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食品の安全確保推進研究事業 (H25-食品-指定-014)
「食品安全行政における政策立案、政策評価に資する食品由来疾患の
疫学的推計手法に関する研究」

食品由来疾患研究のための系統的文献レビュー研究手法

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研究要旨

食品由来疾患の原因のうち、昨年度・一昨年度はカンピロバクター、サルモネラ属菌ならびに志賀毒素産生性大腸菌に焦点を当て、文献調査を行った。医学中央雑誌、MEDLINE ならびに Embase を用いて国内・海外文献の網羅的収集を行い、情報を整理した。抽出した情報をメタ分析にかけ、各続発症に占める先行感染の割合ならびに、感染症から各続発症を発症する割合を算出した。本報告書では、系統的レビューの研究方法を解説し、今後の食品班のレビュー作成に寄与する。

A. 研究目的

系統的レビューとは、ある課題に関して行われた研究を網羅的に検索し、その質を系統的に吟味し、その結果に応じて統計的に統合する手法をいい、エビデンスレベルが最も高いといわれている。本報告書では、標準的手法であるコクラン系統的レビューの研究方法を解説し、今後の食品班のレビュー作成に寄与することを目的とする。

B. 研究方法

コクラン共同計画は、1992 年に最もエビデンスが少ないといわれていた妊娠出産の分野のグループから始まり、系統的レビューの手法を標準化し「コクランライブラリ」に出版した。コクランライブラリには 5000 以上ものコクランレビューがおさめられており、この数は年々増えている。標準的手法であるコクラン系統的レビューの研究方法を解説する。

C. 研究結果および考察

系統的レビューの最初のプロセスは、プロトコール（計画書）を執筆する。プロトコールには、論文でいう背景と方法の部分と同様に、系統的レビューの適格基準やレビューの実施方法、

分析方法などを記載する。プロトコールは常に“we will do this”のように未来時制で書かれる。

また、“the literature will be searched”ではなく“we will search”のように能動態を使用する。

PROSPERO(<http://www.crd.york.ac.uk/PROSPERO/>)という系統的レビューのプロトコールを事前に登録できる制度がある。論文の背景には、以下の4つのカテゴリーを含めて記載する。

- 1) 問題の状態に関する記述：、生物学、診断、予後、有病率または発症率、罹患者または罹患地域への影響
- 2) 治療的介入に関する記述：標準的介入あるいは代替的介入の背景
 - 1.1 薬物に関して - 薬理学、用量、代謝、選択的効果、半減期、持続時間、他剤との相互作用
 - 1.2 複合的介入に関して- 構成要素に関する記述
- 3) 治療的介入がどのように作用するか：理論的理由づけ、理由づけをサポートする経験的エビデンス
- 4) なぜレビューすることが重要なのか：合理的理由に関する簡単な説明、たとえば、不

確かさを解決するエビデンスを集めること

方法は、適格基準（対象者、介入、対照、研究デザイン）、アウトカム（主なアウトカム、副次的なアウトカム）、検索（どのようなデータベースをどのようなキーワードで検索するのか）、バイアスリスクのアセスメント、解析方法に関して記載する。プロトコルが出版されたら、系統的レビューを行う。

まず研究の検索を行う。検索式は検索の経験のある司書に依頼するとよい。システムティックレビューには広範な検索が必要である。通常介入のレビューの場合は、CENTRAL から開始し、レビューに組み入れられる研究の大部分を提供すると思われる MEDLINE や Embase など他の電子的な書誌学的データベースに移ります。また、未公表および進行中の研究なども grey literature といって検索に含める方が publication bias を防ぐことができます。その他のデータベースとしては、国や地域のデータベース（例：医学中央雑誌, AIM, LILACS）、研究テーマによるデータベース（例：AMED, PsycINFO）、学位論文データベース、grey literature 用データベース (OpenGrey, NTIS, google scholar) などがある。検索式は適格基準に基づき対象者、介入、研究デザインの 2-3 項目の最も重要なコンセプトから開始する。着目したコンセプトを記述できるすべての可能な方法について考慮する必要がある。コクラン共同計画では、研究デザインでランダム化比較試験を検索するときは以下の検索式を必ず使用している。

1. randomized controlled trial [pt]
2. controlled clinical trial [pt]
3. randomized [tiab]
4. placebo [tiab]
5. drug therapy [sh]
6. randomly [tiab]
7. trial [tiab]
8. groups [tiab]
9. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
10. animals [mh] NOT humans [mh]
11. #9 NOT #10

