses GMO applications submitted under Regulation (EC) 1829/2003 and/or Directive 2001/18/EC, and deals with more general questions related to the risk assessment of GMOs and derived products. Further details can be found at http://www.efsa.eu.int/science/gmo/catindex_en.html

Expertise required: plant molecular biology, microbiology, biochemistry, toxicology, immunology, allergenicity, human/animal nutrition, statistics,

\(^{50}\) Id. at C 289/A3.
bioinformatics, plant/animal breeding, plant/animal physiology and/or metabolism, plant/soil ecology and ecotoxicology, entomology; (environmental) risk assessment of genetically modified plants/animals/micro-organisms, risk assessment of genetically modified food/feed products, food and feed safety, nutritional assessment, comparative analysis, post market environmental monitoring.

7. The Panel on dietetic products, nutrition and allergies (NDA Panel) deals with questions on dietetic products (i.e. foodstuffs intended to satisfy particular nutritional requirements of specific groups of the population, as defined in Community legislation), human nutrition and food allergy, and other associated subjects such as novel foods. Further details can be found at: http://www.efsa.eu.int/science/nda_en.html

Expertise required: human nutrition, human medicine, food allergy, toxicology, food consumption and exposure assessment, biochemistry, epidemiology, food technology.\textsuperscript{51}

8. The Panel on plant protection products and their residues (PPR Panel) deals with questions on the risk of plant protection products for humans (including user/worker and consumer) and the environment. Further details can be found at: http://www.efsa.eu.int/science/ppr_en.html

Expertise required: pesticide risk assessment; toxicology, occupational health; residues of pesticides in food, food consumption and exposure assessment; ecotoxicology (aquatic/terrestrial), fate and behaviour of pesticides in all environmental compartments (water, soil), including modelling; analytical methods, physical chemical properties of pesticides.

9. The new Panel on plant health (PLH Panel) deals with questions on organisms harmful to plants or plant products posing a threat to the Community crop production and/or biodiversity. It will also carry out peer-review of pest risk assessment at the European level.

\textsuperscript{51} Ibid.\textsuperscript{47}
Expertise required: virology, bacteriology, mycology, botany/weed science, phytopathology, plant disease epidemiology, nematology, entomology, population ecology/population genetics, environmental factors and responses, plant quarantine, pest risk assessment\(^{52}\).

The Scientific Panels are supported by EFSA staff working in EFSA's two science directorates. They may develop scientific outputs on behalf of EFSA, which are distinct from the outputs of the Scientific Panels.

**The Role of Scientific Committee**

The Scientific Committee is responsible for the provision of scientific opinions and advice on multi-sectorial issues falling within the competence of more than one panel, and on issues which do not fall within the competence of any of the panels. The Scientific Committee is also responsible for the general coordination necessary to ensure the consistency in the scientific opinions of the different panels.

*Expertise required:* risk assessment, food consumption and exposure assessment, environmental risk assessment, microbiology, toxicology, human nutrition, epidemiology, animal health, animal welfare, human medicine, veterinary medicine, food hygiene, food technology, chemistry, biology, biochemistry, life sciences\(^{53}\).

**Composition of the Scientific Committee and Scientific Panels**

The Scientific Committee is composed of the Chairs of the Scientific Panels and six independent experts.

The Scientific Panels are composed of an adequate number of independent scientific experts. The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the

\(^{52}\) *Ibid.*  
\(^{53}\) *Id. at C 289/A2.*
Authority's request, in accordance with the procedure referred to in Article 58(2) of Regulation (EC) 178/2002 as amended.54

**Risk Communication**

Communicating on risks associated with the food chain is a key element of the European Food Safety Authority’s (EFSA) mandate. By communicating on risks in an open and transparent way based on the independent scientific advice of its scientific expert panels, EFSA contributes to improving food safety in Europe and to building public confidence in the way risk is assessed.

Describing the likelihood of harm arising from eating some types of food can be difficult. Scientific results cannot always be easily converted into simple guidelines and advice that non-scientists like the public or the media can easily understand or follow. One of the key responsibilities of EFSA is to communicate food and feed safety advice to its principal clients, stakeholders and the public at large in a timely, clear and helpful way, in order to help bridge the gap between science and the consumer. EFSA uses on and offline communications tools including the corporate website, webcasting, participation in events and conferences, a variety of hard copy publications and information materials, press events and information for the media such as press releases and news alerts.55

54 Id. at C 219/A4.
55 [http://efsa.europa.eu/EFSA/AboutEFSA/WhatWeDo/efsa_locale1178620753812_RiskCommunication.htm](http://efsa.europa.eu/EFSA/AboutEFSA/WhatWeDo/efsa_locale1178620753812_RiskCommunication.htm)
EFSA seeks to raise awareness and further explain the implications of assessments from its scientific panels by:

1. Analysing public perception of risks linked to food;
2. Explaining and contextualising risk;
3. Working with key actors including national authorities, stakeholders and media to tailor messages to the needs of different audiences;
4. Ensuring consistency by co-ordinating communications with other risk assessment bodies and risk managers such as the European Commission and EU Member States;
5. Using a wide range of on and offline communication tools.

EFSA coordinates with and takes advice from the heads of communications of national food safety authorities via the Advisory Forum Communications Working Group and has also established a multi-disciplinary expert Advisory Group on Risk Communications, which reports to the Executive Director. Assessing the risks associated with the food chain is a key element of the European Food Safety Authority’s (EFSA) mandate.\textsuperscript{56}

\textsuperscript{56} \textit{Ibid.}
Food Standards Agency

The Food Standards Agency carries out a range of work to make sure food is safe to eat, including funding research on chemical, microbiological and radiological safety, as well as food hygiene and allergy.

