codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5(b) **CX/FH 06/38/5-Add.1**
September 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-eighth Session

The Intercontinental Hotel, Houston, United States of America

APPLICATION OF FOOD SAFETY METRICS IN RISK MANAGEMENT DECISION MAKING – PASTEURIZED LIQUID WHOLE EGGS[1] AT STEP 3

(Proposed Annex to the Draft Code of Hygienic Practice for Eggs and Egg Products)

Prepared by the United States of America

Governments and interested international organizations are invited to submit comments on the document below and should do so in writing **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 20 October 2006.**

PURPOSE

This annex expands upon Section 5.2.2.2 of the Draft Code of Hygienic Practice for Eggs and Egg Products and is intended to provide the risk manager with a practical example of the development and use of food safety metrics[2]. Food safety metrics can be used to help select appropriate food

[1] To be considered on Item 5 (b) **Annex:** Microbiological Treatment and the Application of the Food safety Objectives, Performance Objectives and Performance Criteria.

[2] A food safety metric is a set of parameters to be considered in assessing the adequacy of individual aspects of a food safety system and can include: Appropriate level of protection (ALOP), food safety objective (FSO), performance objective (PO), performance criteria (PC) and related microbiological criteria (MC), product criteria (PdC), and process criteria (PrC). Existing WTO and CODEX documents define these terms.

safety control measures and to establish their relationship to public health goals. The example presented illustrates the potential impact on public health outcomes by changing one component of the food safety metric (i.e., the performance criteria associated with the microbiocidal treatment of a specific pasteurized egg product (i.e., liquid whole eggs). The example presented presumes there is an existing national or regional pasteurized egg products program and the competent authority desires to make changes in the program. These changes are necessitated in light of new information related to the prevalence and level of contamination of raw or unpasteurized egg product with *Salmonella* spp. and evidence that current microbiocidal processes for pasteurization may not be sufficient to protect public health.

Although the Code of Hygienic Practice for Eggs and Egg Products addresses both shell eggs and egg products, the example presented in this annex addresses only one specific liquid egg product. The same principles presented in this annex for calculating a food safety metric can be applied to a broader mix of formulated egg products, as well as to shell eggs.

BACKGROUND

In an effort to present a basic overview of how a change in a food safety metric could affect public health outcomes, only pure liquid whole eggs (i.e., not formulated with salt and sugar, or dried) are addressed in this annex.

In this example, the risk manager has gathered information about the egg products program with the goal of documenting the public health outcomes achieved by current programs and ascertaining whether a change in a food safety metric will improve public health. Generally, this type of information is derived from a microbiological risk assessment and other relevant risk management programs implemented by the national or regional authority[3]. The information includes:

- *Illnesses* -- The level of illness likely associated with pasteurized egg products per year.
- *Servings consumed* -- The total number of servings of pasteurized egg products per year. This example includes foods containing pasteurized liquid whole egg as an ingredient in which the foods will not undergo further microbiocidal treatment.
- *Incoming microbiological loads* -- The type and level of microbiological contamination of raw or unpasteurized egg products immediately prior to pasteurization.
- *Process lethality* -- The degree of lethality for *Salmonella* ssp. applied to egg products during pasteurization.
- *Anticipated process effectiveness*-- The estimate of what the processed egg product systems nationally or regionally are achieving relative to the target lethality.

INFORMATION NEEDED TO DEVELOP FOOD SAFETY METRICS

The following summarizes each type of information that the risk manager relied upon in calculating the food safety metrics for this example. The estimates used for the calculations of each food safety metric are also included.

[3] Information contained in this Annex is generalized, for illustrative purposes, and is based on U. S. Department of Agriculture, Food Safety and Inspection Service (FSIS), public documents, including: Regulations for processed egg products (9 CFR 590); "Percent Positive (%) of *Salmonella* in Pasteurized Egg Products, CY 1995-2005;" "Nationwide Unpasteurized Liquid Egg Products Microbiological Baseline Data Collection Programs: October 2001 – March 2003;" and the FSIS Risk Assessment on Shell Eggs and Processed Egg Products (69 FR 59575, October 5, 2004).

Estimate of illnesses: Attribution of foodborne disease from pathogens of public health concern to egg products provides a basis for informing the risk manager about the effectiveness of an established pasteurization process and the need for changing any current risk management options. Epidemiological approaches, including the analysis of outbreak investigations, case-control studies, and microbial sub-typing can be used to identify the likely sources of human infection with foodborne pathogens. Although no known outbreaks have been associated with pasteurized egg products, for purposes of this illustrative example, sporadic illnesses are likely occurring. *Salmonella* spp. have been found by the national or regional competent authority in pasteurized egg product. The predominant *Salmonella* serotypes in the pasteurized egg products also are associated with common human illness (e.g., *Salmonella* Enteritidis and *Salmonella* Heidelberg).

