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RISK ASSESSMENT IN THE FOOD SAFETY AGENCY (FSA)

June 2008

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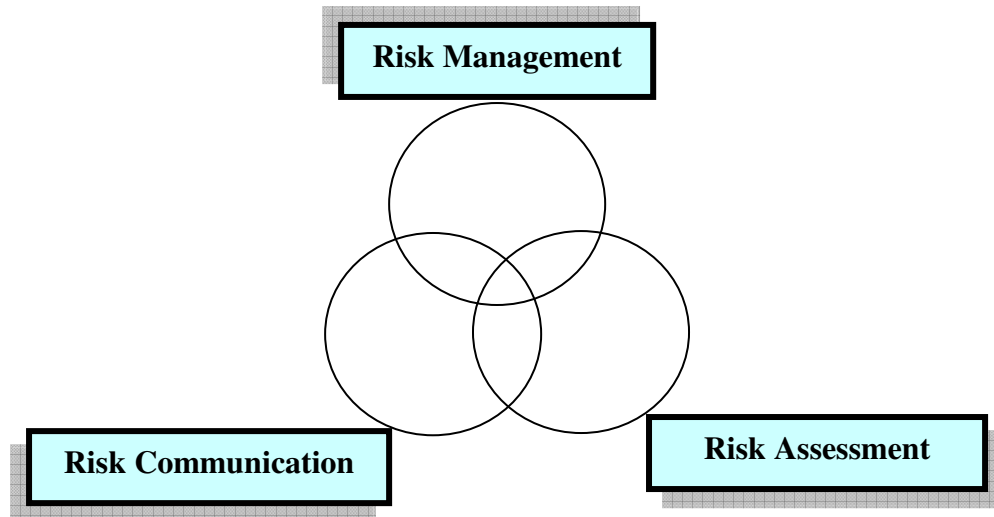
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WHAT IS A RISK ASSESSMENT PROGRAM?



Risk Assessment is one of the three components of Risk Analysis.

Risk Analysis consists of:

Risk Assessment

Risk Management

Risk Communication

Risk Assessment is a scientifically based process for the evaluation of known or potential adverse health effects resulting from human exposure to hazards in food. The process consists of:

Hazard identification

Hazard characterization

Exposure assessment

Risk characterization

NOTE: Throughout this report the term "Risk Assessment" is written in capital letters. This is done for reasons of emphasis only.

TERMINOLOGY ASSOCIATED WITH RISK ASSESSMENT (CODEX DEFINITIONS)

HAZARD: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

RISK: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

RISK ANALYSIS: A process consisting of three components: risk assessment, risk management and risk communication.

RISK ASSESSMENT: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

RISK MANAGEMENT: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

RISK COMMUNICATION: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk manager, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

RISK ASSESSMENT POLICY: Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

RISK PROFILE: The description of the food safety problem and its context.

RISK CHARACTERIZATION: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

RISK ESTIMATE: The quantitative estimation of risk resulting from risk characterization.

HAZARD IDENTIFICATION: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

HAZARD CHARACTERIZATION: The quantitative and/or qualitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

DOSE-RESPONSE ASSESSMENT: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

EXPOSURE ASSESSMENT: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

FOOD SAFETY OBJECTIVE (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

PERFORMANCE CRITERION (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

PERFORMANCE OBJECTIVE(PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOT, as applicable.

WHEN IS A RISK ASSESSMENT NEEDED?

Circumstances that do NOT warrant a quantitative Risk Assessment would include:

1. A risk that is well described by definitive data.
2. A problem that is relatively simple.
3. An issue that is not of regulatory concern

RISK ASSESSMENT SHOULD BE DONE WHEN

1. The data describing a hazard are incomplete.
2. The exposure system is complex
3. The issue is of high regulatory or stakeholder concern.

Specific examples of when Risk Assessments are needed may include the following:

1. When a chemical fails to satisfy assessment threshold;
2. When the current quantitative standards is not met or is not justified;
3. When the current standard is inconsistent with other government policies or guidelines;
4. When FSA has been petitioned for a regulatory action;
5. When a NO-Observed Adverse Effect Level (NOAEL) cannot be established for a chemical;
6. When a data gap analysis is needed;
7. When the hazard is a serious health issue, emerging pathogen and/or public health concern.

WHAT TYPE OF RISK ASSESSMENT IS NEEDED?

Four general types of Risk Assessment likely to be used by FSA are:

RISK RANKING

A comparison of the relative risk among several hazards or foods. These types of assessment techniques might involve a single pathogen associated with multiple foods, a single food that has multiple pathogens, or multiple pathogens and multiple foods. Risk ranking assessments can help establish regulatory program priorities and identify the critical research needs

PRODUCT PATHWAY ANALYSES

The factors that influence the risk associated with specific food/hazard pairs are examined. Ideally it starts at the farm and ends with consumption. These types of assessment techniques help identify the key factors that affect exposure including the impact of potential mitigation or intervention strategies on the predicted risk.

RISK-RISK

A trade-off of one risk for another is considered, i.e. reducing the risk of one hazard increases the risk of another. An example is the determination of the impact on public health by treating drinking water with a chemical (risk to chlorine exposure) vs. the impact of exposure to pathogenic organisms in water not treated.

GEOGRAPHICAL

The factors that either limit or allow the risk to occur are examined. The risk of introduction of disease agents through food animals or animal products (e.g. intentionally as in bioterrorism or unintentionally) can be examined. For example, the risk of introduction of variant Creutzfeldt-Jacob Disease (vCJD) in humans by the transmission of BSE from cattle through meats and animal product pathways might be examined using a geographical approach.

HOW ARE CANDIDATE RISK ASSESSMENTS IDENTIFIED?

