

Incidence of gastroenteritis caused by foods in Japan, 2008

Pathogen	General population mean (2.5-97.5 percentiles)	GP visit mean (2.5-97.5 percentiles)	Fetal cases
Campylobacter spp.	50,923 (29,721-113,360)	3,417 (3,126-4,272)	0

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DALYs for Campylobacteriosis and sequelae in 2008

	YLD(0)	YLL	DALY(0)	No.of days of illness	Disability weight
Gastroenteritis	245	0	245		
No GP	99	-	-	0.027	0.067
GP+Hospitalized	146	-	-	0.095	0.393
Sequelae					
Guillain-Barre-syndrome (Mild)	42	0	42	29.26	0.25
Guillain-Barre-syndrome (Severe)	566	234	800	1	0.14
Reactive arthritis	142	0	142	0.61	0.14
Inflammatory Bowel Diseases	980	120	1,100	44.36	0.26
Total			2,329		

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*From RIVM report 330080001/2006 and RIVM report 215011001/2007

DALYs for Campylobacteriosis and sequelae

Country	Year	DALYs total	DALYs per 100,000
Japan	2008	2,329	1.8
Netherlands	2004	1,500	9.0
Netherlands	2010	1,521	9.2

Reference: RIVM report 330080001,330331004

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DALYs for Campylobacteriosis

Country	Year	DALYs total	DALYS per 100,000
Japan	2008	244.7	0.2
Austria	2003-2005	528.9	6.5
France	2003	222.7	0.4
Germany	2003-2005	6,165.1	7.5
Netherlands	2003	264.7	1.6
Spain	2003-2005	652.8	1.5

Reference: RIVM report 215011001

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Conclusion

- What we did
 - Data collected from available country data
 - Systematic reviews for each sequelae
 - Experts elicitation
 - Calculating DALYs for Campyrobacterial and sequelae
- What we will do
 - Uncertainty analysis
 - Apply to Salmonella and EHEC

参考資料 3

The Foodborne Disease Burden Epidemiology Reference Group (FERG)
について

(資料1)

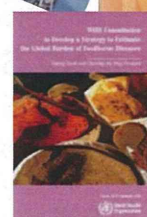
平成23年度厚生労働科学研究
「食品安全行政における政策立案、政策評価に資する
食品由来疾患の疫学的推計手法に関する研究班会議(第1回)」

WHO FERG について

国立医薬品食品衛生研究所
食品衛生管理部第三室長
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WHO - specific BoD work

Name	Purpose
CHERG (Child Health Epidemiology Reference Group; cf.: Child Health Epidemiology at www.who.int/child-adolescent-health/publications/pubCNH.htm)	To estimate cause-specific morbidity and mortality in children under 5 years
MERG (Monitoring and Evaluation Reference Group of the RBM Secretariat; www.rollbackmalaria.org/merg.html)	To develop effective monitoring and evaluation mechanisms for the Roll Back Malaria (RBM) Partnership
Burden of disease from environmental risks (www.who.int/quantifying_ehimpacts/en)	To provide morbidity, mortality and DALY estimates for selected diseases from environmental risks
Quiver (Quantitative Immunization and Vaccination Related Research)	To provide annual estimates of the burden of vaccine-preventable diseases
NTD STAG (WHO Steering and Technical Advisory Group on Neglected Tropical Diseases; www.who.int/neglected_diseases/stag/en/index.html)	To effectively prevent and control NTDs and assess socio-economic impact
LERG (Leptospirosis Burden Epidemiological Reference Group)	To obtain global epidemiological estimates on Leptospirosis.
FERG (Foodborne Disease Burden Epidemiology Reference Group; www.who.int/foodborne_disease/burden/en/index.html)	To provide reliable burden of disease estimates to enable policy-makers and other stakeholders to set appropriate priorities in the area of food safety.



by WHO secretariat

The Initiative:

- Combines **independent expert advice** with **WHO's public health leadership capacity** to assemble globally accepted health information.
- Benefits from **existing WHO experience in Burden of Disease** methodologies.
- Unites **previously dissociated disciplines** - such as risk assessment and epidemiology - to arrive at results that are meaningful to all scientific constituencies.
- Uses a thorough **peer-review process** to ensure scientific rigour, objectivity and credibility of the results.
- Works in **synergy and close partnership** with Member States, technical institutions, non-governmental organizations, industry, donors and other key stakeholders to increase efficiency and avoid duplication.
- Follows a comprehensive **communication strategy** to ensure regular dialogue among stakeholders and the effective distribution and use of results.
- Informs and shapes important **global public health priorities and strategies** that foster health security, economic growth and international development.

