Q1. What frequently visited websites are available to establishments to assist them in making decisions in their hazard analysis?

A1. Information may be available through:

FSIS web site: Resources for Small/Very Small Plants http://www.fsis.usda.gov/Small_Very_Small_Plants/index.asp

Supporting Documentation Materials for HACCP Decisions: From Ohio State University http://www.ag.ohio-state.edu/~meatsci/HACCPsupport.html

National Agricultural Library http://www.nal.usda.gov/

PubMed http://www.ncbi.nlm.nih.gov/entrez/query.fcgi

International HACCP Alliance: http://haccpalliance.org/

Q2. Is an establishment required to use a Mercury-in-Glass (MIG) thermometer as a known standard when performing calibration of thermometers?

A2. No. It is the establishment's responsibility to provide support for the procedure that it uses to calibrate its process-monitoring instruments (e.g. thermometers) to ensure that the instruments are accurate [9 CFR 417.5(a)(2)]. Use of a certified MIG thermometer is recognized as an accurate standard; however, establishments may use other methods or equipment to verify accuracy of thermometers.

Q3. What is the difference between the pre-shipment review required by 9 CFR 417.5(c) and the review of HACCP records required by 9 CFR 417.4(a)(2)(iii)?

A3. Pre-shipment review, as described in 9 CFR 417.5 (c), involves a review of records associated with a specific production of product or establishment designated lots before it is shipped into commerce. The review includes a check to ensure that all critical limits at all CCPs have been met, and that any required corrective actions have been taken. Conversely, an establishment's review of its HACCP records required by 9 CFR 417.4(a)(2)(iii) is an on-going review of records not specifically tied to a production lot. The review under 9 CFR 417.4(a)(2)(iii) provides a snapshot of the broader operation. This ongoing record verification is used by the establishment to ensure that the HACCP records are being completed as designed in their HACCP plan [9CFR417.2(c)(6)] and to ensure that the records demonstrate compliance with 9 CFR 417.5(a)(3) requirements.

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Finally, it is used to ensure that the plant's HACCP system is operating appropriately and is under control.

Q4. If an establishment determines in its hazard analysis that there are no potential food safety hazards, is a justification statement required?

A4. When an establishment conducts a hazard analysis, it assesses its production process to determine whether any food safety hazards are reasonably likely to occur in that process [9 CFR 417.2(a)(1)]. The establishment then records the determinations that it makes as a result of this assessment. The establishment may include statements such as "no hazards identified at this step" in the record of its assessment. Statements of this type are self-explanatory and may be used without a justification statement. FSIS may, however, question any determination in the hazard analysis if, for example, historically a food safety hazard can occur, or new information becomes available regarding a particular process having a potential food safety hazard.

Q5. What is required on a HACCP record documenting ongoing verification activities?

A5. The regulations require that the records documenting an establishment's verification procedures [9 CFR 417.2(c)(7)], as outlined in its HACCP plan, include:

- 1. the verification procedure to be performed in accordance with 9 CFR 417.4(a)(2),
- 2. the results of the verification procedure performed [9 CFR 417.5(a)(3)], and
- 3. the date, time recorded, and signature or initials of the establishment employee making the entry [9 CFR 417.5(b)].