CHAPTER VII
ENFORCEMENT PROVISIONS

INDIA

Responsible Authorities and their responsibilities

Food Inspectors:

1. The Central Government or the State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications to be food inspectors for such local areas as may be assigned to them by the Central Government or the State Government, as the case may be1:

Provided that no person who has any financial interest in the manufacture, import or sale of any article of food shall be appointed to be a food inspector under this section.

2. Every food inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him, may specify in this behalf2.

Powers of food inspectors —

(1) A food inspector shall have power—

a) to take samples of any article of food from—

i. any person selling such article;

ii. any person who is in the course of conveying, delivering or preparing to deliver such article to a purchaser or consignee;

iii. a consignee after delivery of any such article to him; and

2 Ibid.
a) to send such sample for analysis to the public analyst for the local area within which such sample has been taken;

b) with the previous approval of the Local (Health) Authority having jurisdiction in the local area concerned, or with the previous approval of the Food (Health) Authority, to prohibit the sale of any article of food in the interest of public health.

Explanation — For the purposes of sub-clause (iii) of clause (a), "consignee" does not include a person who purchases or receives any article of food for his own consumption.

(2) Any food inspector may enter and inspect any place where any article of food is manufactured, or stored for sale, or stored for the manufacture of any other article of food for sale, or exposed or exhibited for sale or where any adulterant is manufactured or kept, and take samples of such article of food or adulterant for analysis:

Provided that no sample of any article of food, being primary food, shall be taken under this sub-section if it is not intended for sale as such food.

(3) Where any sample is taken under clause (a) of sub-section (1) or sub-section (2), its cost calculated at the rate at which the article is usually sold to the public shall be paid to the person from whom it is taken.

(4) If any article intended for food appears to any food inspector to be adulterated or misbranded, he may seize and carry away or keep in the safe custody of the vendor such article in order that it may be dealt with as hereinafter provided: and he shall, in either case, take a sample of such article and submit the same for analysis to a public analyst:

Provided that where the food inspector keeps such article in the safe custody of the vendor he may require the vendor to execute a bond for a sum of

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3 Ibid.
4 Id. at 20.
money equal to the value of such article with one or more sureties as the food inspector deems fit and the vendor shall execute the bond accordingly⁵.

4A) Where any article of food seized under sub-section (4) is of a perishable nature and the Local (Health) Authority is satisfied that such article of food is so deteriorated that it is unfit for human consumption, the said Authority may, after giving notice in writing to the vendor, cause the same to be destroyed⁶.

(5) The power conferred by this section includes power to break open any package in which any article of food may be contained or to break open the door of any premises where any article of food may be kept for sale⁷:

Provided that the power to break open the package or door shall be exercised only after the owner or any other person in charge of the package or, as the case may be, in occupation of the premises, if he is present therein, refuses to open the package or door on being called upon to do so, and in either case after recording the reasons for doing so:

Provided further that the food inspector shall, in exercising the powers of entry upon, and inspection of any place under this section, follow, as far as may be, the provisions of the Code of Criminal Procedure, 1973 (2 of 1974) relating to the search or inspection of a place by a police officer executing a search warrant issued under that Code⁸.

(6) Any adulterant found in the possession of a manufacturer or distributor of, or dealer in, any article of food or in any of the premises occupied by him as such and for the possession of which he is unable to account to the satisfaction of the food inspector, and any books of account or other documents found in his possession or control and which would be useful for, or relevant to, any investigation or proceeding under this Act, may be seized by the food inspector and a sample of such adulterant submitted for analysis to a public analyst:

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⁵ Ibid.
⁶ Ibid.
⁷ Id. at 21.
⁸ Ibid.
Provided that no such books of account or other documents shall be seized by the food inspector except with the previous approval of the authority to which he is officially subordinate.

(7) Where the food inspector takes any action under clause (a) of sub-section (1), sub-section (2), sub-section (4) or sub-section (6), he shall call one or more persons to be present at the time when such action is taken and take his or their signatures.

7A) Where any books of account or other documents are seized under sub-section (6), the food inspector shall within a period not exceeding thirty days from the date of seizure, return the same to the person from whom they were seized after copies thereof or extracts therefrom as certified by that person in such manner as may be prescribed have been taken:

Provided that where such person refuses to so certify, and a prosecution has been instituted against him under this Act, such books of account or other documents shall be returned to him only after copies thereof or extracts therefrom as certified by the court have been taken.

7B) When any adulterant is seized under sub-section (6), the burden of proving that such adulterant is not meant for purposes of adulteration shall be on the person from whose possession such adulterant was seized.

(8) Any food inspector may exercise the powers of a police officer under section 42 of the Code of Criminal Procedure, 1973 (2 of 1974) for the purpose of ascertaining the true name and residence of the person from whom a sample is taken or an article of food is seized.

(9) Any food inspector exercising powers under this Act or under the rules made there under who—

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9 Ibid.
10 Id. at 22.
11 Ibid.
a) vexatiously and without any reasonable grounds of suspicion seizes any article of food or adulterant; or

b) commits any other act to the injury of any person without having reason to believe that such act is necessary for the execution of his duty; shall be guilty of an offence under this Act and shall be punishable for such offence with fine which shall not be less than five hundred rupees but which may extend to one thousand rupees.

**Public Analysts —**

The Central Government or the State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications to be public analysts for such local areas as may be assigned to them by the Central Government or the State Government, as the case may be:

Provided that no person who has any financial interest in the manufacture, import or sale of any article or food shall be appointed to be a public analyst under this section:

Provided further that different public analysts may be appointed for different articles of food.

The provisions relating to sampling and analysis had been subject matter of litigation in a number of cases.

In *Saumindra Bhattacharya v. State of Bihar and Anr.*

the complainant Ajay Paul, purchased three bottles of Limca from a retailer at village Digha. One of the bottles was opened by the complainant and on consuming the same, he fell sick, vomitted several times, felt nauseated, had loose motions and had to spend a sum of Rs. 3,000/- on medicines etc. The complainant also examined one of the bottles of Limca which remained unopened and found that it contained several dust

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12 *Id. at 23.
14 *Id. at 18.*
15 *Id. at 19.*
16 2009(4) KLT 60(SC)
particles. He filed a complaint under Sections 2, 16, 17 of the Prevention of Food Adulteration Act, 1954, read with Section 320 of the IPC.

Section 12, provides that a purchaser may have a food product analysed and for that purpose may submit the food sample to a public analyst but before doing so he has to inform the vendor at the time of purchase that he intends to have the article analysed. The second proviso further states that the same procedure would be applicable to such purchase and taking of samples as well. The sample which was required to be sealed and kept in the manner required by Section 11. A prosecution for an offence under the Act can be instituted by a purchaser only if the report of the public analyst is produced alongwith the complaint. So, even assuming that some report of the public analyst had been put on record during the pendency of the complaint before the Magistrate, this factor will not cure the defect under Section 20 as the very institution of the complaint without the report of the public analyst was not authorised in law.