Ideas for Risk Assessments can be obtained from a number of sources including:

Stakeholders (consumers, industry)

Consumer advocacy groups

Public health institutions

Follow-up from a completed Risk Assessment

Regulatory/Management staff

Researchers

Other government agencies

EGYPT MUST HAVE RISK ASSESSMENT PROGRAMS IN FOOD SAFETY

- Major food producing / exporting countries use Risk Assessment in their food safety programs. This brings Egypt into line with international best practices in food safety;
- It increases the efficiency and effectiveness of food safety programs along the entire Egyptian food chain, including food imports, food exports and the tourist industry;
- It brings a consistent and internationally accepted system of food safety regulation to all aspects of the Egyptian food chain;
- It is the basis for all food inspections in Egypt. This produces a more efficient and effective system of food safety inspection;

- It allows food analysis laboratories to build expertise and facilities to analyze foods based on food safety risks;
- Egyptian consumers can be more confident of the safety of the Egyptian food supply.

JUSTIFICATION FOR A RISK ASSESSMENT PROGRAM IN FSA

WHO AND FAO both advocate risk-based approaches for the management of health hazards in foods.

Details of the WHO / FAO Risk Analysis Framework (which includes Risk Assessment) are at:

Application of Risk Analysis to Food Standards Issues. Joint FAO/WHO Expert Consultation (1995):

www.who.int/foodsafety/publications/micro/march1995/en/index.html

About Risk Analysis in Food

www.who.int/foodsafety/micro/riskanalysis/en

Principles for Modeling Dose-Response for the Risk Assessment of Chemicals

www.who.int/ipcs/methods/harmonization/draft_document_for_comment.pdf

About Microbiological Risk Assessment (MRA) in Food

www.who.int/foodsafety/micro/about_mra/en/print.html

Updating the Principles and Methods of Risk Assessment: MRLs for Pesticides and Veterinary Drugs

www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/bilthoven_2005.pdf

The Food Safety Risk Assessment of GM Animals

<ftp://ftp.fao.org/es/esn/food/GMtopic4.pdf>

Codex Alimentarius produces Guidelines on Risk Assessment / Risk Analysis:

Principles and Guidelines for the Conduct of Microbiological Risk Assessment

www.codexalimentarius.net/download/standards/357/CXG_030e.pdf

Principles for the Risk Analysis of Foods Derived from Modern Biotechnology

www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf

USA

FDA uses Risk Assessment in food safety programs:

Initiation and Conduct of All "Major" Risk Assessments Within a Risk Analysis Framework

www.cfsan.fda.gov/~dms/rafw-toc.html

RISK ASSESSMENT/SAFETY ASSESSMENT

- General Information
- Allergens
- Chemical
- Food Additives
- Food Defense
- Microbial Risk Assessments

www.cfsan.fda.gov/~dms/ra-toc.html

EUROPEAN UNION

A direct quote from the European Food Safety Authority (EFSA) website states: "EFSA's risk assessment work contributes to improving food safety in Europe and to building public confidence in the way risk is assessed" (For more details see:)

EFSA: Risk Assessment

www.efsa.europa.eu/EFSA/AboutEfsa/WhatWeDo/efsa_locale-1178620753812_RiskAssessment.htm

EFSA: Assessment Methodology Unit (AMU): "It contributes in particular to the development and application of new or refined risk assessment approaches in the field of food and feed safety."

www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_1178664635715.htm

UNITED KINGDOM

The Food Standards Agency (FSA) uses risk assessment:

www.fsascience.net/2007/07/02/chemical_risk_assessment

IRELAND

The Food Safety Authority of Ireland (FSAI) has a useful booklet that categorizes food businesses based on risk assessment:

www.fsai.ie/publications/codes/COP_risk_categorisation.pdf

CANADA

The Canadian Food Inspection Agency (CFIA) uses risk assessment in its food inspection program: "The Health Risk Assessment Model is a tool which may be used by the inspector/auditor as guidance when evaluating the health risk of a product."

www.inspection.gc.ca/english/fssa/polstrat/haccp/manue/app3e.shtml

AUSTRALIA / NEW ZEALAND

Food Standards Australia New Zealand (FSANZ) states: "The methodology that underpins the majority of FSANZ's regulatory decision making is the risk assessment component of risk analysis. This tool facilitates FSANZ's science-based approach to decision making and is critical to the integrity and rigour of those decisions."

www.foodstandards.gov.au/aboutfsanz/scientificcapabilities/riskassessments.cfm

RISK ASSESSMENT AND MAJOR FOOD SAFETY RISKS

BIOLOGICAL

1. Proven hazards

- *Salmonella* spp
- Pathogenic *Escherichia coli*
- *Campylobacter* spp
- *Listeria monocytogenes*
- *Clostridium botulinum*
- *Clostridium perfringens*
- *Staphylococcus aureus*
- *Vibrio* spp
- *Yersinia enterocolitica*
- Select parasites
- Foodborne pathogenic viruses
- Prions

2. Indicators of potential hazards

- *Enterobacteriaceae*
- Moulds
- Yeasts
- Coliform

CHEMICAL

Include:

- **Heavy metals**
 - Cadmium
 - Mercury
 - Lead
- **Pesticide residues**
 - Chlormequat
 - Methamidophos
- **Veterinary drug residues**
 - (Leuco)malachite green
 - Chloramphenicol
 - Nitrofurantoin metabolite SEM
 - Nitrofurantoin metabolite AOZ
 - Nitrofurantoin metabolite AMOZ
 - Sulphonamides
 - Streptomycin
- **Mycotoxins**
 - Aflatoxins
 - Fumonisin
 - Ochratoxin A
- **Food additives**
 - Sulfites
 - Benzoic acid
 - Polyphosphates
 - Color additives
 - Unauthorized use of color additives
- **Food contaminants**

Food contact materials (from packaging, etc). Migration of:

 - Chromium
 - Lead
 - Nickel
 - Isopropyl thioxanthrone
 - Primary aromatic amines
 - Formaldehyde
 - Too high a level of total migration
- **Dioxins**

PHYSICAL

Include:

- Foreign matter such as nails, glass, plastic, etc
- Dead insects, etc.