Foodborne Diseases (FBD) are a growing public health problem worldwide. Their impact is amplified through increasing international travel, population mobility and the globalization of our food supply.

In recognition of this, more than 50 developed and developing countries recently adopted the Beijing Declaration on Food Safety, urging all countries to base their food safety measures on sound scientific evidence and risk analysis.

The WHO Initiative to Estimate the Global Burden of FBD is a critical element in the implementation of the Beijing Declaration. It will provide stakeholders with the scientific evidence to prioritize preventive action, assess the impact of food safety measures and advise on the cost-effective use of resources. It is an integral part of WHO's global efforts to foster public health security and international development.


Estimating the Global Burden of FBD

New epidemiological project by WHO, which started in 2007, WHO FERG

http://www.who.int/foodborne_disease/ferg/

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Health Security and Environment (HSE)
World Health Organization (WHO)
20 Avenue Appia
1211 Geneva 27
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World Health Organization



Structure of WHO FERG

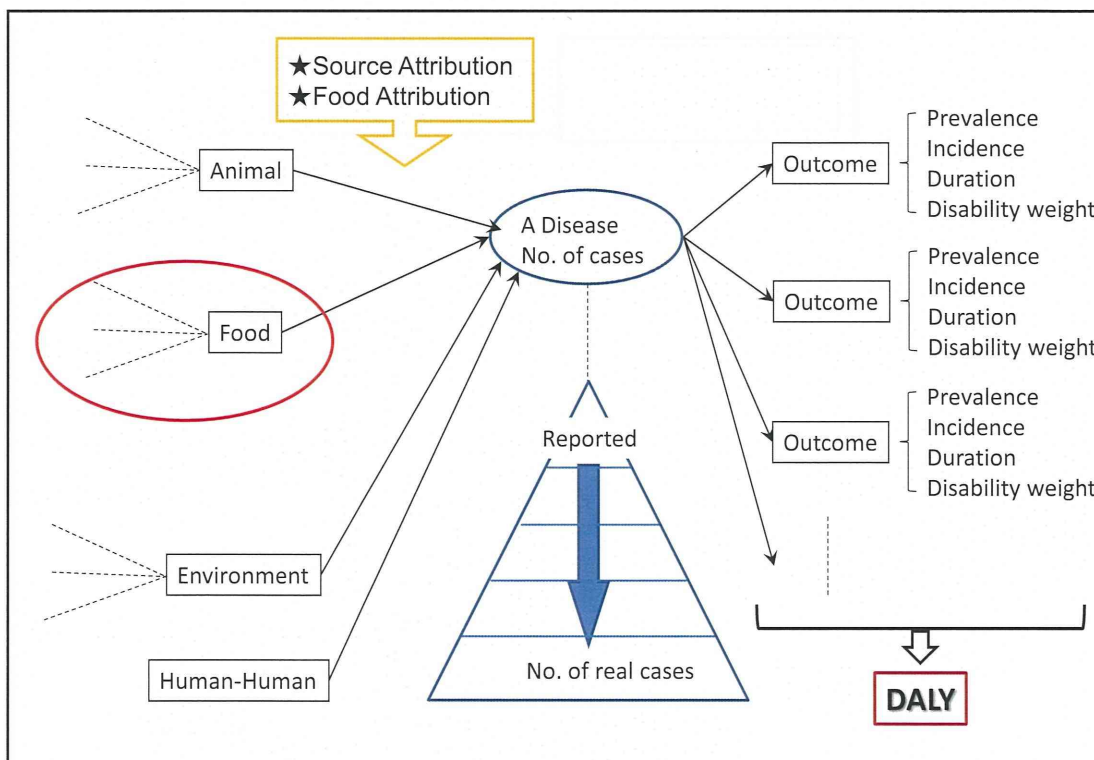
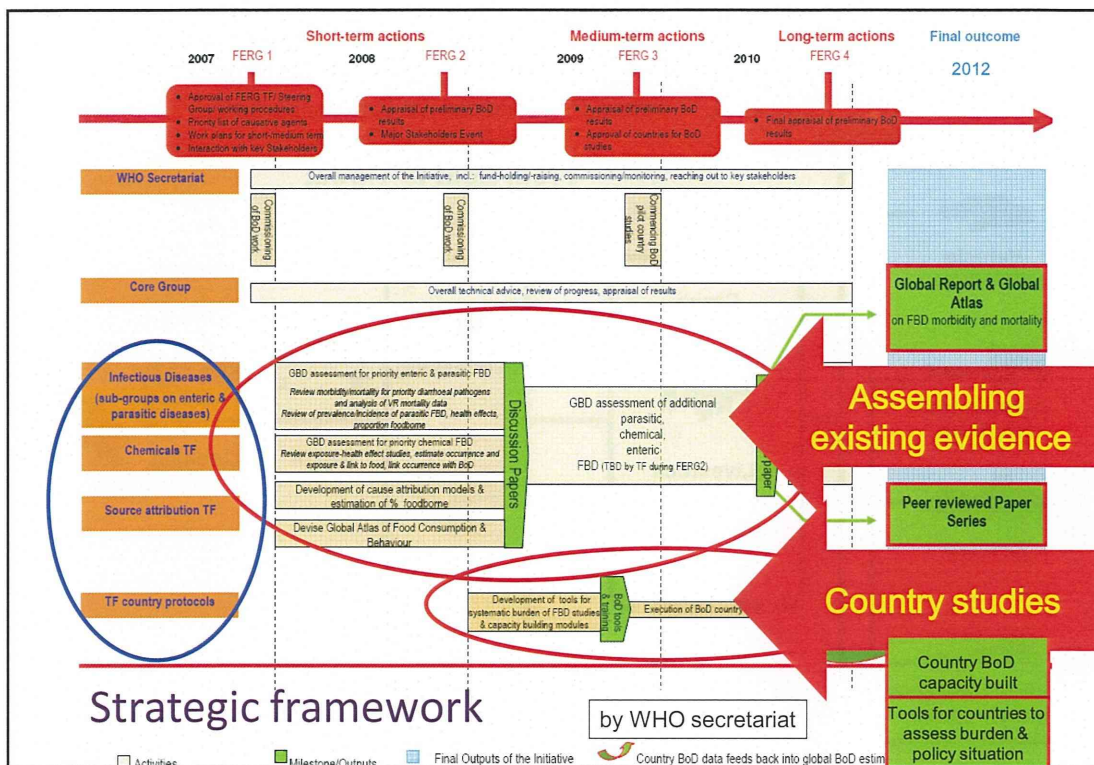
Foodborne Disease Burden Epidemiology Reference Group: FERG

