UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

8091.1
Rev. 1

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PROCEDURES FOR THE FOOD SAFETY AND INSPECTION SERVICE (FSIS) HEALTH HAZARD EVALUATION BOARD (HHEB)

I. PURPOSE

This directive describes the procedures that members of the HHEB are to follow to evaluate the public health risk of potential human health hazards associated with meat, poultry, or egg products. This directive is being reissued in its entirety to update the HHEB procedures and to address issues that the Agency has identified since the directive was first issued in October 2001.

KEY POINTS:

- *Updates current procedures*
- *Describes 3 ways HHEB requests are received*
- *Includes procedures for communicating and tracking HHEB conclusions*

II. CANCELLATION

FSIS Directive 8091.1, Procedures for the Health Hazard Evaluation Board, 10/22/01

III. BACKGROUND

The HHEB serves as the primary group in FSIS to evaluate the public health risk of potential human health hazards associated with meat, poultry, or egg products. The HHEB is convened on an ad hoc basis for acute events that must be resolved in a limited amount of time, generally hours to days. The purpose of the HHEB is to address situations involving potential human health hazards (physical, biological, or chemical) when the Agency is uncertain about the nature or severity of the human health risk and needs additional information to inform its response. The HHEB reviews available scientific information to assess the public health risk associated with potential hazards and draws conclusions to inform Agency decisions. The HHEB does not decide what action the Agency should take in response to a potential hazard. In general, the HHEB is not convened to address situations that can be resolved by applying existing laws, regulations, or policies.

IV. HHEB MEMBERS

A. The Applied Epidemiology Staff (AES) Director or designee from the Office of Public Health Science (OPHS) is to serve as the HHEB chair.

B. A representative from the Office of Policy and Program Development (OPPD) is to serve as a standing member of the HHEB and is to participate in the HHEB regardless of the hazard to be considered. The OPPD representative will be the Policy Development Staff (PDS) Director or designee or the Risk, Innovations, and Management Staff (RIMS) Director or designee.

C. A physician from OPHS, when available, is to serve as a standing member for every HHEB regardless of the hazard to be considered.

D. The HHEB chair is to determine the ad hoc members of an HHEB based on the hazard that the HHEB has been asked to evaluate. HHEB members may include health scientists, microbiologists, toxicologists, veterinarians, risk analysts, epidemiologists, food technologists, statisticians, and other relevant experts within FSIS.

E. The HHEB chair is to invite representatives from other FSIS programs, such as Office of Field Operations (OFO) District Office (DO) staff and inspection program personnel (IPP), the Office of Investigation, Enforcement, and Audit (OIEA), or the Office of Management (OM) Employee Safety, Health, and Wellness Staff, if input from these programs is needed to inform the evaluation. The role of these program representatives is to describe the events that led to the concern that FSIS-regulated products may present a risk to human health and to provide information to help the HHEB properly evaluate the extent and significance of the risk.

F. The HHEB chair is to determine whether there is a need to invite subject matter expert (SMEs) external to FSIS to participate in an HHEB on a case-by-case basis. External SMEs that may serve on the HHEB include officials from other Federal agencies, State agency officials, or academic experts.

V. HHEB REQUEST SUBMITTED DIRECTLY TO OPHS AA

A. The FSIS Administrator, Deputy Administrator, or any AA may submit a request to convene an HHEB to the OPHS AA.

B. Other Agency personnel are to report situations in which the HHEB may need to be convened to their program AAs through supervisory channels.

C. A request to convene the HHEB may be oral or written.

D. After the OPHS AA receives a request to convene the HHEB, he or she is to contact the AES Director and provide the available information on the potential hazard the HHEB has been asked to evaluate.

VI. HHEB REQUESTS IDENTIFIED THROUGH ASKFSIS

A. OFO personnel, in consultation with the Public Health Veterinarian (PHV), Front Line Supervisor (FLS), and the DO are to report incidents involving potential human health hazards associated with meat, poultry, or egg products that are still under the establishment's control through askFSIS.

B. When OPPD receives a report of an incident through askFSIS that involves a potential human health hazard, the OPPD staff officer assigned to the incident is to evaluate the issues involved, along with any supporting documentation, and consult with Agency SMEs in OPHS as necessary to determine the appropriate disposition of the product.