The Food Standards Agency aims to ensure that the chemicals present in food do not compromise food safety. To achieve this they:

- Obtain advice on particular chemicals from their independent scientific advisory committees, or ask those committees to set up working groups (for example, the Phytoestrogen Working Party) to examine issues of concern.

- Commission surveys on levels of chemicals in different foods, in order to estimate total amounts that we consume and check that safety levels are complied with.

- Develop methods of estimating the amounts of food chemicals consumed by consumers, including those of different ages and different dietary habits.

- Ensure that consumer interests are taken into account in the safety assessments of pesticides, veterinary medicines and natural toxicants.

- Liaise and negotiate with other EU member states, the European Commission and international organizations to develop appropriate standards for levels of chemicals in food.

- Commission research on food intolerance, risk assessment of food chemicals, phytoestrogens, molecular toxicology, food additives and food contact materials.57

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57 [www.food.gov.uk/safereating/chemsafe](http://www.food.gov.uk/safereating/chemsafe)
The Agency carries out numerous formal consultations, inviting the views of the food industry, consumers and others on topics ranging from proposed changes in regulations to new food policy initiatives.

Risk Assessment

To determine safe levels of chemicals in food, it is necessary to review all the information on the types of harmful effect that the chemicals might have and then to decide on the amounts that we could consume without risk of suffering these harmful effects. This process is called risk assessment and is conducted by independent scientific advisory committees who are not influenced by any commercial or financial pressures. Members include experts in different types of scientific and medical expertise. In addition, we ensure that the UK committees include lay members to represent the concerns and views of members of the public. The advice of these committees is used in setting acceptable levels for chemicals in food.

There are number of Committees, forums and working groups that advise the Agency on safety and hygiene issues. All of them are listed below:-

General Advisory Committee on Science (GACS)

The General Advisory Committee on Science (GACS), established in December 2007, provides independent advice on the Agency's governance and use of science.

The Committee's work includes horizon scanning, science governance, developing good practice and informing science priorities.

The GACS comprises an independent Chair, four independent expert members, two lay members and the Chairs of the nine scientific advisory committees that advise the Agency, who are members of GACS in an ex officio capacity.

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58 ibid
The GACS is supported by a Secretariat provided by the Food Standards Agency.\(^{59}\)

**Social Science Research Committee**

The Social Science Research Committee (SSRC) was established in April 2008, to help the Agency strengthen its capacity for social science research and to provide advice to the Agency about how it gathers and uses social science evidence.

The SSRC comprises an independent Chair and 11 expert members, including two lay members.

The SSRC is supported by a secretariat provided by the Food Standards Agency.\(^{60}\)

**Advisory Committee on Animal Feeding stuffs**

ACAF advises on the safety and use of animal feeds and feeding practices, with particular emphasis on protecting human health, and with reference to new technical developments.

**Better Regulation Advisory Group**

The Better Regulation Advisory Group (BRAG) was set up in 2006 to undertake independent external scrutiny and challenge of the Food Standard Agency's better regulation initiatives.

BRAG membership includes representatives from all our main stakeholders – business, consumers and local authorities. The Group meets every six months.

**Terms of Reference:**

- To undertake a scrutiny and challenge function on initiatives carried out by the FSA as part of its commitment to the better regulation agenda.

- To act as a key stakeholder constituency.

\(^{59}\) [http://www.food.gov.uk/aboutus/committees/](http://www.food.gov.uk/aboutus/committees/)

\(^{60}\) Ibid.
To review and challenge the process, procedures and outcomes at agreed key milestones of each initiative.

**ACNFP**

The Advisory Committee on Novel Foods and Processes (ACNFP) is a non-statutory, independent body of scientific experts that advises the Food Standards Agency on any matters relating to novel foods (including genetically modified foods) and novel processes (including food irradiation).

The Committee carries out safety assessments of any novel food or process submitted for approval under the EC novel food regulation. Until April 2004, the scope of this regulation included all foods produced using genetically modified organisms. However, GM foods are now subject to approval under a separate regulation. Approval of GM foods now involves centralised risk assessments, which are the responsibility of the European Food Safety Authority (EFSA).61

**Stakeholder meeting on animal feed issues**

The Food Standards Agency holds annual meetings to discuss a range of topical feed-related issues with a variety of stakeholders.

**Committee on Toxicity**

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an independent scientific committee that provides advice to the Food Standards Agency, the Department of Health and other Government Departments and Agencies on matters concerning the toxicity of chemicals.

**Committee on Carcinogenicity (COC)**

The Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) assesses and gives advice on carcinogenic risk to humans.

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It advises on important general principles or new scientific discoveries in connection with carcinogenic risks, co-ordinates with other bodies concerned with the assessment of carcinogenic risks, and makes recommendations for carcinogenicity testing.\(^{62}\)

**Committee on Mutagenicity (COM)**

The Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) assesses and advises on mutagenic risks to humans, advises on important general principles or new scientific discoveries in connection with mutagenic risks, co-ordinates with other bodies concerned with the assessment of mutagenic risks, and makes recommendations for mutagenicity testing.

**Spongiform Encephalopathy Advisory Committee (SEAC)**

The Spongiform Encephalopathy Advisory Committee (SEAC) was set up more than 15 years ago to provide independent expert scientific advice to the Government on spongiform encephalopathies such as BSE, CJD and scrapie. SEAC’s remit is wide-ranging, and covers public health, food safety and animal health issues.

SEAC was the first Government committee to hold its meetings in public, ensuring greater openness and transparency. Meetings are also webcast to open up the work of the committee to a wider audience.\(^{63}\)

**Committee on Nutrition (SACN)**

The Scientific Advisory Committee on Nutrition is a UK-wide Advisory Committee set up to replace the Committee on Medical Aspects of Food and Nutrition Policy (COMA). It advises the UK health departments as well as the Food Standards Agency.