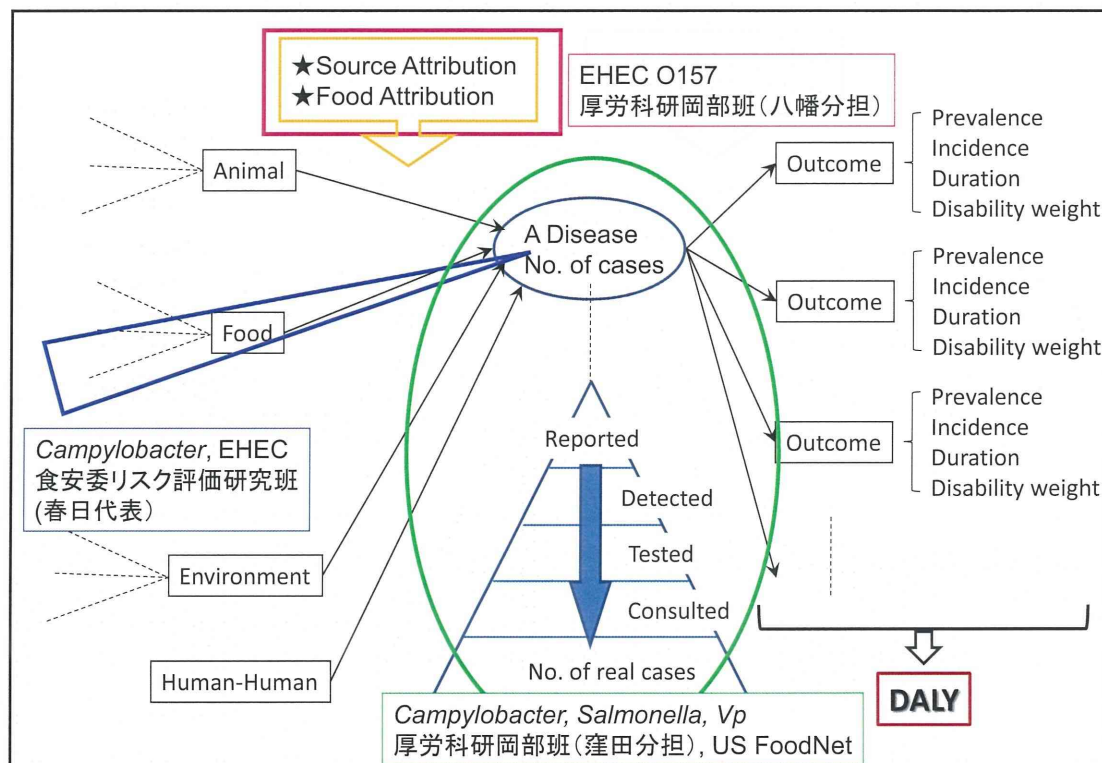
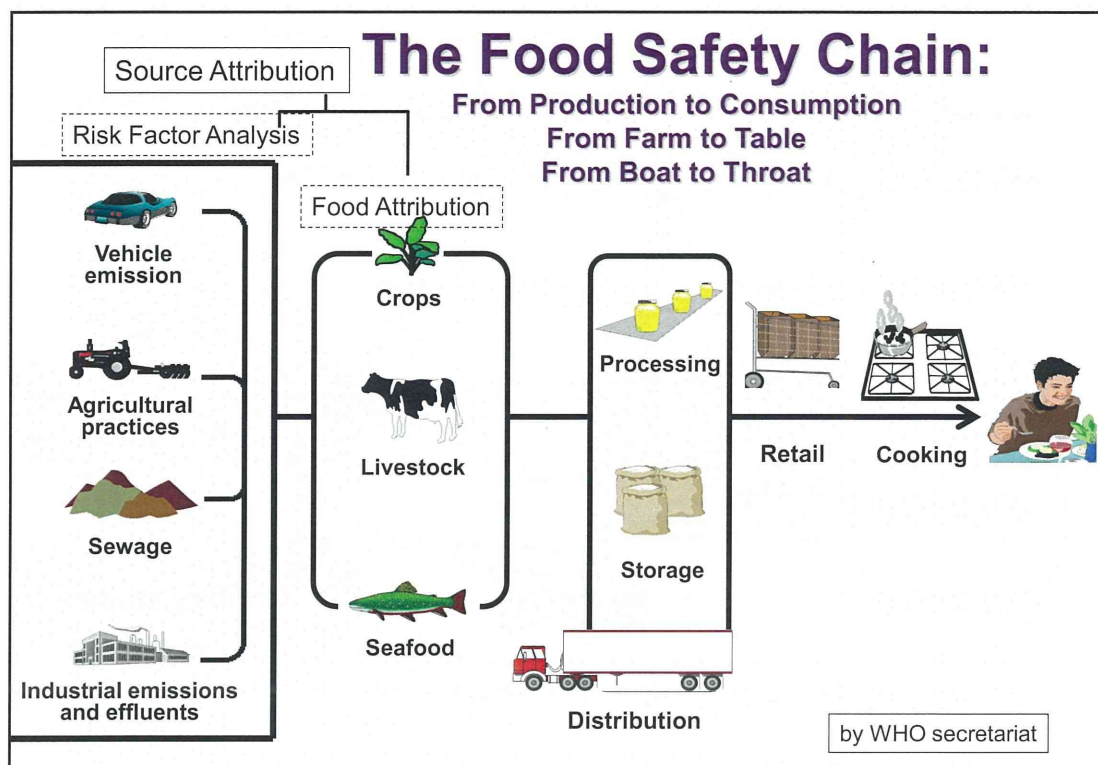
Task Forces

