

**Food Safety Assessment
The Food Emergency Response System
of the Canadian Food Inspection Agency**



**Food Safety Assessment Report
to the Minister of Health**

March 1999

EXECUTIVE SUMMARY

In April 1997 the *Canadian Food Inspection Agency Act* established the Canadian Food Inspection Agency, reporting to the Minister of Agriculture and Agri-Food. Health Canada is responsible for assessing the effectiveness of the Agency's activities related to food safety. The following are key findings from the first food safety assessment of the Canadian Food Inspection Agency's activities, namely, those related to the Food Emergency Response System.

Every year in Canada, emergencies involving the safety of food products occur. The Food Emergency Response System as adopted by the Canadian Food Inspection Agency operates in essentially the same manner as the food emergency system which had been in place previously in Health Canada. The system remains consistent with practices in other inspection programs charged with responding to emergency situations. The assessment team identified some areas where improvements can be made which will provide a greater level of assurance that consumers are protected from hazardous food products in emergency situations.

We conclude that the Agency was, overall, effective in identifying situations in which recalls were necessary, that it assessed the situation and initiated a response in a timely manner, and that it implemented management actions which were, for the most, in accordance with the level of risk. The Agency's role in overseeing and monitoring industry's recall actions can be improved with enhanced guidance in the *Food Emergency Response Manual* and better documentation of the decisions and actions taken.

Key Observations

Roles and Responsibilities

The roles and responsibilities for handling recalls were mainly clear and well understood within the Canadian Food Inspection Agency. These include relationships within the Agency and between the Agency and various stakeholders and partners, including the food industry and provincial officials. The role of the Food Emergency Response System in other food safety emergencies such as sabotage or tampering incidents, reported illnesses and man-made or natural disasters needs to be clarified.

Identifying Food Emergencies

The Agency, for the most part, identified potential food emergencies promptly and investigated them sufficiently to reach a conclusion. Current Agency inspection, sampling and complaint investigation programs are a valuable source of information.

Risk Assessment

The *Memorandum of Understanding between Health Canada and the Canadian Food Inspection Agency concerning Food Safety Emergency Response* describes the respective roles and responsibilities of Health Canada and the Canadian Food Inspection Agency in food safety emergencies. Health Canada and the Agency had different interpretations of when the Agency should request Health Canada to conduct a Health Hazard Evaluation. The Agency and Health Canada considered this a significant problem and it is now being addressed.

The estimation of risk in a potential emergency and the subsequent risk management actions taken were appropriate in the vast majority of situations and the process for determining the risk was carried out in a timely manner. Better documentation of the rationale for recall classification decisions is required.

Emergency Management

The *Food Emergency Response Manual* provides procedures to manage a food recall. Its guidance with respect to public announcements and monitoring the effectiveness of recalls could be improved. The root causes of food emergencies were investigated and the scope of investigation was broad enough to identify all contaminated products in almost all recalls reviewed. Documentation of the progress and subsequent termination of food recalls could be improved. The checklist that is part of the *Food Emergency Response Manual* and that is to be completed for each emergency could include the key information on the success of the recall in removing hazardous products from the marketplace. Overall, these improvements would contribute to assurance that appropriate action is taken to fully protect the public in each food emergency situation.

Performance of the Food Emergency Response System

Few post-emergency reviews were documented for the recalls examined. The Agency has developed a broad performance measurement framework which includes the Food Emergency Response System, a very positive step. It now needs to clarify it and define it further.

Key Recommendations

1. The Agency should continue to ensure that the relative responsibility of the Agency, stakeholders and partners remain current and clear. The area of food safety is constantly evolving and relationships with Health Canada, provincial and foreign governments and industry need on going consideration.
2. The Agency should define roles and responsibilities for the Food Emergency Response System in responding to emergency situations of disaster, reported illnesses, tampering and sabotage, and include procedures for carrying out those responsibilities or refer to other emergency plans or procedures in the *Food Emergency Response Manual*.

3. The Agency should implement procedures agreed-to with Health Canada for assessing the risk of all food safety emergencies for which appropriate standards, tolerances or guidelines do not exist.
4. The Agency should clearly specify in its *Food Emergency Response Manual*:
 - the circumstances in which a public warning is or is not necessary;
 - adequate guidance on the timeliness, adequacy and level of effectiveness checks;
 - information required to review how each food emergency has been managed by Headquarters and the regional offices and to determine its effectiveness.
5. The Agency should, at all stages of the emergency response process, document decisions, rationale, and results of actions taken.
6. The Agency should develop clear policies and procedures describing when and how to use the recall powers of the *Canadian Food Inspection Agency Act*.
7. The Canadian Food Inspection Agency should improve the overall coordination and oversight of food safety emergency activities which take place across both Headquarters and the Regions.
8. To ensure accountability, the Agency should refine the objectives and performance measures for the Food Emergency Response System and use these measures to report on its performance.

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INTRODUCTION

1 Every year in Canada, emergencies involving the safety of food products occur. A food safety emergency is broadly defined as any situation that involves or could involve food which might pose a high risk to humans. Food safety emergencies include Class I recalls, i.e., situations in which there is a reasonable probability that the consumption of a food product will cause adverse health consequences or death, and other high visibility recalls. Food safety emergencies also include complaints involving product-related illness or injuries, sabotage and threat incidents, and man-made or natural disasters that threaten the safety of the food supply. Consequently, it is essential to respond effectively to food safety emergencies in order to protect public health and well-being.

2 On July 1, 1996, Health Canada's food inspection responsibilities, including the coordination of emergency response with respect to food, were transferred from Health Canada to Agriculture and Agri-Food Canada. This transfer was part of the first stage in the consolidation of food inspection and quarantine services into the Canadian Food Inspection Agency. Subsequently, on April 1, 1997, the Agency was formed with the combination of food inspection programs and resources from Agriculture and Agri-Food Canada and Fisheries and Oceans Canada. The Food Emergency Response System assumed by the Canadian Food Inspection Agency is fundamentally the same system which had been in place in Health Canada and Agriculture and Agri-Food Canada.