\(^{62}\) Ibid.  
\(^{63}\) Ibid.
Working Party on Food Contact Materials

The Working Party on Materials and Articles in Contact with Food of Drink (WPFCM) advises the Agency on the research needed to ensure that consumers are protected from chemical migration into food from packaging and other materials in contact with food.

Working Party on Food Additives

This working party discusses legislative developments and provides guidance on research and surveillance on additives in food.

Pesticide Residues Committee

The Pesticide Residues Committee (PRC) is an independent body that was established in 2000. The Committee advises Ministers and the Chief Executives of the Food Standards Agency (FSA) and the Pesticides Safety Directorate (PSD) on a nationwide programme of pesticide residue surveillance in food and drink.

Advisory Committee on Pesticides (ACP)

The Advisory Committee on Pesticides (ACP) is an independent body which advises Ministers on all matters relating to the control of pesticides. Members provide scientific advice on the safe and effective use of pesticides and other pest control methods.

Veterinary Products Committee (VPC)

The Veterinary Products Committee (VPC) was established in 1970 to advise on the safety, quality and efficacy of veterinary medicines, and to consider reports of suspected adverse reactions to veterinary medicines.

Veterinary Residues Committee (VRC)

The Veterinary Residues Committee (VRC) was established in January 2001. Its main role is to advise the Chief Executives of the Veterinary Medicines

64 Ibid.
Directorate and the Food Standards Agency on the planning of the veterinary residues surveillance programmes, and the implications of the results for consumer safety.

**FSA Expert Group on Testing of Milk for Antibiotic Residues**

The group has been set up to advise the Food Standards Agency on scientific and practical aspects surrounding the control of antibiotic residues in milk.

The group's remit is to advise the Food Standards Agency on scientific and practical aspects surrounding the control of antibiotic residues in milk. In particular:

- to develop practical guidance on what constitutes a positive result in a rapid test for antibiotics
- to develop guidance on the procedures to be followed for the reporting of antibiotic test failures, and on the actions to be taken by industry and the enforcement authorities as a consequence of an antibiotic failure
- to recommend a strategy to the FSA in relation to handling the planned European discussions
- to consider potential future issues (horizon scan) in relation to the antibiotic testing of milk

Within the remit it will consider:

- gaps in scientific knowledge
- the content of guidance
- issues with the new policy on antibiotic residues
- the clarity of existing regulatory requirements
- the need for initiatives with other Member States, industry, IDF, kit manufacturers and so on, by, for example, FSA, VMD, NRL
Consultative Group on Campylobacter and Salmonella in Chickens (CGCSC)

The CGCSC was established to ensure stakeholder involvement in the Agency's work on campylobacter and salmonella in chickens.

The group does not provide formal advice to the Agency, or have a decision-making role, but it does have an important role in contributing to technical discussions and providing support to the Agency as it works towards reducing these organisms in chickens.

All the major stakeholders in the chicken production chain are represented on the group including consumers, industry, vets and government officials. The group had been actively involved in the Agency's work to date and discussions with stakeholders have been extremely important as the Agency has developed its strategies for controlling campylobacter and salmonella65.

Food borne Disease Strategy Consultative Group

The Food Standards Agency has established a Consultative Group involving a cross-section of stakeholders to help it in the implementation of the strategy to meet its target of reducing food borne disease by 20% by April 2006. The Group held its first meeting on 21 September 2001.

Enforcement Liaison Group

As part of the Agency's work to strengthen and develop links with local authority food law enforcement, a joint government/local authority group, the Local Authority Enforcement Liaison Group (LAELG) was established in May 1999.

This body was renamed the Enforcement Liaison Group (ELG) in November 200166.

65 Ibid.
66 Ibid.

Creating a forum for businesses, consumers and others is intended to help ensure the success of the proposed change programme and to build co-operation and partnership working. The advisory body will meet at least twice a year.

The 16 members of the advisory body comprise 11 representatives of consumers, food business operators in the red, white and game sectors, primary producers, meat retailers and supermarkets, and MHS contractors, plus the Meat Hygiene Service, Defra, the Welsh Assembly Government, the Scottish Government and the Department of Agriculture and Rural Development in Northern Ireland.

The Advisory Body's independent chair is Patrick Wall, Associate Professor of Public Health in the School of Public Health and Population Science, University College Dublin. He was the first Chief Executive of the Food Safety Authority of Ireland and was chair of the European Food Safety Authority management board.

Notes of meetings will also be published once agreed by members.

**Terms of Reference:**

The Advisory Body will provide advice and make recommendations to the FSA Board on proposed changes to the delivery of official controls in approved meat plants in the UK, covering:

- the progressive move towards full recovery of the costs of official controls from the industry, taking account of the underlying economic position of the industry

- the transformation of the MHS to reduce its total and net costs of operations in GB and improve productivity and efficiency to meet short and medium term targets
- the development of tender specifications for a control body pilot and, if agreed by the FSA Board, its implementation and evaluation

- the implementation of the official control requirements set out in Regulations 854/2004 and 882/2004 taking account of available flexibilities

- the strategy for moving towards a risk-based official control regime including SRM controls and the development of an evidence base to support negotiations while maintaining effective consumer protection, animal health and welfare standards.

The Advisory Body's advice will also be made known to the MHS Board and FSA/MHS change programme teams.

**Meat Hygiene Policy Forum**

The Meat Hygiene Policy Forum (MHPF), was launched on 16 April 2002 by the FSA's then Deputy Chair, Suzi Leather.