Where a power is given to do a certain thing in a certain way the thing must be done in that way or not at all. Other methods of performance are necessarily forbidden. And further it would be an unnatural construction to hold that any other procedure was permitted than that which is laid down with such minute particularity in the sections themselves.17

In Girishbhai Dahyabhai Shah v. C.C. Jani and Anr.,18, the sample of curd, in respect of which the complaint was filed, was collected on 8th April, 1988 and the report of the Public Analyst, whereupon the appellant applied for examination of the second sample on the basis of Section 13(2), was filed on 4th May, 1988, but was made available to the appellant only on 17th July, 1989, i.e. 15 months after the samples had been collected. On 10th November, 1989, the petitioner had prayed for examination of the second sample. The second sample was ultimately examined on 10th February, 1990, i.e. 15 months after the second sample had been collected.

17 Nazir Ahmad v. King Emperor, AIR 1936 PC 253
18 JT 2009(12) SC 80
sent to the Central Food Laboratory on 6th December, 1989, and the report was received on 26th December, 1989.

The appellant contended that the report of the Public Analyst having been served on him only on 17th July, 1989, he was not in a position to apply for examination of the second sample to which he was entitled in terms of the Section 13(2) of the Prevention of Food Adulteration Act, 1954, prior to the said date. It was also his case that since the report had been served on him only on 17th July, 1989, by which time the sample of curd had deteriorated, any further examination of such sample had become meaningless, thereby depriving him of the valuable right conferred on him by Section 13(2) of the Act.

Section 13(2) indicates that on receipt of the report the accused could, if he so desired, make an application to the court within a period of 10 days from the date of the receipt of the copy of the report to get the sample of article of food kept by the Local (Health) Authority analysed by the Central Food Laboratory. But in the instant case, the appellant was prevented from applying for analysis of the second sample before 17th July, 1989, by which time the second sample of curd had deteriorated and was not capable of being analysed.

In the absence of any valid and reliable report with regard to the second sample the order passed by the High Court was set aside and the proceeding pending before the Metropolitan Magistrate was quashed.

In *Benny Thomas v. Food Inspector, Kochi and Anr.*19, the Food Inspector, P.W.I inspected the shop of the appellant by name "Bejoy Fruits and Vegetables". He bought one bottle of synthetic syrup, on paying Rs. 40/-, He sampled it according to the procedure. Analysis showed that the sample did not conform to the standards prescribed under the rules and, therefore, was adulterated. After appreciation of the evidence, the appellant was found guilty, convicted and sentenced accordingly. Appeal by appellant resulted only in reduction of sentence.

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19 AIR 2008 SC 2817
The revision petition did not bring any relief. Appeal was made to challenge the order passed by the Kerala High Court dismissing the Criminal Revision Petition which was filed questioning correctness of the conviction for offence punishable under Section 16(l)(a)(i) read with Section 7(1) and Section 2(ia)(m) of the Prevention of Food Adulteration Act, 1954 and also under Rule 5 read with Appendix B, Item A.07.08 and Rule 50 of the Prevention of Food Adulteration Rules, 1955. The appellant was sentenced to undergo simple imprisonment for one year and to pay a fine of Rs. 2,000/-. Sessions Judge, in appeal modified the sentence and reduced it to simple imprisonment for six months and a fine of Rs. 1,000/-. It was held by the Court that the sentence imposed was minimum and, therefore, the plea, that the sentence is harsh, has no substance.

In *N. Sukumaran Nair v. Food Inspector, Mavelikara*\(^{20}\), a sample of ice-cream purchased by the Food Inspector from the appellant was reported by the Public Analyst to be adulterated because of reduction of milk-fat and total solids in the product. Yet, the Trial Court acquitted the appellant on the ground that Rule 18 of the Prevention of Food Adulteration Rules, 1955 was not complied with inasmuch as the Food Inspector in support of his word did not adduce in evidence the postal receipt to establish that he had sent not only the sample of ice-cream properly sealed and fastened but the specimen impression of the seal too separately, so that the Public Analyst could certify that the seal fixed on the container and the outer cover of the sample tallied with the specimen impression of the seal separately sent by the Food Inspector to him. It was taken that unless the conditions aforementioned were satisfied, the sample was not in a fit condition for analysis.

The High Court reversed the decision of the Trial Court taking the view that when the report of the Public Analyst specified that the seal was fixed on the container and the outer cover of the sample tallied with the specimen impression of the seal separately sent by the Food Inspector, making the sample in a condition fit for analysis that was the end of the matter and that the statement of the Food Inspector was not deficient when the postal receipt was not adduced in evidence.

\(^{20}\) (1997)9 SCC 101
The appellant was convicted for the offence charged and sentenced to undergo simple imprisonment for six months and to pay a fine of Rs. 1000/- in default of payment of which further, simple imprisonment for two months. It was held that the High Court was justified in upsetting the order or acquittal on the aforesaid ground.

In *Krishan Gopal Sharma and Anr. v. Govt. of N.C.T. of Delhi*\(^\text{21}\), adulteration was found under Rule 47 of Prevention of Food Adulteration Rules, 1955. The appellant was a manufacturer of pan masala and mouth freshner and saccharin content was found to be 2000 PPM and in violation of Rule 47. The prosecution initiated proceedings on account of such violation but appeal was made. Under amended Rule 47, saccharin to the strength of 8000 PPM had been allowed on basis of research. It was held that the appellant was entitled to benefit of amendment Rule 47.

In *Calcutta Municipal Corporation v. Pawan Kumar Saraf and Another*\(^\text{22}\), a question arose regarding Rule 4 of Prevention of Adulteration Rules, 1955, that whether report of Director (Central Food Laboratory) would supersede report of public analyst when former report was not in form prescribed. But the Court dismissed petition on ground of delay without expressing any opinion on merit of case.

In *Municipal Corporation of Delhi v. Ghisa Ram*\(^\text{23}\), the Director of Central Food Laboratory reported to the court that the part of the sample sent to him became highly decomposed and hence no analysis was possible. The accused was thereupon acquitted and the acquittal was challenged on the contention that in the absence of a Certificate of the Director the Central Food Laboratory, for any reason whatsoever, the Report of the Public Analyst will stand and the court can act on it. The Court observed that the right of the accused to have the sample analysed by the Director of Central Food Laboratory is a valuable one and such

\(^{21}\) JT 1996(5) SC 102, Also see *State of Gujarat and Anr. v. Rameshchandra Shivratan Kosar and Anr.* etc, (2009)12 SCC 583
\(^{22}\) AIR 1999 SC 738
\(^{23}\) 1967 CriLJ 939
right has been given "in order that, for his satisfaction and proper defence, he should be able to have the sample... analysed by a greater expert whose certificate is to be accepted by court as "conclusive evidence".