3 Currently, at the federal level, the Agency is responsible for enforcing the food safety standards established by Health Canada, including taking all necessary enforcement actions in food-related emergencies. It takes the lead role for investigations and coordinating of food safety emergency response. Health Canada is responsible for establishing food safety policy and standards. Health Canada has a complementary role in conducting risk assessment activities for food-related emergencies and recommending risk management options when no guidelines exist. The Food Emergency Response System is dependant on this partnership which is formalized in the *Memorandum of Understanding between Health Canada and the Canadian Food Inspection Agency concerning Food Safety Emergency Response*.

4 To better understand the Food Emergency Response System, it is useful to view it as a series of essential steps, namely, emergency identification, risk assessment, emergency management and post-emergency review (see Exhibit 1). The procedures for responding to a food safety emergency are found in the *Food Emergency Response Manual*. Based on the pre-existing manual in Health Canada, a revised manual was developed jointly by Agriculture and Agri-Food Canada, Fisheries and Oceans Canada and Health Canada prior to the establishment of the Agency. The manual has been adopted and amended for its current use by the Agency. This manual provides direction to the many individuals potentially involved in managing an emergency response by defining their individual roles and responsibilities.

Identification of Food Safety Emergencies

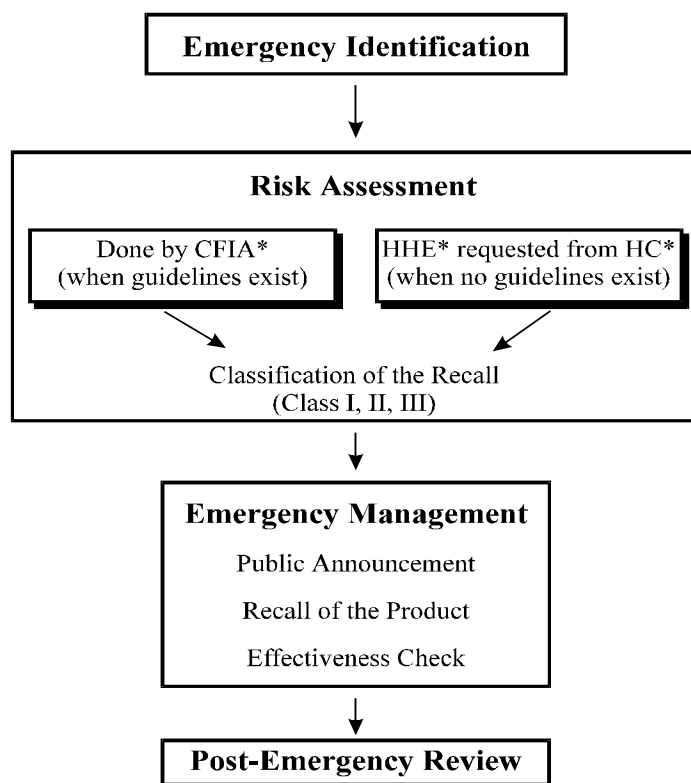
5 The Agency identifies or receives information regarding potential food safety emergencies from many sources (e.g., from ongoing inspection and laboratory activities, consumer complaints and provincial public health services). Agency officials investigate the situation to decide if there is a potential food safety emergency. They also gather relevant information to assess the risk.

Risk Assessment

6 An assessment of the risk posed by a potential emergency situation contributes to making decisions on the appropriate course of action to control the risk. The Agency Headquarters receives relevant information concerning a potential food safety emergency and evaluates the situation by area of concern — microbiological and extraneous material hazards, chemical hazards, marine biotoxins, and compositional hazards (allergens, nutrition, additives or mislabelling). The Headquarters decides whether advice from Health Canada is required and makes a decision regarding the necessity for an emergency response.

Emergency Management

7 Any given food emergency may include a recall — a firm's voluntary removal from further sale or use, of a marketed food that violates legislation enforced by the Canadian Food Inspection Agency. The Agency's regional staff work closely with the manufacturer, importer or distributor of the violative product to develop a strategy for ensuring that any hazardous products will no longer be sold or consumed (see Exhibit 2). Enforcement actions may be initiated as soon as any problem is identified (e.g., detaining products) and may increase as appropriate. A public announcement may be warranted if the hazard involved is serious and the product is in the hands of consumers. The company recalling the product or products must quickly identify the location of products distributed and notify clients who have received them. Recalled products must be removed from sale and segregated from other food products while awaiting proper disposition. The recalled products are then either corrected (e.g., relabelled) or destroyed. The root cause of the problem is investigated to prevent the same problem from recurring. The extent and timeliness of the risk management



* CFIA=Canadian Food Inspection Agency; HC=Health Canada
HHE=Health Hazard Evaluation

Exhibit 1: Emergency Response Steps

actions just described should reflect the relative degree of health hazard of the product being recalled.

8 During a food recall, the primary role of the Canadian Food Inspection Agency is to provide advice on the strategy developed by the firm to recall products from sale, and to closely monitor the effectiveness of the recalling firm in executing its planned actions. The Canadian Food Inspection Agency has the ability under the *Canadian Food Inspection Agency Act*, Section 19, to order a product recall. Regional staff conduct follow-up investigations. They may take samples for laboratory analysis to determine the scope and root cause of the problem, and to ensure that corrective actions have been taken. They may also conduct effectiveness checks to determine whether clients (wholesalers and/or retailers) to whom a product has been sold have been notified of the recall and whether the hazardous product has been removed from sale and properly segregated pending disposition.

9 The Canadian Food Inspection Agency Headquarters is responsible for coordinating emergencies, preparing briefings, working with the Communication Bureau staff regarding news releases and notifying key stakeholders that public announcements have been made. Emergency actions are terminated when the Agency determines that the hazard has been controlled, that a faulty product has been disposed of properly and that any problems have been corrected.

Post-Emergency Review

10 A post-emergency review is a way to identify what went right in the emergency response and what could be improved in handling future emergencies. These reviews provide an opportunity to improve procedures and to clarify roles and responsibilities internally and with external stakeholders (e.g., other government departments, industry associations and the public). They also provide positive direction to other inspection activities carried out by the Canadian Food Inspection Agency.