観察研究の場合のレビューは、検索にデザインをいれないことも多い。検索結果に基づき研究を検索し、適格基準を適応し、データを収集する。基準にあう研究の質の評価（リスクオブバイアス）を行い、結果をメタ分析して表示する。結果を解釈し結論を記載し、考察を書いたら、系統的レビューを出版します。質の評価は、介入研究の場合は、risk of bias (<http://ohg.cochrane.org/sites/ohg.cochrane.org/files/uploads/Risk%20of%20bias%20assessment%20tool.pdf>) という評価を使用しますが、観察研究の場合は、New castle ottawa scale (http://www.ohri.ca/programs/clinical_epidemiology/nosgen.pdf) などを使用する。系統的レビューもピアレビューのプロセスを経ます。コクラン系統的レビューの作成には、フリーソフトの RevMan5.2.3(<http://ims.cochrane.org/revman/download>) を用いて行うとよい。Meta-analysis の分析全般を行うことができる。ただし、meta-regression は RevMan5.2.3 では分析できないため、STATA という統計ソフトを用いる。STATA で meta-regression を行うときは、excel に各論文の変数をまとめて、csv 形式で保存する。prevalence(罹患率)と standard error(SE)、その他の要因となる項目の列を作成する。SE の記載が論文にない場合は、prevalence から手計算で計算する。コマンドは metan y se, random label(namevar=author,yearvar=year)by(country) y はエクセルの項目に y という列を作り prevalence を入れる。se は standard error を入れる。label はフォレスとプロットという図がでてきたときのラベルの指定ができる。by のあとは、ソートしたい変数をいれば、ソートした結果を出すことができる。この場合は国別の結果がでる。このコマンドで、自動的にフォレスとプロットが作成される。異質性が高い場合は統合できないので、解釈には注意する。

D. 結論

系統的レビューは、網羅的な検索と、データの抽出、研究のバイアスの評価、分析という一連の流れがある。検索などは専門家の力を借りながら、

一人でやらないことがエラーを防ぐ上で重要である。また日本からのレビューではEmbaseをいれていないことが多いが、データベースに偏りがなくとも重要である。コクラン系統的レビューでは、検索から1年以内に出版することを義務づけているため、検索してから投稿までスピートが必要になる。

E. 健康危険情報

該当なし

F. 研究発表

1. 論文発表

なし

2. 学会発表

なし

G. 知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

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「食品安全行政における政策立案、政策評価に資する食品由来疾患の
疫学的推計手法に関する研究」

日本の食品安全行政の現状分析

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研究要旨

WHO/FERG の食品由来疾患による健康時間の損失に係るカントリー・スタディの研究枠組みにおいて、DALY's の測定とともに求められている政治状況に関する分析(Policy Situation Analysis)を行った。具体的には、WHO/FERG が示している”Situation Analyses Manual(SAM)”を参考にしつつ、わが国の食品安全行政のフレームに則した形で、まず食品安全基本法及び食品衛生法の体系、並びに食品安全行政(厚生労働省、農林水産省、食品安全委員会、消費者庁)の枠組みの成立について、近年の政治情勢との関係等に着眼してレビューを行った。次いで我が国の食品安全行政に関する Stakeholder のリストアップを一定の方法で行い、さらに食品安全をめぐる直近の課題として、①社会経済環境の変化と食品安全への影響、②レギュラトリーサイエンスの振興、③消費者による食品由来リスクの適切な理解、④東京電力福島第一原子力発電所事故への食品安全行政の対応についてレビューした。

A. 研究目的

WHO/FERG (Foodborne Disease Burden Epidemiology Reference Group) は、WHO の「食品由来疾患による世界的な損失の推計のためのイニシアティブ」(Initiative to Estimate the Global Burden of Foodborne Diseases) に対し技術的助言を行う組織である。

FERG は 2010 年の会合で 2011 年度から国別に、特定の疾患について食品由来での DALY's (Disability Adjusted Life Years) を推計するパイロットスタディを世界 4 カ国で開始することを決定し、日本はアルバニア、ウガンダ、タイとともにパイロットスタディ参加国となった。

この DALY's の推計の研究は専ら疫学的な観点から行われるものであるが、その成果を実際の政策に活かしていくため、FERG の事務局は、パイロットスタディの一環として各国の政治状況に関す

る分析(Policy Situation Analysis(PSA))を同時に行うことを求めている。本研究は一義的にはこの FERG 事務局の要請に応えるものである。

また本研究では、英文でわが国の食品安全行政の概要とここ 10 年余りの歴史について包括的にまとめている。特に 2001 年の我が国における BSE の発生以降変化の著しい食品安全行政と衛生行政を網羅的に捉え、歴史を遡った上で政治的な背景や現下の諸問題を紹介した点や、(本来の趣旨とは若干ずれるが、) 国際的関心の高い東京電力福島第一原子力発電所の事故への食品衛生上の対応を紹介している点に関しては、類似の英文の文献はない。食品安全行政の確立を目指す国々に対して政策立案に際しての参考となることも期待している。

B. 研究計画・方法

主に既存文献(参考文献は文末参照)の調査、

関係省庁のホームページ、及び厚生労働省食品安全部の提供資料を参照した。

(倫理面への配慮)

特になし。

C. 研究結果

1. 平成 23 年度末段階でのとりまとめ

(タイトル” Policy Situation Analysis of the Japanese Food Safety System”)

別紙

2. 概要

(1) とりまとめに際しての基本姿勢

別紙レポートは、WHO/FERG 事務局が示している” Situation Analyses Manual (SAM)” を参考にしつつ、わが国の食品安全行政のフレームに則した形でとりまとめている。SAM は基本的に外部のコンサルタントが、一国の政府に対して、手法を提示しながら具体的な政策分析の実施を促すマニュアルである。そうした分析を行うための枠組みとして、各国に 4 名からなる(日本で言うところの)産学官の重鎮から構成される Senior Advisory Team (SAT) を置き、SAT の選定で関係各界の有識者により Task Force (TF) を構築し、その TF が上記のような分析を行うことが想定されており、本研究で行っている疫学的な研究結果に基づく政策の見直し、といった範囲ではなく、かなり大がかりな、食品安全行政制度全体の見直しを想定したようなものとなっている。食品安全行政に関して制度全体の見直しを行った経験の乏しい国々に対し、今回のプロジェクトを契機として制度全体の見直しを促す為の「方法」を教示する、という意図があるものと思われる。そうした内容であることを踏まえ、当研究班では、SAM で提起されている手法に捉われず、一方でステークホルダーの特定など今までわが国であまり取り込まれていなかった部分については取り込み、併せて関係各国に対してわが国の食品安全行政の現状を伝えることを目指し