In *Chetumal v. State of Madhya Pradesh and Anr.*\(^2\), a certificate was called for from the Director of Central Food Laboratory but the Director had reported that the specimen impression of the seal sent to him did not tally with the seal on the container in which sample was sent to him. In the Certificate the Director mentioned that the article of food was adulterated as some of the elements were not in conformity with the standard prescribed. The trial court thereupon convicted the accused relying on the Report of the Public Analyst which was confirmed in appeal and High Court in revision did not interfere. But this Court set aside the conviction on the ground that under Section 13(3) of the Prevention of Food Adulteration Act, the report of the Public Analyst stood superseded by the certificate issued by the Director of the Central Food Laboratory. Having been so superseded, the report of the Public Analyst could not, therefore, be relied upon to base a conviction. The certificate of the Director of the Central Food Laboratory having been excluded from consideration because of the tampering of the seals, there was really no evidence before the Court on the basis of which the appellant could be convicted. The court could not fall back on the report of the Public Analyst as it had been superseded. The only method of challenging the report of the Public Analyst was by having the sample tested by the Director of the Central Food Laboratory.

In *Nand Lai v. State of Uttarakhand and Anr.*\(^2\), the Appellant was convicted of an offence committed under the Prevention of Food Adulteration Act, 1954. The Appellant was running a grocery shop. A Food Inspector, at the relevant point of time, went to the Appellant's shop and found the Appellant selling and exhibiting mustard oil for sale. He purchased 375 grams of mustard oil from the Appellant and obtained a receipt from him. Subsequently, on the report of the Central Food

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\(^{24}\) 1981 Cri.LJ 1009  
\(^{25}\) AIR 2010 SC 1875
Laboratory, Kolkata, the Appellant was charged under Section 7(1) read with Section 2(1)(m) of the aforesaid Act and on being convicted by the Special Judicial Magistrate (Economic Offences), Roorkee, was sentenced to one year's rigorous imprisonment and a fine of Rs. 2,000/-, and in default of payment of such fine, to undergo rigorous imprisonment for a further period of six months. Learned Counsel appearing for the Appellant urged that the Appellant had been wrongly convicted of the offence alleged against him since the mustard oil in question had been purchased by the Appellant from the open market and was not meant for human consumption, but to be used for lighting lamps during Deepawali. But the said defence of the Appellant was not accepted by the Trial Court, the Appellate Court or the High Court.

In Ramjee Prasad and Anr. v. State of Bihar26, appeal was filed by two accused persons who stood convicted by the High Court for an offence punishable under Section 16(1)(a)(ii) of the Prevention of Food Adulteration Act, 1954 for having been found selling an adulterated food article "Chhena Mithai". The Public Analyst in his report found that the above-mentioned food article was adulterated with starch.

The trial court and the first appellate court tried and convicted the appellants, for an offence punishable under Section 16(1)(a)(i) of the Act and sentenced them to various terms of imprisonment. The matter was taken in revision before the High Court and it was held that a case under Section 16(1)(a)(i) of the Act could not be made out against the appellants, but as the trial court and the first appellate court had mis-applied the penal provision, it was the obligation of the High Court to see that the accused did not escape from criminal liability and accordingly convicted them for an offence punishable under Section 16(1)(a)(ii) of the Act. Section 16(1)(a)(i) of the Act is relatable to Section 2(ia)(m) which provides that a food article shall be deemed to be adulterated if the quality or purity of the article falls

below the prescribed standard or its constituents are present in quantities not within the prescribed limits of variability but which does not render it injurious to health. The High Court, however, thought it fit to render the conviction under Clause 15(1)(a)(ii) of the Act which stipulates that the food article shall be deemed to be adulterated if it is not of the nature, substance or quality which it purports or is represented to be. It was held that as the ingredients of the two provisions are substantially different, the evidence of one cannot lead to a finding of guilt for the other. The appeal was allowed and the appellants were acquitted.

**Support Activities / Authorities**

1) Central Food Committee for Food Standards to advise the Central Government and the State Governments on matters arising out of the administration of the act.

2) Central Food Laboratories:
   - Work as appellate laboratories for the given area.
   - Perform analysis of samples sent by any officer / authority
   - Investigations for the purpose of fixation of standards for any article of food.
   - Investigations in collaboration with Public Analyst for methods of testing

3) State, District and Municipal Laboratories

**Food Safety Approach**

1. **PFA Act and Rules**

The rules given under PFA Act give product specifications, which cover the food safety aspect through parameters like microbiological analysis, physical examination of products for various defects, adulteration that could be stated as food safety hazards. The rules also give limit values of poisonous metals like lead, arsenic copper etc. in various products and the pesticide residue levels.
2. Tenth Plan Schemes

The Ministry of Food Processing Industries had been operating several Plan schemes for the development of processed food sector in the country. The intention is to bring change in various aspects of food business. The schemes are as follows:

A. Scheme for Technology up gradation/ Establishment/Modernization of FPI

a) Set up / Expansion / Modernization of FPI in

- Fruits and Vegetable
- Milk Products
- Meat and Poultry
- Fishery Products
- Cereal, pulses, Oil seeds
- Oleoresins, Spices, Coconut, Mushroom, Hops etc.

b) Modernization of Pulse Milling Unit - installation of driers and dust control system

c) Setting up of Mini Pulse Processing Unit

B. Scheme for Human Resource Development

a) Setting up of Food Processing & Training Centre (FPTC)

b) Creation of Infrastructure facilities for running Degree/Diploma Courses and Training Programmes for Food Processing

c) Training Programmes sponsored by Ministry of Food Processing Industries

d) Entrepreneurship Development Programme

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28 Ibid.
C. Scheme for Quality Assurance, Codex Standards and R & D

a) Total Quality Management (TQM)

b) Promotion of Quality Assurance and Safety Concept

c) Bar Coding

d) Strengthening of Codex Cell

e) Setting up of Quality Control Laboratory

f) R & D in Processed Food Sector

D. Scheme for Strengthening of Nodal Agencies

E. Scheme for Backward and Forward Integration and other Promotional Activities

a) Backward Linkages

b) Forward Integration

c) Generic Advertisement

d) Promotional activities such as participation in Exhibition / Fairs, Supporting Seminars / Workshops / Conferences etc. and Studies and Surveys

e) Preparation of Short duration films and material for different meetings, dissemination of information and bringing of publications

f) Strengthening of F & V P Directorate

g) Strengthening of Industry Associations

h) Food Fortification (To be operated by only the Ministry)29

29 Ibid.
F. Scheme for Infrastructure Development

a) Food Park

b) Packaging Centre

c) Modernized Abattoirs

d) Integrated Cold Chain Facilities

e) Value Added Centre

f) Irradiation Facilities

EUROPEAN UNION

Enforcement Law


The preamble to the regulation states that the scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. To facilitate this, the Community should have access to high-quality, independent and efficient scientific and technical support.

Chapter III of Regulation 178/2002 sets out the provisions governing the establishment and functioning of EFSA. The mission statement setting the aims varied.

