CHAPTER 5 TOOLS FOR PROGRAM ANALYSIS AND IMPROVEMENT: COUNCIL TO IMPROVE FOODBORNE ILLNESS OUTBREAK RESPONSE MANUAL AND TOOLKIT

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1.0. PURPOSE

This Chapter provides an overview of the Council to Improve Foodborne Illness Outbreak Responses (CIFOR) "Guidelines for Foodborne Disease Outbreak Response" and the CIFOR Toolkit, which allows agencies to evaluate organizational structures and program capacity, related to foodborne illness (FBI) outbreak investigations. Rapid Response Teams (RRTs) are designed to have an integral role in the emergency response to outbreaks. As such, these tools used alongside other resources to evaluate other aspects of rapid response and to help integrate RRTs with partner foodborne illness (FBI) responding agencies, evaluating the agencies' individual capacities then supplementing them as needed to improve coordination in a unified emergency response.

2.0. SCOPE

The CIFOR Guidelines for Foodborne Disease Outbreak Response provide a framework for multi-disciplinary and multi-agency collaboration between public health (epidemiology and environmental health), laboratory, and regulatory agencies involved in an FBI investigation. This chapter focuses on the specific response actions and considerations outlined in the CIFOR Guidelines and their related Toolkit, and where they might help in planning for and executing a unified response to FBI outbreaks. The CIFOR evaluation process may be useful for RRTs, agencies with established outbreak response procedures, and for those assessing programmatic gaps with the goal of building upon existing plans and capabilities.

3.0. RESPONSIBILITY

3.1. Agency/Organization Leadership

Before initiating an evaluation based on CIFOR guidelines, leadership of federal, state, and local agencies involved in responses to human and animal food incidents should be made aware of the process, outcomes, and what their individual and collaborative roles would be in supporting the evaluation's findings and advancing improvements.

3.2. RRT Members and Partners

The CIFOR Toolkit suggests prioritizing for evaluation one or more "focus areas" of a jurisdiction's outbreak response. RRT members and partners should:

 Participate in all phases of focus area selection, evaluation, and reporting. For the purposes of the Toolkit and the "Investigation of Clusters and Outbreaks" focus area, participants should include representatives of environmental health, laboratory, and epidemiology units. • Apprise leadership of federal, state and local agencies involved in response to human and animal food incidents of the process, outcomes, and what their potential role would be in supporting findings and advancing improvements.

3.3. Other Partners

Additional participants in an evaluation, including experts in information technology, retail food, legal issues, infectious disease experts etc., should be invited to the process particularly as other elements of the CIFOR Toolkit are used or when specific areas for improvement are identified.

4.0. DEFINITIONS

- Internal v. External
 - Internal Internal to the agency initiating use of the CIFOR Toolkit and having primary or coordinate responsibility for initiating an FBI investigation.
 - External Agencies or other entities that would participate in an FBI investigation but are not part of the original, initiating agency for a response or for the evaluation process.
- CIFOR Council to Improve Foodborne Outbreak Response
- FBI Foodborne Illness
- RRT Rapid Response Team
- MFRPS FDA's Manufactured Food Regulatory Program Standards

5.0. BACKGROUND

RRTs may take advantage of several different tools available to improve the effectiveness and efficiencies of their organizational structures, response capacity, regulatory foundation, and other critical aspects of a human and animal food protection and response program. In addition to the CIFOR *Guidelines for Foodborne Disease Outbreak Response*, other program improvement initiatives include the MFRPS and the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS). These initiatives evaluate food programs primarily from the regulatory and food protection levels. Some elements of each of these tools may seem to overlap with or mirror those in other evaluation tools; however, each serves a specialized purpose in evaluating human and animal food protection and response programs.

In contrast, the CIFOR Guidelines are not focused on the evaluation of core food protection and response programs, but on critical elements of FBI outbreak and cluster investigations and the response. The CIFOR Guidelines and the associated Toolkit examine the roles of regulatory, laboratory, public health organizations at the federal, state, and local levels with respect to an integrated outbreak response. Use of the CIFOR recommendations and tools will aid food protection and response programs and related agencies in understanding organizational models

and best practices that may help integrate investigation activities and improve the overall performance of the RRT and associated investigation partners.