て編集した。

(2) 章建て

具体的な章建ては以下のようなものである。

1. 日本の食品安全システムの沿革

1.1. 食品安全基本法の下での体系の概要

1.1.1. 食品安全基本法の概要

1.1.2. 食品安全委員会

1.1.3. 食品安全委員会によるリスク評価

1.1.4. 食品安全委員会によるリスクコミュニケーション

1.1.5. 食品安全委員会及び食品安全基本法に関する評価

1.2. 食品衛生法及び食品衛生行政

1.2.1. 食品衛生法の概要

1.2.1.1. 食品衛生法の下での規格基準

1.2.1.2. 食品衛生法の下での監視指導

1.2.1.3. 食品衛生法による施設の規制

1.2.1.4. 食品衛生法の下での人員の規制

1.2.1.5. 食中毒発生時の対応

1.2.1.6. 輸入食品安全確保対策

1.2.1.7. 食品表示

1.2.1.8. 厚生労働省のリスクコミュニケーション

1.2.1.9. 罰則規定

1.2.2. 食品衛生行政

1.2.2.1. 食品衛生行政の概要

1.2.2.2. 地方自治体による食品衛生法の施行

1.3. コーデックス委員会との関係

2. ステークホルダー

2.1. 食品安全政策のステークホルダーの特定

2.2. ステークホルダーとしての一般市民

3. 最近の論点 (日本の食品安全政策にとっての機会と挑戦)

3.1. 日本の食品と食事をめぐる環境の変化と、その食品安全への影響

- 3.2. 食品安全政策におけるレギュラトリーサイエンスの振興
- 3.3. 食品由来の健康リスクに関する消費者の適切な理解
- 3.4. 東日本大震災による福島県での原子力発電所事故への対応
 - 3.4.1. 放射性物質に関する規制値の設定
 - 3.4.2. 監視計画及び出荷制限に関するガイドライン
 - 3.4.3. 地方自治体による監視

(3) 章ごとの概要

第1章においては日本の食品安全システムの概要として、食品安全基本法下の体系、食品衛生法下の体系、及びコーデックス委員会との関係について記述した。

第1節では食品安全基本法の概要の紹介、食品安全委員会及びその委員の構成、食品安全委員会によるリスク評価のプロセスの実際、リスクコミュニケーションの手法等についてまとめるとともに、2008年度に行われた、主要消費者団体及び食品業界団体との意見交換において示された食品安全委員会に関する評価を整理した。

また、2002年に農林水産省及び厚生労働省の合同委員会の報告書（「BSE問題に関する調査検討委員会報告」）においてまとめられた、食品安全基本法の成立と食品安全委員会の設置の背景となった、1986年の英国でのBSE発生以降、2000年代前半の我が国におけるBSEの発生への政府の対応の問題点について記述した。また、食品安全基本法の成立をめぐっての（当時）与党自民党と政府との意思決定プロセスや、当該政治プロセスにおける日本生活協同組合連合会の果たした役割をまとめた。更には2009年の消費者庁の設置について、その目的や政治的背景についてまとめた。

第2節では食品衛生法の概要について、大方条文の並びに従い整理した。規格基準に関しては、食品安全委員会への諮問答申プロセスから制定し

た告示等の官報への掲載までを記述した。次いで食品衛生監視の年次の計画策定等について説明するとともに、食品製造加工施設等に係る施設基準の法的枠組みについて記述している。さらに食中毒発生時の対応プロセスについて、保健所の役割を中心に記述するとともに、輸入食品、食品表示（消費者庁による一元的所管等）、リスクコミュニケーションの具体的な措置を説明している。

次いで食品安全行政システムについて、厚生労働省本省、地方厚生局、各種研究機関、検疫所の役割について説明するとともに、地方自治体の権限について記述している。

第3節ではコーデックス委員会と日本政府との関係について記述している。

第2章においてはまずわが国の食品安全行政のステークホルダーを特定する作業を行った。具体的には、

1) 食品安全委員会のホームページから、作業時点で掲載されていた2003年から2010年度までに開催された「意見交換会」又は「関係団体等との懇談会」に出席していた団体の中から、食品安全委員会側から招待された団体の名称を抽出、2) 食品安全委員会企画等専門調査会、農林水産省食糧・農業・農村政策審議会及び厚生労働省薬事・食品衛生審議会食品衛生分科会の委員の肩書から1)と重複していないものを追加、3) 地域レベルの団体名だけが掲げられている場合には全国レベルの団体も追加、4) 分野ごとに分類、5) 名称を英訳、6) 全国レベルの団体を抽出、7) 専門家の意見を聴取、という作業を行った。また作業の結果を示したうえで、わが国の食品安全における生活協同組合の立ち位置について、欧州と異なり消費者の側面と生産者の側面を有しているユニークなものである旨記述した。