FOOD REJECTIONS BASED ON RISK ASSESSMENT ARE MADE AT

Border controls – import rejected

Market control

Company own check

Consumer complaint

Border control – screening sample

LIST OF "HIGH," "MEDIUM" AND "LOW" RISK FOODS IN EGYPT

NOTE 1: In the ranking of foods according to their food safety risk the following numeric scale is recommended:

High = 3

Medium = 2

Low = 1

NOTE 2: Foods are listed in the three risk categories below based on accepted international knowledge on biological, chemical and/or physical food safety risks occurring when these food are consumed.

NOTE 3: The lists of specific foods, and the list of food businesses below, and their categorization will be reviewed annually by the FSA Scientific Committee. Among the criteria determining changes to the two lists will be i) new scientific information; ii) changes in Egyptian food consumption patterns; iii) known contaminants in local food markets; iv) pattern/trends in food import rejections based on food safety issues.

NOTE 4: In the absence of Egyptian food consumption data it is recommended that FSA use the WHO publication: *GEMS/Food Regional Diets. Regional per Capita Consumption of Raw and Semi-processed Agricultural Commodities (2003)*.

www.who.int/foodsafety/chem/gems_regional_diet.pdf

HIGH RISK FOODS: (3)

- Fermented foods

- Meat, Poultry, Fish / Shellfish / Seafood
- Milk and Dairy Products (including soft, semi-soft & cooked cheeses)
- Ice Cream
- Eggs (in all forms)
- Fresh Juices (unpasteurized)
- Nuts and their products
- Seeds
- Ready-to-eat Foods
- Ready-to-eat Salads & salad dressings
- Low-acid mayonnaise
- Low acid canned foods
- Flour
- Fruits (with edible peel)
- Vegetables (green, leafy) & tomatoes
- Tahineh
- Baby & Infant Foods
- Food for Special Dietary Uses
- Bakery goods (non-shelf stable)
- Foods imported in very large quantities

MEDIUM RISK FOODS: (2)

- Herbs and Spices
- Seasoning Mixes (dry)
- Bottled Water
- Canned Acidic Foods (Ketchup, Mustard) and Pickles
- Fruits & Vegetables: (Frozen)
- Fruits and Vegetables (dried)
- Bakery Products (shelf stable)
- Butter
- Prepared but not ready to eat foods (pizza, pot pies, etc)
- Grains

LOW RISK FOOD: (1)

- Sugar, Sugar Syrups and Honey
- Cocoa, Chocolates, Biscuits and Candies
- Tea and Coffee

- Juice concentrates
- Dry soups
- Dry Mixes (Cake mixes, puddings, whiteners)
- Breakfast cereals and Chips
- Rice and Pasta (uncooked)
- Pasta: Dry – All forms
- Carbonated Beverages
- Flavoring Concentrates
- Beans
- Jams & Marmalades
- Salt and Vinegar
- Seasoning mixes (dry)
- Oils and Fats

CLASSIFICATION OF FOOD BUSINESSES BASED ON RISK ASSESSMENT

DEFINITIONS

FOOD BUSINESS

Any undertaking, whether for profit or not, and whether public or private, carrying out any of the activities related to any stage of production, processing, and distribution of food.

HIGH-RISK BUSINESS

Food business operations dealing with high-risk foods/production methods and/or where the potential exists to put vulnerable groups (infants, the frail, elderly, pregnant women and the sick) or large numbers of consumers at serious risk.

MEDIUM-RISK BUSINESS

Businesses involving operations with the potential to pose a significant risk to consumers.

LOW-RISK BUSINESS

Business where the potential to cause harm to consumers is low.

ANNUAL FREQUENCY OF INSPECTIONS

NOTE: During the FSA transition period the following inspection schedule is recommended. After the transition period the inspection schedule will be reviewed.

	<i>Standard Inspection Frequency</i>	<i>Reduced Inspection Frequency</i>
HIGH RISK	2 Full 2 Surveillance	1 Full 1 Surveillance
MEDIUM RISK	1.5 Full 1 Surveillance	1 Full
LOW RISK	1 Full	1 Full/2 years

Surveillance = Check records and key control points in the operation

FACTORS DETERMINING THE RISK CATEGORY OF A FOOD BUSINESS

- The definitions of "High - risk," "Medium - risk" and "Low - risk" businesses
- The consumer profile of the food business, e.g. vulnerable groups
- The scale of the operation of the business
- The type of food
- The nature of the handling or processing
- The control systems in place
- The structure, layout and conditions of the premises

NOTE: Some food businesses, owing to the mixed nature of activities, could fall into more than one risk category. In such cases, they should be treated on the basis of the highest risk category into which they fall.

CATEGORIES OF ESTABLISHMENT

- Primary producers
- Manufacturers and packers

- Distributors and transporters
- Retailers (retail trade)
- Service sector (restaurants, canteens, caterers, etc)
- Manufacturers selling primarily to the final consumer.