It provides those with an interest in meat hygiene issues - consumers, enforcers, retailers, and the meat industry - with the opportunity to discuss meat hygiene issues with the FSA officials responsible for policy development and implementation\(^67\).

**Meat Industry Red Tape Working Group (Pooley Group)**

Final progress report on the recommendations of the Meat Industry Red Tape Working Group to the review of the regulatory burdens.

In September 1999, MAFF and the National Farmers Union set up a joint review of the regulatory burdens on the meat industry, including slaughterhouse regulation and meat hygiene rules and the work of the Meat Hygiene Service. The Meat Industry Red Tape Working Group, chaired by Robin Pooley, reported in


Of the 35 recommendations, 28 were accepted, 4 required further consideration and 3 were rejected. Of the recommendations 29 were for the Food Standards Agency (established in April 2000) to take forward, but 1 was subsequently transferred by agreement to Defra.

**Enforcement Stakeholder Forum**

The Enforcement Stakeholder Forum aims to provide an informal communications vehicle to representatives working in this sector and an opportunity to explore possibilities for productive partnership working.

Stakeholders can also discuss current and emerging issues and hear from the Food Standards Agency about its plans for the next six months\(^\text{68}\).

**Framework Agreement Sub Group**

The Framework Agreement Sub Group, a sub group of the Enforcement Liaison Group, oversees the operation of the Framework Agreement.

**Food Incidents Task Force**

The Food Standards Agency has set up an incidents task force to strengthen existing controls in the food chain.

The aims are to reduce the possibility of future contamination incidents, such as those involving Para Red and Sudan dyes, and to improve the management of such incidents if they do occur.

The task force is chaired by the Agency's Chief Executive, Dr Jon Bell, and members include senior representatives from the food industry, enforcement authorities and consumer organisations, as well as two independent members.

\(^{68}\text{Ibid.}\)
The task force will:

- identify practical ways of reducing the likelihood of food contamination incidents occurring
- identify ways of deciding upon the proportionality of any response
- ensure that the roles and responsibilities of different stakeholders in risk management of food contamination incidents are clearly agreed so that action is taken quickly, effectively and proportionately if incidents do occur
- enable the Agency and other partners to learn quick lessons
- identify ways that the Agency might champion the uptake of the measures identified

The task force is due to report back to the Board on progress in the autumn and will hold its first meeting next month.

**Food Standards Sampling Co-ordination Working Group**

This joint LACORS/Agency working group was set up in May 2003 to help encourage better co-ordination of food standards sampling across local authorities and the Agency, and to promote focused sampling programmes.

During 2003, the remit of the Group was extended to include co-ordination of sampling as part of the Agency’s work to achieve a step change improvement in imported food enforcement.

Membership of the Group includes local authority food standards, food hygiene and port health enforcement officials, as well as Public Analysts, the Health Protection Agency, Defra and representatives from all parts of the Agency with an interest in food sampling and surveillance.

**Additives and Authenticity Methodology Working Group**

The AAMWG evaluates research developed within the authenticity and additives
Membership of the steering group is drawn from a range of stakeholder organisations including advertisers, food manufacturers, retailers, health professionals, consumer groups, child health and food promotion experts and policy makers. Fiona Adshead, the Deputy Chief Medical Officer chairs the Forum.

**Nutrition Strategy Steering Group**

The Nutrition Strategy Steering Group's (NSSG) aim is to help people choose healthier diets by carrying through a range of voluntary nutritional initiatives.

**Terms of reference**

To encourage the delivery of commitments from principal partners (industry, government departments, agencies, and non-government organisations) to progress key strategic dietary health objectives, including those in the Government's White Paper on Choosing Health.

The key initiatives to be considered are:

- reformulation of foodstuffs
- front of pack signpost labeling
- promotion of food to children the Healthy Living Social Marketing Campaign

The group will:

- aim to meet twice a year
- be chaired by public health minister Dawn Primarolo with Dame Deirdre Hutton (Chair FSA) deputising as necessary
- co-opt additional members onto the group on an ad hoc basis to inform its decisions while maintaining a balance of interests
- establish working groups as appropriate
**Animal Feed Law Enforcement Liaison Group**

The Animal Feed Law Enforcement Liaison Group (AFLELG) comprises representatives of UK enforcement bodies and government departments with an interest in animal feed law. It meets twice a year to discuss enforcement related issues, to identify common problems and agree to a consistent and co-ordinated approach to feed law enforcement.\(^{71}\)

**Scottish Food Enforcement Liaison Committee (SFELC)**

SFELC is a group that co-ordinates the food law enforcement and sampling and surveillance activities of Scottish local authorities and comprises representatives of central and local government, consumers and industry.

The committee provides a forum for the discussion of topics relevant to any current problems and may initiate surveys or projects or co-ordinate specific investigations initiated by the local Food Liaison Groups that have been set up in four geographical areas.

**Independent panel on the controls on infant formula and follow-on formula**

An independent panel has been set up to review the effect of the infant and follow-on formula controls, introduced in 2008, on how follow-on formulas are presented and advertised. The review will be carried out over a year and will begin in June 2008.

The review will examine whether, as a result of the new controls, parents/parents to be and careers are clear that the presentation of and advertisements for follow-on formula relate to formula for older babies (6 months and above) and not infant formula. The review will assess whether they are working as expected or whether further action is needed.

\(^{71}\) Ibid.
UK-Wide Scores on the Doors Steering Group

At its meeting on 10 December 2008, the Agency's Board decided that a six-tier national score on the doors (SotD) scheme should be established in England, Wales and Northern Ireland and that a two-tier scheme should continue in Scotland. The Board agreed that a UK-wide Steering Group should be established to provide advice and guidance on the development of the schemes.

