

Food Safety and Security:
Operational Risk Management Systems Approach

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Presented by

**Department of Health and Human Services
US Food and Drug Administration
Center for Food Safety and Applied Nutrition**

INTRODUCTION

The United States Air Force, Office of the Surgeon General is developing guidelines for food safety and security for military personnel. Due to their support for national food safety and security and homeland defense they allowed their document to be used as a model for development of these guidelines. If you need further information, contact Dr. Robert Brackett or Mr. Louis Carson, Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition on (202)260-8920 or by fax on (202) 260-9653.

Our vision: Public Health protection through safe food and water sources.

Our strategy: To both stop and reduce threats before they occur our food safety and security strategy is to:

1. *Identify Food Assets:* Identify our food assets from farm to fork.
2. *Receive Threat Assessments:* Food safety regulatory agencies should develop procedures to receive creditable threats and threat assessments from intelligence personnel (FBI, state Office of Emergency Services, etc.) The threat assessments would be based on availability of agents (biologic, chemical, radiological, physical) and aggressors (terrorists, criminals, subversives etc.).
3. *Conduct Operational Risk Management:* Use ORM to enhance food safety and security by minimizing risk at each step in food production from the farm to the fork. Using ORM we will identify our hazards and conduct risk assessment and risk management for effective food safety and security. The goal is the best food safety and security at the least cost (not at any cost)

FOOD ASSETS

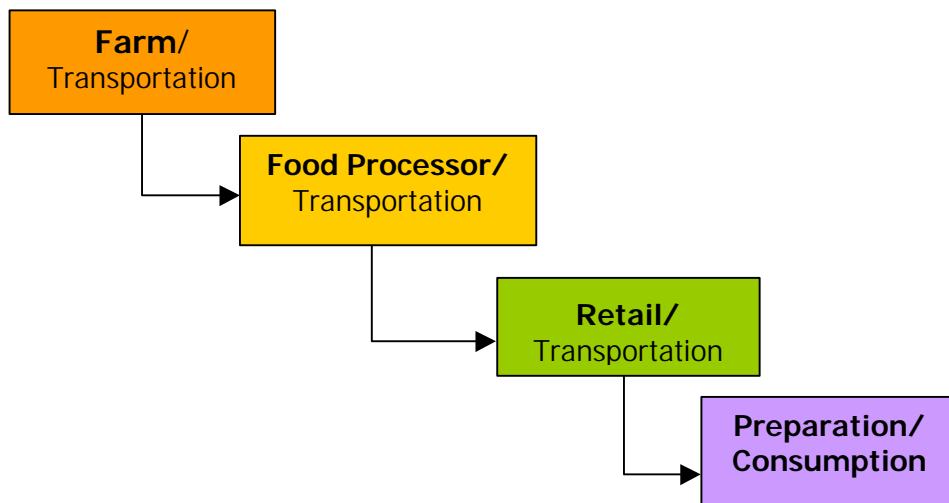
First and foremost, concern is centered on protecting the public, our most important asset by providing them with safe food and water sources. Food and water systems can be very complex and literally stretch around the world. For the purpose of this handbook, we want to identify our national assets.

U.S. Agriculture is a \$200 billion business with over \$55 billion in exports each year (agriculture has a \$1 trillion value and provides 22% of all jobs). The United States is the largest producer of food and agriculture products in the world, and agriculture and food production is the nations largest business. The United States has over 500,000 farms, and over 6,000 meat, poultry and egg product and production establishments.

There are in excess of 57,000 food processors in the United States that provide processed foods to our citizens and exports to the world. These processors include canners, dairy product producers, wineries, and other food and beverage manufacturers and distributors.

The United States produces over 50% of the world's processed tomato products, and the majority of the canned peaches, fruit cocktail, and black ripe olives. It also processes millions of tons of garlic, prunes, and strawberries. Retail food facilities (restaurants, grocery stores, and other operations serving/selling foods direct to the consumer) number in excess of 1.2 million.

Unfortunately microbes, toxins, chemicals, and heavy metals can be used to contaminate food sources on the farm, during food processing during transportation or in the restaurant during food preparation. These types of activities can cause extensive morbidity and mortality, and the economic destruction of our food manufacturers and agricultural industries.



SUMMARY: IDENTIFYING FOOD AND WATER ASSETS

The nations farms, transportation and distribution systems, food processors and retail food establishments are a vital part of our economy and are required for the nations security and health. Local, state and federal food and agriculture regulatory agencies must work together with farmers, ranchers, food processors, food transportation companies and distributors, grocery stores, restaurants and food handlers to address food safety and security from the farm to the fork.

THREAT ASSESMENTS

The threat of terrorism against United States citizens has increased significantly. The nations food supply and agricultural industries could also be subject to this new threat. The nation must develop effective food and agriculture safety and security programs to guard against natural threats and also terrorist attacks. In order to meet our vision of public health protection through safe food and water sources we must stop attacks and also reduce our vulnerability to them before they occur. The United States must be prepared to respond to this new public health and agriculture threat.

Risk analysis of terrorist threats to the public is the responsibility of the FBI. The FBI is the lead law enforcement agency responding to potential terrorist incidents in the nation. The FBI gathers information from numerous sources in an attempt to build a composite picture of threat conditions. This information gathering is shaped by the need to focus on various factors indicating possible terrorist activities (existence, capability, intention, targeting)

As information is gathered on these factors, it is analyzed and a threat level for an area is determined. Basically, the more factors present, the higher the threat level becomes. Incidents of potential food and drug tampering are reported to the FBI. The FBI coordinates investigations of these crime incidents with the appropriate federal agency (FDA, USDA etc). These federal regulatory agencies have current food safety and security procedures and are reviewing new procedures to communicate credible increases in the risk of a terrorist attack to state regulatory agencies and the industries they regulate. Do not presume that an attack against food or water could not occur before an increase in the threat level, as an asymmetric attack is very hard to predict.