RANKING OF BUSINESSES ACCORDING TO FOOD SAFETY RISK

NOTE: The numeric ranking of risk below represents:

HIGH risk = 3

MEDIUM risk = 2

LOW risk = 1

PRIMARY PRODUCERS

Meat, poultry, dairy, fish/seafood	3
Natural Water	3
Fresh fruit and vegetables (primary producers)	3
Honey (Production only)	1

MANUFACTURER

Baby Food (Non milk based)	3
Caterer (Not serving to final customer)	3
Cereal Products	2
Bakery/Confectionery (Egg/cream based products)	3
Bakery/Confectionery (Chocolate/sweets/sugar confectionery)	2
Bakery/Confectionery (Bread, cake, & similar products)	1
Cook-chill	3
Freshly-squeezed juice (sold in small shops)	3
Snack Products (incl. crisps & extruded starch products)	1
Delicatessen Foods (Not serving to final customer)	3
Fruit & Vegetables (Ready-to-eat)	3
Fruit & Vegetables (For further processing)	2
Ice Cream	3
Jam & Jelly	1
Meat & Meat products (Cooked meat)	2

Meat & Meat Products (Raw meat only)	2
Milk Products	3
Oils and Fats	1
Non-alcoholic Drinks (Fruit drinks)	2
Non-alcoholic Drinks (Soft drinks)	1
Alcoholic Drinks	1

PACKERS

Food Packers (Tea, herbs, spices, nuts, etc)	1
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DISTRIBUTORS, TRANSPORTERS & WHOLESALERS

Cash and Carry	3
Dry Goods	1
Bakery/Confectionery (Egg/cream products)	3
Bakery/Confectionery (Chocolate, sweets, sugar confectionery)	2
Bakery/Confectionery (Bread, cake & similar products)	1
Frozen & Refrigerated Storage (Ready-to-eat, including ice cream)	3
Frozen & Refrigerated Storage (Further processing)	1
Fruit & Vegetables (Fresh)	3
Meat & Meat Products (Cooked meat)	3
Meat & Meat Products (Raw meat only)	2
Milk & Milk Products	3
Oils & Fats	1
Non Alcoholic Drinks (freshly prepared)	3
Vehicle Transporting/Selling Raw & Cooked Meat	3
Vehicle Transporting/Selling Perishable Food with Temperature Controls	2
Vehicle Transporting/Selling Perishable Food at Ambient Temperature	3
Central Distribution Center (For retailers, hotels, institutions, etc)	3

RETAILERS

Bakery/Confectionery (Egg/cream based products)	3
Bakery/Confectionery (Bread, chocolate, sweets, sugar confectionery)	1
Delicatessen (Portioning and direct sale to consumer)	3
Fishmonger (Raw fish & other unwrapped ready-to-eat perishable food)	3
Fishmonger (Raw fish only)	3
Butcher (Raw meat & ready-to-eat food)	3

Butcher (Raw meat only)	2
Fruit & Vegetables (Raw only)	3
Food Stall (Ready-to-eat)	3
Food Stall (Raw meat)	3
Food Stall (Fish)	3
Food Stall (Fruit & vegetables, sweets, etc)	2
Grocery (With portioning /open food)	3
Grocery (Prepacked food only)	1
Health Food Shop (With portioning/open food)	3
Health Food Shop (Retail only)	1
Newsagents/Sweet Shops	1
Ice Cream Sellers (Including newsagents etc. with ice cream machines)	3
Supermarket (Mixed activities, open food & preparing to order)	3
Supermarket (Pre-packaged food only)	2
Vending Machine (Requiring temperature control)	2
Vending Machine (Ambient temperature)	1

SERVICE SECTOR

Army Barracks	3
Bed & Breakfast and Guest House (Serving evening meal)	3
Bed & Breakfast and Guest House	1
Caterers (Serving to final customer)	3
Hospital	3
Hostel (Full meal service)	3
Hostel (Breakfast only)	1
Hotel (Mass catering/full meal service)	3
Hotel (Breakfast only)	1
Meals-on-Wheels (Preparation)	3
Meals-on-Wheels (Portioning, distribution & service)	2
Nursing Home (Including long-term care facility)	3
Day Care (Production/preparation)	3
Day Care (Regenerating and serving meals)	2
Day Care (Tea, coffee, biscuits only)	1
Residential Care (Production/preparation)	3
Residential Care (Regenerating & serving meals)	2
Residential Care (Domestic style)	1

Rail Catering (Full meal service)	3
Rail Catering (Trolley service)	2
Pre-school (Preparation)	3
Pre-school (Regenerating & serving meals)	2
Pre-school (Snacks)	1
Prison	3
Public House (Preparation of food)	3
Public House (Regenerating & serving meals)	2
Public House (Serving drinks only)	1
Restaurant, including coffee shops, canteens, etc. (Preparation)	3
Restaurant, including coffee shops, canteens, etc (Regenerating & serving meals)	2
Restaurant, including coffee shops, canteens, etc. (Tea, coffee, biscuits)	1
Schools (Preparation)	3
Schools (Regenerating & serving meals)	2
Take-away (Preparation)	3
Take-away (Service only)	2
Food Stall (Preparation)	3
Food Stall (Service only with temperature control)	2
Food Stall (Service only, no temperature control)	1
Juice Bar	2

MANUFACTURER SELLING PRIMARILY DIRECT TO THE FINAL CONSUMER

Bakery(Eggs/cream)	3
Bakery (Flour products only)	1
Butcher (Mixed products)	3
Butcher (Raw meat only)	2
Delicatessen (Including sandwiches and salads)	3
Ice Cream	3

FACTORS CHANGING THE FREQUENCY OF SAFETY INSPECTIONS

Where compliance and checks are satisfactory, the frequency of inspection may be reduced. In so determining, the following criteria must be considered:

- Prerequisites --- Satisfactory or minor infringements only
- Past Record of Compliance --- Satisfactory or minor infringements only based on the last two inspections
- HACCP --- Compliance with legal requirements
- Training --- Compliance with legal requirements