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30 Ibid.
32 Ibid.
for the Authority includes: providing scientific advice and technical support for the Community’s legislation and policies in all fields which have a direct or indirect impact on food and food safety; providing independent information on all matters within these fields and communicating on risks; contributing to a high level of protection of human life and health, taking account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market; collecting and analysing data to enable food and feed risks to be monitored; providing scientific advice and technical support on human nutrition in relation to Community legislation and assisting on nutritional issues within the framework of the Community health programmes; providing scientific opinions on other matters relating to animal health and welfare and plant health and on products other than food and feed relating to genetically modified organisms; providing a point of reference based on independence, information quality and transparency; co-operating with similar authorities in the Member States; and co-operating with the Commission and the Member States to promote the effective coherence between risk assessment, risk management and risk communication.\textsuperscript{33}

The tasks set for the Authority that will enable it to carry out its mission include: providing the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission; promoting and co-ordinating the development of uniform risk assessment methodologies in the fields falling within its mission; providing scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions; commissioning scientific studies necessary for the accomplishment of its mission; searching for, collecting, collating, analysing and summarizing scientific and technical data in the fields within its mission; undertaking action to identify and characterise emerging risks, in the fields within its mission; establishing a system of networks of organisations operating in the fields within its mission and being responsible for their operation;

\textsuperscript{33} \textit{Id.} at 18f.
providing scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed; providing scientific and technical assistance, when requested to do so by the Commission, with a view to improving co-operation between the Community, applicant countries, international organisations and third countries, in the fields within its mission; ensuring that the public and interested parties receive rapid, reliable, objective and comprehensive information in the fields within its mission; expressing independently its own conclusions and orientations on matters within its mission; and undertaking any other task assigned to it by the Commission within its mission.\(^{34}\)

The Commission, in its role as guardian of the European Community Treaties, is responsible for ensuring that Community legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced. As a Commission service, the Food and Veterinary Office (FVO) plays an important role in fulfilling this task.

The mission of the FVO is, through its evaluations, to:

- to promote effective control systems in the food safety and quality, veterinary and plant health sectors,
- to check on compliance with the requirements of EU food safety and quality, veterinary and plant health legislation within the European Union and in third countries exporting to the EU,
- to contribute to the development of EU policy in the food safety and quality, veterinary and plant health sectors,
- to inform stakeholders of the outcome of evaluations.\(^{35}\)

\(^{34}\)Ibid.

\(^{35}\)Food and Veterinary Office FVO Annual Report, 3 (2001).
Food Safety Approach

Traceability

‘Traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.\(^36\)

In particular, traceability helps facilitate the withdrawal of food and enables consumers to be provided with targeted and accurate information concerning implicated products. Traceability does not itself make food safe. It is a risk management tool to be used in order to assist in containing a food safety problem.

- Traceability has different objectives such as food safety, fair trading between operators and reliability of the information provided to consumers. The Regulation introduces the traceability requirement with in particular the objective to ensure food safety and to assist in enabling unsafe food/feed to be removed from the market.

- Traceability is meant to ensure that targeted and accurate withdrawals or recalls can be undertaken, appropriate information can be given to consumers and food business operators, risk assessment can be performed by control authorities and unnecessary wider disruption of trade can be avoided.\(^37\)

Transparency

The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

i. agendas and minutes of the Scientific Committee and the Scientific Panels;
ii. the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;


\(^{37}\) Ibid.
iii. without prejudice to Articles 39 and 41, the information on which its opinions are based;

iv. the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;

v. the results of its scientific studies;

vi. the annual report of its activities;

vii. requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

The regulation requires that there shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it. Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

Risk analysis

The Regulation establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations, which are undertaken by the EFSA. Depending on the nature of the

39 Ibid.
measure, food law, and in particular, measures relating to food safety, must be underpinned by strong science. The EU has been at the forefront of the development of the risk analysis principles and their subsequent international acceptance.

Regulation EC 178/2002 establishes in EU law that the 3 inter-related components of risk analysis (risk assessment, risk management and risk communication) provide the basis for food law as appropriate to the measure under consideration. Clearly not all food law has a scientific basis, e.g., food law relating to consumer information or the prevention of misleading practices does not need a scientific foundation.\(^\text{40}\)

"Scientific assessment of risk must be undertaken in an independent, objective and transparent manner based on the best available science. Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the EU."

"In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment. These include, for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs, the practical arrangements needed, the socio-economic effects and the environmental effect. Regulation EC/178/2002 establishes the principle that risk management actions are not just based on a scientific assessment of risk but also consider a wide range of other factors legitimate to the matter under question. As additional risk management, Regulation EC/178/2002 also introduces the precautionary principle, indicating that as long as risk analysis is not sufficiently

supported by scientific evidence, preventive action can be ordered as a precautionary action until scientific evidence will become available".41

Rapid alert system

The rapid alert system now covers all foodstuffs and animal feed. The network involves the Member States, the Commission in a management capacity and, innovatively, the Authority as a member of the network.

By means of this rapid alert system, the Member States notify the Commission, which immediately transmits the information throughout the network, of:
- any measure aimed at restricting the placing on the market or forcing the withdrawal or recall of food or feed;
- any measure involving professional operators aimed at preventing or controlling the use of food or feed;
- any rejection of a batch or consignment of food or feed by a competent authority at a border post of the European Union.

Information concerning a food-related risk which is disseminated within the rapid alert network must be made available to the general public42.

UNITED KINGDOM

Enforcement Law

The enforcement of regulations on food standards, safety and hygiene is primarily the responsibility of local authorities.

Responsible Authorities and their responsibilities

Responsibility for enforcement is shared between central and local government bodies. While the making of legislation in the UK is the function of central

government, the enforcement of food law is primarily (but not solely) the responsibility of more than 400 local authorities in the UK, and more specifically Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs).

The Food Standards Agency (FSA) is an independent Government Department and is an enforcement authority in its own right. It is also responsible for enforcement support, advice and audit of enforcement activity with respect to local authority food safety and standards controls43.

The Act gives Food Standards Agency the powers to:

Set standards of performance in relation to enforcement of food law. Monitor the performance of enforcement authorities. Require information from local authorities relating to food law enforcement and inspect any records

Enter local authority premises, to inspect records and take samples. Publish information on the performance of enforcement authorities. Make reports to individual authorities, including guidance on improving performance. Require enforcement authorities to publish these reports and state what action they propose in response44.

Central government's role

Where food law enforcement does not rest with local authorities, it is carried out by central Government or its enforcement agencies.

The FSA, acting through its executive agency the Meat Hygiene Service (MHS) in England, Scotland and Wales, and through the Department of Agriculture and Rural Development (DARD) Veterinary Service in Northern Ireland, is the enforcement authority in respect of around 1,700 licensed premises in the UK producing meat for sale for human consumption. Such premises include slaughterhouses, cutting plants and cold stores. Inspection of the meat industry is essential to protect public health and promote consumer confidence. Formal

43 http://www.food.gov.uk/enforcement/enforceessential/about/
44 http://www.food.gov.uk/enforcement/workwithenforcers/localauthorities/
enforcement, including prosecutions and investigations, is the responsibility of the Agency itself.\textsuperscript{45}

The Department for Environment, Food and Rural Affairs (Defra) has two executive agencies - the Pesticides Safety Directorate (PSD) and the Veterinary Medicines Directorate (VMD) - which carry out European Union (EU) surveillance programmes for residues, and also act as the enforcement agencies for these areas. Inspectors within Defra enforce areas such as marketing and horticulture, at all but the retail level. There are also separate arrangements for dairy hygiene enforcement, which is the responsibility of Animal Health (an executive agency of Defra).