The three components of an operation against food and water systems are: (1) aggressors (2) tactics used by aggressors and (3) agent used by an aggressor. The following are required for an attack:

1. AGGRESSORS

There are five primary types of aggressor: criminals, protesters, terrorists, subversives, and rogue or disgruntled insiders.

2. TACTICS USED BY AGGRESSORS

- A. Exterior attacks occur from outside the facility.
- B. Forced entry is made by creating a new opening in the facility in order to gain access
- C. Covert entry is accomplished by using false credentials or other means of deception or stealth in order to gain access to food or water systems.
- D. Insider compromise involves using someone with legitimate access

3. AGENTS USED BY AGGRESSORS

- A. **Biological** agents (bacteria, toxins, viruses, parasites, etc.) can be delivered in the form of liquids, aerosols, or solids
- B. **Chemical** agents can be delivered as airborne droplets, liquids, aerosols, or solids. They are categorized as classical chemical warfare agents (nerve, blister, blood and choking agents) and toxic industrial chemicals (e.g., pesticides, rodenticides, and heavy metals).
- C. **Radiological** agents are radioactive elements that can be delivered in liquid or solid form.
- D. **Physical** agents are materials that could cause adverse health effects if eaten (e.g., bone slivers, glass fragments, and metal filings).

SUMMARY: THREAT ASSESMENT

The DOD January 2001 Proliferation: Threat and Response report for the first time identified that attacks against the U.S. food supply could affect the economic stability of the country and erode military readiness. There are many chemicals, microorganisms and toxins that meet the criteria for effective terrorist weapons for an aggressor who has developed the tactics for an attack against our food production system.

OPERATIONAL RISK MANAGEMENT

All food production procedures involve risk. All operations require decisions that include risk assessment as well as ORM. Supervisors in food production from the farm to the fork, along with every individual, are responsible for identifying potential risk and adjusting or compensating appropriately. Risk should be identified using disciplined, organized, and logical thought-processes that ensure the best food safety and security possible. Good ORM from the farm to retail can provide many benefits to overall food safety and security.

OPERATIONAL RISK MANAGEMENT RULES

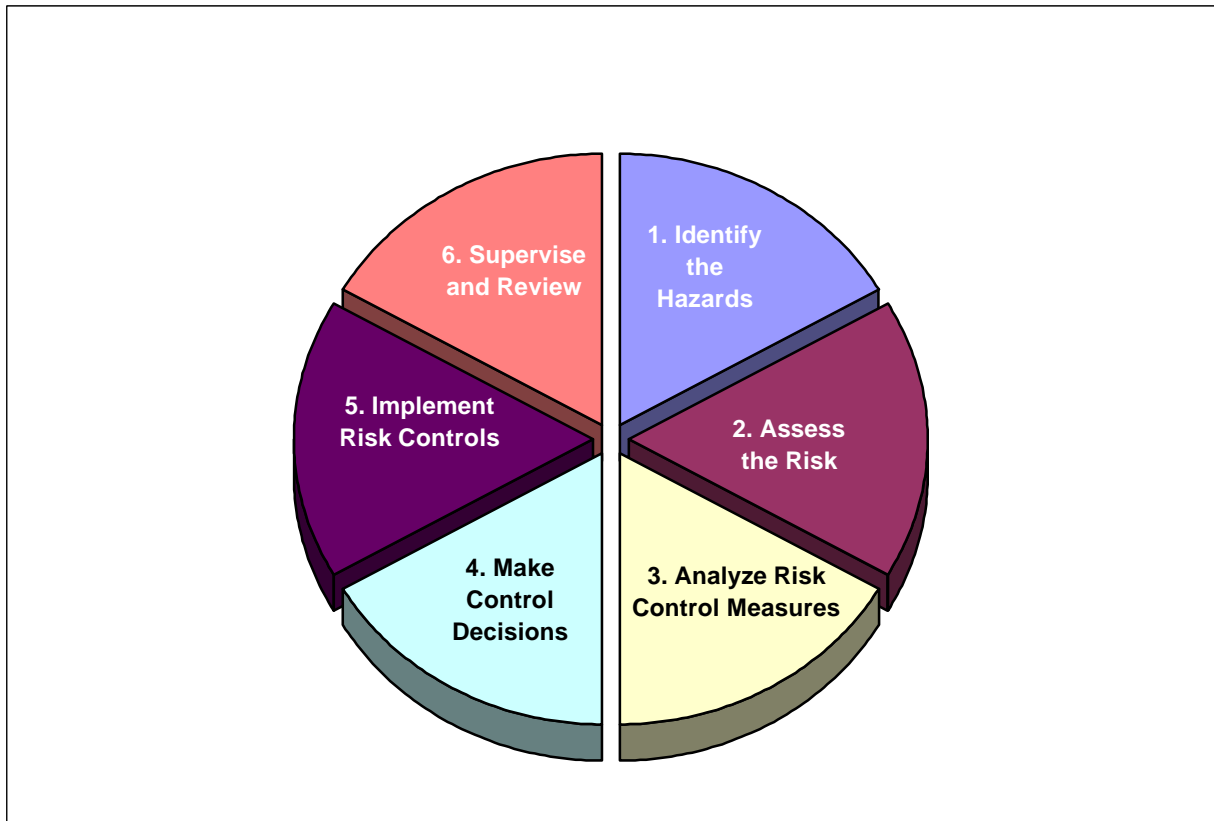
Rule 1. Accept no unnecessary risk. Unnecessary risk comes without a commensurate return in terms of real benefits or available opportunities.

Rule 2. Make Risk Decisions at the Appropriate Level. Making risk decisions at the appropriate level establishes clear accountability. Those accountable for the success or failure of the product must be included in the risk decision process

Rule 3. Accept Risk When Benefits Outweigh the costs. All identified benefits should be compared to all identified costs. As an example a lock on a door, lighting and alarms cost less than a 24-hour guard for the door. We accept the risk of entry by an aggressor because we have put in redundant controls and the benefits of the 24-hour guard do not outweigh the additional cost.

Rule 4. Integrate ORM into Planning at all Levels. To effectively apply ORM, managers must dedicate time and resources to incorporate ORM principles into the planning processes. The making of important risk decisions should be preplanned whenever possible.