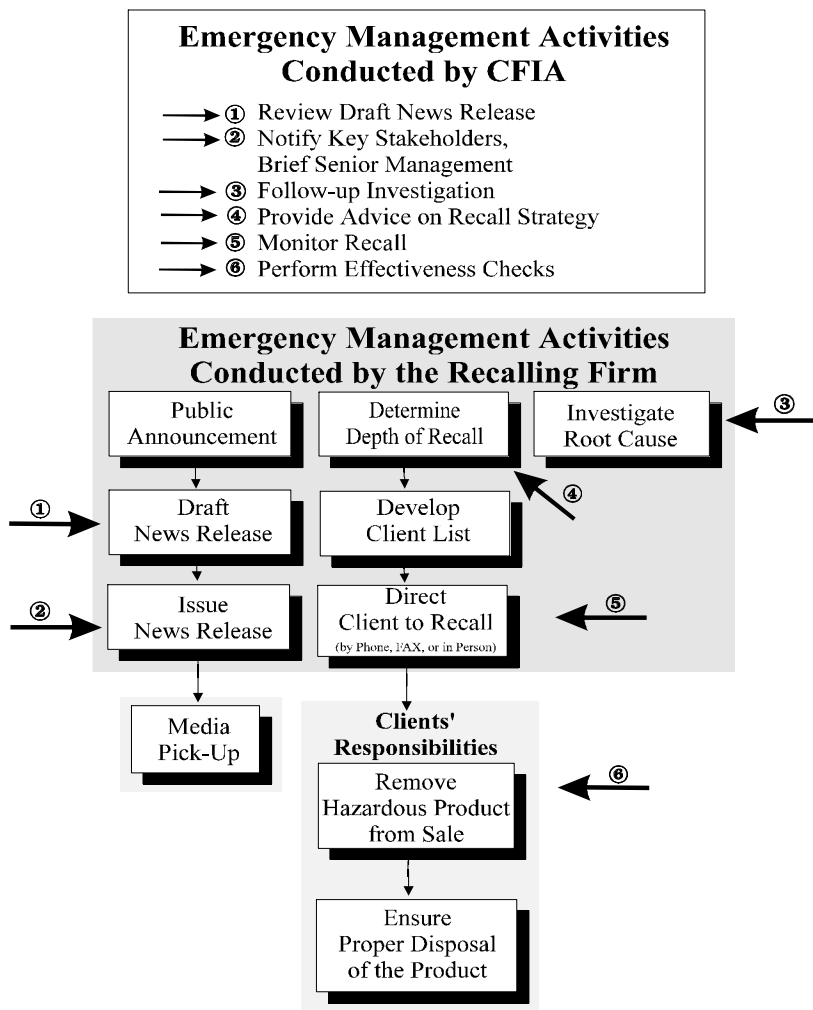


Exhibit 2: Emergency Management Activities

ASSESSMENT OBJECTIVE AND SCOPE

11 The objective of this assessment was to assess the effectiveness of the Canadian Food Inspection Agency in responding to potential and actual food safety emergencies. We examined the Food Emergency Response System's essential steps of emergency identification, risk assessment, emergency management and post-emergency review and their related activities. Our review included the Agency's procedure for requesting Health Hazard Evaluations from Health Canada and the Agency's responses to these evaluations. We did not review the actual risk assessments that Health Canada carried out. We examined a disaster situation and food recalls that occurred between September 1, 1996 and February 5, 1998, some of which resulted from reported illnesses or tampering.

12 During the first part of this period (September 1, 1996 to March 31, 1997), Agriculture and Agri-Food Canada had the lead role for conducting investigations and co-ordinating responses to food emergencies using, as mentioned earlier, the Food Emergency Response System which was transferred from Health Canada. At that time, Health Canada was responsible for auditing the food safety programs of Agriculture and Agri-food Canada and Fisheries and Oceans Canada. On April 1, 1997, the Canadian Food Inspection Agency was created and assumed the lead role for emergency response. The Agency continued to use essentially the same system for responding to food emergencies, however adapted the procedures to suit their organizational framework. Health Canada then became responsible for assessing the effectiveness of the Agency's activities related to food safety. The assessment included recalls from both before and after the creation of the Agency, fulfilling Health Canada's responsibility for audit and then assessment. Since the Food Emergency Response System remained essentially the same, the analysis provides useful information on the strengths of the system and the areas that could be improved.

13 The Agency provided a list of 240 food recalls that occurred during the period covered by our assessment. Sixty were Class I recalls (actual food safety emergencies), 163 were Class II recalls (potential food safety emergencies) and 17 were Class III recalls (non-food safety emergencies -, i.e., incidents posing a low or no immediate health risk). Of the 223 Class I and II recalls, 29.6% were concerned with microbiological hazards; 56% involved allergens and 4% chemical contaminants other than allergens; 10% involved extraneous material; and three recalls (0.4%) involved other concerns.

14 We reviewed and evaluated in detail 49 of the Class I and Class II food recalls. Of these, 21 were initiated in the period during which the Food Emergency Response System was under the direction of Agriculture and Agri-Food Canada and 28 were initiated after the creation of the Canadian Food Inspection Agency. We selected our sample to include Class I and Class II recalls, recalls involving different types of hazards, and recalls initiated from different Regions. We also selected some recalls which included Health Hazard Evaluations by Health Canada and others that did not. In addition, we examined 12 food safety-related incidents that did not result in food recalls. We also examined, in the context of the Food Emergency Response System, the ice storm that took place in January 1998. Finally, we interviewed officials and reviewed files at the Canadian Food

Inspection Agency's Headquarters and in the Pacific, Ontario, Quebec and Atlantic Regions. For more information on this assessment, refer to the "About the Assessment" section at the end of the report.

OBSERVATIONS AND RECOMMENDATIONS

Roles and Responsibilities

15 We reviewed the Canadian Food Inspection Agency's documentation and its understanding of the roles and responsibilities of the Agency, of Health Canada and other external parties in potential and actual food safety emergencies. Our objective was to determine whether their roles and responsibilities were clearly defined and understood.

16 We found that the Canadian Food Inspection Agency personnel who play key roles in the Food Emergency Response System, and whom we interviewed, understood their roles and responsibilities in a food recall.

17 The Canadian Food Inspection Agency's *Food Emergency Response Manual* defines their roles and responsibilities and provides procedures to manage a food recall from the Headquarters level and down to the regional Chiefs of Food Inspection. We found that only two of the four Regions that we assessed have a documented regional emergency response plan, as required by the manual, which describes regional roles, responsibilities and procedures. The Agency relies on personnel in Headquarters and the Regions to carry out activities for effectively responding to food safety emergency situations. Completing the documentation of regional roles and responsibilities will contribute to a clearly defined and understood Food Emergency Response System that can be managed effectively at all levels of operations.