In this respect, the *CIFOR Guidelines* expand upon the foundation provided in other regulatory program evaluation tools. For example, while Standard 5 of the MFRPS, "Food Related Illness, Outbreak, and Hazards Response" examines capabilities related to foodborne illness outbreaks, MFRPS focus primarily on the regulatory aspect of a program. Use of the CIFOR Toolkit will contribute to programmatic efforts to meet MFRPS Standard 5, though it emphasizes other elements of FBI investigations.

Human and animal food protection and response programs and RRTs that are interested in using this evaluation tool should use the *CIFOR Guidelines* and the Toolkit together. The *CIFOR Guidelines* describe the major functions needed during an FBI outbreak including planning and preparation, disease surveillance and outbreak detection, investigation of clusters and outbreaks, and control measures. The CIFOR Toolkit provides a mechanism for using the concepts in the *CIFOR Guidelines* to evaluate existing state and local human and animal food protection and response programs and their associated operations and capabilities. Use of the Toolkit will help these human and animal food protection programs to become more familiar with the *CIFOR Guidelines* and identify and improve practices and capabilities that affect the performance of the RRT.

CIFOR Toolkit worksheets provide a valuable starting point for systematically assessing activities related to various components of outbreak investigation. Once completed, these worksheets provide a basis for use of other RRT manual elements including recall procedures, working with other agencies, and additional capabilities. Additional tools, job aids, and model protocols may be found in other chapters of the RRT Manual and in the CIFOR Clearinghouse on-line (see Comparison Table at the end of this chapter).

The CIFOR Toolkit facilitates an analysis of the different components and factors contributing to an effective FBI investigation. Of the four "Tracks" described in the Toolkit, it is suggested that the first one that should be evaluated for RRTs is "Investigation of Clusters and Outbreaks" including constituent Focus Areas within that Track: Environmental Health Investigations, Epidemiology Investigation, and Laboratory Investigation. (See Document E, "Selecting Focus Areas Worksheet" and *CIFOR Guidelines* Chapter 5.) RRTs should review information found in Chapter 5 of the *Guidelines* that discusses the investigation process, in addition to using the appropriate CIFOR Toolkit worksheets as described below. Chapter 6 of the manual, "Control Measures-Debriefings, Procedures for Removing Food from the Market" also discusses a key element of FBI response that should be examined and used for planning, protocol development and FBI investigation efforts.

The "Keys to Success" in each section of the CIFOR Toolkit discuss the core capabilities necessary for different elements of an FBI investigation, including

specific activities, communication, relationships, resources, and other factors that contribute to the improvement of response team capabilities. Ongoing use of the Toolkit and evaluation process will support efforts to improve and maintain overall RRT capacity.

6.0. SAFETY

N/A

7.0. EQUIPMENT/MATERIALS

- Texts referenced in this document
- Conferencing equipment, phones, email/internet/computer, fax machines, scanners, and/or mail
- Access/use of FoodSHIELD
- Local area networks
- Meeting rooms
- Contact list

8.0. PROCESS DESCRIPTION

The following documents are developed with the intention of facilitating the integration of RRTs into existing human and animal food protection and response programs enhancing the ability to rapidly respond to human and animal food incidents through coordinating the activities and supplementing the capacity of all organizations involved. Use of the national FBI outbreak investigation process and evaluation standard, *CIFOR Guidelines* and Toolkit, provides a consistent nationwide basis for evaluating the mechanism of integrating and coordinating the RRT with partner organizations and the impact of these actions on process improvements and FBI investigation outcomes. The toolkit provides a mechanism for continued improvement through consistent evaluation of the outbreak response process for participants. Use of the process described advances the goal of full integration of the national human and animal food safety system across all levels.

