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

FSIS DIRECTIVE

8091.1

10/22/01

PROCEDURES FOR THE FSIS HEALTH HAZARD EVALUATION BOARD

I. PURPOSE

This directive explains the duties of the FSIS Health Hazard Evaluation Board (HHEB) and the procedures the HHEB follows when evaluating meat, poultry, and egg products to determine whether their consumption may pose a human health risk.

II. CANCELLATION

FSIS Directive 10,530.3, Contamination Response System (CRS) dated 3/23/93.

III. [RESERVED]

IV. REFERENCES

The Meat, Poultry, and Egg Products Inspection Regulations.

FSIS Directive 8080.1, Revision 3 - Recall of Meat and Poultry Products.

V. POLICY

Under the HACCP system regulations at 9 CFR § 417.1, a food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. Biological hazards are infectious agents (including living organisms and prion proteins) that can make food unsafe to eat. Chemical hazards can be either naturally-occurring or added. Physical hazards are extraneous materials that are not expected in a food that may cause illness or injury.

VI. What is the HHEB and what is its purpose?

A. The HHEB will be the primary group that reviews the public health significance of any human health hazard about which a regulatory decision needs to be made by the Agency.

B. The purpose of the HHEB is twofold. First, when there is reason to be concerned, but no definitive determination, as to whether a product that is about to enter or has entered commerce may be injurious to health, the HHEB would be called upon to assess the nature and severity of the hazard and to provide information to the Agency for an Agency decision on regulatory action, (e.g., withhold the marks of inspection, request a recall, detention or seizure of product). Second, the HHEB would be called upon in other than emergent situations to provide an assessment of product safety (e.g., an assessment regarding the toxicity of a foreign material found in product). The HHEB does not decide on or recommend regulatory or other action but provides information for such decisions or recommendations.

C. The HHEB will rapidly communicate information from its meetings concerning a human health hazard to the Deputy Administrator, Office of Public Health and Science (see section X of this Directive).

VII. Who comprises and leads the HHEB?

A. The HHEB is an ad hoc committee composed of representatives from various offices within FSIS. The Director of the Human Health Sciences Division (HHSD), Office of Public Health and Science (OPHS), at the request of the Administrator, Associate Administrator, or any Deputy Administrator, convenes and chairs the HHEB. The HHEB may include physicians, health scientists, microbiologists, toxicologists, veterinarians, chemists, program analysts, epidemiologists, food technologists, and other relevant experts from within FSIS.

B. The minimum membership of the HHEB will include one physician, one epidemiologist, and one representative from the Office of Policy, Program Development and Evaluation.

C. Other government (either Federal or State) experts from outside FSIS or one non-governmental expert (for example from academia, non-governmental scientists, public health experts or from industry that is not tied to the specific problem) may also be called to participate, when appropriate.

VIII. When is the HHEB convened?

A. The HHEB is convened at the request of the Administrator, Associate Administrator, or any Deputy Administrator when the Agency is presented with a situation in which a human health hazard needs to be evaluated. The need may be raised by the FSIS Administrator; FSIS staff members, including the Technical Service Center and Field Operations Staff; the FSIS Recall Committee; or industry. The official requesting the HHEB will provide the chair of the HHEB with a written statement of the human health impact assessment needed for an Agency decision.

B. The HHEB does not meet on matters that are covered by an existing Agency precedent (e.g., an FSIS regulation). However, an appropriately empowered Agency official (the Administrator, Associate Administrator, or any Deputy Administrator) may decide that it is appropriate to have the HHEB reconsider an existing precedent.

C. Decisions of the HHEB on the nature and severity of a hazard or the safety of a product will be made on a consensus basis. (Consensus is to be among the members of the HHEB with a scientific background.)

IX. How does the HHEB conduct its evaluations?

A. When the HHEB conducts an evaluation of a health hazard that may be presented by a product, it will assess:

1. any disease or injuries that have already occurred from the ingestion of the product.

2. the potential health hazard to relevant segments of the population, including children, immuno-compromised persons, or the elderly who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

3. the degree of seriousness of the health hazard to which the populations at risk would be exposed.

4. the likelihood of occurrence of the hazard.

5. the consequences (immediate or long-range) of occurrence of the hazard.

NOTE: It is not the purpose of the HHEB to duplicate the processes of the Recall Committee, nor is it the purpose of the HHEB to participate in every meeting associated with every potential food product recall.

X. How and to whom will the HHEB report its findings?

The HHEB provides a concise written summary of its deliberations, signed by the Chair (with members listed), to the Deputy Administrator, OPHS. Supporting documentation is submitted as appendices to the summary if needed. The Deputy Administrator, OPHS, will provide the written summary to the appropriate decision-maker, (e.g., Administrator, Associate Administrator, or Deputy Administrator) for consideration.

/s/
Philip S. Derfler

Deputy Administrator
Office of Policy, Program Development
And Evaluation