

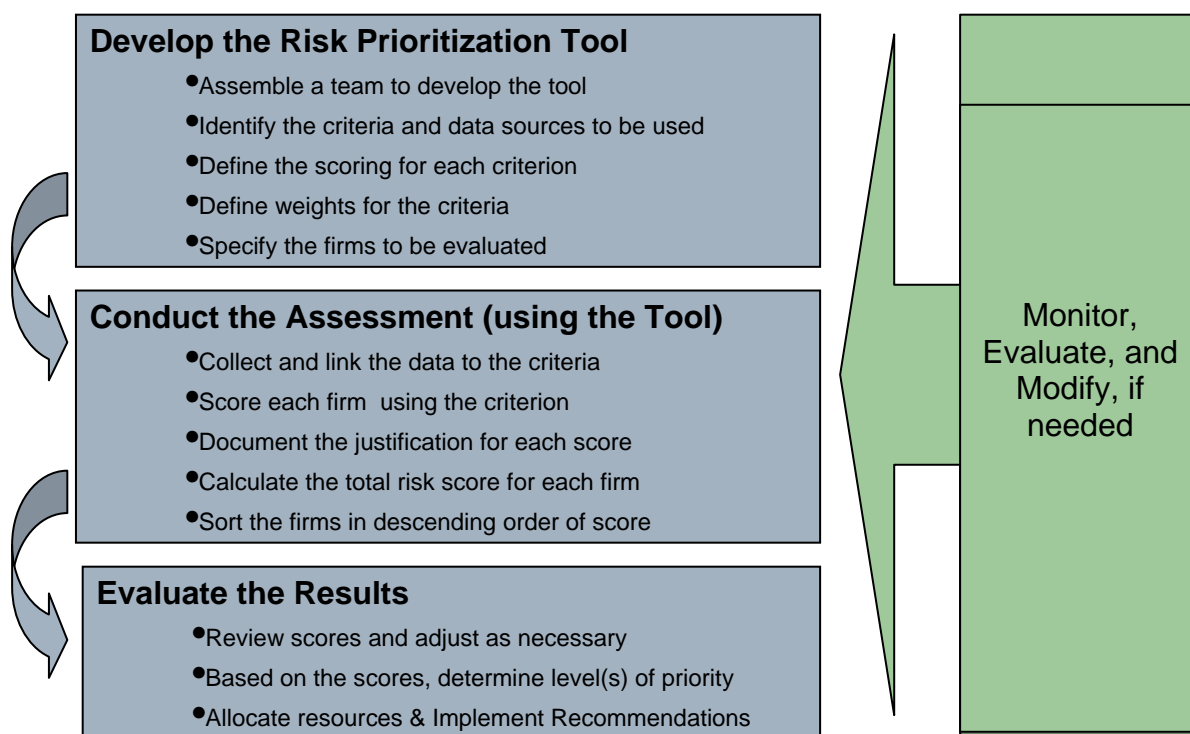


Memorandum

Date: August 9, 2011

Subject: Multi-Criteria Decision Analysis Methodology Used to Prioritize Inspection of Egg Farms for Monitoring Compliance with the Egg Safety Rule

CFSAN is developing and implementing risk based processes to more efficiently prioritize needs and allocate resources. While public health risk has always been incorporated into the decision making process for planning resource allocation, it is recognized that this process must become more transparent, standardized, and inclusive of stake holders. Over the last few years, CFSAN has made significant strides to bridge these gaps. In order to streamline its resource prioritization efforts, CFSAN has established a general procedure for developing and implementing the use of a Risk Prioritization Tool, depicted in Figure 1 below, which is the tool used for developing Egg Firm Prioritization.



Following this procedure, a public health risk based prioritization tool was conceptualized, developed, and used to systematically and transparently prioritize the egg farms that will receive comprehensive inspections under the Egg Safety Rule. The outcome is a calculated risk score for each farm. The formula to calculate the score is a sum of the criteria scores multiplied by the weighting assigned to each.

The risk score for each farm was determined using the following criteria:

1. **Production volume:** A farm's production volume is defined by the number of laying hens. Only farms with more than 50,000 laying hens were considered.
2. **Registration status:** A farm is either registered, or not registered. Non registered firms with more than 50,000 laying hens are flagged for potential inspection.
3. **Public health risk:** A farm's public health risk is a function of the number of recalls, outbreaks and consumer complaints related to the farm, Sec 421.(a)(1)(B)
4. **Other indicators:** Factors that *could* adversely impact how a farm implements food safety measures, and lead to food safety problems that adversely impact public health. Sec 421.(a)(1)(F)

FSMA Reference for criteria: Public Law 111-353-Jan. 4, 2011

TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

- (a) TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 106, is amended by adding at the end the following:

SEC. 421. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

(a) IDENTIFICATION AND INSPECTION OF FACILITIES.—

- (1) IDENTIFICATION.—The Secretary shall identify high risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors:
 - (A) The known safety risks of the food manufactured, processed, packed, or held at the facility.
 - (B) The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.
 - (C) The rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls.
 - (D) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 801(h)(1).
 - (E) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) or 806, as appropriate.
 - (F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.