OPERATIONAL RISK MANAGEMENT IMPLEMENTATION



ORM Process Definitions

Mission: The desired outcome (food safety and security)

Management: Directs the food safety and security operation by defining standards, procedures and controls. Management process cited in 80 percent of reported mishaps by the National Safety Council other root (systemic) cause factors for mishaps:

- ✓ *People*: Most common root cause, doesn't know (training)
Doesn't care (motivation) can't do (selection)
- ✓ *Machines*: Poor design, poor performance, repairs not made,
not used as intended, no upkeep or replacement
- ✓ *Plant or Environment forces*: Weak facility design, lighting, noise,
Température, ventilation, contamination

Systems Management: ORM is a system-based concept. This means that ORM users understand that operational mistakes and errors have their origin in the design of the system (people, machines, plant/environment and management). Overall system effectiveness is required in order to meet the mission of food safety and security.

Flow Diagram: List of food production events in sequence required to understand the flow of events in food production from farm to fork.

Hazards: A description of a condition with the potential to cause illness, injury or death, property damage or business degradation. Not an indication of its significance to food safety and security.

Hazard Identification: Choose an area or step in food production and conduct an onsite visit. Use the:

- ✓ “What If Tool,” conduct a brainstorm session with experts and supervisors on creditable hazards that could result in food contamination. Get input from operational personnel.
- ✓ “Cause and Effect Diagram,” Draw a fishbone cause and effect diagram on a worksheet. Evaluate people, procedures, machine and plant/environment causes that could result in a contaminated product.

Risk: A hazard for which we have estimated the severity and probability with which it can impact our food safety and security mission. Supervisors and leaders want to deal with risks, not hazards, because hazards do not have an explicit mission connection.

Risk assessment: Identifying hazards and determining impact on food safety and business or mission (high risk, low risk steps 1 and 2). Remember risk can increase if threat conditions increase. The purpose of risk assessment is to allow us to focus on the worst hazard first.

Severity: Is usually based on worst creditable food safety and security event that can affect the business or mission. Creditable means an event that has some reasonable probability of occurring, not simple an event that conceivable could occur (see attached matrix).

Probability: The probability for a hazard is the closet match with the five levels of probability (see attached matrix). When working with an operation the probability is the

cumulative probability of all hazards. Probability is never certain and should be based upon past events, data and expert analysis or group analysis. The probability of a food safety and security mishap goes up in high threat conditions.

Exposure: Is usually captured in probability (the more times we do something the more probable it is) or in severity (the more people exposed the greater is the potential severity). However, there are occasions when it is important to consider exposure in its own right in the final ranking of risks.

Modified risk control matrix: There can be inconsistency in risk assessments because there are at least two dimensions of subjectivity involved in the use of the risk assessment matrix. Interpretations of exposure, severity and probability may be different based on experience. This can be reduced by group discussions and averaging the ratings of several individuals. Remember the goal is to ultimately identify all risks in order of importance in order to prioritize risk control efforts.

Risk management: Analyze food safety and security risks and implement risk control decisions (steps 3, 4 and 5). Remember to conduct a risk assessment after controls are in place to ensure risks are reduced.

Unnecessary risk: Understand what unnecessary risks are and accept risk when the benefits actually outweigh the cost. In assessing risk the three primary causes for unnecessary risks are:

1. Not aware of the risk
2. An incorrect assessment of cost versus benefit
3. Interpreting “Bold Risk Taking” to mean gambling

Risk acceptance: Some degree of risk is a fundamental reality. The goal is the best food safety and security at the least cost, not at any cost.

- ◆ Risk management is a process of tradeoffs.
- ◆ Risk is a matter of perspective; keep problems in proper perspective.
- ◆ Weigh risks and make judgments based on knowledge, experience, and mission requirements.
- ◆ There is no best solution. Use good judgment.
- ◆ Complete safety is a condition that seldom can be achieved in a practical manner.
- ◆ Risk is inherent in all operations; risk can be controlled using ORM

Step 1: Identify the Hazards in Operation

The first step in conducting ORM is to identify the hazards for each activity or step in the process of food preparation. To understand the flow of events in food production, first list the sequence for food preparation. The food-purchasing contracts should be reviewed to ensure the products are from an approved source. This means the food processor and distributor were inspected by a recognized state or federal food safety regulatory agency. To be from an approved food source, the product would also be produced on a farm meeting regulatory requirements for food safety (pesticide use, antibiotic use etc).

The final flow diagram would appear as below:

Produce, milk, eggs and other farm products transported in refrigerated truck to food processor at food processor transported in refrigerated truck to distributor stored at distributor then transported in refrigerated truck to restaurant unloaded at restaurant dock placed in dry, frozen or refrigerated storage food preparation in restaurant kitchen placed in restaurant serving line leftovers returned to kitchen

ORM in a Restaurant

An ORM review was conducted on the restaurant identified in the flow diagram above. The following hazards were identified in the during step one of an ORM review of the restaurant identified in the flow diagram above:

Step 1. Identify Hazard	
Operation Activity/Event	Hazard Identified in Operation
1. Unloaded at restaurant dock by vendor driver	1.a No identification on drivers and different drivers are used (this person has ability to contaminate bulk food products) b. Trucks are not sealed or locked upon arrival and are making other deliveries c. Unauthorized personnel can enter restaurant through unsecured back door at any time
2. Placed in dry, frozen or refrigerated storage	2a. Storage areas are not monitored at all times and driver has access to entire storage area and kitchen. b. The facility does not have emergency lighting and it serves meals 24 hours a day. d. No tracking system to identify lot numbers on dry food sources served in facility that may have been recalled
3. Food preparation in restaurant kitchen	3a. Exterior door from kitchen area to outside is not secure and can be used to enter kitchen area by aggressor b. No pressure backflow preventor on oven hood cleaner can result in water contamination c. Entry to kitchen area from serving line is not restricted