18 The *Food Emergency Response Manual* and the two existing regional emergency procedures manuals do not clearly define roles and responsibilities or refer to specific procedures for responding to other emergencies such as confirmed sabotage and threat incidents, complaints involving confirmed product-related illness and man-made or natural disasters which threaten the safety of the food supply. The Agency has four emergency plans and the *Food Emergency Response Manual* should identify the relationship of the Food Emergency Response System to other related emergency response plans, for example, the Agency's Regulatory Affairs Division and the Food and Agriculture Emergency Response System were involved in the response to the ice storm. The ice storm as a food safety emergency is discussed in paragraph 37.

Recommended Actions: The Canadian Food Inspection Agency should ensure that all Regions have fully documented regional emergency procedures, and that these are consistent with the *Food Emergency Response Manual*.

The Agency should define roles and responsibilities for the Food Emergency Response System in responding to emergency situations of disaster, reported illnesses, tampering and sabotage, and include procedures for carrying out those responsibilities or refer to other emergency plans or procedures in the *Food Emergency Response Manual*.

Agency's response: The Agency agrees and has put in place a process to ensure each Area has documented emergency procedures consistent with the *Food Emergency Response Manual*.

The Agency has developed an Emergency Management Framework for natural disaster, sabotaging, tampering and reported illnesses. These procedures will be referenced in the *Food Emergency Response Manual*.

19 The *Memorandum of Understanding between Health Canada and the Canadian Food Inspection Agency concerning Food Safety Emergency Response* outlines their respective roles and responsibilities. We found, however, that both parties had different interpretations of when the Agency should request Health Canada to conduct a health hazard evaluation. Once this was brought to the attention of Health Canada and the Agency, both parties began and continue work to clarify the *Memorandum of Understanding*.

20 Key stakeholders with respect to emergency response include municipal, provincial and foreign governments; non government organizations such as consumer associations; and the food industry itself. We found that the Canadian Food Inspection Agency Headquarters and Regions have provided these external stakeholders with current contact lists of Agency staff (at both national and regional levels) who are responsible for making decisions in emergencies. The *Food Emergency Response Manual* clearly identifies whom to contact when a potential emergency situation arises.

21 Formal agreements with other stakeholders contribute to effective communication and help avoid confusion over responsibilities and actions taken during a food safety emergency. In addition to providing contact lists, it would be beneficial if the *Food Emergency Response Manual* referred to the roles and responsibilities of stakeholders and referred to any agreements with these stakeholders. We found that relationships established earlier, primarily with provincial governments, by the former departments from which the Agency was derived, continue to exist. We

also found that Memoranda of Understanding (agreements) between the former departments and provincial authorities to clarify their respective roles and responsibilities in emergency situations were still in force as confirmed in a letter from the Agency to these stakeholders. The Agency intends to update and consolidate these working agreements.

Recommended Action: The Canadian Food Inspection Agency should ensure that the relative responsibilities of the Agency, stakeholders and partners remain current and clear. They should carry out their plan to update and consolidate formal agreements respecting their role and responsibilities in relation to their stakeholders, including Health Canada and provincial authorities, in food emergency situations.

Agency's response: Arrangements are in place between the Agency and all provinces regarding relative responsibilities. Work is underway to consolidate and update these existing arrangements with provinces.

In May 1998 a review of the *Memorandum of Understanding between Health Canada and the Canadian Food Inspection Agency concerning Food Safety Emergency Response* was initiated. Both the Agency and Health Canada have clarified the circumstances where the Agency should request a risk assessment.

Health Canada and the Canadian Food Inspection Agency have developed the *Foodborne Illness Outbreak Response Protocol* and discussions are underway with the territories and provinces to finalize the arrangement.

Identification of Food Safety Emergencies

22 Quickly and accurately identifying potential food safety emergencies is essential to reduce the public's exposure to hazardous food products. We examined actual and potential food safety emergencies to determine how they had been identified; the systems used to collect, report on and track information; the promptness and effectiveness of the Agency in identifying potential emergencies; and its use of emergency telephone numbers. The Food Emergency Response System historically has not defined standards for timeliness with respect to identification of emergencies. The Canadian Food Inspection Agency has not developed such standards. Accordingly, we calculated the time the Agency took to respond by subtracting the date on which the Agency had received notice of a potential emergency from the date when the recall started. To evaluate timeliness we examined each recall's documentation for any unexplained delay in initiating and

conducting an investigation. As well, we assessed the Agency's effectiveness in identifying potential emergencies by reviewing some files for evidence of a documented, comprehensive investigation of incidents that did not result in a recall.

23 We found that the Agency's programs such as import and domestic product sampling, environmental sampling, plant inspection, and consumer and trade complaint investigations were key sources of information on food safety issues which led to the identification of potential emergencies.

24 A preliminary assessment of information on food safety issues is needed to determine whether an emergency situation actually exists. We found that for 94% of the recalls reviewed, the Agency had completed its preliminary assessment of information on potential emergencies promptly, many within 24 hours, an excellent record. We noted delays in only 3 of the 49 recalls. These delays were associated with initiating and conducting investigations and laboratory analyses.

25 In addition to the 49 recalls reviewed, we evaluated 12 incidents and inspection results from one Region related to situations which initially appeared to be a potential emergency but ultimately no recall was considered necessary. This was to assess the effectiveness of identifying emergencies. We found that these incidents were sufficiently investigated to reach a conclusion on the existence of a potential emergency in most cases (75% of incidents).

26 The Canadian Food Inspection Agency has established emergency numbers, known to key stakeholders, in case a food safety concern arises outside of normal business hours. After-hours emergency numbers have been established at Headquarters and in the Regions. This is consistent with the practices in other inspection programs. The Agency may want to consider providing after-hours emergency numbers to consumers. We note that the consumer does have the option of pursuing other channels such as local Public Health Units, hospitals or a doctor and we found no evidence of a problem arising from this situation during our assessment.