The CIFOR Guidelines and Toolkit are the result of a multi-year process and are consensus recommendations for FBI outbreak investigation. The toolkit provides a mechanism for continued process improvement through consistent evaluation of outbreak responses. Use of the process described can result in improved and better aligned multi-agency and multi-disciplinary FBI investigations leading to a more nationally integrated human and animal food safety system.

8.1. Initiate Workgroup on Use of CIFOR Toolkit

To effectively use the CIFOR Toolkit, a workgroup should be formed to carry out the overarching assessment of the program and specific areas needing further evaluation. The workgroup should comprise members of at least the three core response areas (i.e., environmental health, epidemiology, and laboratory) and others familiar with the outbreak response process. Additional expertise may be brought to the workgroup as well. Information on past outbreak investigations and after-action summary reports from formal exercises may be used to provide information for the initial CIFOR evaluation tool, as described in Document E of the Toolkit, "Selecting Focus Areas Worksheet".

This process narrows the number of areas for evaluation, although multiple subworkgroups may be formed to address other response issues.

8.2. Refine Workgroup as Necessary

Assess workgroup expertise and experience and determine if additional members may be needed.

8.3. Prepare Background Resources

Familiarize partners with the CIFOR Toolkit worksheets, identify additional needed resources, and review historical information prior to use of actual worksheet. To use the worksheets effectively, participants should review previous outbreak response reports, plans, and activities. A complete background information sheet will be developed based on these resources as part of the evaluation process which will inform conclusions about the RRT and FBI Investigation.

A review of the CIFOR Guidelines by all members is also essential to the success of the Workgroup and evaluation process.

The RRT manual, including the introductory chapter "Working with Other Agencies", "Communication Standard Operating Procedures", "Tracebacks", "Incident Action Plans, Situation Reports, and After-Action Reports" and other sections relevant to your objectives and RRT should be evaluated.

Additional process and subject matter evaluation tools should also be reviewed and discussed prior to use of the CIFOR Guidelines so that findings and issues relevant to the RRT and FBI response can be introduced.

Historical documents on past FBI response efforts, and formal after action reports (AARs), should be examined to identify issues for discussion and evaluation.

8.4. Utilize CIFOR Toolkit Guidelines to Identify Strengths and Weaknesses

Following the selection of specific capabilities to be assessed, use the CIFOR worksheets individually then as a group to identify core strengths, weaknesses and resources in the food protection and response program areas. Use the appropriate portions of the CIFOR Toolkit to support your analysis and evaluation. Avoid duplication of effort, i.e., between two separate program evaluation processes

such as MFRPS and CIFOR, and tailor your use of the CIFOR Toolkit to the specific needs and issues of your agency.

8.5. Share Findings with Contributing Partners and Leadership

Upon completing worksheets and use of the CIFOR Toolkit, assemble analysis and core findings and distribute to members of Workgroup and internal and external leadership as appropriate.

8.6. Comments and Reviews

Distribute CIFOR worksheets to members of the workgroup and internal leadership for feedback and comments. Once all comments are reviewed and incorporated as appropriate, distribute to appropriate parties.

8.7. Crosswalk Findings to Other Program Standards

In addition to completion of the Toolkit evaluation, findings should be crosswalked, when possible, to the MFRPS and to the VNRFRPS. Such standards help form the basis for foodborne illness outbreak response through strengthening of the core regulatory program. The Crosswalk will be updated once the new CIFOR edition is cleared and ready for publication.

8.8. Develop Strategic Plan

Based on the findings from use of the CIFOR Toolkit, and evaluation of other best practice tools and resources, consider outlining areas for improvement and develop a strategic plan.

8.9. Continue Evaluations in Other Focus Areas

Carry out evaluations of other areas (e.g., communications) that contribute to the overall success of FBI investigations. See Metrics chapter of RRT Best Practices Manual.

8.10. Measure Improvement Through Actual Events and Exercises

Consider the development of, or adoption of, metrics to measure improvement in specified areas of FBI outbreak response and assess following actual events and exercises. Develop plans to address gaps, resources, and capabilities based on after action reports and metrics assessments.

9.0. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

The levels assume that agencies with higher level capacities meet all the elements, while agencies with lower-level capacities meet only some of them.