In the national or regional program illustrated in this annex, egg products are pasteurized and expected to be free of detectable pathogens of public health concern, particularly *Salmonella* spp. However, as a result of an inadequate microbiocidal treatment, these products could lead to adverse public health outcomes.

An inadequate microbiocidal treatment could be due to a higher level of contamination of the unpasteurized product than expected, or to misapplication of the treatment. Consequently, pathogens may survive the pasteurization process. In addition, insanitary handling practices after pasteurization could lead to inadvertent cross-contamination of pathogen-containing product with product treated to destroy pathogens. To simplify the example, post-processing contamination was not considered. Evidence of an inadequate microbiocidal treatment can be ascertained through end-product testing, aside from human illness epidemiologically linked to the product. When such testing is conducted nation- or region-wide, the results, over time, provide an indication as to how consistent the industry is in controlling for the presence of *Salmonella* spp. in pasteurized egg products.

Using a dose-response curve that relates the probability of illness to a function of the number of *Salmonella* cells consumed, a total of approximately 2,775 illnesses are predicted prior to changing the PC. Upon changing the PC and re-running the risk assessment model, the new, predicted illnesses are approximately 280. Overall, the percent reduction in human illness would be approximately 90% after changing the PC.

Servings consumed: Information about the number and size of servings of pasteurized egg products consumed in a given period of time provides an understanding of the potential exposure of the population to egg product that may be inadequately pasteurized. For the example presented in this annex, pasteurized egg products are assumed to be consumed as part of the main meal (e.g., as an ingredient in homemade mayonnaise and salad dressing). A national or regional survey of daily food intake patterns for a population can serve as the source for this type of information.

The number of available servings of the product consumed annually by the population is 47 billion, with each serving being 100 ml. In terms of the number of illnesses per 15 million servings (100 ml each), using a dose-response curve that relates the probability of illness to a function of the number of *Salmonella* cells consumed, a total of approximately 1.2 illnesses per 15 million servings are predicted. Upon changing the PC and re-running the risk assessment model, the new, predicted illnesses per serving is approximately 1.0. Overall, the percent reduction in human illness would be approximately 90% after changing the PC.

Incoming microbiological loads: Knowledge about the raw materials used to make pasteurized liquid whole eggs should be obtained. Baseline studies could be designed to identify the degree of contamination associated with *Salmonella* and other pathogens of public health concern in the raw or unpasteurized eggs. These microbiological testing results, including consideration of possible temperature abuse prior to the application of the microbiocidal treatment, represent a distribution,

including the maximum contamination that might be present at the pasteurization step. These results could be reported as the distribution of colony forming units (CFUs) per ml prior to pasteurization. These results directly impact the adequate design of the microbiocidal treatment.

The enumerative distribution of microorganisms can be expressed in a variety of ways (e.g., the geometric mean of the Most Probable Number (MPN) per ml; or the estimated mean expressed as cfu/ml). For purposes of this example, the estimated mean is used. For raw or unpasteurized whole egg product, the estimated mean is 160cfu/ml of *Salmonella* for whole egg. The distribution of the baseline MPNs was incorporated into the risk assessment and modeled in order to provide an estimate of the likelihood of survival of one or more cells of *Salmonella* following the microbiocidal treatment.

Process lethality: Lethality is a measure of the effectiveness of a treatment for eliminating the public health pathogen(s) of concern (e.g., *Salmonella* spp.). In the case of egg products, a goal in establishing an appropriate lethality could be to ensure that there is a sufficiently low likelihood of a cell of *Salmonella* surviving. By assessing the estimate of *Salmonella* in the raw or unpasteurized product from a baseline study, statistical estimates can be derived that account for the probabilities of surviving *Salmonella* in the post-pasteurized product, at various lethality levels, reported as the $\log_{10}$ reduction treatment. A variety of D-values was assessed in order to account for the common serotypes of *Salmonella* found in pasteurized egg products, and the risk assessment was used to model the effect of the D-value on the number of predicted illnesses. In addition to ensuring that there is a sufficiently low likelihood of a cell of *Salmonella* surviving the microbiocidal treatment, for a fixed amount of product consumed (100 ml is the assumed size of a serving, for calculation purposes), the risk manager can devise the microbiocidal treatment requirement to ensure that there also is a sufficiently low likelihood of survival of the pathogen in a high percentage of samples consumed.

Since proper pasteurization of liquid egg product is dependent upon exposure of every particle to the microbiocidal treatment for the necessary amount of time, the proper design and operation of pasteurization equipment, including adequate consideration of fluid dynamics and the degree to which turbulent flow is achieved, is critical to assure the delivery of an effective treatment.