The Egg Marketing Inspectorate (EMI) is an Inspectorate within Defra responsible for checking standards in egg production, packaging and distribution centres. EMI works throughout England and Wales, wherever eggs are produced, graded, packaged, imported, exported, bought or sold. Scotland and Northern Ireland have their own Inspectors.\textsuperscript{46}

Local government role

The Act gives local enforcement officers wide powers to inspect any stage of the production, manufacturing, distribution and retail chain. Food premises are inspected at a frequency dependent upon risk. Enforcement officers also have the power to take samples of food for testing to ensure compliance with food legislation.

Local authorities have a responsibility to investigate any food complaints passed on to them by consumers.

\textsuperscript{45} Ibid.  
\textsuperscript{46} Ibid.
Enforcement officers have powers to take action against a food premise, which does not comply with food law. This enforcement action can range from issuing warnings and improvement or prohibition notices, to instigating prosecutions.\(^{47}\)

**Support Activities/Authorities**

The Local Authorities Coordinators of Regulatory Services (LACORS) provides one link between local food enforcement and central Government, giving advice and guidance to local authorities as well as advising the FSA on food enforcement issues.

1) **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 2001.

The LAELG developed the Framework Agreement on local authority food law enforcement. All the executive arms of the Agency are represented in the Group. Local authority representation encompasses food hygiene and food standards and feeding stuffs enforcement officials as well as representatives from the Chartered Institute of Environmental Health and the Trading Standards Institute. The Group also includes representatives from key consumer and industry stakeholder organisations.\(^{48}\)

2) **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.

\(^{47}\) *Ibid.*

\(^{48}\) [http://www.food.gov.uk/enforcement/enfcomm/](http://www.food.gov.uk/enforcement/enfcomm/)
Stakeholders can also discuss current and emerging issues and hear from the Food Standards Agency about its plans for the next six months.\footnote{Ibid.}

3) 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.

We believe the Forum will help us improve our policy delivery by facilitating the flow of information between our stakeholders and ourselves by identifying potential difficulties at an early stage and finding mutually agreeable solutions.\footnote{Ibid.}

The Forum has a two-tiered structure comprising:

\begin{itemize}
\item [g)] A Meat Hygiene Policy Forum - representatives from organisations with a direct interest in meat hygiene policy (consumers, enforcers, policy makers, meat industry and retailers); and
\item [h)] A system of Meat Hygiene Policy Forum Advisory Sub-Groups convened on an ad-hoc basis to consider particular issues in depth and provide the Policy Forum with expert or technical advice. Membership of the Forum is balanced both in terms of background interest and geographical coverage.
\end{itemize}

In particular, the FSA sees consumer involvement as crucial to the success of the Forum and is looking forward to welcoming consumer groups to the meetings.\footnote{Ibid.}
4) **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.


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.

5) **Framework Agreement Sub Group**

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

6) **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.\(^{52}\)

7) **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.

\(^{52}\) *Ibid.*
8) 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.

9) 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 scores 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 schemes53.

Food Safety Approach

A) Food sampling:

The Food Standards Agency supports local authorities’ food sampling programmes that are regularly carried out to ensure the safety of food supply. Food sampling forms an integral part of local authorities’ food law enforcement and it can provide useful information to help effective enforcement of food law and contribute to improved food safety and standards. The Agency provides local authorities with practical guidance on food standards and feeding stuffs sampling to help ensure that enforcement arrangements are consistent and proportionate54.

B) Food Alerts:

Food Alerts are the FSA’s way of letting local authorities and consumers know about problems associated with food and, in some cases, provide details of specific action to be taken.

53 Ibid.
54 http://www.food.gov.uk/enforcement/monitoring/samplingresources/
They are issued under two categories
1. Food Alerts: for Action
2. Food Alerts: for Information

Food Alerts are also copied to Consultants in Communicable Disease Control, Trading Standards Officers and food trade organisations, to alert them to current food issues. They are often issued in conjunction with a product withdrawal or recall by a manufacturer, retailer or distributor\(^5\).

**AUSTRALIA**

The Ministry of Health and Ageing is responsible for enforcement of the act as per the Food Regulation Model.

The model comprises:

1) Ministerial Council, which comprises Ministers from all the States and Territories and the Government. Its function is to develop food regulatory policy in the form of policy guidelines. It can adopt, amend or reject standards and request these to be reviewed.

2) Food Regulation Standing Committee to coordinate policy advice to the Ministerial Council.

3) Implementation Sub-Committee to oversee a consistent approach to implementation and enforcement of food regulations and food standards regardless of whether food is sourced from domestic producers, export registered establishments or from imports. Implementation of food regulation covers the full spectrum of activities once a food standard or regulation comes into force. It includes interpretation, compliance, audit, verification, inspection and enforcement, as well as industry support schemes, emergency management, monitoring and surveillance and risk communication.

\(^{55}\) [http://www.food.gov.uk/scotland/regsscotland/foodalertsscotland/](http://www.food.gov.uk/scotland/regsscotland/foodalertsscotland/)
4) Food Standards Australia – a statutory authority responsible for developing food standards based on scientific/technical criteria, consistent with Ministerial Council policy. The standards are developed for composition, labeling, and contaminants, including microbiological limits, that apply to all foods produced or imported for sale covering the whole of the food supply chain. It also provides information to consumers to enable better customer choice. It coordinates national food surveillance; enforcement and food recall and provide risk assessment advice on imported food\textsuperscript{56}.

**Food Regulatory Model**

The system is based upon a strengthening of the partnership between government, consumers and industry, increased Ministerial direction on policy in the development of food standards\textsuperscript{57}.

**Australia and New Zealand Food Regulatory Model**

The Food Regulations Model also supports enhanced stakeholder consultation. A consultative mechanism is established to provide stakeholder views to the Standing Committee and the Ministerial Council on the development of policy guidelines for food standards development\textsuperscript{58}.

**Food Safety Approach**

1) Food Safety Program:

Food safety program means a program set out in a written document retained at the food premises of the food business, including records of compliance and other related action, that:

(a) systematically identifies the potential hazards that may be reasonably expected to occur in all food handling operations of the food business;


\textsuperscript{57} Ibid.