The Steering Group has been set up with a view to shared learning and commonality of approach, as far as possible. It is chaired by Steven Esom who has a background in the food industry, and its membership comprises consumer, local authority, food industry and Agency representatives.\(^72\)

AUSTRALIA

Food Standards Australia New Zealand. : The Authority

Food Standards Australia New Zealand's role is, in association with others, to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe and nutritious food supply.

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991*. The object of this Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals.\(^73\):

> a. a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;

\(^72\) Ibid.

\(^73\) Part -I, Section 2A of *Food Standards Australia New Zealand Act, 1991*. 67
b. an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;

c. the provision of adequate information relating to food to enable consumers to make informed choices;

d. the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.\(^74\)

**Role of FSANZ**

The Australian Government is committed to improving the health and well-being of all Australians by ensuring a safe food supply and well-informed consumers in Australia. Safe food and well-informed consumers will assist in maintaining and improving the health of the community while contributing to an internationally competitive food industry. FSANZ assists in achieving this objective through the development of evidence-based food standards supported by collaborative arrangements with stakeholders such as primary producers and processors, manufacturers, retailers, consumer organisations and public health bodies.

Food standards developed by FSANZ are based on risk analysis using the best available scientific evidence.

**Key Strategic Directions:**

- Continue to develop and maintain effective food standards.
- Further improve the evidence-base for food standards setting.
- Collaborate with regulatory partners in producing an effective and seamless food regulatory system.

\(^{74}\) *Ibid.*
• Strengthen and evaluate levels of engagement with consumers and other stakeholders.

• Strengthen the capacity to identify and provide an effective and timely response to current and emerging issues related to food.

Any individual or organization, whether within Australia, New Zealand or any other country, may make an application to FSANZ seeking to change the Code. FSANZ itself may also seek to change the Code by raising a 'proposal'. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code. In the case of both applications and proposals, there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. However, the consultation process will differ for matters that are urgent or minor.

All applications are subject to an ‘Administrative Assessment’ on receipt by FSANZ as under:


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The First Stage - is to conduct an Initial Assessment. This involves the development of an Initial Assessment Report, which sets out the background to the application or proposal and is used primarily to stimulate useful input from stakeholders by raising issues and asking questions.

Public submissions are invited through notices in newspapers, email advice to interested stakeholders and on the FSANZ website.

The Second Stage - is the Draft Assessment stage. After considering any submissions, a report is prepared for the Board's consideration. Most of the analytical work is undertaken at this stage including a comprehensive scientific risk assessment and a regulatory impact analysis (incorporating a cost or risk benefit analysis).

The FSANZ Board makes a Draft Assessment and, in accordance with the FSANZ Act, approves the Draft Assessment Report, which is released for public comment. The report is listed on the FSANZ website and stakeholders advised of its availability.

The Report includes a proposed draft standard or a draft variation to a Standard, unless the Application is rejected or the Proposal abandoned by the FSANZ Board.

The Third Stage - is the Final Assessment stage. After considering any further public submissions received following the Draft Assessment stage, a Final Assessment Report is prepared for consideration by the Board. If the Board approves the draft standard or variation, the Board notifies the Australia and New Zealand Food Regulation Ministerial Council of its decision.

After the Ministerial Council considers the proposed standard or variation, it may be gazetted in Australia and New Zealand to become a part of the Code. As a result, it is automatically incorporated into Australian Commonwealth, State and Territory and New Zealand food laws.

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FSANZ invites comments from the public when considering new food standards or varying existing standards in order to ensure that decision-making is underpinned by as much information as possible. To achieve this, it welcomes input from the public, from industry and from health professionals. The requirement to consult with the public is built into FSANZ’s legislation.

Assessment reports are available for viewing and downloading from the FSANZ website.78

While developing or reviewing the standards FSANZ gives regard to policy guidelines formulated by the Ministerial Council, which are:

(a) The need for standards to be based on risk analysis using the best available scientific evidence;
(b) The promotion consistency between domestic and international food standards;
(c) The desirability of an efficient and internationally competitive food industry;
(d) The promotion of fair-trading in food;
(e) A written policy guidelines formulated by the Council for the purposes of this paragraph and notified to FSANZ79.

USA

Food and Drug Administration

Federal responsibility for the direct regulation of food in the United States has primarily been delegated to the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA)80.

78 Ibid.
80 Neal D. Fortin J.D., Food Regulation Law, Science, Policy and Practice, at 23 (2009).
FDA is an agency within the Department of Health and Human Services and consists of centers and offices.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, nation’s food supply, cosmetics, and products that emit radiation.

The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Advisory committees and Panels

The Food and Drug Administration, to assist in its mission to protect and promote the public health, uses 48 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.

Food Advisory Committee:

The Food Advisory Committee is a technical and scientific committee that advises the Commissioner in discharging its responsibilities as they relate to issues of food safety, food science, and applied nutrition, and as required, any product for which the Food and Drug Administration has regulatory responsibility.

Functions -

The Committee provides advice to the Commissioner of Food and Drugs and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related health issues that the FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to:

(1) Broad scientific and technical food or cosmetic related issues;

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81 http://www.fda.gov/AboutFDA/CentersOffices/default.htm
82 http://www.fda.gov/AdvisoryCommittees/default.htm
(2) The safety of new foods and food ingredients;

(3) Labeling of foods and cosmetics;

(4) Nutrient needs and nutritional adequacy; and

(5) Safe exposure limits for food contaminants.

The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

Structure -

The Committee shall consist of 17 standing members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, and other relevant scientific and technical disciplines. Fifteen shall be voting members, of which two shall be technically qualified who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee shall have two nonvoting members who are identified with industry interests.