The established overall process lethality for *Salmonella* in the national or regional program is 4.7 $\log_{10}$ reduction for liquid whole eggs. Risk assessment data suggesting inadequate lethality of existing processes recommended increasing the process lethality to 6.0 $\log_{10}$ reduction for liquid whole eggs. The treatment is designed at the 95% upper confidence bound tolerance for the 95^{th} percentile of the distribution of the probabilities of a cell of *Salmonella* surviving among 100 ml samples of pasteurized product not being greater than 10%.

Anticipated process effectiveness: By assessing the actual temperature and time combination, as well as the formulation of ingredients incorporated into the egg product, the flow characteristics during the process, and pH, estimates can be made regarding the actual lethality achieved during pasteurization. Such information can be acquired through a survey of national or regional industry practices. Such information provides an understanding as to the minimum level of lethality that is being applied to pasteurized egg products in the national or regional program. As noted above, current industry practice is achieving a 4.7 $\log_{10}$ reduction of *Salmonella* spp. in liquid whole eggs

OVERVIEW OF FOOD SAFETY METRIC CALCULATIONS

In this example, pasteurized egg products are assumed to be produced in a country where a pre-existing regulation specifying a particular microbiocidal treatment to eliminate pathogens was established at a time prior to the use of a risk assessment. Consequently, the design of the

regulations may not have been explicitly tied to a specific public health goal. During the intervening years, a risk assessment on pasteurized egg products was conducted. Using information derived from existing regulations (e.g., the current process effectiveness) and the new risk assessment, food safety metrics can be back-calculated, as follows (See Table 1 for a summary of the food safety metric results):

Appropriate Level of Protection (ALOP) – The ALOP is intended to represent the level of public health protection that is actually achieved. In order to articulate a measure of the level of public health protection in relation to pasteurized egg product safety, a risk assessment can be used. The risk assessment estimate of illness can be tied to the most likely number of human illnesses associated with pasteurized egg products, predicted from food attribution estimates and other public health investigative approaches.

In this example, the contribution of human illness associated with the current pasteurization program for whole egg products is estimated to result in approximately 2,775 illnesses annually, or 1.2 illnesses per 15 million servings (100ml each). Although the estimated number of illnesses associated with the current pasteurization program (ALOP) is being tolerated by the national or regional program, the risk manager now has new evidence derived from the baseline study of raw or unpasteurized product and a survey of processing capability achieved, which suggest that the microbiocidal treatment is no longer adequate. The risk manager has concluded that, through the data collected in the baseline study of raw or unpasteurized egg product, the level of contamination is higher than previously thought. Moreover, through a survey of industry practices, some pasteurization processes are now known to achieve a lethality that may not be adequate to consistently destroy *Salmonella.* Consequently, the current regulatory requirement for the microbiocidal treatment (i.e., the Performance Criteria – PC) is not adequate to ensure that there is a sufficiently low likelihood of *Salmonella* surviving the pasteurization treatment nationally or regionally. Evidence to support the risk manager's determination includes the following: *Salmonella* has been found in end-product tests over the previous few years even when the operators of the pasteurization treatments followed the regulatory requirements; and there was no evidence of post process contamination.

The competent authority has identified that the national or regional program must reduce the number of illnesses associated with pasteurized whole egg product by at least 90%. Consequently, the ALOP remains as currently described until the new PC is implemented, whereby a new ALOP can be articulated. Other food safety metrics are affected by the risk management decision to change the PC, as described below.

Food Safety Objective (FSO) – In order to articulate a measure of the maximum frequency of a hazard in pasteurized egg products currently tolerated in support of the ALOP, the value is determined by the risk manager to be the same as that for the ALOP. However, for this example, since the competent authority has identified that the current level of illness is too high and must be modified, the best representation of the FSO is the percent reduction in human illness resulting from a planned change in the PC. The competent authority has determined that a 90% reduction in the number of illnesses is necessary for protection of public health. Using a risk assessment, the maximum frequency in which *Salmonella* can be present in a serving can be estimated.

Performance Objective (PO) – Pasteurized egg products are expected to be free of detectable, viable pathogens of public health concern. Thus, for purposes of this example, end-product samples collected by the competent authority are expected to have fewer than 1cfu of *Salmonella* in 100ml of product using laboratory techniques capable of detecting *Salmonella* at this level.

Performance Criteria (PC) – For this example, at the time that the pasteurized egg product regulation and policies were established by the competent authority, it was presumed that the microbiocidal treatment would result in an adequate reduction in *Salmonella*. The regulatory requirements for the microbiocidal treatment expected specified a prescribed time and temperature to be achieved (see the discussion on Process Criteria – PrC below). However, over time, added ingredients in the various product formulations, as well as elevated distributions of contamination in raw or unpasteurized product, may have contributed to a decreased control of *Salmonella*, while still meeting the prescribed time and temperature requirements. The risk manager has determined that a more rigorous PC is necessary in order to ensure that the PO is met and that viable pathogens of public health concern are adequately destroyed. Using the risk assessment model, an estimate of the human health impact resulting from a change in the PC can be assessed.

