# FSIS DIRECTIVE	8091.2	12/1/16

PROCEDURES FOR THE HAZARD IDENTIFICATION TEAM

I. PURPOSE

This directive describes the role of the Hazard Identification Team (HIT) that was established for managing the process of tracking, evaluating, and prioritizing potential emerging or evolving food safety risks related to meat, poultry, and egg products. The HIT is the Agency's central body for tracking these identified food safety risks within FSIS and bringing them into FSIS's broader enterprise governance (EG) decision-making process, described in FSIS Directive 1040.1, *The FSIS Enterprise Governance Decision-making Process*. This directive also describes the process by which any FSIS employee can submit an issue to the HIT and the procedures members of the HIT are to follow once an issue has been submitted.

II. BACKGROUND

A. The HIT, located in the Office of Public Health Science (OPHS), provides a systematic, proactive approach to evaluate and track identified emerging or evolving food safety issues and makes scientific recommendations to the OPHS Office of the Assistant Administrator (OAA) about whether the Agency should focus additional resources to further assess or address the issues. Emerging or evolving issues that are identified and determined to pose a potential "high risk" will be presented to FSIS's EG triage and joint boards as part of a broader, coordinated effort to prioritize and consider these issues.

B. FSIS adopted the internationally accepted definition and evaluation criteria for emerging food safety risks (FAO 2013[1], FAO 2015[2]). These risks are defined as "a risk that results from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure or susceptibility to a known hazard."

NOTE: The internationally accepted definition of an emerging risk and criteria were adapted from the Emerging Risk Identification Program.[3]

C. As such, the HIT serves as the focal point for information related to emerging or evolving food safety issues for FSIS and is tasked with anticipating, identifying, and evaluating emerging food safety risks. The HIT serves as a primary pathway through which an emerging or evolving food safety issue and any corresponding risk evaluation findings and scientific recommendations are brought to the attention of the Management Council (MC). The OPHS OAA, or designee, will bring forward HIT-identified high priority issues to EG triage and joint boards. The information and recommendations HIT provides to the EG boards are central to the Agency's decision-making on emerging food safety issues.

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[1] Food and Agriculture Organization of the United Nations. 2013. Horizon scanning and foresight: an overview of approaches and possible applications in food safety. Rome (available at: http://www.fao.org/3/a-i4061e.pdf).
applications in food safety. Rome (available at: http://www.fao.org/3/a-i4061e.pdf).
[2] Food and Agriculture Organization of the United Nations. 2015. *Enhancing Early Warning Capabilities and Capacities for Food Safety*. Rome, Italy.
[3] European Food Safety Authority.2007. Definition and description of "emerging risks" within the EFSA mandate. EFSA/SC/415 final. Parma, Italy (available at: http://www.efsa.europa.eu/en/scdocs/doc/escoemriskdefinition.pdf).

D. The HIT is coordinated by representatives from the following three OPHS staffs:

   1. Applied Epidemiology Staff;

   2. Risk Assessment and Analytics Staff; and

   3. Science Staff.

E. The HIT Charter can be found at: FSIS Hazard Identification Team Charter.

III. HIT MEMBERS AND THEIR RESPONSIBILITIES

A. The HIT Coordinators, three representatives from the separate OPHS staffs listed in paragraph II. D., are responsible for:

   1. Managing the HIT process from identification of potential emerging or evolving food safety issues, through evaluation and prioritization of these issues, to communication of risk evaluation findings and scientific recommendations to the OPHS OAA, which involves:

      a. Communicating across FSIS to encourage and support the submission of identified potential emerging or evolving food safety issues that may influence the Agency's decision-making;

      b. Conducting an initial review (i.e., "triage") of potential emerging or evolving issues using established risk evaluation criteria (i.e., potential public health impact, novelty, soundness, imminence, scale, and severity);

      c. Presenting the issues and the initial triage prioritization to the HIT Steering Committee (see paragraph B in this section) for final prioritization designation;

      d. Tracking and maintaining a detailed record of each issue and its current status on the HIT SharePoint site, the group's central information-management system; and

      e. Conducting periodic reevaluations of previous low- and medium-priority issues annually or when new scientific information becomes available to determine whether these issues are evolving into larger concerns or a higher priority;

   2. Meeting on a weekly or ad hoc basis as needed to discuss newly identified or evaluated issues;

   3. Providing regular reports to the OPHS OAA, OPHS Leadership Team, and the Data Coordination Committee (DCC);

   4. Supporting the formation of HIT Task Forces as needed to further evaluate high-priority issues; and

   5. Working closely with OPHS Directors and OAA to ensure emerging issues are considered in strategic, operational, and research planning.