Level	Description
1	No awareness or familiarity with CIFOR Guidelines and CIFOR Toolkit. No FBI investigation process or capabilities have been evaluated using the CIFOR Toolkit.
2	Knowledge of FBI response capabilities. CIFOR Toolkit is used to assess one or more FBI response elements and a draft evaluation report is produced.
3	Engage with partner agencies, industry, and other FBI responders. Key parties ¹ review and provide input on the draft evaluation report.
4	Capacity built to implement the development of an integrated human and animal food protection and response program (through assessment, corrective action plans, and strategic planning). The evaluation report is used to guide development of protocols for the RRT/human and animal food protection and response program, planning, and responses to exercises or actual incidents.
5	Full use of CIFOR Guidelines and Toolkit and RRT Chapters and related resources. FBI investigation protocols undergo routine ² evaluation using CIFOR Toolkit process.

9.2. Process Overview

- Identify Achievement level (table above). Identify agency goals and existing
 commitments to one or more process improvement initiatives (e.g., MFRPS,
 etc.). Review crosswalk (attached) that identifies similarities and differences
 of key initiatives related to human and animal food emergency response and
 process improvements.
- Review CIFOR Guidelines (especially Chapter 5) and introductory CIFOR "Toolkit" sections including "Toolkit Overview – Document A" and "Selecting Focus Areas Worksheet – Document E".
- Form a workgroup, including members of the RRT where appropriate, to carry out the evaluation process to identify potential focus areas where improvements may be needed. Ensure familiarity of all participants with the CIFOR Guidelines and related documents (the RRT Manual and CIFOR guidelines complement each other and should be used in tandem for the process).
- Once the primary focus areas for a full evaluation have been identified, select the appropriate CIFOR Toolkit worksheet to guide the analysis (e.g., Focus Area 8 Worksheet: Environmental Health Investigation" CIFOR Toolkit worksheet)
- Use the CIFOR tools and the findings from the analyses to develop a strategic improvement plan. Prioritize areas for improvement and develop plans to address other outstanding issues.

¹ As determined by the RRT member agency leading this effort or the RRT Steering Committee/equivalent.

² As agreed upon by RRT member agencies involved in the evaluation. CIFOR suggests a yearly evaluation.

- Modify and revise existing protocols and procedures as necessary based on findings.
- Assess advances related to the CIFOR criteria in annual exercises and/or after-action reports on actual incidents.

10.0. RELATED DOCUMENTS

- RRT Best Practices Manual, US Food and Drug Administration, 2017
- Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response. Atlanta: Council of State and Territorial Epidemiologists, 3rd Edition
- Voluntary National Food Retail Food Regulatory Program Standards (VNRFRPS)
- Manufactured Food Regulatory Program Standards (MFRPS)
- Food Related Emergency Exercise Bundle (FREE-B)

11.0. REFERENCES AND OTHER RESOURCES

- Manufactured Food Regulatory Program Standards (MFRPS) https://www.fda.gov/media/131392/download
- Voluntary National Retail Food Regulatory Program Standards
 (VNRFRPS)https://www.fda.gov/food/guidanceregulation/retailfoodprotection/programstandards/ucm245409.htm
- National Association of State Departments of Agriculture Food Emergency Response Plan Guidancehttps://www.nasda.org/wp-content/uploads/2024/04/FERP-Supplemental-Information.pdf
- Council to Improve Foodborne Outbreak Response Guidelines for Foodborne Disease Outbreak Response and related resources
 - Guidelines http://www.cifor.us/
 - Toolkit https://cifor.us/products/toolkit
 - Clearinghouse https://cifor.us/clearinghouse
 - Crosswalk
 https://cifor.us/search/searchClearinghouseResults?q=crosswalk
- FoodSHIELD https://www.foodshield.org/