	<p>unauthorized personnel can enter kitchen</p> <p>e. Only one backup person if foodhandlers ill. Can result in inadequate staffing and use of unauthorized personnel</p> <p>f. Employees hired from local unemployment agency with only work reference contact. No procedures to conduct complete or random criminal background or drug testing.</p> <p>g. Employees locker room provided for changing clothes requires employees to provide own lock. Management cannot enter lockers to check on unauthorized use.</p> <p>j. New employees are hired into graveyard shift does not allow adequate observation</p>
4. Placed in restaurant serving line	<p>4a. Leftovers returned to kitchen could be contaminated</p> <p>b. Individuals have open access to salads and desserts on serving line. Provides ability to contaminate.</p>

Step 2: Assess the Risks

The next step after hazard identification is to assess the risk of each hazard. When we know the various impacts a hazard may have on food safety and security and have an estimate of how likely it is to occur we can now call the hazard a risk. Risk is the probability and severity of loss or adverse impact to the food product from exposure to the hazard. The second aspect of risk assessment is the ranking of risks into a priority order. Remember something that is not a significant risk should still be corrected if it is simple to control.

There are three key aspects of risk. Probability is the estimate of the likelihood that a hazard will cause a loss. Some hazards produce losses frequently, others almost never do. Severity is the estimate of the extent of loss that is likely. The third key aspect is exposure, which is the number of personnel or resources affected by a given event or, over time by repeated events. To place hazards in rank order we must make the best possible estimate of the probability, severity, and exposure of a risk compared to other risks that have been detected.

1. **Assess Hazard Probability:** Determine the probability that the hazard will cause a negative event (severity). Use the cumulative probability of all causative factors. Probability may be determined through estimates or actual numbers. Use experience, analysis, and evaluation of historical data when possible. Supporting rationale for assigning a probability can be documented for future reference and to acknowledge uncertainty. Probability categories are frequently, likely, occasional, seldom, unlikely.
2. **Assess Hazard Severity:** Determine the severity of the hazard in terms of its potential impact on people and our mission for food safety and security. Cause

and effect diagrams, and “What If” analysis are some of the best tools to assess risk in food production. What is the impact on business? People? Things? (Plant, facility etc). Severity assessment should be based upon the worst possible outcome that can reasonably be expected. Severity categories are catastrophic, critical, moderate, and negligible.

3. Assess Hazard Exposure: Surveys, inspections, observations, and mapping tools can help determine the level of exposure to the hazard and record it. This can be expressed in terms of time, proximity, volume, or repetition. Does it happen often and involve a lot of people. Repeated exposure to a hazard increases the probability of a mishap occurring. Understanding the exposure level can aid in determining the severity or the probability of the event. Additionally, it may serve as a guide for devising control measures to limit exposure.

Using the risk assessment matrix (see attached) the severity and probability for each hazard is identified (see exposure definition above). This process should be conducted individually and then compared with others conducting the same assessment in order to determine the most appropriate risk level. Each risk is labeled with its significance (high, medium, etc.). This allows us to see both the relative priority of the risk and their individual significance.

ORM in a restaurant (continued)

The next step after hazard identification in the restaurant ORM example above would be to conduct a risk assessment of each of the hazards and identify a risk level and ranking for each hazard as identified below:

Step 2. Assess the Risk (example of step 2 from our restaurant review above)			
Hazard Identified in Operation	Assess the Risk	Risk Level	Rank
(1) a. No identification on drivers and different drivers are used. b. Trucks are not sealed or locked upon arrival and they are making other deliveries c. Unauthorized personnel can enter restaurant through unsecured back door at any time	1.a. Driver could be an aggressor and contaminate food in bulk form. The severity or potential impact of this hazard is critical due to its large effect on many people and operation (foods could be contaminated in bulk). The Probability is seldom (seldom associated with identified illness outbreaks).	1a. Medium/11	4a
	b. (Same as one)	b. Medium/11	4b
	c. (Same as one)	c. Medium/11	4c
2a. Storage areas are not monitored at all times and driver has access to entire storage area and kitchen. b. The facility does not have emergency lighting and it serves meals 24 hours a day.	2a. Bulk food could be contaminated and the results could be critical. The probability is seldom but it is possible for aggressor to have access.	2a. Medium/11	4d
	b. Aggressor could cut power to building and stop food service. This could cause moderate damage to operation and loss of	b. Low/14	5a

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<p>c. No tracking system to identify lot numbers on dry goods served in facility that may have been recalled</p>	<p>food products. The probability is seldom but possible. c. If food is contaminated during production and associated with illness all similar food would have to be destroyed not specific lots and individuals would have to be informed of potential illness associate with product even though none may have been served. Could be critical and probability is likely because recalls occur frequently</p>	<p>c. High/4</p>	<p>1</p>
<p>3a. Exterior door from kitchen area to outside is not secure and can be used to enter kitchen area by unauthorized personnel b. No pressure backflow preventor on soft drink lines or oven hood cleaner can result in water contamination. c. Entry to kitchen area from serving line is not restricted unauthorized personnel can enter kitchen. d. Only one backup person if foodhandlers ill. Can result in inadequate staffing and use of unauthorized personnel. e. Employees hired from local unemployment agency with only work reference contact. No procedures to conduct complete or random criminal background or drug testing. f. Employees locker room provided for changing clothes requires employees to provide own lock. Management cannot enter lockers to check on unauthorized use. g. New employees are hired into graveyard shift does not allow adequate observation.</p>	<p>3a. Aggressor could enter from these areas and potentially harm people, food, or machines due to unrestricted access. This could occur occasionally with critical severity. b. Water contamination could occur due to this hazard from a design or maintenance defect. Could potentially expose large group to contaminated ice or water with Critical results. This could be an occasional occurrence with broad exposure. c. An aggressor could enter the kitchen area and potentially result in people, equipment or facility damage with critical results to large group. The probability of occurrence is seldom. d. The individual hired to work temporally may not be trained properly or be an aggressor. This could result in damage to people, equipment and facility with critical results to a large group. The probability of occurrence is unlikely e. The individual hired may be a criminal or aggressor of another type. This individual has access to food, equipment and facility and could cause critical damage. The probability of occurrence is seldom. f. An aggressor could contaminate food resulting in Critical damage to people. The probability of occurrence is unlikely. g. An aggressor hired as a new employee could do critical damage to people, equipment, and facility due to decreased observation. The probability of this occurring is occasional</p>	<p>3a. High /7 b. High/7 c. Medium/11 d. Medium/11 e. Low/15 f. Medium/11 g. High/8</p>	<p>2a 2b 4e 4f 6 4g 3</p>
<p>4a. Leftovers returned to kitchen could be contaminated b. Individuals have open access to salads and desserts on serving line. Provides ability to contaminate</p>	<p>4a. An aggressor could contaminate with moderate results because small number would eat leftover. The probability of occurrence is seldom. b. An aggressor could do critical damage to food by contamination with an agent. The probability of occurrence is seldom. (Has occurred)</p>	<p>4a. Low/14 b. Medium/11</p>	<p>5b 4h</p>