27 We found that the systems used to collect, report on and track information on consumer complaints and on internal activities, such as product sampling, laboratory analysis and plant inspections, varied in content and the degree of on-line accessibility. This is not surprising as the Agency was formed by the consolidation of the resources and inspection programs from three departments. The computerized Incident System records and tracks complaints, investigations, recalls and other food safety actions. This food safety information tracking system came to the Agency with the transfer of Health Canada's food inspection responsibilities. It was operational only within the Food Inspection Division and was not available to the Fish Inspection Directorate or the other commodity divisions within the Food Inspection Directorate. The Agency has recognized that an integrated, computerized database would allow the Agency's various divisions to have across-the-board, common access to information on food safety incidents. As the technical capability to modify the Incident System was not available, the Agency is developing such a new integrated computerized system, with an implementation target date of April 1999.

Recommended Action: The Canadian Food Inspection Agency should continue with its plans to establish an integrated database which would provide a common source of information throughout the Agency on food safety incidents, provide uniform reporting for emergency response activities, and allow easy tracking of the progress of potential emergency investigations and actual emergency activities.

Agency's response: The Issues Management System will be operational and will replace the current individual tracking systems prior to December 1999. This system will track all emergencies for the Agency (Food, Animal and Plant).

Risk Assessment

28 The process for assigning the level of risk associated with a potential emergency is a complex process that often requires the collaborative effort of both Health Canada and the Canadian Food Inspection Agency. An established process for quickly assigning the level of risk associated with a potential food safety emergency would contribute to an effective response to any potential food safety emergency. We expected that the process would reflect the respective roles and responsibilities for both Health Canada and the Agency as outlined in the *Memorandum of Understanding concerning Food Safety Emergency Response*.

29 We examined the process that the Agency used to assign a level of risk to a potential emergency situation. We reviewed recalls to determine whether the decisions on risk were timely and had been documented. We also determined whether the Agency had followed the process for assigning a level of risk in emergency situations as defined by the *Food Emergency Response Manual*.

30 The *Memorandum of Understanding between Health Canada and the Canadian Food Inspection Agency concerning Food Safety Emergency Response* and the *Food Emergency Response Manual* both state that the Agency will request a Health Hazard Evaluation (risk assessment) from Health Canada when no standards, tolerances, policies or guidelines exist. Health Canada and the Agency however had different interpretations of when the Agency should request Health Canada to conduct a Health Hazard Evaluation. There was no common understanding of which policies, tolerances and guidelines the Agency can use to assess the risk on its own, nor regarding the use of precedence for assessing risk. Consequently, we found that in 33 of 46 applicable recalls reviewed, the Agency evaluated and assigned the level of risk without a Health Hazard Evaluation from Health Canada. As described earlier (see paragraph 19) the Agency and Health Canada are clarifying the *Memorandum of Understanding*. As mutually agreed-upon, Health Canada is developing guidelines for use by the Agency to address the majority of potential

food safety emergencies and both have agreed to specific procedures to follow in assessing the risk for other food safety emergency situations.

31 In 90% of the recalls reviewed, the risk was accurately estimated. In 5 of the recalls reviewed, the risk had been underestimated and a public announcement would have been warranted. In 2 other recalls in which the risk was properly estimated further action to protect consumers in terms of expanding the public warning or informing the targeted population at risk should have been undertaken. We saw no evidence or indication of problems or health impacts on the public occurring in these situations.

32 The Recall Classification indicates the relative degree of health hazard presented by a product as detailed in Exhibit 3. We found that the various officials involved in food emergencies both at the Agency and at Health Canada interpreted the Recall Classification differently. To some it represented the severity of the hazard, to others, the risk to the population (taking into consideration the likelihood of a susceptible population consuming the hazardous product) or the action taken to control the situation. As a result there is no commonly agreed-upon basis for what constitutes a Class I, II or III recall. This does not necessarily affect the management of food safety emergencies but a common understanding of terms would enhance a common understanding of each situation.

“Recall Classification” means the numerical designation i.e., Class I, Class II or Class III, assigned by the CFIA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II is a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause any adverse health consequences.

Exhibit 3: Definition of Recall Classification, *Food Emergency Response Manual*

Recommended Action: The Canadian Food Inspection Agency should implement procedures agreed-to with Health Canada for assessing the risk of all food emergencies for which appropriate standards, tolerances or guidelines do not exist.

Consideration for Improvement: The Canadian Food Inspection Agency may consider a review of the recall classification system to ensure it is uniformly interpreted.

Agency's response: The Agency has clarified with Health Canada which tolerances, guidelines or policies are considered appropriate for identifying the risk of potential emergencies. The actual tolerances, guidelines and policies will reside in policy manuals/stand alone manuals etc.

The Agency is reviewing recall classification to ensure it is uniformly interpreted.

33 Documenting the decisions made in food safety emergencies and the rationale for those decisions are important aspects of the Agency's records. Decisions on recall classification were typically documented and recall forms were completed by the regions. However, we found no written records of the rationale for decisions made at the regional level regarding the nature of the hazard and level of risk. At the headquarters level, we found that recalls involving microbiological hazards were rarely supported with documentation detailing the classification decision and the rationale for it. The recalls involving allergens were often supported by notes of discussions with Health Canada regarding the hazard and the level of risk and the rationale for classification decisions. Documentation of the rationale for these decisions can be used as part of a post-emergency review to ensure that the decisions were science-based.

34 The Food Emergency Response System historically has not defined standards for timeliness with respect to initiating and completing the process for assigning a level of risk to food safety emergencies. The Canadian Food Inspection Agency also does not have such standards. Accordingly, we calculated the time taken to determine the level of risk by subtracting the date on which the Agency had become aware of the potential emergency from the date on which the level of risk had been assigned. To evaluate timeliness, we examined each recall's documentation for any delays in the process of assigning a level of risk that could have been avoided by the Agency.

35 We found that in most cases, decisions were made promptly. For 61% of the recalls, the time the Agency took to assign the level of risk associated with a potential emergency situation was one day or less, a very good record.

36 We found 8 recalls in which there were delays in determining the level of risk. These delays related primarily to the time taken to transmit the information to appropriate officials within the Agency or to request a Health Hazard Evaluation from Health Canada. It should be noted that in 3 of these 8 recalls the Agency initiated a recall to the retail level as soon as the problem was identified and before a final decision on the level of risk had been reached. Typically, the Agency's inspectors would work with the manufacturer once a problem is identified to initiate risk management actions such as detaining and relabelling products not yet distributed.