B. The HIT Steering Committee, made up of OPHS Directors and chaired by the OPHS Assistant Administrator (AA), or AA designee, is responsible for:

1. Determining the final prioritization of the identified emerging issues initially evaluated by the HIT Coordinators;

2. Deciding whether or not to form a HIT Task Force, taking into strategic consideration OPHS resources, to further evaluate high-priority issues;

3. Establishing a timeline for completion of an evaluation of an emerging issue for presentation to the OPHS OAA; and

4. Evaluating Task Force findings and finalizing scientific recommendations for presentation to the OAA for strategic planning purposes and consideration as part of FSIS's broader EG and decision-making process.

NOTE: As necessary, the HIT coordinators, on behalf of the HIT Chair, are to invite senior leadership from other program areas to attend HIT Steering Committee meetings and provide input to the HIT Steering Committee.

C. HIT Task Forces, ad hoc task forces typically made up of 2-4 OPHS subject matter experts, are responsible for:

1. Characterizing emerging food safety issue risks based on the established risk evaluation criteria;

2. Preparing a brief report on findings within a short time period (≤45 days); and

3. Making preliminary scientific recommendations to the HIT Steering Committee, for finalization and subsequent presentation to the OPHS OAA for possible further consideration as part of FSIS's broader EG and decision-making process.

D. Task forces convened on an ad hoc basis have a precedent in OPHS's Human Health Evaluation Board (HHEB) and provide information on a specific assigned topic within a short timeframe. An HHEB is called in response to an imminent public health concern that needs to be resolved in a limited amount of time, while HIT Task Forces are to characterize emerging or evolving food safety issues for strategic planning purposes. HIT Task Forces are generally smaller in size than an HHEB task force, with the size and type of membership determined on specific expertise needed to conduct a rapid evaluation of an emerging food safety issue determined to be a high priority based on initial risk evaluation during triage. Further differences between HIT and HHEB task forces are described in Table 1: HIT vs HHEB. It is important to note that the HIT and HHEB processes are complementary; a HIT issue could lead to an HHEB issue or vice versa.

Table 1: HIT vs. HHEB

HIT	HHEB
Emerging food safety issue that could affect food supply more broadly	Incident has occurred that affects specific product
Exposure to hazards in FSIS-regulated product is often uncertain	Exposure to hazards in FSIS-regulated product is known or highly likely
Information from the HIT evaluation and corresponding preliminary recommendations are a first step toward identifying potential emerging or evolving food safety issues of concern for consideration, through FSIS's broader governance	Recommendations are a final step, tailored to the specific product in question

process, for risk management decisions	
Process supports strategic planning and awareness of emerging or evolving food safety risks	Process supports immediate FSIS action with regard to specific product

IV. HIT WORKFLOW

A.   A diagram of the HIT workflow is shown in Attachment 1. The HIT networks with FSIS personnel and external partners, through Agency liaisons, where assigned, to gather information on emerging food safety issues. Any FSIS employee may identify an issue, though they are commonly identified through the following internal and external inputs:

1.   Internal:

   a.   Staff within any FSIS program area;

   b.   Agency work groups (e.g., Shiga toxin-producing *Escherichia coli* work group); and

   c.   Committees (e.g., DCC).

2.   External:

   a.   Interagency work groups;

   b.   Public meetings, workshops, symposia, scientific publications;

   c.   Academia, including researchers and cooperative extension partners;

   d.   State, Federal, and international partnerships and networks; and

   e.   National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and other advisory committees.

B. Once an issue is identified, the person who raised the issue is to submit a HIT Issue Initiation Form, available on the HIT SharePoint Site. Completed forms are to be submitted via e-mail to: HazardIdentificationTeam@fsis.usda.gov. The submission of this form begins the tracking and triaging process facilitated by the HIT Coordinators.

NOTE: Those who cannot access the HIT SharePoint Site may request a copy of the HIT Issue Initiation Form by sending an e-mail to the HIT Coordinators at HazardIdentificationTeam@fsis.usda.gov.