THE IMPACT OF A FOOD SAFETY RISK ASSESSMENT PROGRAM ON

FOOD INSPECTION SERVICE

It allows both FSA and all segments of the food industry to:

- Operate a food inspection service that has a uniform and consistent program in Risk Assessment in relation to the safety of food for human consumption. After adoption of Risk Assessment programs the food safety inspection service will then be based on: 1) good science and 2) international best practices;
- Adoption of Risk Assessment practices will make the food inspection service more effective and efficient. This will give significant cost-reductions while increasing the protection of the Egyptian population from food safety hazards;
- Adoption of Risk Assessment practices will build confidence and trust in the relationship between food inspectors and the food industry because both will be operating with uniform and consistent food inspection procedures;
- Adoption of Risk Assessment principles will allow the Food Safety Authority to work with the food industry to adopt an "assist and prevent" rather than a "police and punish" approach to food safety. It will move the onus on to the food industry to comply with an internationally accepted system for accessing food safety risk;
- The inspection of food imports and exports will be improved in both effectiveness and efficiency;
- It will provide greater assurances to the Egyptian population and to the growing tourist industry that the food supply in Egypt is safe.

LABORATORY SERVICES

Adoption of a Risk Assessment program will allow FSA to:

- Streamline laboratory needs based on risk assessments. This will produce greater efficiency, and cost-effectiveness over the present system;
- Prioritize future needs in terms of personnel and equipment to meet new food safety hazards;

- Provide an improved interactive environment between FSA and the Egyptian food industry and with food importers and exporters.

PUBLIC AWARENESS

There will be:

- Increased consumer confidence in the safety of the Egyptian food supply;
- A better opportunity for FSA to develop an effective public awareness campaign that is now based on Risk Assessment principles which are based on good science;
- Increased opportunities to build useful and productive relationships with the Egyptian media.

INITIATION AND CONDUCT OF ALL “MAJOR” RISK ASSESSMENT WITHIN A RISK ANALYSIS FRAMEWORK

Much of the information in this section has been adopted from a U.S. Food and Drug Administration report on Risk Assessment published in March 2002 and available at:

www.cfsan.fda.gov/~dms/rafw-toc.html

To support and promote the use of a Risk Analysis framework for initiating and conducting “major” risk assessments FSA should:

1. **Adopt a decision-based approach to identify and select Risk Assessments:**
Available resources, regulatory needs and public health concerns should be considered in the selection of Risk Assessments
2. **Establish a procedure:**
This is for the conduct of Risk Assessment within a Risk Analysis framework. The procedure should identify the boundaries and responsibilities of key participants in the Risk Analysis process
3. **Develop criteria to evaluate the quality of data:**
Specify what information is needed to scientifically evaluate the usefulness of a study or data set used for Risk Assessment
4. **Develop evaluation guidelines:**
This is done for Risk Assessments and for supporting data developed by stakeholders and submitted to FSA
5. **Formalize a peer review process:**

This will encourage critical evaluation and review of FSA's Risk Assessments by Egyptian government and non-government experts in a manner that improves the science and acceptance of complex Risk Assessments

6. Build capacity:

This will allow the conduct of complex Risk Assessments by providing training opportunities for current staff, hiring new staff or using contractors (as needed), and acquiring additional resources such as computers, software, and dedicated workspace.

WHAT ARE “MAJOR” RISK ASSESSMENTS?

“Major” Risk Assessments are:

1. Non-routine and complex
2. May be qualitative or quantitative
3. Involve multiple government agencies and are cross-cutting in nature
4. Require the commitment of significant resources to complete.

Therefore, routine safety/Risk Assessments do NOT fall within this category

GUIDING PRINCIPLES FOR RISK ASSESSMENTS WITHIN A RISK ANALYSIS FRAMEWORK

1. Risk Analysis is a valuable tool for FSA to use to enhance the scientific basis of regulatory decisions. All “major” Risk Assessments conducted by FSA should be performed within the Risk Analysis framework. Using this framework, project goals are accomplished through the efforts of Risk Assessment, Risk Management and Risk Communication teams.
2. Risk Assessment of complex topics should be conducted in an iterative manner that allows refinement of the Risk Assessment question(s), key assumptions, and the data used in the model. An iterative process requires active participation and collaboration among the various Risk Analysis teams and with other interested parties.
3. An open exchange of information and ideas (communication) within and among the Risk Assessment, Risk Management and Risk Communication teams is critical for successful conduct of Risk Assessment projects. As such, stakeholders including consumer groups, all or appropriate segments of the food industry, and other GOE Ministries should be identified early in the process and communication should occur frequently with them during the assessment.
4. Risk Assessments conducted by FSA should be identified and selected using a decision-based approach that considers the appropriate use of FSA's resources to provide the best scientific analysis to solve high priority public health problems.

5. Resources needed to effectively and efficiently conduct Risk Assessments must be identified and allocated prior to commissioning the assessment.
6. Realistic timeframes with intermediate milestones must be established and agreed to by all participants when the Risk Assessment is commissioned. Timeframes must consider the iterative nature of Risk Assessments.
7. The Risk Assessment should be as simple as possible while providing risk managers with the information needed to make decisions.
8. The Risk Assessment process must be transparent. All assumptions, data, and decisions that impact the Risk Assessment conclusions and risk management actions must be clearly documented and shared with interested parties.
9. Draft Risk Assessment documents and models must undergo peer review by GOE and non-government experts using a process that allows for extensive evaluation and critical review of the assessment.
10. FSA must continue to build capacity to conduct Risk Assessments through research, training, hiring and other means such as using contractors.

CHARACTERISTICS OF SUCCESSFUL RISK ASSESSMENTS

TRANSPARENT

Including stating any biases that impact the Risk Assessment, clearly and concisely documenting the assessment, and using a participatory process. Transparency includes clearly stating all assumptions used in the assessment, providing the scientific rationale, and documenting the data used to estimate the impact of the various factors influencing the risk.