Other Authorities:

USDA Food Safety and Inspection Service (FSIS)

Oversees

- Domestic and imported meat and poultry and related products, such as meat - or poultry - containing stews, pizzas, and frozen foods.

83http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisorCommittee/wcm120646.htm
- Processed egg products (generally liquid, frozen, and dried pasteurized egg products)\textsuperscript{84}.

\textbf{Food Safety Role}

The Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which regulate meat, poultry, and egg products are enforced by:

- Inspecting food animals for diseases before and after slaughter.
- Inspecting meat and poultry slaughter and processing plants.
- With USDA’s Agricultural Marketing Service, monitoring and inspecting processed egg products.
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents.
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, and for plant sanitation, thermal processing, and other processes.
- Ensuring all foreign meat and poultry processing plants exporting to the United States meet U.S. standards.
- Seeking voluntary recalls by meat and poultry processors of unsafe products.
- Educating industry and consumers on safe food-handling practices.

For more information: www.fsis.usda.gov

\textbf{U. S. Environmental Protection Agency}

\textbf{Oversees}

- Drinking water
- Pesticide safety

\textsuperscript{84} \textit{Supra} note 80 at 25.
Food Safety Role

- Establishes safe drinking water standards.
- Regulates toxic substances and wastes to prevent their entry into the environment and food chain\(^85\).
- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides\(^86\).

For more information: [www.epa.gov](http://www.epa.gov)

MALAYSIA

Standards Malaysia

Food safety responsibilities throughout Malaysia are executed through a system of administration including the central, state, district and local authority levels. Within the Ministry of Health, the Food Quality Control Unit, which was established in 1974, is responsible for: the overall technical supervision of food safety activities; formulation of legislation, codes of practice and guidelines; determination of food safety policies; adoption of food sampling and food premises inspection strategies; and coordination of activities at the state and district levels\(^87\).

The Department of Standards Malaysia (STANDARDS MALAYSIA) is an agency under the ambit of Ministry of Science, Technology and Innovation (MOSTI).

Standards Malaysia was officially launched on 28 August 1996 following the incorporation of Standards and Research Institute of Malaysia (SIRIM) into SIRIM Berhad. Standards Malaysia took over the statutory roles in

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\(^{85}\) Ibid.

\(^{86}\) Id., at 26.

\(^{87}\) Centre for Science’s report on “Food Safety Around The World”, 13, June (2005).
standardization, formerly carried out by SIRIM. In addition, Standards Malaysia is also entrusted with the responsibilities of accreditation\textsuperscript{88}.

Its roles and functions are governed by the Standards of Malaysia Act 1996 (Act 549).

As standards give a very significant implication to the nation’s economy and the well being of consumers, STANDARDS MALAYSIA has established a national standards development structure (Figure) in accordance with the provisions in the Act to ensure the transparency and relevancy of the standards developed\textsuperscript{89}.

\textsuperscript{88} \url{www.standardsmalaysia.gov.my}

\textsuperscript{89} Ibid.
The Minister of Science, Technology and Innovation has the overall responsibility for the structure. The Minister is responsible for the approval of the draft Malaysian Standards recommended by STANDARDS MALAYSIA and also its gazettement. The Minister has also established the Malaysian Standards and Accreditation Council as an advisory body to advise the Minister in respect of standardization policies, programs, schemes projects and activities\textsuperscript{90}.

**MALAYSIAN STANDARDS AND ACCREDITATION COUNCIL (MSAC)**

The Minister has appointed the members of the MSAC which comprises 15 representatives of various concerned groups or categories of interest. These include a representative of successor company (SIRIM Berhad), five representatives from the government and not more than seven other members who in the opinion of the Minister have wide experience or special knowledge in matters relating to the function, powers and activities of the MSAC. The Director-General of STANDARDS MALAYSIA is an ex-officio member of the MSAC, and a member of the MSAC holds office for a three-year-term. The MSAC in accordance with subsection 14 of the Act 549 has established four national committees, deemed to assist its duties:

- National Standards Committee (MyNSC)
- National IEC Committee (MyENC)
- National Accreditation Committee (MyNAC)
- National Medical Testing Accreditation Committee (MyNMTAC)

Memberships of all the national committees are for a term of three years. The secretariat of MSAC, MyNSC, MyENC, MyNAC and MyNMTAC is at STANDARDS MALAYSIA\textsuperscript{91}.

\textsuperscript{90} Ibid.
\textsuperscript{91} Ibid.
NATIONAL STANDARDS COMMITTEE (MyNSC)

The main functions of the MyNSC are:

- To recommend to the MSAC the strategies, programs and activities to promote industrial efficiency and development and for consumer protection through standardization.

- To establish the Industry Standards Committees with its specified term of reference to oversee technical work of standardization both at national and international levels.

NATIONAL IEC COMMITTEE (MyENC)

The MyENC was established to represent Malaysia as the member in the International Electrotechnical Commission (IEC). The main functions of the MyENC are:

- To represent Malaysia’s interest in all matters pertaining in the working group, the IEC and its various committees.

- To recommend attending appropriate meetings for purposes of representing national views and submitting appropriate documentations and propositions.

- To coordinate and formulate a national stand in respect of the IEC draft standards and standards and other matters relating to the IEC.

- To establish National IEC Sub-Committees where necessary and to provide advice to these subcommittees; and

- To perform any other functions as may be determined or delegated by the Council\(^\text{92}\).

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\(^{92}\text{Ibid.}\)
NATIONAL ACCREDITATION COMMITTEE (MyNAC)

MyNAC was established to discharge the duties delegated by MSAC pertaining to accreditation issues. The main functions of the MyNAC are:

- To provide advice to MSAC on accreditation matters.
- To establish accreditation criteria, requirements, policies and procedures for the consideration of MSAC.
- To assist MSAC to facilitate the review of accreditation procedures and operations.