C. HIT Coordinators are to serve as a resource and provide support during the submission process. HIT Coordinators are to track and update information related to the submitted issue in the central information-management system to keep the submitter informed of the status of their submission and all relative materials and decisions. All FSIS employees can review this information on the HIT SharePoint Site.

D. HIT Coordinators are to review the Issue Initiation Forms and consider the highlighted issues based on the established risk evaluation criteria (i.e., potential public health impact, novelty, soundness, imminence, scale, and severity) before further resources are committed to addressing the issue. HIT Coordinators are to provide an overview and a scientific assessment of the issue in relation to the aforementioned evaluation criteria. To facilitate a systematic and consistent evaluation process, a template for capturing relevant details of the triage process is available on the HIT SharePoint site. The HIT's scientific

assessment should characterize the strength of evidence that the issue represents an emerging food safety issue which merits Agency resources and should be communicated in one of three categories:

1. High Priority – There is compelling evidence that the issue meets multiple HIT evaluation criteria highlighted above, including impact, scale, and imminence, and is therefore an emerging food safety issue;

2. Medium Priority – There is evidence that the issue meets one or more HIT criteria and may be an emerging food safety issue; or

3. Low Priority – There is little or no evidence that this issue meets any of the HIT evaluation criteria.

E. Based on the results of this scientific assessment, HIT Coordinators are to recommend a priority ranking. HIT Coordinators are to invite other program areas to provide input on the ranking and recommendations. The HIT Steering Committee will make a final determination of the ranking of emerging issues based on the scientific assessment and program input. With any prioritization level, the Steering Committee may determine that another program area, work group, or other entity is better suited to handle the issue or has already encountered and begun addressing the issue, and, therefore, the Steering Committee is to recommend a referral outside of HIT. Issues are to be prioritized into one of the following categories:

1. High Priority – Issues triaged with high priority are tracked and recommended by the HIT Steering Committee to a HIT Task Force for further evaluation and characterization;

2. Medium Priority – Issues triaged with medium priority are tracked and, if and when new relevant science or other information becomes available, periodically reevaluated and reclassified as needed; or

3. Low Priority – Issues triaged with low priority are tracked but do not require immediate action because they are unlikely to present a concern in FSIS-regulated products. HIT Coordinators are to record each issue and the reasoning behind its classification in the database. If and when new relevant science or other information becomes available, it will be periodically reevaluated and reclassified as needed.

F. Throughout the entire process, HIT Coordinators are to track and update information related to a submitted issue in the central information-management system to keep the submitter informed of the status of their submission and all related materials and decisions. All FSIS employees are able to review this information on the HIT SharePoint site.

G. On High Priority issues, HIT Task Forces are to further evaluate the potential emerging risk based on established criteria, synthesizing relevant information, and consulting other FSIS program areas, Federal agencies, or external partners if necessary, within a short amount of time (e.g., up to 45 days). HIT Task Forces are to provide findings and initial follow-up recommendations in a short briefing document to the Steering Committee. Recommendations could include:

1. Revisiting the issue in a certain number of months or years;

2. Conducting a systematic review of the literature;

3. Forwarding for consideration by the NACMCF;

4. Proposing activities to fill key data gaps, which could include appropriate microbiological or chemical testing, either through in-house sample collection or through partnership with the Agricultural Research Service (ARS) or others;

5. Developing a risk profile;

6. Commissioning a risk assessment or exposure assessment;

7. Planning and coordinating a presentation in cooperation with the [FSIS Scientific Seminar Series](#) (though this action may also be deemed appropriate for Low- or Medium-Priority issues, with Coordinator and Steering Committee agreement);

8. Initiating discussion with government partners, including the Centers for Disease Control and Prevention, Animal and Plant Health Inspection Service, ARS, Food and Drug Administration, Environmental Protection Agency, through Agency liaisons, where assigned, or academia; or

9. Presenting HIT evaluation findings to for consideration in the broader EG and decision-making process through the EG triage and joint boards.

NOTE: If the Management Council determines that it is appropriate, the findings are added to FSIS research priorities.

H. The HIT Coordinators are to review and standardize briefing notes, including preliminary recommendations, in order to present a Task Force's conclusions to the Steering Committee. The Steering Committee is to discuss and agree upon final recommendations which are then elevated to the OPHS OAA.