REVEAL BIASES

CLARITY

PARTICIPATORY PROCESS

TEAM-ORIENTED

Quantitative Risk Assessments are too complex to be conducted by a single person. They require the input and critical evaluation of experts in a number of scientific disciplines including:

Microbiology

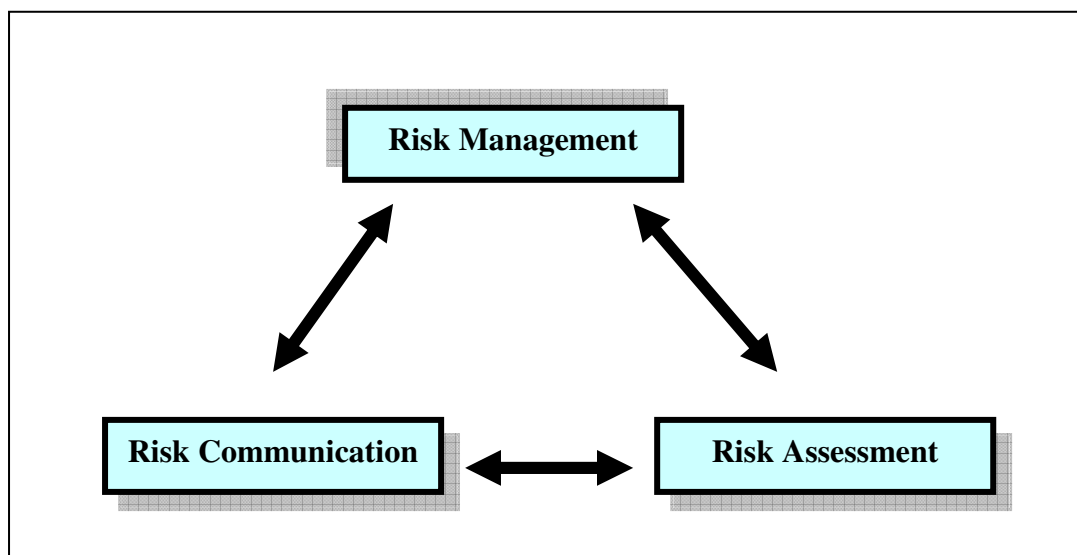
Chemistry

Epidemiology

Medicine
Statistics
Food Science / Food Technology
Toxicology
Food Policy

ITERATIVE

Risk Assessment for complex topics should be an iterative process, and this iteration will require communication and collaboration among the various risk analysis teams and other interested individuals. This is seen in the Figure below



OTHER DESIRED CHARACTERISTICS OF RISK ASSESSMENT TEAMS

STRUCTURED

The generally accepted paradigm for microbial, as well as chemical contaminants, includes separating the assessment activities into four components:

Hazard identification

- Exposure assessment
- Dose-response assessment
- Risk characterization

DESCRIPTIVE

An important part of Risk Assessment is determining the degree of uncertainty in relation to the results and distinguishing this from the variation that is inherent in any biological system. The accuracy of a Risk Assessment is dependent on the quality of the available data. When definitive data are lacking, the uncertainty about the available information is represented in the Risk Assessment using a range of possible data values. One way to decrease uncertainty is to conduct research to provide improved data.

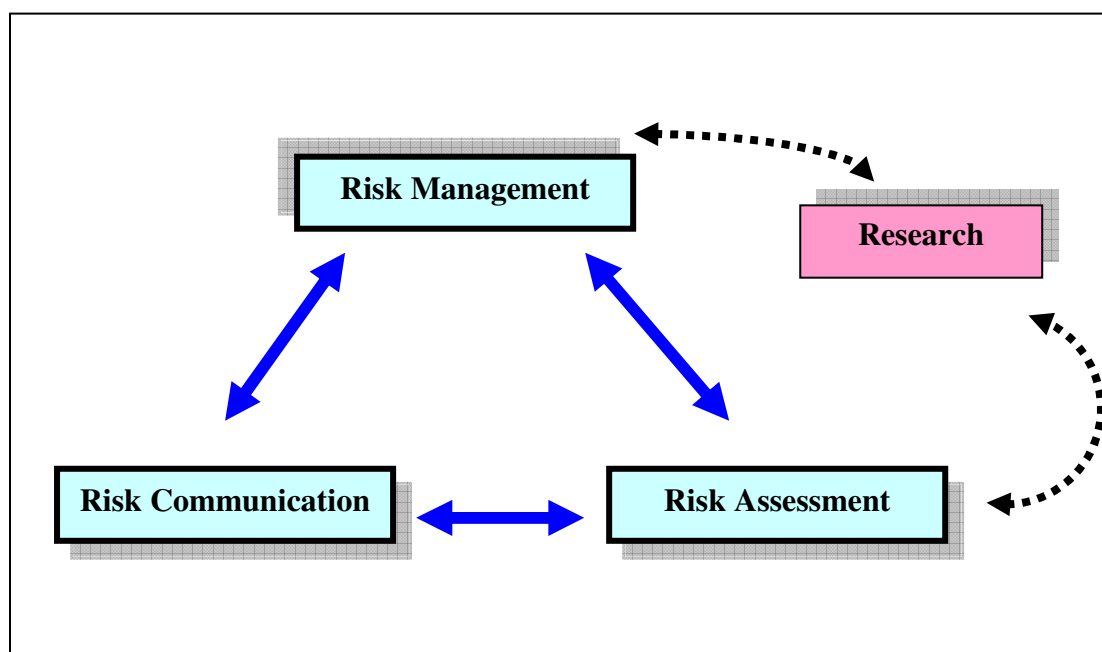
FLEXIBLE

Risk Assessment models should be flexible, such that they can be easily revised when new data or information become available.