NATIONAL MEDICAL TESTING ACCREDITATION COMMITTEE (MyNMTAC)

The main functions of the MyNMTAC are:

- To represent Malaysia’s interest in all matters pertaining to medical laboratory accreditation.
- To recommend to relevant authorities attendance at appropriate meetings for purposes of presenting views and submitting appropriate proposals in the national interest.
- To coordinate and formulate a national stand in respect of all matters relating to standardization and accreditation of medical laboratory.
- To establish Sub-Committees where necessary and to provide advice to these sub-committees.\textsuperscript{93}

SIRIM BERHAD

STANDARDS MALAYSIA has appointed SIRIM Berhad as the sole National Standards Development Agency under the provisions of the Act 549.

\textsuperscript{93} Ibid.
The Standards Management Department is given the mandate to fulfill SIRIM Berhad’s obligations as the sole designated National Standards Development Agency by effectively managing, at the technical level, the standards development structure in Malaysia and representation in relevant regional and international standards committees to meet the expectation of all stakeholders.

SIRIM Berhad has recently taken a further step in enhancing the development of Malaysian Standards it signed an agreement with ASTM International (originally known as American Society for Testing and Materials). The partnership has strengthened the tie between the two organisations in order to aid in the development of Malaysian Standards to support the country’s economic advancement.

**INDUSTRY STANDARDS COMMITTEES (ISCs)**

ISCs are established by the NSC to oversee and coordinate the standards development process within their respective scopes as endorsed by NSC. There are currently 24 ISCs in various fields of standardization as per Figure 1. The committees which are managed by SIRIM Berhad are also responsible for approving the draft of Malaysian Standards so prepared and recommending to the STANDARDS MALAYSIA for final approval as Malaysian Standards by the Minister.

The ISCs may establish Technical Committees and Working Groups for the purpose of developing Malaysian Standards. In addition, ISCs shall identify the current needs and recommend priorities of national standardization within its scope and approve the annual program for standards development.

In the area of international standardization, the ISCs may identify and recommend to the STANDARDS MALAYSIA, delegate(s) to be sponsored for attending the international meeting where necessary.

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TECHNICAL COMMITTEES (TCs)

The TCs which are established by the ISCs are responsible for developing, preparing and reviewing Malaysian Standards for general and specific scope. TCs are also responsible for approving release of draft Malaysian Standards for the purpose of soliciting public comments and reviewing the comment(s) received. The TCs shall be responsible for supporting its parent ISC by studying and commenting and/or voting on the relevant draft international standards. The TCs may establish working group(s) for the purpose of undertaking specific tasks.

WORKING GROUPS (WGs)

The WGs are responsible for the work on specific projects determined by ISC/TC. STANDARDS WRITING ORGANIZATIONS (SWOs) Cabinet in 1991 has approved the strategy to expedite the pace of the development of Malaysian Standards to achieve 6000 standards by the year 2010 by appointing specialized bodies to develop standards within their expertise. The bodies which are called SWOs are appointed by SIRIM Berhad to undertake standards development work. The draft standards produced by SWOs can be directly submitted to ISC for approval provided that the SWO develops standards through balanced committees and the committees have released the draft for public comment and review the comment(s) received. For SWOs that develop standards without having a balanced committee, draft standards produced by such SWOs have to be submitted to TCs for subsequent processes\(^6\).

Development of Malaysian Standards

Malaysian Standards

Malaysian Standards are consensus documents developed by Standards Development Committees (SDC) within the Malaysian Standards Development System and approved by the Minister of Science, Technology and Innovation in accordance with the Act 549. Malaysian Standards specifies the optimum

\(^6\) Ibid.
requirements of quality and safety for voluntary use by the public. A standard becomes mandatory when a regulatory agency enforces its use through the relevant Acts or regulations. The process for development of a Malaysian Standard is as shown in Figure below.

Categories of Malaysian Standards

- Specification
- Testing methods
- Codes of good practice / recommendations
- Terminology / glossaries / vocabulary / symbols / nomenclature
- Classification / grading

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Ibid. 82
JAPAN

Under the Ministry of Health, Labour and Welfare (MHLW), the administration of food safety is with the Department of Food Safety under the Pharmaceutical and Food Safety Bureau.

The Department of Food Safety, Pharmaceutical and Food Safety Bureau, has a responsibility of Specifications and standards.

Standards Evaluation Division of the Department of Food Safety establishes specifications/standards for food, food additives, pesticide residues, animal drug residues, food containers, and food labeling. The Office of Health Policy works on Newly Developed Food for Labeling of specified uses, nutrition labeling standards, foods with health claims, dietary supplements, and safety assessment of genetically modified foods.

Establishment of standards

1) Mycotoxins:

Standards are basically established through in-depth discussion at the Food Safety Commission and the Pharmaceutical Affairs and Food Sanitation Council. First, the Food Safety Commission conducts toxicity evaluation based on evaluations by the JECFA and establishes the “no-observed-effect level (NOEL)” or “no-observed-adverse-effect level (NOAEL)” for each mycotoxin. Then, the Commission determines the tolerable daily intake (TDI) by applying appropriate safety factors. In light of the evaluation by the Commission, the Pharmaceutical Affairs and Food Sanitation Council establishes standard limits for individual foods. In the standard setting, the Council takes account of food consumption, loss during food preparation, and Codex standards. Standard limits are established so that the sum of limits on individual foods for a mycotoxin does not exceed the tolerable daily intake (TDI).
Illustration on the establishment of standards for deoxynivalenol
(A mycotoxin):

Deoxynivalenol (DON) is a mycotoxin produced by fungi of genus Fusarium. It contaminates cereal grains, like barley, wheat, and oats. This family of fungi cause Fusarium head blight in barley when a humid climate, like rainy season, coincides with the timing of flowering-to-maturing.98

The DON poisoning of humans is characterized by gastrointestinal symptoms such as nausea, vomiting, and diarrhea. In dosing tests in mice, effects on thymus, spleen, heart, and liver were reported. DON is highly thermo-stable and is not reduced in ordinary cooking processes.99

The MHLW conducted an investigation to identify the contamination of grains with DON in 2001, and considerably high levels of DON were detected in some samples. The following are investigation results:

The Joint Subcommittee of Food Standards and Toxicity under the Pharmaceutical Affairs and Food Sanitation Council discussed whether standards for DON should be established.