Step 3: Analyze Risk Control Measures

The third step is to analyze risk control measures for the potential hazards that could be introduced into the operation and were identified through the risk assessment step above. Action is taken to investigate specific strategies and tools that reduce mitigate, or eliminate risk. Starting with the highest risk identify as many risk control options as possible for all the risks. Effective control measures reduce or eliminate one of the three components (probability, severity, or exposure) of risk. You should also consider what the risk control costs and how various risk control options work together. The following are risk control options:

- *Reject*-We can and should refuse to take a risk if the overall costs of the risk exceed its benefits to the business or operation. In the example above placing new employees on the midnight shift with no background checks and providing them a locker that only they have access to is a high risk that should be rejected.
- *Avoid*-Avoiding risk altogether requires canceling or delaying the job, or operation, but is an option that is rarely exercised due to operational need. In the example above allowing open public access to the salad bar is a medium risk that has resulted in a bioterrorism incident when salmonella was sprinkled on fruits and veggies, blue-cheese dressing and potato salad at a salad bar. A decision to avoid this hazard by removing the salad bar could be made. As stated above this option is rarely exercised.
- *Delay*-It may be possible to delay a risk. If there is no time deadline or other operational benefit to speedy accomplishment of a risky task, then is often desirable to delay the acceptance of risk. During the delay, the situation may change and the requirement to accept the risk may go away. In the example above a decision may be made to keep the medium risk salad bar but to not use it and go to individual servings when general public threat announcements are made or other concerns with aggressors occur.
- *Transfer*-Risk transfer does not change probability or severity of the hazard, but it may decrease the probability or severity of the risk actually experienced by the individual or organization accomplishing the operation/activity. As a minimum the risk to the original individual or organization is greatly decreased or eliminated because the possible losses or costs are shifted to another entity. An example would be a food commodity group (dairy, produce, etc) developing an audited certification program for food safety and security. The group could work together to reduce risk to individual members by such actions as purchasing insurance to cover losses by members in good standing from food contamination from emerging pathogens (*E coli* 0157:H7 etc) or from potential aggressors (terrorist).

- *Spread*- Risk is commonly spread out by either increasing the exposure distance or by lengthening the time between exposure events. In the example above deliveries to the restaurant by unidentified drivers is a medium risk. Lengthening the time between deliveries (events) could spread the risk of this hazard. The restaurant could move from daily deliveries to twice a week.
- *Compensate*-We can create redundant capability in certain special circumstances. An example is to plan for a back up, and then when a critical piece of equipment or other item is damaged or destroyed we have capabilities available to bring on line to continue the operation. In the example above the low risk (could become larger risk if aggressor tried to remove current staff) created by having only one properly trained back-up food handler could be reduced by working with other restaurants and develop a pool of secure and properly trained food handlers for on call use by all the group.
- *Reduce*-The overall goal of ORM is to plan operations or design systems that do not contain hazards. A proven order of precedence for dealing with hazards and reducing the resultant risks is:
 1. **Plan or Design for Minimum Risk.** Design the system to eliminate hazards. Without a hazard there is no probability, severity or exposure. In the example above the back dock for restaurants should be designed with secure delivery doors that trucks can back up to and unload their products securely on the dock and not enter facility. Staff would move products directly from dock to storage with entry doors in dock area. This prevents any aggressor from entering the dock, delivery truck or storage areas.
 2. **Incorporate Safety Devices.** Reduce risk through the use of design features or devices. These devices usually do not effect probability, but reduce severity: an automobile seat belt doesn't prevent a collision but reduces the severity of injuries. In the example above installing a pressure backflow preventor can reduce the high risk for water contamination from the oven cleaner.
 3. **Provide Warning Devices.** Warning devices may be used to detect an undesirable condition and alert personnel. In the example above the high risk of unauthorized potential aggressors entering the facility through the kitchen door to the outside can be reduced by installing a panic bar that prevents the exit from being used except in an emergency such as a fire.
 4. **Develop Procedures and Training.** Where it is impractical to eliminate hazards through design selection or adequately reduce the associated risk with safety and warning devices, procedures and training should be used. In the example above staff can be trained to report suspicious activities and stop or report unauthorized personnel. Procedures could be developed for reward programs for staff actively promoting and supporting food safety and security efforts with new ideas or actions.

In most cases it will not be possible to eliminate risk entirely but it will be possible to significantly reduce it. In making control decisions for the restaurant example above determine the effect of each proposed control on the risk associated with the hazard. The estimated values for severity and probably after implementation of the control measure and the change in overall risk assessment from the risk assessment matrix should be re-reviewed and recorded. Finally, prioritize risk control and for each hazard prioritize those risk controls that will reduce the risk to an acceptable level. The best controls will be consistent with operational objectives and optimize available resources. When implementing risk controls, try to apply risk controls only when the operation is actually at risk. Apply redundant risk controls only when practical and cost effective.