C. After assessing the askFSIS incident, the OPPD staff officer is to provide technical information for the DO and OFO personnel that reported the incident to consider in determining the appropriate disposition of the affected products.

D. If an incident involving a potential human health hazard reported through askFSIS involves a complex or novel issue that cannot be resolved through the standard procedures described above, including issues associated with chemical residues, the OPPD staff officer assigned to the incident is to notify the OPPD AA through appropriate supervisory channels. Some examples of complex or

novel incidents that have been addressed by HHEBs in the past include inadvertent addition of hand sanitizer to a poultry chiller; inadvertent incorporation of a mercury thermometer into product during processing; and the intentional application of an EPA-registered insecticide to treat live cattle for flies 45 minutes before slaughter when the material safety data sheet (MSDS) stated that cattle may be slaughtered 3 days after treatment. Complex or novel incidents will generally be identified on a case-by-case basis.

E. If the OPPD AA believes that an HHEB should evaluate an incident reported through askFSIS, he or she is to contact the OPHS AA and request that an HHEB be convened. The OPPD AA is to consider the factors in section VIII. A. of this directive to determine whether to request an HHEB.

NOTE: If OFO IPP or other FSIS personnel contact OPHS directly regarding an incident involving a potential human health hazard, OPHS personnel are to inform the OPHS AA. FSIS personnel contacting OPHS directly are to also notify their appropriate management authorities. The OPHS AA will determine whether the incident should be submitted to the HHEB for consideration.

VII. HHEB REQUESTS SUBMITTED THROUGH RECALL COMMITTEES

A. Recall Committees are to follow the procedures in section II. I. of FSIS Directive 8080.1, "Recall of Meat and Poultry Products," if they need to determine the human health risk associated with adulterated or misbranded products that have entered commerce.

B. Recall Committees are to reference existing precedents to assess the need to recall a meat or poultry product. They are also to consult with Agency SMEs and reference existing precedents to determine the significance of the human health risk associated with the affected product.

C. If a Recall Committee is unable to effectively assess the potential human health risk associated with a meat or poultry product because the situation under consideration involves a complex or novel issue for which there is no existing precedent or policy, the Recall Management and Technical Analysis Staff (RMTAS) Director or designee is to notify the OFO AA.

D. If the OFO AA determines that an HHEB should evaluate an incident involving a product that is the subject of a recall, he or she is to contact the OPHS AA and request that an HHEB be convened. The OFO AA is to consider the factors in section VIII. A. of this directive to determine whether to request an HHEB.

VIII. PRELIMINARY CONSIDERATIONS BEFORE CONVENING AN HHEB

A. When they are notified of a situation involving a potential human health hazard, either through askFSIS or a recall situation, the AA OPPD and AA OFO are to consider the following questions to determine whether to request that the AA OPHS convene an HHEB.

1. Is there an Agency regulation or policy that addresses the hazard?

2. If there is a regulation or policy, is it sufficient to address any potential human health risk that may be associated with the hazard?

3. Even with the existence of a regulation or policy, is there a need to evaluate the hazard in light of the potential public health risk?

B. If the AA OPHS accepts a request for an HHEB and submits it to the AES Director, the AES Director or designee is to determine whether it is necessary to convene an HHEB. The only reason not to convene an HHEB is if another HHEB has evaluated the same or a similar hazard in the past and the circumstances involving the current hazard are similar enough for the Agency to rely on the

previous evaluation.

C. If, after conducting a preliminary review, the AES Director or designee determines that an HHEB is not needed because a previous HHEB has evaluated the same or a similar hazard, he or she is to inform the AA OPHS. If the AA OPHS agrees with the determination, he or she is to inform the AA that submitted the HHEB request and provide the results of the prior HHEB evaluation.

D. If, after conducting a preliminary review, the AES Director or designee determines that an HHEB is needed to evaluate the hazard, he or she is to chair the HHEB and follow the procedures in section IX of this directive.

IX. PROCEDURES TO CONVENE THE HHEB

A. When an HHEB is needed to evaluate the public health risk associated with a potential human health hazard, the HHEB chair is to identify the appropriate HHEB members and inform them when the HHEB will convene. The HHEB chair is to forward to the members any available information on the potential hazard that the HHEB has been asked to evaluate.

