CHAPTER 3
INDUSTRY RELATIONS

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1.0. PURPOSE

The purpose of this document is to assist state human and animal food regulatory agencies in identifying various types of industry-regulatory interactions, improving their relations with human and animal food industries, firms, and trade associations. This document directs the focus on level and extent of engagement desire, understanding the different types of interactions among agencies, and recognizing aspects that help and hinder industry-regulatory interactions. The term “Industry” in this document includes individual human or animal food firms (growers, manufacturers, wholesalers, retailers that are impacted by the emergency) as well as trade associations. While the primary audience of this document is regulatory agencies, this should not preclude other governmental and private entities from using this as a resource.

2.0. SCOPE

This document serves as a high-level orientation to industry-regulatory interactions. It is meant to guide regulatory agencies in assessing their current level of relations with industry and to identify steps for improvement. This is not a comprehensive manual of the subject nor is it an obligatory process; every agency differs in resources, responsibilities, and priorities. Leadership of regulatory agencies involved in responses to human or animal food incidents are encouraged to apply the best practices described in this chapter to any processes and procedures regarding industry relations that are appropriate for and/or currently in use by their jurisdictions.

3.0. RESPONSIBILITY

3.1. Agency/Organization Leadership

Leadership of federal, state, and local agencies involved in responses to human or animal food incidents will jointly work to apply the best practices described in this chapter to any processes and procedures regarding industry relations that are appropriate for and in use by their jurisdictions.

3.2. RRT (or investigatory team, in states without an RRT) Leadership

RRT leadership is responsible for ensuring that the personnel assigned to respond to human or animal food incidents have been provided with the Incident Command System (ICS) and investigation-related training necessary for them to successfully complete the tasks they are assigned.

3.3. RRT Members (or investigatory team, in states without an RRT)

RRT members are responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multi-disciplinary and multi-agency response teams.

4.0. DEFINITIONS

N/A

5.0. BACKGROUND

Building and maintaining good relationships between regulatory agencies and industry are important for several reasons. There is a shared public health vision between industry and regulatory agencies that is important to foster and capitalize upon. While there exists an inherent tension between the regulatory agencies and the regulated industry, public health, and the economy benefit when the relationship is constructive rather than antagonistic. Industry often knows more

than regulatory agencies about itself and in many cases will have much deeper knowledge of their products, how they are made, how they move through commerce, and how those things have changed over time. Industry associations and individual companies can often be assets to regulatory agencies, containing a wealth and depth of subject matter expertise on areas including sourcing, standards, audits, processing, marketing, logistics, and consumer preferences. They can help regulatory agencies better understand risks in the marketplace and can also help to reach consumers on overarching efforts like hand-washing campaigns, and aid in specific responses like product recalls.

Additionally, industry members can serve as a great source of information on challenges specific to those regulated commodities and can keep regulatory agencies abreast on the issues and concerns faced by the respective communities, beyond just outbreaks and illnesses. Through valuable information sharing about emerging trends and the latest challenges faced by industry, regulators anticipate potential roadblocks in the integrated food safety system, but also recognize how these issues can significantly influence their willingness and bandwidth to comply to regulatory program standards. By demonstrating that regulatory agencies are cognizant and understanding of their challenges and constraints can further strengthen the relationship and build trust between regulatory agencies and industry, as illustrated in the unprecedented COVID-19 pandemic. Industry members are integral stakeholder to the national Integrated Food Safety System (IFSS) and should be invited to collaborative food protection platform, such the Coalition of Food Protection Task Force (CFPTF), which is comprised of representatives from each state task force, FDA, FSIS, and Subject Matter Experts (SMEs) from local, state, tribal, territorial, federal regulatory agencies, academia, and include industry inputs in the development of preventive strategies to protect food supply.

Industry can also benefit from engaging in partnerships with regulatory agencies. In many cases, regulatory agencies were created because of significant health and safety issues within the food and agriculture sector. These agencies represent the public and are charged with licensing, testing, and enforcement of businesses and products. As issues emerge in the public and in the media, including new threats and awareness of vulnerabilities of the food supply, there will be calls to address those issues through changes in legislation and regulation. By actively engaging with regulatory agencies through trade associations and other groups, industry can help provide a perspective on proposed language that can lead to more workable final products and less contention during the legislative process. Through interaction with regulatory agencies, industry can also better learn about how these agencies work, what their legal and program constraints are, and other important issues that may aid in understanding why and when regulatory actions are taken.

6.0. SAFETY

N/A

7.0. EQUIPMENT/MATERIALS

N/A

8.0. PROCESS DESCRIPTION

8.1. Types of Industry-Regulatory Interactions

There are multiple examples of interactions between industry and the regulatory communities that can lead to positive results for both.

8.1.1. Temporary or ad-hoc working groups

These are working groups comprised of regulatory agency and industry representatives that are formed on a temporary basis to make a specific decision or complete a specific task. Examples include updating a state food code, or creating guidelines for reducing the risk of *Salmonella* contamination on a commodity.

8.1.2. On-going working groups

These are working groups, comprised of regulatory agency and industry representatives, that are formed for continued collaboration around a subject. Examples include: Food Protection Task Forces or Food Defense/Agro-Terrorism Working Groups.