- Enteric diseases
- Parasitic diseases
- Chemicals & toxins
- Source attribution
- Country Studies

Country Studies Task Force

- Burden estimate and policy situation analysis
- Country studies
 - Pilot studies (2011-)
 - Full studies





参考資料 4

FERG Country studies overview

**Foodborne Disease Burden Epidemiology Reference Group:
Country Studies Task Force**

Overview of Proposed Country Study

Thank you for expressing interest in conducting a national burden of disease study. We believe that such country studies will have benefits for the participating countries as well as the World Health Organization (WHO) as it develops a global estimate of the burden of foodborne diseases.

This document is one of two that we ask you to review prior to preparing a formal proposal to conduct the study. This document provides an overview of the proposed study, so that you understand your potential commitment. The other document provides a template for the preparation of a formal expression of interest, with requests for specific information that will help WHO assess how to get the best value from the resources that are available. The resources to support country studies are limited, and there are specific data and information that are needed, as well as requirements to be representative in terms of global coverage. WHO will review the information provided in the light of these requirements, as part of the process of choosing countries in which studies will be conducted.

Dr Danilo Lo Fo Wong

Acting Director, Department of Food Safety and Zoonoses

World Health Organization

Background

The Foodborne Disease Burden Epidemiology Reference Group (FERG) was established in 2007 by the World Health Organization (WHO) under the leadership of WHO's Department of Food Safety and Zoonoses (FOS). The purpose of the Group is to estimate the global burden of diseases commonly transmitted through food. Five task forces have been established within the FERG – among them are the enteric (bacteria and viruses), parasites, a chemicals/toxins task force, one task force dealing with attributing diseases to particular food sources and the country studies task force (CSTF). The latter is charged with developing protocols for burden of disease studies at country level and overseeing the execution of such studies, which also include policy situation analyses.

Country Studies Task Force Objective and Rationale:

To provide guidance to countries for conducting national burden of foodborne disease (FBD) studies that:

- (i) deliver burden of disease estimates in the area of foodborne diseases;
- (ii) contribute to burden of disease scientific and 'knowledge translation' capacity development within the country;
- (iii) provide results that are translated into food safety policy for the country involved; and,
- (iv) contribute to estimates of the global burden of foodborne disease being prepared by FERG.

Anticipated uses of burden of foodborne disease information from country studies:

WHO has produced a pamphlet describing the purpose and value of country studies. Briefly, the anticipated uses of the results from these studies are:

1. Prioritisation of food safety as an issue within a country.
2. Prioritising of specific food safety issues within a country.
3. Provision of a baseline against which to evaluate future food safety interventions.
4. Assistance with harmonisation of international trade and regulatory standards. Assessment of equivalence of food safety controls for import and export risk assessments (e.g. within the context of Codex Alimentarius).
5. Contribution to the regional and global estimates of the burden of foodborne diseases (note that WHO will only publish estimates for specific countries with their express consent).

Scope of this Document

This overview document is intended to inform those responsible for preparing a detailed proposal to WHO to undertake a country burden of foodborne disease study (which includes a policy situation analysis to be conducted prior or in parallel to the burden study). While WHO can supply some resources to undertake the study, the country itself will have to commit some resources (personnel, infrastructure) and this overview will describe those needs.

This overview describes a country study in broad terms and will be supplemented later by a more detailed protocol to provide guidance to the scientists undertaking the study itself.

This document contains:

- Participants and roles;
- Process and timeline;
- Principles guiding the conduct of the study;
- Elements required for a national foodborne disease burden study;
- Elements and processes for policy situation analysis to support the translation of study results into policy;

Participants and roles

1. Primary contact/champion, from the country that is the subject of the study (formal contact point for interactions with WHO and FERG, local project coordinator).
2. Scientists and other parties from the country that is the subject of the national burden of foodborne disease study. Some of these scientists will be the principal investigators in the burden of disease study, while others will contribute to an expert elicitation process. It is not essential that scientists skilled in burden of disease estimation are available; scientists with relevant skills (e.g. epidemiology, statistics) that can be trained or guided by FERG would be suitable. Two to three full time staff usually form the core team with a secretary or administrative assistant are required. The skills required for a study include demography, epidemiology, statistics, clinical medicine, public health, policy analysis (involvement limited to the execution of the policy situation analysis) and source attribution. It is recommended to include in the core group one or two computer analysts. Representatives from national statistics institutes are likely to have ready access to a wide variety of data and should be included in the project team. It will be essential to involve representatives from the food industry, agriculture, and consumers, to create engagement and also act as potential sources of information and data.
3. Stakeholders from the country that is the subject of the national burden of foodborne disease study (policymakers and end users of burden of disease information, for example representatives from the food industry and agriculture). A policy situation analysis should be reviewed by assessors independent of FERG and the country itself.
4. WHO Secretariat associated with FERG (management of interaction between WHO and participating country, management of access and ownership of study and results).
5. Members of FERG, and associated Task Forces, principally the Country Studies Task Force (CSTF). The CSTF is composed of two linked groups:

- Burden of Disease Group: advisory role on study methods and processes, integration and extrapolation of study results as inputs to FERG regional and global estimates.
- Knowledge Translation and Policy Group: advisory role on policy situation analysis and 'knowledge translation' methods and processes, provision of technical guidance on how to produce information that is useful and meaningful for policy makers.

Process and timeline:

1. Initial workshop: Before the study begins there will be initial engagement (probably in the form of a workshop) with government and scientific stakeholders and end users within the country to:
 - Discuss the purpose of the study;
 - Develop a shared understanding for the need for FBD burden data; among key food safety stakeholders;
 - Outline the burden of disease and policy situation analysis protocols; and,
 - Create a work-plan and timetable.