ORM in a restaurant (continued)

The next step after hazard identification and analysis of the risk is to rank the risks and then conduct an analysis of the proposed risk control measures. This risk control analysis and ranking are identified below:

Step 3. Analyze Risk Control Measures			
Hazard Identified in Operation	Risk Level Rank	Risk Control Measures	Rank/
2d. No tracking system to identify lot numbers on dry goods served in facility that may have been recalled	2d High/4	2d. – Maintain on site complete list of where food products and ingredients are purchased, including name, street address, phone and fax numbers.	4.
		2d. –Maintain on site records of invoices and bills of lading for all purchases, records of employees work shift, copies of menus and records of invoices and bill for all.	5.
		2d. – Maintain on site list containing the names and numbers of primary and secondary contacts of all regulatory agencies.	3.
		2d. – Develop written plans for ensuring and maintaining a proper chain of custody, storage and/or destruction of all recalled products.	2.
		2d. – Identify in contracts that food products purchased will have commodity codes and expiration dates with written explanations provided to restaurant (for recall purposes).	1.
3a. Exterior door from kitchen area to outside is not secure and can be used to enter kitchen area by unauthorized personnel	3a. High /7	3a. – Provide warning device by installing a panic bar that prevents the exit from being used except in an emergency such as a fire.	1.
		3a. – Post the door with signs that identify it is not an exit except in emergencies	2.
3b. No pressure backflow preventor on soft drink lines or oven hood cleaner can result in water contamination	3b. High/7	3b. –Incorporate safety device by installing backflow preventor on oven line	2.
		3b. –Install backflow preventor on oven line and soft drink line.	1.
		3b Stop using the oven cleaner.	3.
3j. New employees are hired into graveyard shift does not allow adequate observation	3j. High/7	3j. Reject this risk and have new employees complete probation or at least their first 90 days on a day shift with increased oversight.	1.

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3g. Employees locker room provided for changing clothes requires employees to provide own lock. Management cannot enter lockers to check on unauthorized use.	3g. High/8	3g. Reject this risk and have management provide locks for all lockers. Management would have master key and authority to enter lockers for periodic safety and security reviews.	1.
(1) a. No identification on drivers and different drivers are used.	1a. Medium/11	1.a. Lengthening the time between deliveries (events) could spread the risk of this hazard. The restaurant could move from daily deliveries to twice a week. 1a. Contract with vendors that conduct security checks on employees and require drivers to have picture identification visible on them and provide restaurant with pictures of drivers prior to delivery.	2. 1.
1b Trucks are not sealed or locked upon arrival and they are making other deliveries	1b. Medium/11	1b. Establish requirement in contract that trucks be sealed or locked at all times. 1b Establish requirement in contract that vendor have locked truck from distributor to restaurant.	1. 2.
3d. Entry to kitchen area from serving line is not restricted unauthorized personnel can enter kitchen	3d. Medium/11	2a Have staff stay in serving line area at all times customers are in facility. 2a Put up security cameras 2a Put up signs that identify entry into kitchen is for authorized personnel only	2. 3. 1.
3f. Employees hired from local unemployment agency with only work reference contact. No procedures to conduct complete or random criminal background or drug testing.	3f. Medium/11	3f Establish procedures at hiring where new employees sign authorization to submit to drug testing and authorize management to conduct criminal background checks on employees. 3f The same procedure as above, but random drug testing and backgrounds checks are made on all staff.	2. 1.
4b. Individuals have open access to salads and desserts on serving line. Provides ability to contaminate	4b. Medium/11	4b.Avoid this hazard by removing the salad bar 4b. Keep the medium risk salad bar but do not use it and go to individual servings when general public threat announcements are made or other concerns with aggressors occur. Delay the risk during high threat times.	2. 1.
3e. Only one backup person if food handlers ill. Can result in inadequate staffing and use of unauthorized personnel	3e. Low/15	3e. -Compensate by working with other restaurants and develop a pool of secure and properly trained food handlers for on call use by the entire group. 3e. - If food handlers ill reduce menu 3e – If food handlers ill change to self-serving types of food so individual assistance is not required.	1. 2. 3.
2b. The facility does not have emergency lighting and it serves meals 24 hours a day.	2b Low/14	2b Purchase an emergency power generator 2b Reduce hours of operation 2b Purchase emergency battery operated lights for building with extra flashlights	2. 3. 1.
4a. Leftovers returned to kitchen could be contaminated	4a. Low/14	4a Never return leftovers to kitchen 4a. Don't return leftovers to kitchen during times of high threat. 4a Review cooking procedures to reduce leftovers.	3. 2. 1.

4d. Staff reports that food products are taken by customers and then put back.	4d. Low/14	4d. Put up signs that identify food should not be returned 4d Have customer pay when enter facility.	2. 1.
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Step 4: Make Control Decisions

In the example above the hazards identified were conditions that could impair our mission to accomplish food safety and security. The hazards were analyzed and we estimated the severity, probability and scope with which it could impact our mission for food safety and security. This evaluation of the hazard establishes a risk level. Then in the above step the risks were ranked from highest to lowest and several proposed controls were identified for each risk. Restaurant management should review the proposed controls with you and then with their staff. After controls have been selected to eliminate hazards or reduce their risk, determine the level of residual risk for the selected course of action.

- Accept the plan as is: Benefits outweigh risks (costs), and total risk is low enough to justify the proposed action if something goes wrong. The decision maker must allocate resources to control risk. Available resources are time, money, personnel, and/or equipment.
- Modify the plan to develop measures to control risk. The plan is valid, but the current concept does not adequately minimize risk. Further work to control the risk is necessary before proceeding.
- Elevate the decision to a higher authority. The risk is too great for the decision-maker to accept, but all measures of controlling risk have been considered. If the operation is to continue, a higher authority must make the decision and accept the risk.

There are several important points to keep in mind when making a risk control decision. Involve the personnel impacted by the risk control to the maximum possible extent in the selection. They can almost always provide ideas to enhance the various options. In addition, be sure to carefully evaluate the impact on the operation of the risk control action. The objective is to choose the option that has the best overall favorable impact on the operation. Be sure to consider all the positive benefits and negative (cost, lower morale, lower productivity) factors associated with the risk decision. It is also important to make risk decisions at the right level. In determining the level, ask who will be accountable if the risk produces a loss. That person should have a voice in the risk decision or actually make it. Once the best possible set of risk control options has been selected, the individual in charge must accept this decision. Remember, the goal is not the least level of risk; it is the best level of risk for overall food safety and security.