Recommended Action: The Canadian Food Inspection Agency should ensure that the level of risk associated with a potential food emergency is always assigned in a timely manner.

Agency's response: While noting that most recalls are undertaken in a timely manner, the Agency has consolidated decision making for food emergencies under the Vice President, Operations. Service standards are being developed which will ensure timely decision making.

37 In January of 1998, an ice storm threatened food production and processing industries and, consequently, the food supply in parts of Ontario, Quebec and the Atlantic Provinces. The *Food Emergency Response Manual* defines natural or man-made disasters which affect the safety of the food supply, as food emergencies. As such, the ice storm met the definition of a food emergency. We evaluated the response of the Agency to the ice storm and investigated how the potential risk posed by the ice storm on the safety of the food supply in general was assessed. We found the Food and Fish Inspection Directorates did not initiate action within the Food Emergency Response System during the ice storm. The Regulatory Affairs Division co-ordinated the Agency's response under the Food and Agriculture Emergency Response System. The Agency was active for example, negotiating to have Ontario milk processed in United States of America plants and Quebec milk processed in the Atlantic provinces. Headquarter's responsibilities were transferred to the Ontario Region to maintain the Agency's operational capabilities during the ice storm. Inspectors addressed specific situations in the plants they inspected. We saw no evidence of health impacts on the public related to problems with food safety arising from the ice storm. In retrospect, both the Agency and Health Canada consider that it would be appropriate to develop a more proactive approach to the management of such situations.

Emergency Management

38 As soon as the decision is made that an emergency response is required, the Canadian Food Inspection Agency begins taking steps to manage the emergency. To evaluate emergency management, we examined the related activities, including public announcements, investigations of emergency situations, food recalls and recall effectiveness checks. We expected that the Agency would carry out effective emergency management activities without delay and as expeditiously as possible, commensurate with the level of risk.

39 The purpose of a public warning is to alert consumers (i.e., the public) that they may have bought or otherwise obtained a product that presents a serious hazard to health and to advise them not to consume it. We noted that the Canadian Food Inspection Agency's regional staff work with the recalling firm to get an agreement on the issuance and the content of a public warning in a timely manner. Headquarters staff, jointly with the Communications Bureau staff, review the content of the public announcement and arrange to distribute the news release to the media. Public warnings can

be issued by either the recalling firm or the Canadian Food Inspection Agency. The *Food Emergency Response Manual* provides little guidance on the circumstances in a Class I or Class II recall that would make a public warning necessary or unnecessary (see paragraph 31).

40 The Canadian Food Inspection Agency was developing an information package for the food industry at the time of this assessment. The package is designed to improve the content of news releases and the procedures for releasing them. Templates for public warnings for microbiological and allergy hazards are part of this package. The templates may also facilitate industry preparation of news releases. Suggestions were provided by Health Canada to the Agency during the assessment to ensure key information will be included in each of the templates.

41 For the recalls that we reviewed the Agency used media monitoring to assess the factual accuracy of public announcements but not to determine the extent of media coverage. The attention a news release receives can vary because its reporting is at the discretion of the media. Measuring the effectiveness of a news release could include monitoring the actual geographic media coverage, determining the extent to which the public has been made aware or received information in a release and has understood the message and taken action. It can be useful to determine whether further action is necessary to ensure that the public does not consume hazardous products which they may have bought. It can also be useful to determine whether news releases are the most effective means of alerting the public to a food emergency.

Recommended Actions: The Canadian Food Inspection Agency should clearly specify in its *Food Emergency Response Manual* the circumstances in which a public warning is or is not necessary.

The Canadian Food Inspection Agency should update the templates for public warning to ensure they include all key information.

Consideration for Improvement: The Agency may consider monitoring the effectiveness of public announcements.

Agency's response: The Agency has policies and procedures for issuing public warnings which it will continue to follow.

The Canadian Food Inspection Agency has updated the template for public warnings to include all key information.

The Agency monitors the effectiveness of public announcements for recalls and will continue to develop other means of distributing information to the public such as through the Canadian Food Inspection Agency website (www.cfia-acia.agr.ca).

42 Once the Agency has decided that a product recall is required, the recalling firm must immediately assemble a list of clients to be notified of the recall. Manufacturers often use intermediate companies to distribute their products to wholesale, retail or directly to users. The recalling firms may contact all retailers or users directly or they may rely on the distributors to contact retailers or users and notify them of the recall. An effective, prompt recall requires each link in the distribution chain to be able to produce accurate, complete client lists.

43 Agency staff request recalling firms to provide them with a list of retailers or users that have received the product being recalled to allow the Agency to check the effectiveness of the recall. Industry does not always keep complete records and in six of the recalls reviewed, the client lists were not readily available.

44 It is important to identify the root cause of each food safety emergency to help prevent recurrence of a similar situation. We found that the Agency had investigated the source of the problem which resulted in a food product recall in all but one of the recalls reviewed involving domestically manufactured food products. When a hazard has been identified in a specific lot of a manufactured food product, it is important to investigate other product lots and other suspect products to determine whether the hazard is also present. We found that the scope of the Agency's investigation was broad enough in the vast majority of cases to identify all contaminated products or product lots.

45 Where a company's recall strategy is not appropriate or the recall of a hazardous food product is impeded by an uncooperative company, we expected that the Agency would act to protect the public, for example by alerting targeted populations or seizing products. In only two of the 49 recalls we reviewed, we found that the Agency had to deal with firms that would not cooperate to quickly recall hazardous products. Actions taken were eventually successful in getting these companies to cooperate, but not without delays.

46 Under the *Canadian Food Inspection Agency Act*, to address similar situations in the future, the Canadian Food Inspection Agency can consider ordering a product recall under Section 19. At

the time of the assessment, it had not yet published policies or procedures for doing so.

Recommended Action: The Agency should develop clear policies and procedures describing when and how to use the recall powers of the *Canadian Food Inspection Agency Act*.

Consideration for Improvement: The Agency may investigate further the capability of food manufacturers, wholesalers and distributors to develop client lists in a timely and effective manner.

Agency's response: The Agency has developed procedures describing when and how to use the recall powers under the *Canadian Food Inspection Agency Act*. These will be referenced in the *Food Emergency Response Manual*.

An interim procedure has been implemented that will require the public announcement to be directed toward the widest likely geographic area if a distribution list is not available.

