PHR 450, F8
2/13/06, 8 pm

Operational Risk Management — Tampering and Terrorism

HACCP plans are based on the perceived probability of hazards, as you learned in the risk analysis and quantitative risk assessment lessons. Now, there is a significant trend to consider food threats that are not accidental, whereby the phrase "Food Safety and Security" is current.

We have been dealing with *food safety* since the start of the course. It is important to note that, until fairly recently, *food security* referred to one's probability of having anything to eat. That is, there is still a significant proportion of the world's population (including many in the U.S.) who, if they ate today, are not sure that they will eat again tomorrow. The new meaning of *food security* is based on concern that someone will intentionally contaminate food so as to cause consumer illnesses. Prevention in the U.S. (nationally) has been delegated to the Federal Bureau of Investigation (FBI).

The following derives from a document entitled "Food Safety and Security: Operational Risk Management Systems Approach, November 2001," presented by DHHS, US Food and Drug Administration, Center for Food Safety and Applied Nutrition. Although there are many related documents on the FDA web site, a search for this title yielded nothing.

In the new food security rhetoric, those who are likely to make food unsafe are called *aggressors*. 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 said to be required for an attack:

1. *Aggressors* — There are five primary types of aggressors: criminals, protesters, terrorists, subversives, and rogue or disgruntled insiders.
2. *Tactics used by aggressors*
    A. Exterior attacks occur from <u>outside</u> 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* — [biological, chemical, radiological, physical]

A procedure that is being taught as a means to deal with this kind of food security problem is called **Operational Risk Management**. The *rules* of ORM are said to be:

1. Accept no unnecessary risk.
2. Make risk decisions at the appropriate level.
3. Accept risk when benefits outweigh the costs.
4. Integrate ORM into planning at all levels.

There are resemblances to HACCP planning here — more to come.

Note that this bears considerable resemblance to HACCP, except that any "CCPs" will not

generally be amenable to real-time observation, establishment of critical limits, and recording. On the other hand, some approaches to pre-selected remedial measures may be applicable. Briefly, the steps are applied as follows:

Identify risks — The example presented involves restaurants. Risks are supposed to be considered from the farm on which the food is produced to the person who eats the food, with a further note that leftovers are sometimes returned to the kitchen and may have been maliciously contaminated while accessible to consumers. The specific examples are built on delivery of foods by truck and on storage, preparation, and serving of the food. Obviously, one can envision many ways that malicious tampering could occur.

Assess the risks — Here is an "Operational Risk Assessment Matrix" that has been applied:

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

Terms are defined as follows:

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 illnesses.
- *Negligible* — Less than minor business degradation, and illnesses.

Note that these categories bear a slight resemblance to the classes of recalls defined earlier in the course, except that this time the perceived "victim" is the food company, rather than the consumer.

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.

These definitions are directed to the consumer impact of an event; they are worded very imprecisely.

Application of the risk assessment matrix is presented in a very complex way. If one applies it as the designers envision, it should be possible to assign numerical ranks and priorities to the various hazards or risks that were first listed.

Analyze risk control measures — Many possibilities are discussed. Among the more concrete suggestions are:

1. Plan or design for minimum risk
2. Incorporate safety devices
3. Provide warning devices
4. Develop procedures and training

All of these are compatible with basic HACCP and could be incorporated into a HACCP plan. Many specific examples of measures applicable in restaurant operations are given and ranked according to their suitability and probable usefulness.

Make control decisions — Once a plan exists, someone needs to assess it and approve it or modify it. "Elevate the decision to a higher authority" is another suggested option.

Implement risk controls — Aspects discussed are:

- Make implementation clear
- Establish accountability
- Promote support

Again, these sound much like HACCP.

Supervise and review — This comes down to something like verification and validation. A particularly noteworthy point is "Review the ongoing cost benefit of control."

PARTS OF THE FOOD SYSTEM OUTSIDE OF RESTAURANTS ARE ALSO ADDRESSED BRIEFLY. They seem to say "don't be too trusting and do keep more records" in each of the following contexts:

- Farm/source
- Food processor (interestingly, says "Minimize the need for signs or other indicators of food product storage")
- Retail food service (may include grocery stores, as well as restaurants, or not)
- Transportation/distribution
- Security of finished products
- Security plans — This addresses corrective responses in case of an *event* and says guard

your computers and your water supply.

The California Department of Health Services had a 2004 web site for Operational Risk Management of food, but apparently has withdrawn it.

FDA documents, which are available via the internet, are:
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 21, 2003:

Guidance for Industry
Food Producers, Processors, Transporters, and Retailers:
Food Security Preventive Measures Guidance

http://www.cfsan.fda.gov/~dms/secguid6.html

November, 2003:

Guidance for Industry
Retail Food Stores and Food Service Establishments:
Food Security Preventive Measures Guidance
FINAL GUIDANCE

http://www.cfsan.fda.gov/~dms/secgui11.html

An international approach has been published by the Food Safety Department of the World Health Organization, January 31, 2003:

Terrorist Threats to Food:
Guidance for Establishing and Strengthening Prevention and Response Systems.

http://www.who.int/foodsafety/publications/general/en/terrorist.pdf