BASED ON SOUND SCIENCE

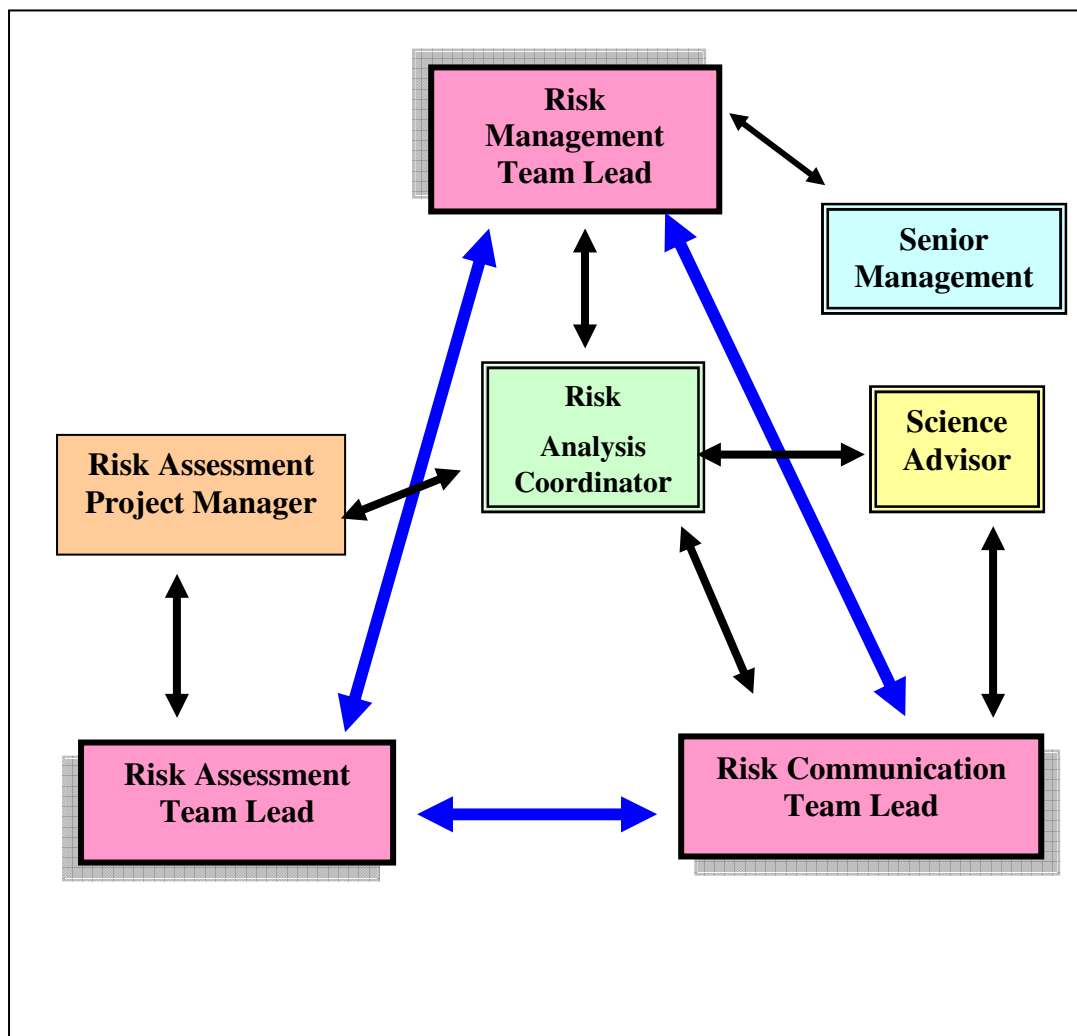
Sound science protects the Risk Assessment from external pressures. The Risk Assessment team should specify what it considers sound or competent science for each type of research that is used in the Risk Assessment.

The role of research in risk analysis is shown in the following Figure:



RISK ANALYSIS TEAMS

Risk analysis teams are functionally separate but interact on a frequent and regular basis. This is seen in the following Figure



Is responsible for formulating the Risk Assessment questions to be addressed, providing key assumptions and oversight of the assessment, and developing a management action plan.

RISK ASSESSMENT TEAM (RA)

Is responsible for conducting the assessment, and refining as necessary, the assumptions provided by the risk management team, explaining the uncertainty of the results and the impact of assumptions on the results.

RISK COMMUNICATION TEAM (RC)

Is responsible for providing input to the RA and RM teams based on the identification and understanding of stakeholder concerns, information needs, and perceptions; promoting an

ongoing exchange of information about the project with all interested parties; and developing public health messages based on the assessment results and management plans.

A team leader should be identified for each of the risk analysis teams. This person is responsible for ensuring that all activities of the team are conducted in a timely manner.

SCIENTIFIC ADVISOR

The role of the Scientific Advisor is to ensure that the science of the assessment is not compromised by the policy needs of the risk management team. The Scientific Advisor must act to preserve credibility and transparency in all decisions and is responsible for resolving any science vs. policy issues.

RISK ANALYSIS COORDINATOR

This person assists the risk management, assessment, and communication teams by coordinating and managing the activities and helping to facilitate communication within and among groups.

RISK ASSESSMENT PROJECT MANAGER

This person is responsible for administrative and technical management of the process. In contrast the Risk Assessment team leader is mainly responsible for the technical conduct of the assessment. For Risk Assessments that are more limited in scope and complexity, a single individual might function as both the Risk Assessment project manager and the Risk Assessment team leader.

The relationship and interaction of the risk analysis teams, the science advisor, the risk analysis coordinator, and the risk assessment project manager are indicated in the figure above.