Specific topics that should be discussed at this initial workshop are:

- available country specific sources of data;
- core syndromes and hazards to be addressed by the study;
- relevant data available from publicly available databases that WHO has assembled;
- identification of scientists from the country to conduct the study, as well as additional experts for a future expert elicitation process;
- engagement with stakeholders, particularly those from the food industry, agriculture and consumers; and,
- language/translation issues.

Prior to the initial workshop as much preliminary data and information as possible will be gathered by a team composed of staff from both FERG/WHO and the participating country. Concurrent with this process will be the development of a policy situation analysis (the policy situation analysis may commence prior to this initial workshop). The policy situation analysis should involve independent reviewers as well as involving government and scientific parties.

2. The study process will be guided by a detailed protocol currently being developed by FERG. A draft for use with pilot studies is expected to be completed by late 2010 (with revisions to be made after pilot studies). This protocol will largely be adapted from the Global Burden of Disease Study Operations Manual (final draft Jan. 2009) with specific modifications to apply to foodborne diseases/source attribution and policy situation analysis. A brief overview of the study elements is provided below.
3. To provide estimates of source attribution that are otherwise unavailable, and collate additional unpublished data, at least one expert elicitation meeting will be

held during the study. The meeting will generate quantitative estimates of parameters appropriate to each relevant hazard according to protocols being developed by FERG (by late 2010).

4. The timeframe for each country study is anticipated to be 1-2 years. The country studies will be conducted in two stages:
 - Pilot studies (probably six): commencing early 2011.
 - After the pilot studies the process and protocols will be reviewed, to be completed by mid 2011.
 - Full country studies (potentially twelve or more, including if appropriate countries who have conducted pilot studies), to commence in late 2011.

Pilot Studies:

The primary purpose of the pilot studies is to act as a test of feasibility and the draft protocol for the country burden of disease studies. Consequently they are likely to address only a selection of hazards, and some aspects (e.g. source attribution and expert elicitation) will only be undertaken in a preliminary way (if at all). Participation in a pilot study does not mean that a country will not be able to undertake a full burden of illness study after the pilot.

Expert elicitation:

It is anticipated that an expert elicitation process will be undertaken to provide source attribution estimates on a regional basis. A protocol for this process is under development (to promote consistency) but will not be available for the pilot country studies. Regional source attribution estimates will be used to generate global burden of disease estimates, as these data will only be reported on a regional basis. The regional source attribution estimates may then be used by individual countries for their own estimates, or an expert elicitation for the specific country may be undertaken.

The expert elicitation process will be a parallel work stream to the country studies. Piloting of the expert elicitation protocol will occur separately from the pilot country studies.

DALY calculations:

These will not be undertaken as part of the pilot studies. There are a number of issues for FERG to work through before these calculations can be undertaken; once these are resolved, countries undertaking burden of disease studies will be offered training and assistance with performing these calculations.

Principles:

1. The national burden of disease study will, to the greatest extent possible, be conducted by scientists from the country itself. Capacity building and training are important objectives of the country study.

2. The scope of the study must include a core set of foodborne hazards and associated diseases identified by FERG and its Task Forces (see Table below), but there will be the opportunity for the country to discuss which additional hazards and/or diseases which it considers relevant and might be added to ensure that the burden assessment is as demand-driven as possible.
3. The national burden of disease will largely be estimated from existing data; if this is not available at the national level, extrapolation from alternative sources will be considered. The suitability of these alternative sources will be subject to review using analyses that the CSTF has already initiated. The only aspect of the study where new data may be generated is for chemical hazards, where measurement of suitable biomarkers may be needed to estimate exposure. Resources for research to generate new data will be negotiated between WHO and the participating country.
4. Planning of the national burden of disease study should be undertaken in a participatory manner, involving key food safety stakeholders.
5. Ownership of the study and results: The data and results of the study will belong to the participating country, and scientific staff at country level are encouraged to publish the results in the peer-reviewed literature. All original data will be sent to WHO upon completion of the study. The country will grant WHO full and non-exclusive, royalty-free and perpetual license for analysis and publication of the data (publication only in aggregated regional format) in the FERG Global Atlas and Report. For the purposes of coordination the country should agree not to publish any results without consultation with WHO
6. The need for regional (within the country) as well as national estimates will be considered.
7. An important consideration will be the collation of information that describes the representativeness of the data for the national population.
8. Foodborne disease will be attributed to specific foods/commodities as much as possible, to enable policy development. However, the available data may only permit identification of high risk foods, rather than quantitative estimates of attribution to those foods.
9. The primary aim is to estimate the disease burden such that the disability adjusted life years (DALY) metric can be derived. However, the research effort will aim to respond to policy-makers' and end-users' data requirements, maximise the relevance and usefulness of the research results and create a robust, accessible and contextualized knowledge base. Such supplementary data may be important in providing cost-effectiveness information, which is crucial to the translation of results into practice. Examples of this type of data are: health system costs, costs to agricultural sector through lost production/poor animal health.
10. The reference year for the study will be 2005 (this is the year for which the burden will be estimated; data from earlier studies may need to be updated or adjusted).
11. Extrapolation of partial or incomplete datasets to national and regional estimates, as well as the use of indirect indicators, will be performed according to protocols developed by FERG.
12. Attribution estimates will be universally applied at the point of consumption, but source/reservoir/processing points of attribution will also be considered where they inform risk management. While the risk factor of interest to FERG is exposure to the hazard through food it will be essential for the study to gather data that also allows risk factor analyses from exposure via other pathways within the remit of the Source Attribution Task Force (water, animal contact, person to person etc.).