\textsuperscript{58} Ibid.
(b) identifies where, in a food handling operation, each hazard identified can be controlled and the means of control;
(c) provides for the systematic monitoring of those controls;
(d) provides for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control;
(e) provides for the regular review of the program by the food business to ensure its adequacy; and
(f) provides for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program.59

2) Food Recall:

A food business engaged in the wholesale supply, manufacture or importation of food must:

i. have in place a system to ensure the recall of unsafe food;
ii. set out this system in a written document and make this document available to an authorised officer upon request; and
iii. comply with this system when recalling unsafe food.60

USA

Principal federal regulatory organizations are Department of Health and Human Services’ (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Services (FSIS) and Animal and Plant Health Inspection Services (APHIS) and Environmental Protection Agency (EPA). Federal, state, and local authorities have complementary and interdependent food safety roles in regulating food and food processing facilities. The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out

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59 Australia New Zealand Food Standards Code Chapter 3, Standard 3.2.2 (Division 1, Clause 1).
60 Australia New Zealand Food Standards Code Chapter 3, Standard 3.2.2 (Division 3, Clause 12).
the mission of the Food and Drug Administration (FDA). Major food safety authorizing statutes include the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, Food Quality Protection Act and Public Health Service Act. Procedural statutes, which regulatory agencies must follow, include the Administrative Procedure Act, the Federal Advisory Committee Act, and the Freedom of Information Act.

Responsibilities

The FDA is charged with protecting consumers against impure, unsafe and fraudulently labeled food other than in areas regulated by FSIS. CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled.

Following are the functions of FDA:

- Inspection of establishments
- Collection and analysis of samples
- Monitoring of imports
- Pre-market review (e.g., food and color additives)
- Notification programs (e.g., food contact substances, infant formula)
- Regulations/agreements (e.g., memoranda of understanding)
- Consumer studies, focus groups
- Laboratory research
- develop/improve methods for detecting pathogens and chemical contaminants in food
- determine health effects of food contaminants
- determine effects of processing on food composition
- determine health effects of dietary factors
• investigate factors that contribute to virulence of biological contaminants\textsuperscript{61}.

**Responsibilities of CFSAN**

- the safety of substances added to food, e.g., food additives (including ionizing radiation) and color additives
- the safety of foods and ingredients developed through biotechnology
- seafood and juice Hazard Analysis and Critical Control Point (HACCP) regulations
- regulatory and research programs to address health risks associated with food borne, chemical, and biological contaminants
- regulations and activities dealing with the proper labeling of foods (e.g., ingredients, nutrition health claims)
- regulations and policy governing the safety of dietary supplements, infant formulas, and medical foods
- food industry post market surveillance and compliance
- industry outreach and consumer education
- cooperative programs with state, local, and tribal governments
- international food standard and safety harmonization efforts\textsuperscript{62}.

**Other Authorities**

**Food Safety Inspection Service (FSIS)**

The Food Safety Inspection Service (FSIS) is responsible for ensuring that meat (derived from cattle, sheep, swine, goats, and horses) and poultry products moving in interstate and foreign commerce are safe, wholesome for consumption, and accurately labeled. Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7,400 Federal inspectors carry out inspection laws in some 6,200 plants. Inspectors check

\textsuperscript{61} \url{http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/WhatWeDo/default.htm}  
\textsuperscript{62} Ibid.
animals before and after slaughter. They prevent diseased animals from entering the food supply and examine carcasses for visible defects that can affect safety and quality. FSIS also inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled. To address specific concerns, inspectors can test for the presence of pathogenic microorganisms and violative drug and chemical residues. The Agency operates three field laboratories to provide analytical support.

Environmental Protection Agency (EPA)

EPA coordinates governmental action on behalf of the environment through integrating research, monitoring, standard setting, and enforcement activities. Among its many duties, EPA regulates pesticides. Through the Office of Pesticide Programs (OPP) EPA determines the safety of new pesticide products, sets tolerance levels for pesticide residues in foods, which FDA then enforces, and publishes directions for the safe use of pesticides. EPA also establishes water quality standards, including the chemical content of drinking water. These standards are used by FDA as guides in its regulation of bottled water sold in interstate commerce for human use.

APHIS

APHIS Import requirements depend on both the product and the country of origin. Plants and plant materials usually must be accompanied by a phytosanitary certificate issued by an official of the exporting country. Livestock and poultry must be accompanied by a health certificate, also issued by an official of the exporting country. Animal products, such as meats and hides, are restricted if they originate in countries that have a different disease status than the United States.

APHIS regulates the importation of animals that enter the country through land ports along the borders with Mexico and Canada. Imports of livestock and poultry

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64 Id. at 8.
from other countries must be quarantined at one of four animal import centers in Newburgh, N.Y., Miami, Fla., Los Angeles, Ca., Honolulu, Hawaii.

Also, at many ports, APHIS officers inspect and sample seed imported from foreign countries to ensure that it is accurately labeled and free of noxious weeds. APHIS also maintains 14 plant introduction stations, the largest of which is at Miami, Fla., for commercial importation of plant materials. In addition to certifying to the health of agricultural exports, APHIS officials mount a proactive approach to the marketing of U.S. crops and livestock overseas.\textsuperscript{65}

\textbf{Centers for Food Disease Control and Prevention}

Investigates with local, state and other federal officials sources of food-borne disease outbreaks. Maintains a nationwide system of food-borne disease surveillance: Designs and puts in place rapid, electronic systems for reporting food-borne infections. Works with other federal and state agencies to monitor rates of and trends in food-borne disease outbreaks. Develops state-of-the-art techniques for rapid identification of food-borne pathogens at the state and local levels. Develops and advocates public health policies to prevent food-borne diseases. Conducts research to help prevent food-borne illness. Trains local and state food safety personnel.

\textbf{U. S. Department of Agriculture}

Enforces food safety laws governing domestic and imported meat and poultry products 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

\textsuperscript{65} \textit{Id.} at 15.
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes
- Making sure 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
- Sponsoring research on meat and poultry safety
- Educating industry and consumers on safe food-handling practices

Co-operative State Research, Education and Extension Service:

The Co-operative State Research, Education, and Extension Service (CSREES) is an agency within the U.S. Department of Agriculture (USDA), part of the executive branch of the federal government.

National Agricultural Library, USDA / FDA Food borne Illness Education Information Center:

- Maintains a database of computer software, audiovisuals, posters, games, teachers' guides and other educational materials on preventing food-borne illness
- Helps educators, food service trainers and consumers locate educational materials on preventing food-borne illness.

National Oceanic and Atmospheric Administration:

Through its fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards.

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66 http://www.usda.gov
68 Ibid.
69 Ibid.
U.S. Department of the Treasury – Bureau of Alcohol, Tobacco and Firearms
Enforces laws governing production and distribution of alcoholic beverages70.

U.S. Customs Service:
Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations71.

U.S. Department of Justice:
Prosecutes companies and individuals suspected of violating food safety laws. Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts72.

Federal Trade Commission:
Enforces a variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising73.

State and Local Governments:
1. Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other food produced within state borders
2. Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions
3. Prevent the sale of unsafe food products made or distributed within state borders74.

70 Ibid.
71 Ibid.
72 Ibid.
73 Ibid.
74 Ibid.
Food Safety Approach

Food Transportation

The Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) are working together (see the 2010 Advance Notice of Proposed Rulemaking1) to implement the Sanitary Food Transportation Act of 2005 which requires that FDA prescribe sanitary transportation practices to ensure that food (including animal feed) transported by motor vehicle or rail is not transported under conditions that may adulterate the food. This section also contains links to existing regulations and guidance documents that address food transportation75.