第3章においては、わが国の食品安全政策の課題として4点を挙げて、動態的な把握を試みた。

「日本の食品と食事をめぐる環境の変化と、その食品安全への影響」では、環境の変化として社

会的要素、経済的要素、(狭義の)環境的要素があるとの酒井(2008)の指摘、「食品安全政策におけるレギュラトリーサイエンス(RS)の振興」については、「日本では…(RSという)カテゴリーや(RS)の活用に対する認知が学術界でも行政サイドでも十分でない」との新山(2010)の指摘、「食品由来の健康リスクに関する消費者の適切な理解」では、食品の専門家が使い、消費者の誤解を招く2つの言葉(「日本の食の安全は守られている」「食品にゼロリスクはない」)があるという唐木(2010)の指摘を敷衍した上で、それぞれわが国の食品安全行政の在り方について検討した。

一方で、「東日本大震災による福島県での原子力発電所事故への対応」の箇所は、事態が現在もなお進行中であることから、「放射性物質に関する規制値の設定」「監視計画及び出荷制限に関するガイドライン」「地方自治体による監視」の事実関係の記述に留めている。この記述の箇所については、来年度以降においても随時更新をしていく必要がある。

D. 健康危険情報

なし

E. 研究発表

なし

F. 知的所有権の取得状況

なし

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Policy Situation Analysis of the Japanese Food Safety System

1. Outline of the Japanese Food Safety System

It is needless to say that the safety of food is of major concern to the public. Many changes surround the dining table of the Japanese. Import of foodstuff has been increasing backed by the globalization, requests from foreign countries to open the agricultural market and diversification of the taste of people. Newly-found hazards such as enterohemorrhagic E. coli O-157 or abnormal prions have been reported. Technological enhancements in agriculture such as genetic modification have made progress that such technological products easily reach the pantry of any family. All those factors affected the people's awareness and concern for food safety, and such concern has been amplified by the reports of various events and crises related to food and its safety. In September 2001, first BSE infected cattle was found in Japan, and people's anxiety for food safety reached its peak. (See Chart 1-2) (See Column 1 for the report made by the Joint Commission to Review and Analyze BSE incidents and the responses of the government.)

Those changes in food supply as well as the concerns of the public has lead to the major modification of administrative laws related to food safety in 2003, and the establishment of Food Safety Commission (FSC), which is a governmental body related to food safety to conduct risk assessment independent from the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW), that assume the role of risk management. (See Column 2 for the political process for the establishment of FSC.) Separation of risk assessment body from risk management agencies is beneficial in terms of securing transparency of the evaluation of risk, and enhances the credibility and accountability of the decisions of the related agencies based on sound science.

In this chapter, we will first explain the framework of such triune¹ framework of food safety administration in Japanese government, then move on to the explanation in detail of the duties of MHLW and the Food Sanitation Law that is under the jurisdiction of that Ministry, and the overall structure of the food safety administration, including the local governments. Finally we would like to raise several current issues related to food safety policies.

1.1. Overall framework under Food Safety Basic Law

1.1.1. Outline of the Food Safety Basic Law (FSBL)

In article 1 of the FSBL, the purpose of the Law is stated as follows; "In consideration of the

¹ In addition to the three agencies, there are two national government agencies that are related to food safety. The Ministry of the Environment deals with the food safety regulation related to environmental pollution; and newly-established (in September, 2009. (See Column 3)) Consumer Affairs Agency deals with the planning and implementation of food labeling policies, which needs to be handled by MAFF (under Japan Agricultural Standards (JAS) Law) and MHLW (Food Sanitation Law and Health Promotion Law (related to the labeling for nutritional facts)).

vital importance of precise responses to the development of science and technology, and to the progress of internationalization and other changes in the environment surrounding Japan's dietary habits, the purpose of this Law is to comprehensively promote policies to ensure food safety by establishing basic principles, by clarifying the responsibilities of the state, local governments, and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation, in order to ensure food safety". "Food-related business operators" includes those engages in the business of food collection, production, import, processing, cooking, storage, transport, or sales (wholesale, retail or eatery). It is prescribed that the food safety measures should be "based on the simple recognition that the protection of the health of our citizens is a top priority (article 3)", "appropriate(ly) at each stage of the food supply process (article 4)", and "on the basis of scientific knowledge and in sufficient consideration of international trends and the opinions of citizens with respect to ensuring food safety (article 5)". From article 6 to article 9, the role and responsibility of the stakeholders for food safety policy, i.e., national government, local government, food related business operators and consumers, are clearly stated. From articles 11 to 21, the concept of risk analysis – composed of "risk assessment" conducted by FSC, "risk management" conducted mainly by MAFF and MHLW, and "risk communication" provided by FSC, MAFF, MHLW and other stakeholders – is introduced. While the articles of FSBL above are conceptual – do not define specific duties or code of conducts of anybody –, they indicate the basic ideas of the Japanese food safety policy in a comprehensive manner.