The Joint Subcommittee concluded that standards under Article 11 of the Food Sanitation Law were necessary to reduce health risk from the intake of DON and to prevent health hazards. The Subcommittee stated that a guideline level of 1 ppm should be applied for wheat until the standard is set.100

The Joint Subcommittee concluded at a meeting held that additional investigations targeted at wheat, household-use wheat flour, and baby foods were necessary to obtain enough data for establishing standards. The subcommittee mentioned that investigations for wheat should be focused on yearly changes in DON concentration in crops. The MHLW will establish standards after the results of

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98 The Nineteenth seminar for visiting food hygiene experts of Policy planning and Communication division, standards and evaluation Inspection and safety division (2006).
99 Ibid.
100 Ibid.
additional investigations become available, taking discussion by the CAC into account.

2) Establishment of MRLs for pesticides / veterinary drug residues etc.

The Ministry of Health, Labour and Welfare to establish MRLs for pesticides at the time of registration by the Ministry of Agriculture, Forestry and Fisheries.

The establishment of an MRL begins with the submission of an application for registration to the Ministry of Agriculture Forestry and Fisheries (MAFF). Upon receiving notification from the MAFF of the application, the MHLW will request the MAFF to provide the documents required for safety evaluation under Article 12 of the Food Sanitation Law. These documents include acute toxicity, subacute toxicity, chronic toxicity, carcinogenicity, reproductive toxicity, teratogenicity, genetic toxicity, pharmacokinetic and general pharmacological parameters, animal metabolism, and plant metabolism as well as residue data for commodities treated with target pesticides.\(^{101}\)

The MHLW will ask the Food Safety Commission for opinions concerning health effects after obtaining the necessary documents. In response to the consultation, the commission will conduct a health risk assessment and establish the ADI (Acceptable Daily Intake). In establishing the ADI, the NOAEL (No-Observed-Adverse-Effect Level), which is basically determined from animal studies, and the safety factor are used. The MHLW will have the Pharmaceutical Affairs and Food Sanitation Council establish MRLs. MRLs will be established based on an exposure assessment, using the ADI established by the Food Safety Commission.

Currently, Japan uses the theoretical maximum daily intake (TMDI) method and estimated daily intake (EDI) method for the exposure assessment. The MRLs for a pesticide are allocated to individual foods so that the calculated daily intake of the pesticide does not exceed its ADI. Residue data obtained for the pesticide when applied in accordance with the use direction claimed on the registration

\(^{101}\) ibid.
application are the basis for the MRL on the specific crops\textsuperscript{102}.

When the commission determines that no ADI can be set for a pesticide, the MRL will be established for the pesticide as N.D. (no detection) meaning the limit-of-detection level\textsuperscript{103}.

\textbf{Harmonization with Codex standards}

The SPS (Sanitary and Phytosanitary) Agreement of the WTO Agreement requires each member country to harmonize its food safety regulations with international regulations, in order to minimize the impact of discrepancies in regulation between member countries on trade. Based on this principle, Japan accepts Codex standards as far as possible when establishing MRLs, unless the acceptance may pose a major problem\textsuperscript{104}.

\textbf{THAILAND}

\textbf{National Bureau of Agricultural Commodity and Food Standard}

Under the comprehensive government food safety reform, a new governmental unit, the National Bureau of Agricultural Commodity and Food Standard (ACFS), was established in the Ministry of Agriculture and Cooperatives (MOAC).

ACFS is responsible to coordinate collaborative operations on agricultural commodities and food standards. ACFS functions include the following:

1. Promulgation of national standards on agricultural commodity and food products.

2. Serving as the accreditation body for national food and agricultural standards.

\textsuperscript{101} Ibid.
\textsuperscript{102} Ibid.
\textsuperscript{103} Ibid.
\textsuperscript{104} \url{http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm}
3. Cooperation and negotiation on technical issues in foreign trade as well as in matters relating to relevant international standard setting organizations (e.g. Codex)\textsuperscript{105}. Additional responsibilities of ACFS include being the “focal point” of CODEX, the Agreement of Sanitary and Phytosanitary Measures (SPS) etc. ACFS has coordinated, encouraged and supported all stakeholders in Thailand to actively participate in the works of these organizations. This has facilitated the harmonization of national standards and regulations with international standards.

In addition TISI (Thai Industrial Standards Institute) is involved in standards preparation.

TISI is the leading agency for standardization for the country and internationally recognized for its operation\textsuperscript{106}.

**Standards development**

1. National standards development TISI develops both mandatory and voluntary Thai Industrial Standards (TISs) to suit the need and the growth of industry, trade and economy of the country. Standards are developed according to the government policy in consumer’s protection, industrial promotion to be competitive in the world market, environmental protection and natural resources preservation\textsuperscript{107}.

2. International standards development TISI participates in the development of international standards of the International Organization for Standardization (ISO), and the FAO/WHO Foods Standards Programme (Codex Alimentarius Commission)\textsuperscript{108}.


\textsuperscript{106} Ibid.