47 The *Food Emergency Response Manual* indicates that the primary responsibility for effectiveness checks is with the recalling firm and states that “the Canadian Food Inspection Agency, sometimes assisted by other health agencies, may carry out its own effectiveness checks as part of monitoring the recalling firm's performance.” The purpose of a recall effectiveness check is to verify that retailers have received notification about the recall and have actually removed the recalled products from sale. We found the regional Agency staff view effectiveness checks as very important and that they are their primary means of monitoring a recall. In fact, effectiveness checks had been conducted by the Agency for almost all recalls that we reviewed. We consider this to be a sound practice, even though it differs from the approach called for by the *Food Emergency Response Manual*.

48 The guidance and procedures for monitoring recalls found in the *Food Emergency Response Manual* are consistent with the practices currently in place in other regulatory programs. We noted, nevertheless, that these are often minimal and could be improved. For example, in the guidance to the food industry and Agency

The firm's recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted by the recalling firm as follows:
Level A - 100 percent of the total number of consignees to be contacted;
Level B - Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
Level C - 10 percent or less of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis; or
Level D - No effectiveness checks.

Exhibit 4: Level of Effectiveness Checks,
Food Emergency Response Manual

staff on levels of effectiveness checks (see Exhibit 4) we noted that: the categories relate to the percentage of consignees to be contacted with no reference to the percentage of products covered by the effectiveness check; one of the categories is very broad (greater than 10% and less than 100%); and the relationship between the level of effectiveness check and the recall classification is not stated. The percentage of retailers to be contacted during an effectiveness check is left to the discretion of individual managers or inspectors, and is often based on their experience. The manual does not provide regional managers and inspectors with any guidance on how quickly to act to initiate or complete the effectiveness checks the Agency chooses to carry out. Regional emergency procedures, where available, also fail to provide such guidance.

49 Timely monitoring of the effectiveness of the industry's food recall in an emergency situation can be important. It should be noted that delays in conducting effectiveness checks do not imply an ineffective or delayed recall. Prompt effectiveness checks, on the other hand, allow the industry or the Agency to identify problems in the recalls being conducted and allows prompt corrective action to be taken. For this reason, we examined the timeliness with which the Agency conducted the effectiveness checks.

50 The Food Emergency Response System historically has not defined standards for timeliness with respect to effectiveness checks. The Canadian Food Inspection Agency has not developed such standards. Accordingly, we calculated the time taken to monitor the effectiveness of the recall by subtracting the date when the recall started from the date of the last effectiveness check that the Agency conducted. To evaluate timeliness, we reviewed each recall's files for any explanation of a problem or justification for a time lag encountered during the recall.

51 We found it took more than 10 days to monitor the effectiveness of the recall for 14 Class I recalls and more than 20 days for 10 Class II recalls and the recall files did not provide any explanation of a problem or justification for a time lag encountered during the recall or effectiveness check. These delays occurred for recalls involving more than one Region (11 recalls) and for recalls in which the Agency had to wait for the industry's list of retailers and clients who had received the suspect product (5 recalls).

52 The *Food Emergency Response Manual* states that the Canadian Food Inspection Agency and the recalling firm must, before terminating a recall, agree that the recalled product has been removed from sale, and that it has been properly disposed of or any related problems corrected. However, the manual provides little procedural guidance in this area. As a result, we found that the agreement between the Agency and the recalling firm to terminate a recall is generally handled informally. Information necessary to demonstrate that the recalled product had been successfully removed from the marketplace and properly disposed of, such as the percentage of recalled products recovered and the percentage of retailers that had successfully removed the recalled product from sale, had not been documented by the Agency. The level of effectiveness checks completed by either the recalling firm or the Agency was often not known (in 57% of the recalls reviewed). The rationale for the level of effectiveness checks conducted by the Agency for each recall had not been documented and could not be assessed. Therefore, we were unable to determine

the success of the recalls reviewed in removing hazardous food products from the marketplace.

53 The *Food Emergency Response Manual* includes an emergency management checklist which provides a quick means of gathering essential information regarding a food safety emergency response. This checklist is currently limited to information on what Headquarters did in managing emergencies and does not include similar information for the Regions. The checklist also does not list information essential to demonstrate a recall was successful in removing hazardous products from the marketplace and was appropriately terminated. The information gathered in the emergency management checklist may also be a practical reference for post-emergency reviews.

Recommended Actions: The Canadian Food Inspection Agency should clearly define in the *Food Emergency Response Manual* what information is required to review how each food safety emergency has been managed at Headquarters and Regional offices and to determine its effectiveness. The Agency should ensure that this information is routinely gathered and analysed.

The Agency should review the *Food Emergency Response Manual* to clarify the guidance regarding the timeliness, adequacy and level of the effectiveness checks.

Agency's Response: The Agency uses an updated checklist to capture information required to perform post-emergencies reviews. The Canadian Food Inspection Agency will continue to utilize this information to conduct post-emergencies reviews.

The Canadian Food Inspection Agency has ensured its emergency procedures provide adequate guidance regarding timeliness, adequacy and level of effectiveness checks. As the Agency gains more experience, procedures will be amended to reflect changing circumstances.

54 We found that recalls often cover several Regions. Recall activities are organized at the Headquarters level and in each of the Regions involved. However, no one person or group was responsible for overall coordination and oversight of the operations carried out at both Headquarters and the Regions, or had access to all key documentation associated with a food safety emergency recall. We found that the time taken to complete emergency management activities varied significantly in the 49 recalls we reviewed.

Recommended Action: The Canadian Food Inspection Agency should improve the overall coordination and oversight of food safety emergency activities which take place across both Headquarters and the Regions.

Agency's Response: To enhance overall coordination and oversight the Agency has consolidated decision making and responsibility for food emergency response under the Vice President of Operations.

Post-Emergency Reviews

55 Post-emergency reviews give the Canadian Food Inspection Agency a unique opportunity to assess and to make improvements in the Food Emergency Response System based on experience. An effective post-emergency review and evaluation examine the circumstances that led to the emergency, the actions taken in response, how promptly they were taken and how well the players carried out their responsibilities.

56 Regional and Headquarters management informed us that post-emergency reviews often consist of meetings or informal discussions between management and/or staff involved in the emergency. We found documentation of those discussions in only one recall. We found that of the 28 emergencies that we reviewed (Class I recalls and Class II recalls with a public warning), two comprehensive post-emergency reviews had been documented.