There is no single method of preventing or detecting terrorist activity with agents that could be introduced into a food or water system. A multifaceted approach is required to guard against an intentional contamination event. Existing safeguards and safety measures used to protect food and water from naturally occurring contamination are a

good starting point. The addition of ORM for food safety and security will be effective deterrents for many terrorist scenarios in our example we accepted the plan as is.

Step 5: Implement Risk Controls

Once the risk control decision is made, resources must be made available to implement the controls. Part of the process of implementing control measures is to inform personnel in the system of the risk management process results and subsequent decisions. Careful documentation of each step in the risk management process facilitates risk communications.

- **Make Implementation Clear.** To make implementation clear fully involve operational personnel, the control measure must be deployed in a method that ensures it will be received positively. Designing in user ownership and describing the benefits of successful implementation. Provide guidance and even conduct small tests on changes before fully implementing'
- **Establish Accountability.** Be clear on accountability; who is responsible for implementation of the risk control. To be successful, management must be behind the control measures put in place. Prior to implementing a control measure, ensure you have approval at the appropriate level. Most failures with risk control are driven by the failure to properly involve personnel impacted by the risk control in the development and implementation of it.
- **Promote Support.** Develop the best possible supporting tools and guides to help in implementation, such as standard operating procedures for safety and security. The easier you make the task the greater the chance for success. Be sure to identify reasonable timelines for implementing. To be fully effective, risk controls must be sustained. This means maintaining the responsibility and accountability for the long haul. Provide management support and positive motivation with incentives for promoting and supporting food safety and security.

Step 6: Supervise and Review

Supervise:

- ✓ Assure controls are effective and in place
- ✓ Maintain implementation schedule for controls
- ✓ Assure needed changes are detected
- ✓ Correct ineffective risk control

Review:

- ✓ Obtain feedback from operator involved
- ✓ Select critical indicators and measure risk (knowledge, attitude, mishaps)
- ✓ Supervisor conducts work site spot check once a day to review controls
- ✓ Conduct a brief skill and knowledge quiz on food safety and security control requirements. Goal is 95%.
- ✓ Review the ongoing cost benefit of control

The sixth step of ORM “Supervise and Review” involves the determination of the effectiveness of risk controls implemented for food or water safety and security. This review process must be systematic and ensure control recommendations have been implemented. In addition, the need for further assessment of an operation due to unanticipated change could result in additional risk management actions. A review by itself is not enough. A feedback system must be established to ensure that the corrective or preventive action taken was effective and that any additional corrective action can be implemented as required. Feedback can be in the form of briefings, lessons learned, or update reports to management are beneficial.

OTHER PREVENTIVE MEASURES

In addition to physical risk control security measures, improvements in routine operations can have a significant impact on reducing threats to food. Routine sanitation can be the most valuable tool to mitigate risk from both intentional and non-intentional biologic contamination.

- Monitor hygiene practices.
- Have foodhandles shower in, and/or change into uniforms without pockets just before arriving in the work area.
- Wash hands thoroughly after any non-food preparation activity.
- Sanitize equipment when necessary to protect against contamination with undesirable microorganisms.
- Take steps necessary to prevent cross contamination with other materials such as wood, glass, and metal.
- Wear latex or other similar gloves when appropriate.
- Wear hairnets, headbands, caps, and beard covers when necessary.
- Do not eat food, chew gum, drink beverages, or use tobacco in areas where food may be exposed or where equipment or utensils are washed.
- Store clothes and other personal belongings in designated areas separate from food or water production and storage areas or utensil/equipment washing areas.

- Store chemicals such as pesticides and cleaning agents away from food or water production areas.
- Leftovers from meals should be monitored to ensure appropriate disposal. This prevents hazardous foods from being re-served or mixed with the next meal.

Minimum Safeguard And Security Measures

In implementing food safety and security systems, the following measures will greatly promote the protection of food or water system.

Eliminate Opportunity for Forced Entry

Defeat of the **forced entry** tactic relies not only on physical barriers, but also detection (electronic sensors, etc.) and interception by a responding force. The purpose of physical barriers is to delay an intruder long enough for a responding force to successfully apprehend the intruder.

Eliminate Potential for Insider Compromise

The basic defeating strategy for **covert entry** or **insider compromise** tactics is to keep people from entering areas that they should not enter. This strategy relies on the use of restricted entry to certain areas, guards, or detection systems. Further, hiring or contracting considerations may be changed based on the risk of an intentional contamination. Other actions to consider:

- Establish locations within the facility where access to assets can be limited to authorized personnel only.
- Minimize the number of entrances to controlled areas.
- Provide locks for entry doors, windows, and roof openings.

Improve Prevention and Control Measures for Food Safety and Security

The following are basic actions recommended for each stage of the food production process. These actions will prevent or mitigate against aggressor attempts to introduce contaminants into the food or water supply of a facility:

Management of Food Security

Security procedures

- Assign responsibility for security
- Reward and hold all staff accountable for being alert to and reporting signs of tampering with product or equipment, other unusual situations, or areas that may be vulnerable to tampering

Procedure for investigating unusual activity

- Immediately investigate all reports of unusual activity
- Document all investigations
- Report all problems to Security Forces

Employees

- Pre-hiring screening for all employees, including seasonal, temporary and contract
- Obtain work references
- Perform criminal background checks
- Place new employees on day shift with increased oversight during probation
- During hiring process obtain authorization to conduct random drug testing

Daily Rosters

- Make them specific to shift
- Know who is and who should be on premises, and where they should be located

Identification

- Issue photo identification badges with identification number; limit employee access to those areas necessary for the employee's position

Restricted access

- Limit access to those areas necessary for the employee's position (e.g. card entry to sensitive areas, cypher locks)

Personal items

- Restrict personal items allowed in establishment
- Prohibit personal items (e.g. lunch containers, purses) in food handling areas
- Reduce the amount of personal belongings brought to the facility. Examples include purses, gym bags, thermoses, drink containers, etc.
- Management should provide locks for locker areas and establish authority (during hiring process etc.) to enter lockers for periodic safety and security reviews. Metal mesh lockers provide additional security because contents are visible.