Data that may be useful for source attribution include: food categorisation system, food consumption data, prevalence of hazards in the food supply, incidents and outbreaks of foodborne disease, dietary patterns, data that indirectly informs estimates of the prevalence and burden of foodborne disease (e.g. presence/absence of animal reservoirs, food preparation practices, domestic production versus food importation etc.). These data should be collated during the course of the study for analysis during the calculation of the burden estimates.

13. Throughout the study, collaborative approaches and regular interaction between researchers and research users will be fostered at country level, and local capacity to create and respond to opportunities of bringing research into policy-making strengthened.

Contributions to the country study:

From WHO and FERG:

Protocol for foodborne disease burden of disease study: to ensure alignment of the study to the overall goals of FERG

Global and regional context: information generated from systematic reviews and other deliberations conducted by FERG. Information relevant to the specific country that is identified during FERG activities will be collated and provided to the country at the commencement of the study.

Ongoing communication: with WHO and FERG during the FBD study

Assistance: with statistical/epidemiological analyses and 'knowledge translation' as required

Tools for facilitating the transfer of research into policy-making, including a protocol for policy situation analysis, implemented by policy experts in the participating country and supported by the context mapping subgroup of the Country Studies Task Force

From the participating country:

Human resources: staff with previous experience of conducting burden of disease studies OR staff with expertise in epidemiological methods to be trained in burden of FBD methodology and 'knowledge translation' approaches, staff to commit to undertaking a burden of FBD study (1-2 years of commitment), a policy situation analysis as well as other activities aiming to promote research utilisation.

Infrastructure resources: needed to complete a burden of FBD study and related 'knowledge translation' activities.

Country infrastructure: laboratory capacity to generate relevant data, relevant country-level data for burden studies e.g. vital registration; household surveys;

other sources of data or good infrastructure for collecting such data, established links with potentially useful networks¹.

Elements of a country specific burden of disease study

(adapted from WHO National Burden of Disease Study Manual: <http://www.who.int/healthinfo/nationalburdenofdiseasemanual.pdf>)

Major tasks to be undertaken

- (i) Demographic baseline: population and total mortality by age, sex, and geographical region for the reference year. These data are already available for each country at the UN Population Division.
- (ii) Cause of death analysis: based on vital registration data, verbal autopsy data, sentinel surveillance sites and others. This information is usually sent to WHO by most countries.
- (iii) Description of non-fatal outcomes: acute diseases and sequelae to be defined by FERG Task Forces. Incidence data preferably to come from representative community-based studies. Available country specific surveillance data to be assessed and if necessary fitted into an estimated surveillance "pyramid" for relevant illnesses, or (if possible) hazard specific pyramids.
- (iv) Review of Internal Consistency of Disease Estimates
- (v) Source/food attribution analysis including expert elicitation (replaces Comparative risk assessment: risk factor analysis)
- (vi) Calculation of YLDs and YLLs leading to DALYs. These calculations to be undertaken in close collaboration with scientists at WHO and FERG, according to procedures as specified in the detailed protocol being prepared by FERG (specific training may also be provided by FERG for this part of the burden of disease study process). WHO and FERG guidance on this part of the study is essential to ensure that the DALY estimates are internally consistent and in line with global mortality and morbidity estimates.
- (vii) Sensitivity Analysis
- (viii) Draft report and external peer review/quality assurance processes
- (ix) Final Report
- (x) Dissemination of results

¹ For example INDEPTH DSS (Demographic Surveillance Systems); Measure DHS (Demographic and Health Surveys); Health Metrics Network (WHO); World Health Surveys (WHO); Global Salm-Surv (WHO) now GFN)

Elements of policy situation analyses

To identify pathways of influence and determinants favourable for research up-take, national policy situation analyses will comprise:

Major tasks to be undertaken

1. Systematic analysis of the political context:

1.1 Analysis of the international food safety political environment:

analysis of factors external to a country which affect policy-makers and food safety policy processes within the country, such as:

- international integration of the country, export and import from and to the region and internationally, activities of multinational food corporations, aid dependency, aid priorities and donor policies,
- activities of foreign governments and international food safety bodies relevant to domestic food safety e.g. the Codex Alimentarius Commission.