Food Safety Programs

FDA has developed a comprehensive Food Protection Plan to address the changes in food sources, production, and consumption that we face in today's world. Building upon and improving an already sound food safety protection capability, the new plan presents a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack. FDA's Food Protection Plan builds in prevention first, then intervention, and finally, response. This new strategy will help ensure that Americans continue to benefit from one of the safest food supplies in the world. The Office of Food Protection1 provides advice and council on the strategic and substantive agency-wide domestic and imported food related matters, including the Food Protection Plan.

Product-specific information


75 http://www.fda.gov/Food/FoodSafety/default.htm
76 Ibid.
Food Allergens

To help Americans avoid the health risks posed by food allergens, Congress passed the Food Allergen Labeling and Consumer Protection Act of 2004. The law applies to all foods regulated by FDA, both domestic and imported, that were labeled on or after January 1, 2006. (FDA regulates all foods except meat, poultry, and certain egg products.)

Food Contaminants & Adulteration

The Federal Food, Drug, and Cosmetic Act (FFDCA) provides the U.S. Food and Drug Administration (FDA) with broad regulatory authority over food that is introduced or delivered for introduction into interstate commerce. Section 402(a)(1) of the FFDCA provides that a food is deemed to be adulterated if it contains any poisonous or deleterious substances, such as chemical contaminants, which may or ordinarily render it harmful to health. Under this provision of the FFDCA, FDA oversees the safety of the U.S. food supply (domestic and imports), in part, through its monitoring programs for natural toxins (e.g., mycotoxins), pesticides, and anthropogenic (e.g., industrial chemicals, such as dioxins; cooking or heating related chemicals, such as acrylamide; trace elements, such as lead) contaminants in food and the assessment of potential exposure and risk.

Implementation of HACCP

The FDA has adopted a food safety program, which focuses on preventing hazards that could cause food borne illness. FDA requires the food industry to implement HACCP, for both the domestic and imported products.\(^7\)

\(^7\) Ibid.
MALAYSIA

Enforcement Law

Food Act 1983

Food Regulations 1985

Responsible Authorities and their responsibilities

The Ministry of Health is primarily responsible for enforcement of the act. 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 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.78

Responsibilities

Authorized officers are appointed as under the act who are responsible for enforcement of food hygiene and safety. They are involved in prosecution work, collection of food samples, and inspection of food premises and promotion of health education.79

An authorized officer may at any time for the proper and better performance of his duty:

1. Enter any premises which he believes to be food premises and examine any food found therein and take samples of such food, and examine anything that he believes is used or capable of being used for the preparation,

preservation, packaging, storage, conveyance, distribution or sale of the food;

2. Open and examine any package which he believes contains any food to which this Act applies;

3. Mark, seal or otherwise secure, weigh, count or measure any food, the preparation, preservation, packaging, storage, conveyance, distribution or sale of which is or appears to be contrary to the Act\(^\text{80}\).

**Support Activities / Authorities**

Veterinary Department and Fishery Department are also involved in Food Safety enforcement. The department of Veterinary Services is the leading agency responsible for the development of livestock sector in the country and is also responsible for ensuring food safety and quality of livestock products\(^\text{81}\).

The Standards and Industrial Research Institute of Malaysia (SIRIM) lays down standards for various food products. SIRIM provides its services to the industry as well. If the products satisfy the standards, the SIRIM mark may be used on the product\(^\text{82}\).

**Food Safety Approach**

1. **Formulation and Review of Food Legislation :**

Malaysia is constantly revising the food laws, regulations and standards so as to be in line with current needs as well as international requirements\(^\text{83}\).

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\(^{82}\) [www.sirim.my](http://www.sirim.my)

\(^{83}\) FAO/WHO Regional Conference on Food Safety for Asia and the Pacific Seremban, Malaysia, “Prioritization and coordination of capacity building activities food safety control system in Malaysia” 24-27 May (2004).
2. Certification:

Malaysia has initiated and implemented the Malaysian Certification Scheme (MCS) for Hazard Analysis and Critical Control Points (HACCP) since 1997 and has formulated four (4) guidelines to facilitate successful implementation of the system by the food industries. The Ministry of Health practices third party certification and is involved in the surveillance auditing of food factories. Malaysia has also formulated the Guidelines on Good Hygiene Practices for Small and Medium Scale Food Industries towards HACCP. These guidelines provide a guide on basic hygienic and sanitation requirements and to fulfill prerequisite requirements for the implementation of HACCP to small and medium scale industries.

Various government agencies play an active role in promoting Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP), the application of HACCP and Halal Certification.

3. Enforcement

Enforcement activities such as sampling, premise inspection, import and export control have been intensified. This is achieved in part by improving infrastructure with regards to data collection and monitoring as well as equipment. The Food Safety Information System of Malaysia (FoSIM) has been established to link FQCD, 34 entry points, 11 food laboratories and the Customs Department in order to better manage safety of imported food.

4. Laboratory Services

Laboratory capacity building has always been given top priority, as they are one of the most crucial infrastructures needed for an effective and efficient food safety system. Various approaches are being undertaken by the Ministry of Health to ensure that laboratories are able to meet the increasing demand and complexities.

84 Ibid.
of food analysis including new requirements imposed by the Food Regulations 1985.

5. Research and Monitoring

In view of the need for a science based approach to food safety, the research activities have now focused on data collection for purposes of risk assessment. These activities are to monitor incidence of food-borne diseases, including food poisoning; to monitor environmental problems related to food; and to monitor food for microbiological and chemical contamination. The baseline information on the status of specific contaminant levels in relevant foodstuffs will also help prioritize issues of concern.

6. Participation in International and Regional Fora

In meeting the global challenges, Malaysia is playing a bigger role in activities related to food safety at international and regional levels including Codex, ASEAN, APEC, ASEM, WTO (SPS and TBT) and others.\textsuperscript{85}

JAPAN

Enforcement Law

Food Sanitation Law

Food Safety basic Law

Responsible Authorities and their responsibilities

The Ministry of Health, Labour and Welfare (MHLW) enforces the law through the Department of Food Safety under the Pharmaceutical and Food Safety Bureau. The food safety administrative work is carried out under the Food Safety Basic Law and related laws including the Food Sanitation Law, the Abattoir Law, and

\textsuperscript{85} Ibid.

the Poultry Slaughtering Business Control and Poultry Inspection Law\textsuperscript{86}.

Department of Food Safety, Pharmaceutical and Food Safety Bureau comprises:

1. Policy Planning and Communication Division:

   General coordination of responsibilities under the jurisdiction of the Department of Food Safety, risk communication.

2. International Planning Coordinator:

   General coordination of international affairs under the jurisdiction of the Department

3. Office of Port Health Administration

   Quarantine business, inspection of imported food.

4. Standards Evaluation Division

   Establishment of specifications/standards for food, food additives, pesticide residues, animal drug residues, food containers, and food labeling\textsuperscript{87}.