1.1.2. Food Safety Commission (FSC) (See Chart 1-3)

From articles 22 to 38 of FSBL, organizations and roles of the Food Safety Commission (FSC) are prescribed. FSC is placed under the Cabinet Office and reports directly to the Prime Minister for their responsibilities (articles 22, 23). It is conventional that the Prime Minister nominates the special Minister who supervises FSC, and that Minister assumes the responsibility of the Prime Minister prescribed in FSBL. The Commission itself is composed of seven experts with "superior insight into ensuring food safety", whose appointment requires the approval of both Houses of the Diet (article 29). Four of the experts at the Commission must serve full-time.

Under the Commission, various Expert Committees (currently 14) are set up. Eleven committees conduct risk assessment on health hazards according to their specific expertise, while the other three committees handle strategic planning, risk communication, and emergency response, respectively. Those "experts" at the Expert Committees need not serve full-time (article 36). Therefore, relevant experts of various health hazards could be chosen among the academic researchers (university professors, research institute scientists, etc.) who are at the forefront of specific scientific area. They can bring in the most recent scientific knowledge and

expertise from the academia. The “experts” are pressured to bring in the state-of-the-art science, as the discussion and the results of the Expert Committees are open and under scrutiny of the concerned parties, including their peer scientists.

The Commission has its own secretariat staff.

1.1.3. Risk Assessment conducted by FSC (See Chart 1-4)

There are two ways to begin the risk assessment by FSC. Much of the past assessments have been conducted based upon the requests of the risk management bodies (MAFF, MHLW, etc.). Risk management bodies are obliged to submit the request to FSC by article 24 of FSBL when they create or modify the regulation prescribed by the relevant laws, such as Food Sanitation Law or Agricultural Chemicals Regulation Law. Another way is so-called “self-tasking risk assessments” – the assessments begun by the initiative of the Commission itself. Examples of such “self-tasking risk assessments” include the issues of “food-borne pathogenic microorganisms”, “lead in food, apparatus and containers/packages²”, and “beef/beef offal imported to Japan from countries with no BSE report”.

For the stakeholders and other concerned people, and the scientists who are not the Expert Committee members, “public comment” process is prepared to reflect their opinions. Article 13 of the FSBL prescribes that “in formulating policies to ensure food safety, necessary measures for promoting the mutual exchange of information and opinions among persons or parties concerned, such as provision of information concerning the policies and the granting of opportunities to comment on those policies, shall be taken to reflect public opinion in the formulation of the policies and to ensure the transparency and fairness of the process”. Once the draft for the risk assessment report is compiled, the report is put to such “public comment” process. Article 39 of the Administrative Procedure Law prescribes that “the period for submission of Comments” “shall be 30 days or more from the date of public notice”. In some cases, during the public comment period, opinion exchange meeting is held with stakeholders to offer direct comments on the assessments. Usually such meeting is held for the issues of significant public concern.

From July 1st, 2003 to September 14th, 2011, FSC received 1559 requests from the risk management bodies. In addition, there are 10 self-tasking risk assessments. Of 1569 assessments, 1069 has been completed, 10 are under public comment, and 497 are in progress³.

Once the assessment has been completed after deliberation at the Expert Committee and public comment process, the FSC will finalize the report and notify their conclusion to the relevant

² From the perspective of securing safe cooking and supply of food, food apparatus, containers and packages are regulated under Food Sanitation Law.

³ FSC website <http://www.fsc.go.jp/hyouka/singijokyo.pdf>, accessed on September 22th, 2011

risk management bodies (MAFF, MHLW, etc.). The FSC will monitor how the policies are implemented by the risk managers, and makes recommendation in the name of the Prime Minister to adopt certain policy to the risk management bodies when necessary, pursuant to items 3 and 4 of article 23.

1.1.4. Risk Communication conducted by FSC

In addition to the opinion exchange meeting during the risk assessment process described in 1.1.3., more casual meetings, such as “Science Café” or “Food Safety Workshop” are held either by FSC itself or co-sponsoring with other bodies such as local governments.

There are other methods of communication with public. One is the “Food Safety Hotlines” – accepting the opinions from the public concerning food safety by telephone. Of those questions gathered by the hotline, frequently asked questions and the answers to them are posted on the website.

Another way of seeking for the public opinion is the “Food Safety Monitors” system. The FSC periodically asks questions to the monitors to recognize public awareness of and concerns about food safety. The monitors are composed of those who have the experience of working for food industry, have engaged in research in food, have been worked as medical or educational occupation such as nurses or teachers, and other consumers in general. The FSC assembles the gathered opinions and their responses, and put it on the website of FSC.

FSC occasionally assembles the “Fact Sheets”, to explain to the general public about the major concerned hazards to food safety. These fact sheets are prepared in a timely manner to reflect the concern of the public, and are committed to offer the newest scientific expertise and knowledge, including the recent result of risk assessment.

1.1.5. Evaluation of the FSC and FSBL

In FY 2008, FSC held discussion meetings with Consumers Japan, Consumption Science Foundation, and Japan Food Industry Center (See Chart 2-1 for the characters of those stakeholders) on reflection of the five years’ experience since the establishment of the FSC and enforcement of FSBL.