B. The HHEB chair is to schedule the HHEB meeting. The HHEB chair is to ensure that all HHEB members, as well as representatives of the FSIS program that identified the need to convene the HHEB, are invited to participate.

C. When the HHEB is convened, the HHEB chair is responsible for facilitating the meeting and documenting the HHEB's deliberations and conclusions. Documentation of HHEB data and information, analysis, deliberations, and conclusions is to be stored for future reference following procedures in section X of this directive.

X. HHEB DELIBERATIONS

A. Before the HHEB begins to evaluate the public health risk associated with a potential hazard, the FSIS program that initiated the request for the HHEB is to present the situation to the HHEB.

B. After the initial presentation of the potential hazard, the HHEB will conduct the following activities to proceed with its deliberations.

1. A review of the establishment's documentation of the incident, including toxicological assessments, mitigations already implemented and, as applicable, reconditioning plans for the affected products.

2. A review of each HHEB SME's scientific literature, available data, calculations with respect to the concentration of the potential hazard in the product, potential level of human exposure to the hazard, and other relevant calculations and perspectives, including:

    a. Previous calculations if they were done for a similar situation in the past;

    b. Current calculations and how they differ from previous calculations; and

    c. The HHEB SME's perspective on how these calculations apply to the situation that the HHEB has been asked to evaluate.

3. A presentation by the OPHS physician on the medical literature, available data, calculations with respect to the concentration of the potential hazard in the product, potential level of human exposure to the hazard, and other relevant calculations and perspectives, including:

a. Previous calculations if they were done for a similar situation in the past;

b. Current calculations and how they differ from previous calculations; and

c. The medical perspective on how these calculations apply to the situation that the HHEB has been asked to evaluate.

4. A scientific discussion among all HHEB members to assess the available information.

C. When the HHEB conducts an evaluation of a potential human health hazard associated with an FSIS-regulated product, it is to assess:

1. The potential health hazard of concern, (e.g., physical, biological, or chemical);

2. The distribution of the potential hazard within the affected product, (e.g., is product affected by the potential hazard limited to a few units or is the potential hazard evenly distributed throughout the production lot?);

3. Any disease or injuries that have already occurred, or that could potentially occur, from the ingestion of the product;

4. The potential adverse health effects to relevant segments of the population, including children, pregnant women, immune-compromised persons, or the elderly who are expected to be exposed to the affected product, with particular attention paid to the adverse effects to those individuals who may be at greatest risk;

5. The severity of the adverse health effects that exposure to the potential hazard could have on the general population and sub-populations that may be at greater risk; and

6. The level of exposure to the hazard (dose) needed to impact human health on an acute or chronic basis.

D. The HHEB is to determine the nature and severity of the public health risk associated with the potential hazard it has been asked to evaluate on a consensus basis. The HHEB's characterization of the risk is to address the factors described above.

XI. COMMUNICATING AND TRACKING THE HHEB'S CONCLUSIONS

A. HHEB members are responsible for submitting documentation, calculations, scientific literature, analyses, and assessments to the HHEB Chair prior to the Board meeting.

B. The HHEB chair is responsible for drafting a concise written summary of the HHEB's deliberation and conclusions. The HHEB chair is to submit the initial draft summary to the OPHS AA and the HHEB members for review and clearance.

C. The HHEB chair is to close the HHEB after all HHEB members have concurred with the write-up and conclusions.

D. The OPHS AA is to give the final written summary to the AA or other Agency official who requested the evaluation of the hazard.

E. When the HHEB chair closes an HHEB, he or she is to assign a tracking number and post the written summary and any supporting documentation to the HHEB tracking system on the OPHS SharePoint site.

XII. DATA ANALYSIS

The AES/OPHS will review the HHEB summaries entered into the HHEB tracking system and analyze the data to identify new or emerging issues identified through the HHEB's evaluations. This analysis will be completed quarterly, and compiled and shared with relevant FSIS personnel yearly.

XIII. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 8091.1**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select "**General Inspection Policy"** from the drop-down menu.
Category Field:	Select **"Regulations/Agency Issuances"** from the drop-down menu. from the drop-down menu.
Policy Arena:	Select **"Domestic (U.S. only)"** from the drop-down menu.

When all fields are complete, press **Continue.**

Assistant Administrator
Office of Policy and Program Development