1.2 Analysis of the national political context:

analysis of:

- structural factors, including national political, social and economic trends and pressures, culture and value systems which shapes the food safety policy-making process,
- health system structures, surveillance systems and the integration of food safety health promotion strategies.
- the domestic food safety system, its institutions and management system, operations and capacity as well as resource allocation to food safety.
- SWOT of food safety and food security/agricultural production.
- food related customs.

2. Development of a policy process matrix:

assessment of country-specific food safety policy-making processes and mechanisms, i.e.:

- the way national policy agenda setting, formulation, adoption, implementation and evaluation takes place,
- opportunities and timing for food safety research input into formal policy processes.

3. Mapping of information sharing and access mechanisms

- analysis of current practices of information sharing, access and utilisation of food safety actors and other relevant food safety stakeholders.
- identification of institutional and technical obstacle of knowledge sharing, access and utilization.

4. Stakeholder analysis and political interest map

analysis of:

- actors, organizations and mediating agents involved (food safety) policy-making and their interests with regard to supporting/resisting the development of effective food safety policies, their capacity and degree of power/influence in food safety policy-making, and their reasons and resources for exerting influence (incl. the identification of drivers of change),
- actual and potential alliances and links among actors.

5. Identification of pathways of influence and outreach strategies

Table of hazards and syndromes to be addressed by the study

N.B. This table represents a preliminary list. It is expected that topics will be amended as studies progress, and as health outcomes of importance are clarified by individual Task Forces (e.g. sequelae).

Hazard	Information Needed	Method Of Obtaining Information
Chemicals		
Aflatoxin	<ol style="list-style-type: none"> 1. Incidence studies of acute aflatoxicosis (by age and sex); 2. Longitudinal study to assess sex-specific risk of developing HCC (relative and absolute), accounting for confounding (alcohol consumption etc) including settings where Hep B absent; 3. Diet studies assessing intake of aflatoxin against validated exposure biomarkers and in countries with high rates of HCC; 4. Ecological study to explore association between stunting in children and aflatoxin exposure; 	<ol style="list-style-type: none"> 1. Existing study to be identified OR original (community-based) cohort study 2. Existing study to be identified OR retrospective cohort study 3. Direct diet studies (including laboratory assessment of contamination) - China? 4. Regression analysis of country data on stunting (WHO nutritional database) with country level aflatoxin exposure
Cassava Cyanide	<ol style="list-style-type: none"> 1. Diet studies assessing levels of cassava in food (including effects of processing) and intake of cassava cyanide by age groups; 	<ol style="list-style-type: none"> 1. Existing study to be identified OR direct diet studies (including laboratory assessment of contamination)
Peanut Allergens	<ol style="list-style-type: none"> 1. Incidence studies of adverse reactions to peanut consumption (by age and sex from developing countries); 	<ol style="list-style-type: none"> 1. Existing study to be identified OR direct diet studies (including laboratory assessment of contamination)
Dioxins Etc	<ol style="list-style-type: none"> 1. Studies assessing levels of dioxins in human milk 	<ol style="list-style-type: none"> 1. Conduct human milk survey OR obtain data from global survey of human milk (WHO/UNEP) for all persistent organic pollutants
Lead	<ol style="list-style-type: none"> 1. Studies assessing levels of lead in food in comparison to total lead exposure (in developing countries) 	<ol style="list-style-type: none"> 1. Existing study to be identified OR direct diet studies (including laboratory assessment of contamination)
Ciguatera	<ol style="list-style-type: none"> 1. Incidence studies of acute fish and shellfish poisoning (by age and sex); 	<ol style="list-style-type: none"> 1 a. Existing study to be identified OR original (community-based) cohort study 1 b. Obtain outbreak information collated by FERG Enteric Diseases Task Force
Methyl mercury	<ol style="list-style-type: none"> 1. Information on levels of methylmercury in hair 	<ol style="list-style-type: none"> 1. Existing study to be identified OR community-based studies collecting human