Consumers Japan pointed out various issues. Included in their opinions are that; the information disclosure had improved (including HP); providing opportunities for consumer inputs is worth appraisal; the authority to make recommendation to the risk management bodies, such as on the evaluation of the inspection system of the imported foods, had not been exercised; several meetings were not disclosed⁴; the FSC should conduct assessments by its own initiative more

⁴ FSC responded that the meetings were basically open, except for the meeting that deals with matters that might violate the intellectual property if disclosed, such as matters related to the

aggressively; the FSC should have their own examination laboratory to support their self-initiative assessments; the idea of risk analysis should be proliferated more to the public; the FSC should make better use of the opinions of the consumers, among others.

Consumer Science Foundation indicated that; it's better to have FSC's own laboratory; the risk communication should be improved so as to make the consumers understand the "safety zone" that the most current science could tell; existence of the FSC was not well recognized by the public; outputs should be disclosed not only through the homepages but also the materials of broader significance, such as the newspapers or other mass media; more timely disclosure of information at the time of crisis is needed, etc..

Japan Food Industry Center stated that; public awareness of the FSC was low; risk communication should be improved so that the consumers could easily realize the issues and associated risks; the FSC should always exchange dialogue with mass media or the expert scientists; the idea that there's no "risk-free food" was getting understood by the public; FSC's information materials were too difficult for general consumers; the FSC should be strengthened by authorizing for compulsory risk control, among others.

Of all those opinions and recommendation raised, their acceptances were generally positive for the establishment of the FSC and the introduction of triune framework within food safety administration under the idea of risk analysis.

1.2. Food Sanitation Law and Food Sanitation Administration

1.2.1. Outline of the Food Sanitation Law (FSL)

In article 1 of the FSL, the purpose of the Law is stated as follows; "The purpose of this Law is to prevent the sanitation hazards resulting from eating and drinking by enforcing the regulations and other measures necessary, from the viewpoint of public health, to ensure food safety and thereby to protect citizens' good health". By the 2003 reform bill of the Law, that were submitted to the Diet in tandem with the bills to establish the FSC⁵, the words "to ensure food

patented issues.

⁵ Under Japanese Constitution, not only the House members but the Government can submit the bill to establish/amend/abolish the law. It used to be conventional that most of the bills that pass the Diet were submitted by the Government, whereas the bills submitted by House members were rarely passed or even put on the table. Currently, due to the political reform movement that has been energized for more than a decade to lead the politics not under the initiative of governmental bureaucrats but under the initiative of the politicians themselves (House members), the bills submitted by the House members are more likely to be passed or seriously discussed at the Diet than in the past. The 2003 comprehensive, government-wide reform bill of food safety systems and regulations were submitted by the Government in a conventional way. The Cabinet Office, MAFF, and MHLW have submitted reform bill(s) to the Laws under respective jurisdiction.

safety” and “to protect citizens’ good health” were inserted to the article indicating the purpose of the Law.

After the articles defining the responsibilities of national government, local government (article 2), food-related business operators (article 3), and the general principle for handling foods and food additives (article 5), the Law prepares several articles that prohibits the sales, etc., of specific foods or food additives that are hazardous to the health of the consumers (unhygienic foods (article 6), foods with special method of consumption (such as unconventional concentration, etc.)(article 7), comprehensive prohibition of specific foods from specific country/area (article 8), and prohibition of meat, etc. of livestock and poultry with certain sickness (article 9).

1.2.1.1. Specifications and standards under FSL (Chart 1-5)

The law prescribes the regulation of food additives (article 10) and regulatory specifications and standards for food, etc. (article 11 and 18).

Only the framework of such specifications and standards are defined by the Law; the administrative notifications made by the MHLW stipulate in detail about composition, production, processing and cooking standard of foods in general as well as the specific standards applied to various types of foods according to each nature. Foods or food additives that are not following the standards, or manufactured by the methods against the prescribed specifications are prohibited from production, importation, sales, etc..

In addition, the Abattoir Law and the Poultry Slaughtering Business Control and Poultry Inspection Law are prepared to prescribe the specific regulation for meat of livestock and poultry, respectively.

Upon the establishment/amendment/abolishment of those regulations, MHLW is obliged to submit the request to FSC to hear their opinion (see 1.1.3.). FSC notifies to MHLW their opinions about the asked (potential) health hazards and risks. In case of chemicals or other substances, the FSC’s opinions include the ADI (Acceptable Daily Intake) when necessary.

After receiving the opinions of the FSC, MHLW will review their current regulations and inquire their draft of establishment/amendment/abolishment to the Pharmaceutical Affairs and Food Sanitation Council, an advisory committee of the Minister of Health, Labour and Welfare. The Council sends the draft to the relevant Subcommittee, and, based on the conclusion of the Subcommittee, the Council responses to MHLW for their opinions. In parallel, the MHLW puts the draft regulation to the public comments. For public comments, the same Administrative Procedure Law applies (see 1.1.3.) as applied to FSC. The opportunities for the scientific community to input their expertise resembles those in the FSC decision-making process. Also, the MHLW notifies WTO for its new regulation to seek if it meets the international trade rule.

When the public comment process has finished, the MHLW must consult with the Consumers

Affairs Agency for the draft regulation. After the Consumers Affairs Agency responds and gives consent to the draft, MHLW may decide the final regulation, and notify the regulation to the public via Official Gazette.