57 Documentation of the details of recall classification and rationale, effectiveness checks, disposal or correction of recalled products and the termination of recalls for the recalls that we reviewed was inconsistent. This information can be used to effectively monitor each emergency and conduct a meaningful post-emergency review. The emergency management checklists (see paragraph 53) could form the basis for these reviews.

Recommended Actions: The Canadian Food Inspection Agency should conduct and document comprehensive post-emergency reviews on a more regular basis especially for complex emergencies.

The Agency should, at all stages of the emergency response process, document decisions, rationale, and results of actions taken.

Agency's response: The Agency currently is conducting post-emergency reviews and documenting post-emergency reviews which include a review of roles and responsibilities. The Agency sees post-emergency reviews as an excellent means to continually improve the recall system.

The Agency is currently documenting the decisions, rationale and results of actions taken at all stages of the emergency response process. The Issues Management System will capture a large amount of the required documentation electronically.

Agency's Monitoring of the Food Emergency Response System

58 The Canadian Food Inspection Agency has a statutory responsibility to monitor and report on its performance which includes the food emergency response system. For that purpose, the Agency has developed a performance measurement framework which includes, as one activity, product recall and emergency response. For this activity it sets as the outcome "product deviations are effectively and efficiently managed by partners" and includes as possible measures speed of response and qualitative assessments. This is a very positive step.

59 On their own, these general objectives and measures are too broad to provide an adequate basis against which to measure and report on performance. There is a need to make these operational and to clarify what the Agency specifically expects to accomplish and how they are going to know that they have accomplished it. For example, one measure identified was speed of response. There is a need to define it further and specify targets or standards.

60 Clearly defining objectives and related performance measures for the Food Emergency Response System would also allow the Agency to give clear direction to its staff and facilitate the conduct of post-emergency reviews. The performance measures could be included in the checklist of information gathered on each recall (see paragraph 53). This would be an easy and efficient way to gather the relevant information necessary for monitoring and reporting on performance.

Recommended Action: The Canadian Food Inspection Agency should refine the objectives and performance measures for its Food Emergency Response System and use these measures to report on its performance.

Agency's response: The Agency reports on the performance of its food emergency response in its annual report to Parliament and will continue to improve its performance reporting in this area.

CONCLUSION

61 The following points summarize our conclusions with respect to the criteria used for the assessment. We recognize that the Food Emergency Response System adopted by the Canadian Food Inspection Agency operates in essentially the same manner as food emergency systems which had been in place previously in Health Canada and Agriculture and Agri-Food Canada. These were and remain consistent with practices for other inspection programs charged with responding to emergency situations. However, the assessment team believes that improvements can be made which will provide a greater level of assurance that consumers are protected from hazardous food products in emergency situations.

Roles and responsibilities: The roles and responsibilities for handling recalls were mainly clear and well understood within the Canadian Food Inspection Agency. The role of the Food Emergency Response System in other food safety emergencies such as sabotage or tampering incidents, reported illnesses and man-made or natural disasters needs to be clarified. The *Food Emergency Response Manual* does not provide specific procedures for these types of food safety emergencies, or reference to other emergency plans and the role and responsibility of all other stakeholders that may play a role in a food emergency response.

Identification of food safety emergencies: Recalls were, for the most part, identified promptly and investigated sufficiently to reach a conclusion. Current Agency inspection, sampling and complaint investigation programs are a valuable source of information.

Risk assessment: The estimation of risk in a potential emergency situation and the subsequent risk management actions taken were appropriate in the vast majority of situations and the process for determining the risk was carried out in a timely manner. Better documentation of the rationale for recall classification decisions is required.

Emergency management: The *Food Emergency Response Manual's* guidance with respect to managing public announcements and monitoring the effectiveness of recalls could be improved. These improvements would contribute to assurance that the appropriate action is taken to fully protect the public in each food emergency situation. Improved documentation of the progress and subsequent termination of each food safety emergency may contribute to more effective management of these situations.

Performance of the Food Emergency Response System: The Agency has developed a performance measurement framework which includes the Food Emergency Response System. This is a very positive step. These general objectives and performance measures need to be made operational and should clarify what the Agency specifically expects to accomplish and how they are going to know that they have accomplished it.

62 We conclude that the Agency was, overall, effective in identifying situations in which recalls were necessary, that it assessed the situation and initiated a response in a timely manner, and that it

implemented management actions which were, for the most, in accordance with the level of risk. The Agency's role in overseeing and monitoring industry's recall actions can be improved with enhanced guidance in the *Food Emergency Response Manual* and better documentation of the decisions and actions taken.

ABOUT THE ASSESSMENT

Objective

The objective of this assessment was to assess the effectiveness of the Canadian Food Inspection Agency in responding to potential and actual food safety emergencies.

The criteria against which the Food Emergency Response System was assessed, are:

- , The roles and responsibilities for implementation of the Food Emergency Response System should be clearly defined and understood.
- , The Canadian Food Inspection Agency should identify potential emergencies with food safety impact in a timely manner.
- , The Canadian Food Inspection Agency should have an established process for determining, in a timely manner, the level of food safety risk associated with potential emergencies.
- , The Canadian Food Inspection Agency should manage food safety emergencies in a timely manner and in accordance with the level of risk.
- , The Canadian Food Inspection Agency should monitor the effectiveness of emergency response activities and make improvements when required.

Scope and Approach

The scope of this assessment included food safety emergencies that occurred between September 1, 1996 and February 5, 1998. We examined in detail 49 recalls that occurred during this period. We also looked at an additional 12 incidents in which no recall was considered necessary. The recalls in our sample included Class I (emergencies) and Class II (potential emergencies) recalls, different types of hazards, and covered different regions. Some of the recalls included Health Hazard Evaluations by Health Canada while others did not. We also examined the Agency's response to the ice storm that took place in January 1998 with reference to the Food Emergency Response System.

The examination was conducted at the Canadian Food Inspection Agency's Headquarters and within four Regions: Pacific, Ontario, Quebec and Atlantic. It included interviews with officials, file and document reviews, analysis of data gathered on the 49 recalls examined in details and review of the performance framework of the Agency as it relates to the Food Emergency Response System.

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