12.0. ATTACHMENTS

 Attachment A – Comparison Table: RRT Best Practices Manual to CIFOR Guidelines

13.0. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	10/11/2012	RRT CIFOR WG (TX**, MA, MI)
1.1	R	1/24/2013	ORA OP
1.2	R	5/26/2017	ORA/OP
2.0	R	3/1/2023	ORA/OP-AFDO Compiled Revisions
3.0	R	12/1/2024	ODP-AFDO Compiled Revisions

^{*}Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)

Change History

- 1.1 Minor editorial revisions made to Achievement Levels and Attachment A for clarification purposes.
- 1.2 Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.
- 2.0 AFDO compilation for 2023 Edition of RRT Manual
- 3.0 AFDO compilation for 2025 Edition of RRT manual. Updated FDA program names resulting from the 10/2024 FDA reorganization

^{**}Workgroup Lead

Attachment A – Comparison Table: RRT Best Practices Manual to CIFOR Guidelines

This table aims to identify related sections between the RRT Best Practices Manual and the CIFOR Guidelines and Toolkit and should not be interpreted as interchangeable. Please note that while these documents may contain content that touches on similar topics or is complementary, each of these documents serve a specific program or constituency. While it is encouraged for human and animal food regulatory and public health programs to leverage multiple response tools as appropriate for their program, human and animal food regulatory and public health programs receiving federal funding for response capacity development should always defer to the requirements as set forth in that funding agreement.

DESCRIPTIO	N OF RRT CHAPTER	CIFOR GUIDELINES AND TOOLKIT
Chapter 1	Working with Other Agencies	Chapter 3.1 – Agency Roles
Chapter 2	Federal-State Cooperative Programs	No corresponding CIFOR content at this time
Chapter 3	Industry Relations	Chapter 3.6 – Communication Chapter 6.5.4 – Communication with the Industry
Chapter 4	Exercises	No corresponding CIFOR content at this time
Chapter 5	CIFOR	
Chapter 6	Food Emergency Response Plans (FERPs)	Chapter 3 – Planning and Preparation
Chapter 7	Communication Standard Operating Procedures (SOPs)	Chapter 3.6 – Communication
Chapter 8	Incident Command System Concepts in RRTs	Chapter 3.10 – Incident Command System
Chapter 9	Rapid Response Team (RRT) Training	Chapter 3.2 – Outbreak Investigation and Control Team
Chapter 10	Tracebacks	Chapter 6.2 – Control of the Source
Chapter 11	Joint Inspections & Investigations	Chapter 5.2.5 – Coordinate Investigation Activities Chapter 7 – Special Considerations for Multijurisdictional Outbreaks
Chapter 12	Environmental Sampling & Records Collection	Chapter 3.2 – Outbreak Investigation and Control Team
Chapter 13	Recalls	Chapter 6 – Control Measures

DESCRIPTION OF RRT CHAPTER		CIFOR GUIDELINES AND TOOLKIT
Chapter 14	After Action Reviews	Chapter 5.2.8 – Conduct a Debriefing at End of Investigation Chapter 6.7 – After-Action Meetings and Reports Chapter 7.5 – Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS
Chapter 15	Metrics	Chapter 8 – Performance Indicators for Foodborne Disease Programs
Relevant Concepts & Tools	Subsection A: RRT Capacity Building Process & Framework for Developing Rapid Response Capability	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection B: Response Concepts/Framework	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection C: Crosswalks of Frameworks/Concepts	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection D: Useful Tools in Improving Foodborne Outbreak Response	No corresponding CIFOR content at this time
Relevant Concepts & Tools	Subsection E: Conference Call Etiquette	Chapter 3.6 – Communication
Relevant Concepts & Tools	Subsection F: Overview: Incident Action Plans, Situation Reports, and After Action Reports	Chapter 7.5 – Multijurisdictional Outbreak Investigations After-Action Reports and Reporting to eFORS
Reference	Subsection A: Acronyms	No corresponding CIFOR content at this time
Reference	Subsection B: Glossary of Key Terms (Definitions)	Appendix 1 – Glossary
Reference	Subsection C: List of Reference Documents	Appendix 3 – List of Key Websites and Resources Cited
Reference	Subsection D: About the RRT Program	No corresponding CIFOR content at this time