1.2.1.2. Inspection and guidance under FSL

There are several articles under FSL that provides certain authorities to the national and local governments and their officials for inspection, monitoring and guidance on food safety (such as articles 25, 26, 28, or 30). By such inspection, monitoring and guidance, the government supervises whether the aforementioned prohibitive regulations (articles 6, 10, etc.) and specifications and standards-type regulations (articles 11 or 18) are duly followed.

Under article 28, the relevant authorities (central or local government) may “request a business person or other relevant persons to submit the necessary report, or have their officials visit places for business, offices, warehouses, and other places, inspect food, additives, apparatus or containers and packaging to serve for the purpose of marketing or to use in business, business facilities, books and documents, and other articles, and remove food, additives, apparatus or containers and packaging to serve for the purpose of marketing or to use in business, without charge, within the limit necessary for using them for the purpose of testing”. In addition, under article 30, the relevant authorities “shall have food sanitation inspectors⁶ implement monitoring and guidance”. For the domestic distribution of foods, the relevant authorities are the prefectural governments, and the food sanitation inspectors belong to the “Public Health Offices” (see 1.2.2.2.) to conduct their day-to-day operations. Food sanitation inspectors hired by the national government conduct the import inspection at the Quarantine Stations.

To conduct such inspection, monitoring and guidance in an effective and efficient manner, the FLS orders the government to establish the Surveillance and Administrative Guidance Guideline (article 22) and Plans (articles 23 to 24).

The Guideline shall be assembled by the national government. It provides nationwide basic principles on food safety inspection and surveillance, specifies matters (hazards) that require special monitoring and guidance or the framework of the implementation of monitoring and guidance.

⁶ In the same article it is prescribed that the relevant authorities “shall appoint food sanitation inspectors from among their officials to have them enforce the authority thereof prescribed in Article 28, paragraph (1) and perform the duties of guidance on food sanitation”. Paragraph (4) of Article 30 prescribes that the qualifications of the food safety inspector is decided by the Cabinet Order, and the Cabinet Order describes that the food safety inspector must be 1) a medical doctor, dentist, pharmacist or the veterinarian, 2) with educational background in food safety related subject such as medicine or veterinary medicine, 3) nutritionist with two years’ working experience in food safety related government administration, or 4) a person who completed the necessary course at a food safety inspector training facility registered to MHLW.

The national government sets up the Plan for the inspection, monitoring and guidance for imported foods. The Plan includes the matters (hazards) that require intense monitoring and guidance taking into account the circumstances of the exporting countries and regions. (See 1.2.2. for actual implementation)

The local government sets up the Plan for the implementation of food safety measures for foods distributed or consumed within its own jurisdiction. The Plan includes the matters (hazards) that require intense monitoring and guidance according to the local situation of food production, distribution, manufacturing and/or processing, etc.. (See 1.2.2. for actual implementation)

1.2.1.3. Regulations against facilities under FSL

Article 51 of the FSL prescribes that the "prefectural governments shall establish the necessary criteria for facilities for restaurant businesses or other businesses which have an extraordinary impact on public health" by Prefectural Ordinance⁷. The scope of such businesses is prescribed by the Cabinet Ordinance, and currently there are 34 types of businesses specified. Examples of those regulated businesses are the restaurants, bakeries, milk processing, meat sales, among others. Article 52 of the FSL prescribes that anybody who intends to conduct those 34 businesses must obtain approval from the prefectural governor.

For abattoir facilities and poultry processing facilities, equivalent authorities are given to the prefectural governor by the Abattoir Law and Poultry Slaughtering Business Control and Poultry Inspection Law, respectively.

1.2.1.4. Regulation against personnel under FSL

Article 48 of the FSL prescribes that "a business person who produces or processes dairy products, additives" that require "special consideration with regard to sanitation in the process of production or processing"" shall place a full-time food sanitation supervisor for each facility to have him/her supervise the production or processing in a sanitary manner". This regulation was introduced in 1957 in reaction to the baby formula contamination scandal by arsenic. Now the scope of regulation has been widened to include meat, margarine, or shortening, in addition to baby formula and food additives.

By the administrative guidance, MHLW advises the prefectural governments to request to the food industry to set up the "food sanitation leader" other than the businesses who is required to set up "food sanitation supervisor" by FSL to urge the industry to pay attention to food safety in their daily business.

⁷ The Local Autonomy Law prescribes that the local governments can establish the Ordinances (local rules and regulations) as far as they are not against the national laws (article 14 of the Local Autonomy Law).

Again, for abattoir facilities and poultry processing facilities, equivalent requests are made to set up the personnel within the facility who is responsible for the food sanitation by the Abattoir Law and Poultry Slaughtering Business Control and Poultry Inspection Law, and their administrative ordinances, respectively.

1.2.1.5. Measures against food poisoning outbreak (Chart 1–6)

In Japan, by the article 58 of the FSL, medical doctors who have consulted the patients (including suspected patients) of food poisoning must report (within 24 hours) to the relevant Health Centers (see 1.2.2.2. for health centers) for the cases. In addition, by the Law Concerning Prevention of Infection of Infectious Diseases and Patients with Infectious Diseases, certain pathogens such as enterohemorrhagic *E. coli* O-157 are designated as one of the diseases that the medical doctors must notify its occurrence to the Health Centers. Director of the relevant Health Center, who is basically a medical doctor, must immediately report the incident to the prefectural governor and administrative authorities, and shall conduct the investigation (article 58). Technical officials who engage in such investigation at the local government include medical doctors, pharmacists, and veterinarians. The investigation includes epidemiologic investigation to designate the poisoned food, and bacteriologic and physicochemical investigation of the fecal materials or suspicious food, among others.