Using new baseline data on the distribution of contamination in raw or unpasteurized egg products, a new microbiocidal treatment level was prescribed by the risk manager. Calculation of the microbiocidal treatment level was based on the distribution of contamination of the pre-pasteurized product such that: 1) A sufficiently low likelihood that a cell of *Salmonella* will survive the microbiocidal treatment for a fixed amount of product consumed (e.g., the 95% upper bound to the 95th percentile of the distribution of contamination); and 2) there is a sufficiently low likelihood of survival of the pathogen in a sufficiently high percentage of samples tested (e.g., the microbiocidal treatment is sufficient to ensure that for a 100 ml sample containing this upper bound level, there would be no greater than a 10% chance of surviving *Salmonella)*.

Microbiological Criteria (MC) – Pasteurized egg products are expected to be free of detectable, viable pathogens of public health concern. Although pasteurized liquid egg products generally require refrigeration (i.e., the product is not sterilized), temperature abuse during handling and distribution throughout the food distribution chain and by the consumer is not likely to result in appreciable growth of surviving cells of the pathogen. Thus, for purposes of this example, any sample of pasteurized product is expected to have fewer than 1cfu of *Salmonella* in 100 mls of product. Any sampling plan, particularly one that is designed to have high confidence of detecting low level contamination, would require a substantially large number of samples. Such sampling might not be practical to conduct on a routine basis. Monitoring and verification of the production process in order to demonstrate that the validated microbiocidal treatment is properly applied are necessary on an on-going basis.

Product Criteria (PdC) – For liquid, pasteurized egg products, there are no known physical or chemical attributes of the product that if properly applied as a control measure would ensure that pathogens of public health concern are adequately controlled.

Process Criteria (PrC) – For this example, in order to articulate how the industry could meet the PO and MC, the competent authority established one prescribed time and temperature combination for whole pasteurized egg product. To illustrate how the PrC differs for the new PO versus the existing PO, the PrC is reported for 3.5 minutes. Other combinations of time and temperature are feasible provided that an equivalent level of public health protection can be achieved. To determine the appropriate time and temperature combination of the PrC necessary to achieve a given PO for pasteurized whole egg product, a thermal death curve of *Salmonella* in the egg product matrix is necessary. Generally, such information is available in published literature. For illustrative purposes, the following is a step-by-step description of how to determine the PrC for the example in this annex:

Determining the PrC:

- Step 1: Obtain the thermal death curve for *Salmonella* in pasteurized whole egg product.

- Step 2: Identify the D-value and z-value for a given $\log_{10}$ reduction at a given temperature[4].
- Step 3: Determine the required log reduction.
- Step 4 Calculate the time needed at a specific temperature to achieve the desire log reduction.[5]

Table 1 – Summary of Food Safety Metric Results

Processed Egg Product Type	**ALOP**	**FSO**	**PO**	**PC**	**MC**	**PdC**	**PrC**
Liquid Whole Egg	Current ALOP: 2,775 illnesses annually, or less than approximately 1.2 illnesses per 15 million servings annually Target ALOP: 280 cases of illness annually	Projected 90% reduction in illnesses from current ALOP (280 illnesses annually, or less than approximately 1.0 illnesses per 15 million servings annually)	Less than 1cfu/100ml	Old PC = 4.8 $\log_{10}$ reduction New PC = 6.0 $\log_{10}$ reduction	n/p	n/a	Old PrC = 61.1 degrees Celsius (142 degrees Fahrenheit for 3.5 minutes) New PrC = 61.6 degrees Celsius (143 degrees Fahrenheit for 3.5 minutes)

[4] D value (decimal reduction time) is the time required to destroy 90 % of the microorganism of concern a specified temperature. Z value is the temperature required for a 90% reduction in a microbial population derived from the thermal death time curve.

[5] Calculation of the required temperature or time needed to destroy microorganisms are defined in microbiological textbooks. An example of these calculations is as follows: In Equation 1: Z = (T1-T2)/ (log D2-log D1) where Z = z value, D1 is the D value at time T1 and D2 is the D value at time T2; in Equation 2: T2 =T1 + Z (log D1-log D2) where D1 = 0.74, T1 = 61.1 degrees C, Z = 4.8 degrees C, and the D value at 3.5 minutes (D2) = 3.5/6.0 = 0.5883; and to calculate T2 at 3.5 minutes, substitute in Equation 2: T2 = T1 + Z(log D1-log D2) -- T2 = 61.1 + 4.8 (log 0.74 - log 0.5883) = 61.6 C.