The various roles and responsibilities of participants in risk analysis are summarized in the table:

Participant	Roles and Responsibilities	
(Senior) Management Team	[Includes Center director, deputy director, senior science advisor] Allocates resources (staff, budget); Selects risk assessments to be conducted	Responsible to ensure that risk assessment (RA), risk management (RM), and risk communication (RC) activities meet the center's objectives and mission.
Leadership Team	[Includes management team plus office/staff directors] Recommends risk assessments to be conducted	Responsible to ensure that recommended risk assessment projects meet the Center's needs. Allocates resources for risk analysis activities

Participant	Roles and Responsibilities	
Science advisor	[CFSAN's Senior Science Advisor] Arbitrates science/policy issues	Responsible to ensure that policies do not bias the assumptions, data, conclusions, or interpretations of the risk assessment
Risk Management Team (RM)	Team Leader coordinates activities with the Risk Analysis Coordinator (CO)	Poses the specific risk assessment question (s) to be answered; Identifies scope of the assessment and provides to RA in the form of a charge; Provides RA with key assumptions to be used; Conducts gap analysis of current RM strategies; Develops a RM action plan; Identifies RM options, implementation strategies, and measures effectiveness; and Identifies and implements plans for research needed to address data gaps.
Risk Communication Team (RC)	Team Leader coordinates activities with the CO; and interacts with stakeholders	Identifies the strategies for the exchange of information with various stakeholders, including their risk communication needs and concerns; Develops and distributes RC messages for the assessment and management action plan; and Develops outreach action plan; Evaluate success of risk communications throughout and at the end of the risk analysis process
Risk Analysis Coordinator (CO)	Coordinates activities with RM, RC, and RA; and supervises the PM and clerical assistant	Serves as contact person for the assessment within the Center; Works to remove barriers identified by the RA/RM/RC; Implements budget and tracks progress of the assessment; and assists RA, RM, and RC teams with planning the roll-out.
Risk Assessment Project Manager (PM)	Coordinates assessment activities with the CO and works closely with RA team leader	Identifies barriers to completing the risk assessment and informs the CO; Assists with identifying risk assessment team members; Manages the conduct of the RA including maintaining project files, work processing, document assembly, references, quality

Participant	Roles and Responsibilities	
		control, desktop publishing, timelines, scheduling of team meetings; and Assists CO with implementing roll-out plan.
Risk Assessment Team (RA)	Team lead reports and barriers and project concerns to the PM	Members serve as technical experts for the conduct of the risk assessment in various identified subject matters; Develops assumptions used in modeling; Gathers and assembles data used in modeling; Performs the risk assessment; prepares risk assessment report/document(s); and Identifies research data gaps.

AREAS RISK ANALYSIS TEAMS SHOULD DISCUSS AT VARIOUS POINTS IN THE PROCESS

DURING THE PLANNING OF THE RISK ASSESSMENT

1. The risk management question and its significance to the specific Risk Assessment questions(s) and how the assessment answers relate to the risk management options.
2. How the teams should interact and at which specific points in the assessment process.
3. Interaction and communications with other interested parties, including their agencies.
4. The type of Risk Assessment (quantitative vs. qualitative; risk ranking, product pathway, risk-risk) and whether this is the best approach to answering the questions.
5. Resources needed and timeline for conducting the assessment.

DURING THE CONDUCT OF THE RISK ASSESSMENT

1. A conceptual diagram of the major steps of the Risk Assessment model.
2. Method of collecting data, criteria for choosing which data to include in the assessment, how the data are used in the Risk Assessment model.

3. Specific data inputs and outputs for the conceptual model.
4. Use of key assumptions provided by risk managers.
5. Identification of modeling assumptions.
6. Criteria used to select the various distribution/models used.
7. Sensitivity of assumptions and impact of conclusions.
8. Methods of presenting the results.

DURING THE RISK ANALYSIS TEAM REVIEW OF THE RISK ASSESSMENT

1. Answer(s) to the Risk Assessment question(s).
2. Uncertainty/sensitivity analysis.
3. Data gaps or research needed to refine the Risk Assessment.
4. Transparency of the document.

Risk Analysis Activities		Responsible Party*		
		RA	RM	RC
Select the risk assessment			X	
Plan and allocate resources		X	X	X
Performance	Conduct the risk assessment	X		
	Develop management action plan		X	
	Develop communication messages			X
Review	Risk assessment documents	X	X	X
	Management action plan		X	
	Communication messages		X	X
Issue	Risk assessment documents	X		
	Risk management action plan		X	
	Risk communication messages			X
RA= risk assessment team; RM= risk management team ; and RC= risk communication team.				

ROLL-OUT PLAN OF A COMPLETED RISK ASSESSMENT

- A press contact list
- Talk points / press announcements / briefing materials / question and answers
- Schedule and hold public meeting(s)
- Plan and hold stakeholder briefing(s)
- Plan and hold other briefings or presentations, as needed
- Make and distribute printed copies of document(s) to stakeholders and public
- Prepare and post Risk Assessment document(s) on FSA web page.

ADDITIONAL USEFUL INFORMATION ON RISK ASSESSMENT

Additional useful information is available under the following headings:

Communication Between the Risk Managers and Risk Assessors
www.cfsan.fda.gov/~dms/rafw-apx.html (Page 2)

Risk Communication Activities www.cfsan.fda.gov/~dms/rafw-apx.html (Page 5)

Criteria for Identifying Candidate Risk Assessments
www.cfsa.fda.gov/~dms/rafw-apx.html (Page 8)

Criteria for Evaluating Technical Feasibility
www.cfsan.fda.gov/~dms/rafw-apx.html (Page 9)

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