I. The OPHS OAA is to review and modify the recommendations as necessary and may commission further analysis or research to collect more comprehensive scientific and public health information on the emerging issue. On a periodic basis, the OPHS OAA, or their designee, will present emerging food safety issues of concern before the EG joint boards for triage, and further consideration as part of the broader Agency-wide coordinated governance and decision-making process.
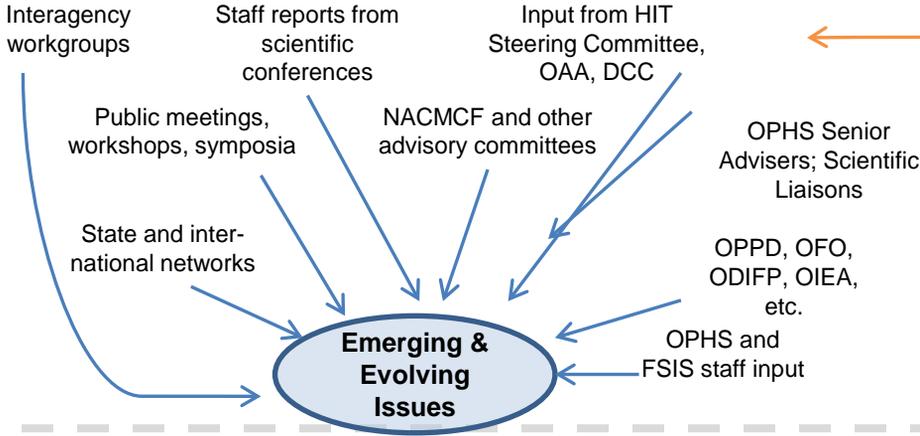
V. QUESTIONS

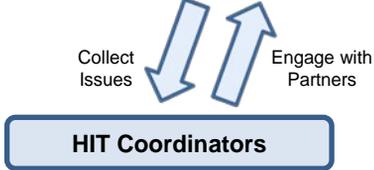Refer questions regarding this directive to the HIT Coordinators at HazardIdentifcationTeam@fsis.usda.gov.

Assistant Administrator
Office of Policy and Program Development
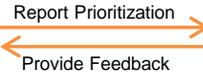
Hazard Identification Team Work Flow

Information Streams

Interagency workgroups

Staff reports from scientific conferences

Input from HIT Steering Committee, OAA, DCC

Public meetings, workshops, symposia

NACMCF and other advisory committees

OPHS Senior Advisers; Scientific Liaisons

State and inter-national networks

OPPD, OFO, ODIFP, OIEA, etc.

OPHS and FSIS staff input

Emerging & Evolving Issues

Collect Issues

Engage with Partners

HIT Coordinators

1. Track issues in information management system.
2. Qualitatively screen issues: high/medium/low priority.

Report Prioritization

Provide Feedback

Supply Information Streams

HIT Steering Committee

- OPHS Dep. Asst. Administrator
- Staff Directors (SciS, AES, RAAS)
- Laboratory representation

Determines final prioritization based on evaluation criteria. OPHS resources are considered, and conclusions may include referring an issue to another staff or program area as appropriate.

Triage

High Priority
Convene a HIT Task Force to synthesize available information and provide recommendations.

Medium Priority
"Active" projects. Refine available information and identify knowledge gaps. Review regularly for reclassification as high or low priority.

Low Priority
No immediate action. Record issue, disposition, and reasoning in database.

Synthesis

HIT Task Force

1. Each Task Force is created to address one specific issue (similar to HHEB).
2. Consists of 2-4 OPHS employees, who may consult additional subject matter experts.
3. Prepares a short briefing note, synthesizing available information and knowledge gaps.
4. Provides briefing note within specified timeframe (determined by Steering Committee).
5. Makes recommendations to OAA for next steps.

HIT Coordinators

1. Advise Task Forces and track progress.
2. Review and standardize briefing notes and recommendations.
3. Present Task Force conclusions to Steering Committee.

HIT Steering Committee

1. Decides immediacy of addressing emerging and evolving issues.
2. Gathers input from OPHS OAA and other program areas.

Output

Integrate into FSIS's broader enterprise governance process.

OPHS OAA

1. Reviews and modifies recommendations.
2. Presents identified emerging or evolving issues as part of broader FSIS enterprise governance/decision making process.

Management Council

OFS

FSIS Program Areas* (OPPD, OFO, ODIFP)

Increased coordination and communication agency-wide.

* Engage other programs for enterprise-level prioritization, planning, and coordinated implementation (based on OPHS OAA recommendations).