Training in security procedures

- Provide staff training in food safety and security procedures and inform them to report all unusual activities.
- Place new employees on day shift with increased oversight during probation;

Farm/source

- Promote participation in industry quality assurance programs. Examples include the FDA guidelines for Microbiologic Safety in Produce and shell egg QA production program
- Develop plans for isolation, cleaning and disinfection
- Keep records on animals, feed, seed and other products purchased and brought onto the farm
- Restrict entry to farm. For high confinement livestock production could even include employees showering in and out, vehicles being sprayed with disinfectant and other biosecurity precautions
- Conduct work reference checks on all employees
- Illuminate building exteriors and exterior sites where feed and other products are stored

Food Processor

- Improve onsite security programs, such as restricting rights of entry and exit, locking up storage bulk ingredient containers and mounting video surveillance at key internal processing hubs.
- Verify work references for seasonal employees. Conduct random basic criminal and drug checks on all employees
- Develop clearly documented well-rehearsed product recall plans, with crisis management teams that can quickly assess the scope of potential problems and contain them
- Written plans for deciding upon and evaluating the scope of a recall
- List containing the names and numbers of primary and secondary contacts of all regulatory agencies
- Minimize the need for signs or other indicators of food product storage
- Provide metal or metal-clad doors on facilities.
- Eliminate potential hiding places within the facilities where a contaminating agent could be temporarily placed before introduction

Retail Food Service

Raw materials, dry goods and packing

- Use only known, secure, state or locally licensed or permitted sources for all ingredients, compressed gas, packaging, and labels.
- Include in purchase and shipping contracts a requirement that suppliers and transporters practice appropriate food security measures

- Conduct work reference checks on all employees and random criminal background checks and have authority to conduct random drug testing
- Restrict access to food preparation areas to authorized personnel only.

Physical security

- Secure doors, windows, roof openings, vent openings, trailer bodies, railcars, and bulk storage tanks (e.g. locks, seals, sensors, warning devices)
- Use metal or metal-clad doors
- Account for all keys to establishment
- Have security patrols of the facility and video surveillance
- Minimize number of entrances to restricted areas and post areas that unauthorized personnel should not have access to
- Eliminate potential temporary hiding places for intentional contaminants
- Provide adequate lighting both interior and exterior
- Keep parking areas away from storage and water facilities

Storage of hazardous chemicals (e.g. cleaning and sanitizing agents, pesticides)

- Secure storage areas and not in food storage area
- Limit access to storage areas
- Supervise maintenance and sanitation staff
- Keep timely and accurate inventory of hazardous chemicals
- Investigate missing stock or other irregularities immediately

Transportation/Distribution

Suppliers

- Inspect incoming ingredients, compressed gas, packaging, labels, and product returns for signs of tampering or counterfeiting
- Require transportation companies to conduct background checks on drivers and other employees with access to the product (comply with state and local laws in doing this)
- Require locked and sealed vehicles/containers, and require seal numbers to be identified on shipping documents. Verify shipping seals with shipping papers.

Traceability of ingredients, compressed gas, packaging, and, salvage products, rework products, and product returns

- Include in purchasing contracts a requirement that suppliers will have commodity codes and expiration dates with written explanations provided for recalls and other food safety actions
- Use operating procedures that permit subsequent identification of source of ingredients, compressed gas, packaging, labels,
- Keep timely and accurate inventory of ingredients, packaging, labels, Investigate missing stock or other irregularities and report any problems to OSI

Security of Finished Products

- Keep timely and accurate inventory of finished products
- Investigate missing stock or other irregularities and report any problems to local legal authorities
- Include in contracts for shipping (vehicles and vessels) a requirement that they practice appropriate security measures
- Perform random inspection of storage facilities, vehicles,
- Require transportation companies and warehouses to conduct background checks on staff (drivers/warehouse personnel; state and local laws may apply)
- Require locked and sealed vehicles/containers, and identify seal number on shipping documents

Security Plans

Action Plan for tampering or terrorist event

- Include step-by-step SOP for triaging the event
- Include evacuation plan
- Maintain floor and flow plan in secure location and with local fire officials
- Include strategy for continued operation (e.g. at alternate facility)
- Include investigation procedures

Communication protocol

- Have internal, fire, and police emergency phone numbers available
- Identify critical decision-makers
- Identify local, state, and federal government contacts

Computer security

- Restrict access to computer process control systems for food products and critical data systems to those with appropriate clearance (e.g. passwords)

Security of water

- Secure water wells, storage and handling facilities
- Test for potability regularly
- Identify alternate sources of potable water (treat on-site or on-site storage)

OPERATIONAL RISK ASSESMENT MATRIX

		PROBABILITY				
		Frequent	Likely	Occasional	Seldom	Unlikely
		A	B	C	D	E
SEVERITY	Catastrophic	I	Extremely High	High		Medium
	Critical	II	Extremely High	High	Medium	
	Moderate	III	High	Medium		
	Negligible	IV	Medium	Low		
		Risk Levels				

SEVERITY

- *Catastrophic* – Complete business failure due to food product contamination resulting in deaths.
- *Critical* – Major business degradation, due to food product contamination resulting in severe illnesses.
- *Moderate* – Minor business degradation, due to food product contamination resulting in minor illness.
- *Negligible* – Less than minor business degradation, and illnesses

PROBABILITY

- *Frequent* – Occurs often to individual and population is continuously exposed
- *Likely* – Occurs several times and population are exposed regularly
- *Occasional* – Will occur and occurs sporadically in a population
- *Seldom* – May occur and occurs seldom in a population.
- *Unlikely* – So unlikely you can assume it will not occur and occurs very rarely in a population.