5. Office of Health Policy on Newly Developed Food

   Labeling of specified uses, nutrition labeling standards, foods with health claims, dietary supplements, safety assessment of genetically modified foods.

6. Inspection and Safety Division

   Food inspection, health risk management such as measures for food poisoning, safety measures for poultry and livestock meat, dissemination and promotion of the HACCP approach, GLP, measures for environmental contaminants, sanitary control of rendering plants.

7. Office of Import Food Safety

\textsuperscript{86} The Nineteenth seminar for Visiting Food Hygiene Experts, 2006 of Department of Food Safety Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare.

\textsuperscript{87} Ibid.
In addition, the local governments help formulating and implementing policies with an appropriate sharing of roles with the national government. They conduct inspection of and give advice to food-related businesses. They grant a license to businesses that operate within the jurisdiction concerned, and suspend licensed businesses and/or revoke operation if they violate the law. They also conduct food testing. These activities are executed through health centers under the jurisdiction concerned88.

**Food Safety Approach**

Japan has introduced a Risk Analysis Approach to food safety work. The approach is to scientifically assess risks and develop necessary measures based on the risk assessment.

The risk analysis consists of three components:

1) **Risk assessment**
   i. The risk assessment is under the responsibility of the Food Safety Commission, and administrative agency independent of the agencies that are responsible for risk management89.
   
   ii. The risk assessment is based on the latest scientific knowledge.

2) **Risk management**
   i. Related agencies establish food safety standards, based on risk assessment results, taking into account the opinions of interested parties, such as consumers.

   ii. Related agencies implement provisional risk management measures in a prompt and appropriate manner, when necessary from a preventive viewpoint.

Risk Management is a responsibility of Ministry of Agriculture, Forestry and

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88 Ibid.
89 Ibid.
3) Risk communication

- Information on food safety must be published.
- Related agencies must provide interested parties, such as consumers, with opportunities to express their opinions.

THAILAND

Enforcement Law

Food Act B.E 2522

Responsible Authorities and their responsibilities

Minister of Public Health is designated by law to be in charge of the execution of the Food Act B.E.2522, and is empowered to appoint competent officers, promulgate regulations and set other activities in order to carry out the provisions of the act.

The Food and Drug Administration of the Ministry of Public Health and the Provincial Offices of Public Health are responsible for legal food control operations with the support of food analytical services of the Department of Medical Sciences.

The Thai Food and Drug Administration of the Ministry of Public Health is an agency whose primary duty by virtue of the act is implementation and enforcement of the law, and is to guarantee the quality and safety of food.

Responsibilities

The Food Control Division of Food and Drug Administration is responsible for

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90 Ibid.
91 Ibid.
92 Ibid.
93 http://www.fda.moph.go.th/eng/food/details/foodControl.stm
94 Ibid.
regulating food control activities by means of:

1. Setting up food standard and specification as well as hygienic and labeling requirements
2. Controlling of the production and importation of food products.
3. Approval for registration of specific-controlled food.
4. Approval for advertisement.
5. Approval of packaging materials
6. Inspection of food manufacturing premises and salers
7. Sampling and quality assessment of food products
8. Taking legal action eg. Seizure, product recalls, prosecution
9. Conduction epidemiological study
10. Promotion of consumer awareness and voluntary compliance of food manufacturers
11. Controlling of food plants to meet national standard by using GMP
12. Collaboration with government agencies, private sectors as well as international organizations in the manners of technical cooperation.
13. To assemble, disseminate and exchange information related to food.

Support Activities / Authorities

1. Department of Medical Science, Ministry of Public Health provides food analytical services for all food control activities of the Food and Drug Administration.

2. Provincial Institute: At the provincial level, Provincial Health Offices (76 Provinces) throughout the country are delegated by the FDA to take responsibility for certain extents according to the Food Act. The Provincial Health Offices are in charge of food control in each provincial boundary. It coordinates its policies with the Central Institute (FDA) and its duties and responsibilities are similar to those of the FDA. These provincial personnel are

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94 www.fda.moph.go.th/eng/food/details/foodControl.stm
Food Control Division of Food and Drug Administration (FDA) is responsible for regulating food control activities as follows:

1. **Pre-marketing Control**

   Activities include issuance of Manufacturing License and Importation License to manufacturer and importer respectively; registration of controlled food products before marketing; approval of food additives to be used in foods, labeling and advertising approvals.

   I. **Manufacturing License**:

   Plant lay-out is to be submitted for approval and plant inspection by food inspector is required before and manufacturing license is issued. This license is to be renewed every three years.

   II. **Importation License**:

   A license is required in order to import food into Thailand. A licensed importer may import various kinds of food providing that they are approved by the Thai FDA. The designated storage or warehouse has to be inspected and approved by the Thai FDA before a license is issued. An importation license is to be renewed every three years as well.

   III. **Product Registration**:

   If a food product, either manufactured or imported, is categorized as Specific-Controlled Food, it must be registered. Analysis of the product as well as details of the process and ingredients is required for the registration process and the
standard of these food products have to meet the standard specified in the Ministerial Notification96.

IV. Labeling Approval:

Some products such as dietary supplements are required to bear labels containing Thai language and subjected to be approved by Thai FDA prior to sell in the market. For food products, in general, labeling must follow the Notifications of the Ministry of Public Health No.194 (B.E.2544).

V. Advertising Approval:

Any form of advertisement for food through any media is subjected to be approved by Thai FDA. False or deceptive advertisement on quality or benefit of food is prohibited.

2. Post-marketing Control

The purpose of Post-marketing Control is to ensure that food distributes to consumers are wholesome and have quality that complies with the national food standard. As a result, this measure deals primarily with the activities of enforcement. Inspection of all food factories and premises throughout the country is conducted regularly, together with sampling of food products for analysis and assaying to ensure compliance with legal requirements. In case of violations, actions like seizure, recall, and prosecution will be executed. In general, there are two types of inspections:

(a) Regular Inspection:

This is planned inspection to ensure that the FDA annual plan on food has been done successfully.

- Routine Inspection:- This is a periodic inspection particularly to the premise received licenses.

96 Ibid.

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- Surveillance Inspection: to inspect manufacturing premises, warehouse for importer, sellers to comply with the regulation concerned.
- Point of Entry Inspection: This is done by food inspectors stationed at the ports to ensure the safety of food products entering into the country comply with the regulations concerned\(^97\).

(b) Suspected or Petitioned Inspection
a. This is a particular type of inspection with specific aim to investigate and gather necessary evidence for taking legal action.
b. This includes an inspection to find out the cause of the complaint or rejected food from the importing country, so as to solve the problems of food manufacturers and food products.

3. Food Surveillance

The aim of food surveillance is to assure the safety and quality of food items distributed in market place. Food surveillance is conducted by several ministerial organisation and TFDA also plays a main role in this activity. Food are taken from market place and then analyzed to ensure the conformity to the standards.\(^98\)

\(^{97}\) Ibid.  
\(^{98}\) Ibid.