Upon the report of the Director of the Health Center about the massive outbreak (over 50 patients and includes the possibility of such outbreak), the prefectural governor must report to MHLW for the incident. In some cases, MHLW notice the outbreak may happen nationwide by the reports from the prefectures informing the same incident happening simultaneously. MHLW requests the prefectural governor(s) to investigate if 1) the number of the food poisoning patients is or may become 500 or more, or 2) food poisoning patients are or may become geographically widespread and the matter requires urgent actions.

In 1998, 3,010 cases, 46,179 patients of food poisoning incidents have been reported. Some ups and downs are observed, but in general, food poisoning incidents are decreasing to count only 1,048 cases and 20,249 patients in 2009. MHLW points out in the White Paper (Fiscal year 2009) that the decrease reflects the enhancement of personal hygiene as well as sanitation practice in each household, shop and restaurant, or the food industry in general, and the thoroughness of the sanitation management by the companies, in reaction to the increased concern for food safety by the reports and broadcasts of various food safety-related incidents. On the other hand, number of patients per case has increased from 15.3 in 1998 to 19.3 in 2009, which is still small compared to those in 80s or 90s, which counted over 35 in several of those years.

Detailed statistics on food poisoning incidents (in English) can be accessed by the following website.

http://www.mhlw.go.jp/english/topics/foodsafety/poisoning/dl/Food_Poisoning_Statistics_2009.pdf

1.2.1.6. Measures securing imported food safety

The National Government Plan for the inspection, monitoring and guidance for imported foods (See. 1.2.1.2.) prescribes measures to secure the safety of imported foods to be comprised of three processes. First process is the measures at the exporting countries. Through the bilateral discussion with governments of exporting countries, the MHLW promotes various food safety measures of the exporters such as sanitary supervision upon manufacturing, tightened supervisions or pre-export inspection. Second process, which is the measures conducted by the border inspection at the quarantine; they include monitoring inspection⁸ and "ordered inspection" to be applied to the imported foods whose possibility of violation are high. Third process is the various measures for distribution and consumption of foods in domestic market, as applied to domestically-produced foods.

1.2.1.7. Food Labeling

From the perspective of food safety, FSL stipulates that appropriate standards and regulations on food labeling should be formulated to provide the consumers and related businesses precise information so as to enable them to make rational recognition and choice of food (article 19). "False or exaggerated labeling or advertising, which may cause harm to public health" is prohibited (article 20).

Consumer Affairs Agency (CAA) now takes over the role of food labeling regulation from MHLW since September 1st, 2009. They also regulates the labeling regulation under the Japanese Agricultural Standards Law (JAS), which has been formerly under the jurisdiction of MAFF. (see footnote 1)

1.2.1.8. Risk Communication by MHLW

Article 64 of FSL prescribes that the Minister of Health, Labour and Welfare shall publicly disclose the necessary matters and seek opinions of the public at the time of planning and determining regulatory specifications and standards. For the Prefectural Governors, upon formulating the surveillance and administrative guidance plan; same regulations are applied *mutatis mutandis*. Article 65 prescribes that the Minister and the Governors shall publicly disclose the information about the state of implementation of the policies related to food sanitation and seek widely the opinions of the public regarding the said policies.

⁸ Statistical methods to reflect the import quantity, frequency of violation or degree of hazards are employed to decide the targeted foods and hazards, etc. of strict monitoring.

To meet these requirements, Department of Food Safety of MHLW conducted various risk communication measures. According to the Department, followings are the risk communication measures taken by them in FY 2008.

- 1) Holding of the meetings for exchanging opinions
 - Held meetings for exchanging opinions on BSE, Plan for Surveillance and Administrative Guidance on Imported Foods, Positive List Oriented System, food additives, and health food, among others.
 - Attended at the meetings for exchanging opinions, held by the Food Safety Commission, MAFF, local governments, etc., as a speaker, panelist, or in other capacities.
- 2) Website
 - Enhancement of contents such as an animated video about surveillance of imported foods by the quarantine station.
- 3) Training for risk communication personnel
 - Provided training for local government staff
- 4) Coordination with concerned administrative organizations; facilitation of exchange with consumer groups, etc.
 - Coordination with concerned administrative organizations; participation in the meeting for exchanging opinion hosted by consumer groups, etc.
- 5) Public comments and other actions
 - Seeking public comments, holding public Council meetings, and other actions for information disclosure
- 6) Others
 - Created educational resources on prevention of food poisoning for use at schools

1.2.1.9. Penal Provisions

Articles 71 to 79 prescribes penalties (criminal and non-criminal) on the violation of the articles of FSL. It is generally understood that the premeditation of the person who conducts the violation is required.

1.2.2. Food Sanitation Administration

1.2.2.1. Overview of the food sanitation administration (See Chart 1-6)

There are four main groups of organizations within MHLW. First, the administrative organization at the headquarter. Department of Food Safety, which enforces the FSL, is under Pharmaceutical and Food Safety Bureau. Generally, much of the day-to-day operative issues are decided by the Director-General of the Department of Food Safety, and the Director General