8.1.3. Foodborne illness outbreak investigation or crisis event response

These are interactions during a foodborne illness outbreak investigation or response to a human or animal food emergency. Particularly in a natural or man-made disaster, the regulatory agencies and industry may need to work closely together in both the response and recovery phases, including coordination in a Joint Information Center (for more information, see “Incident Command System – Best Practices” in the RRT Best Practices Manual).

8.1.4. Training, education, and other outreach

These are opportunities to share best practices and knowledge with industry representatives. These include in-person events, such as classroom training or workshops, or informational materials delivered on fact sheets or web sites. They can be co-hosted/co-authored by the working groups mentioned above or can be stand-alone offerings based on need. These can also occur as “cross-training”, or

joint training, in which industry and regulatory representatives train together (for example, ICS or food defense joint trainings).

8.2. Issues to Consider with Working Groups

There are several considerations that need to be factored into creating and maintaining working groups. The points below describe important areas that should be discussed internally by both industry and regulatory, and then between the two.

8.2.1. Creating a working group

Ideally, a working group should be working before an issue or problem arises. When possible, be pro-active versus reactive when addressing emerging issues.

8.2.2. Defining the working group mission

Defining the mission of a working group is fundamental to its success. The mission should state whether the working group is designed to be temporary or on-going. If there is a specific product, deliverable, or outcome that needs to be developed by this group, this should be clearly stated along with a deadline for the product.

8.2.3. Identifying who to include

The working group mission, goals, and deliverables should help to identify potential group members. Consider identifying and recruiting members from different sized entities within an industry or industry sector, since they will have different needs, resources, and viewpoints. The RRT Best Practices Manual may be useful in laying out the scope of work, especially if multiple agencies at the state and local levels are responsible for the subject area (see “Working with Other Agencies”, “Communication Standard Operating Procedures (SOPs)”, and “Joint Inspections & Investigations” sections of the RRT Best Practices Manual).

8.2.4. Procedural and logistical considerations

When building a working group, there are several procedural and logistical considerations to be made. It is strongly suggested that regulatory-industry groups delineate the procedures by which the group will operate. These include:

- **Formation of the group:** How will members be invited and chosen? Will this be determined by the Governor, Commissioner/Secretary/Director? Will there be a general announcement and call for interest, allowing everyone who wants to take part to do so? Or will it be a select invitation?
- **Governance of the group:** How formal will the structure be? Will there be shared leadership of the group between industry and regulators? Is there a need for a charter or bylaws? Will there be voting that binds the group to a decision? If so, will minority viewpoints be included in any reports or

documents? Will there be meeting minutes taken or annual reports written? If so, what is the distribution of these documents – group members only or available to the public?
- **Membership length of service:** What will be the term of service of the members? How will vacancies be filled?
- **Logistical support:** Who will provide administrative staff resources to support the working groups? Will members receive reimbursement for their travel and related expenses?

8.2.5. Open meetings and public records laws

Several states have laws governing open meetings and public records. These vary by state and agencies, and legal counsel should be consulted regarding applicability. This also includes minutes and notes taken at these meetings, as well as membership lists and contact information.

8.2.6. Securing confidential information

It is important to identify types of confidential information that could be sought or shared by the working group, respect the legal bounds for sharing and securing this information, and set working group guidelines based on the laws and policies that govern its members. For instance, it may be helpful for the agencies to understand how industry manages some part of the process or for the work group to tour a facility to better understand how something works. However, that may be proprietary or confidential business information. State laws vary on disclosure, so agencies should consult with legal counsel to determine the access and availability of information collected through participation in this group.

Securing information also includes development of processes within the regulatory agency for information security and to ensure other working group members representing private businesses do not receive an advantage from information access. For these situations, seeking information from industry associations or trade groups may be more appropriate than from individual businesses as these groups will have an understanding about proprietary sensitivities and can provide information at a generic level. Documents such as confidentiality agreements, if applicable, should be in place before the start of a working group.

The following are additional special considerations for securing information:
- **Protected Critical Infrastructure Information (PCII)**: Some information provided by the private sector to federal, state, or local agencies may be considered PCII, meaning that it was gathered as part of the national effort to protect critical infrastructure, including the food and agriculture sector. This information is voluntarily provided by industry to government and helps provide a better understanding of threats, risks, and vulnerabilities. However, under federal law it cannot be disclosed to the public and it also cannot be used for any regulatory or enforcement actions.

- **Information supplied by federal agencies (CDC, FDA, USDA)**: Some information may be provided to state or local agencies through agreements with the FDA or USDA that with limits on further disclosure. Federal law prohibits working group review of these kinds of materials if the working group contains any members who do not have explicit authorization to review such documents.
- **Protecting regulatory information distributed to working group members**: Regulatory agencies may have internal policies and procedures (for example, how inspections are planned and carried out). Depending on state open meetings and public records laws, disclosure of any documents—including those considered internal or sensitive—may result in them being considered public. They may also become public through loss or intentional distribution by working group members; measures to safeguard against such distribution should be taken.
- **Competing interests between industry and regulatory entities and among different types/sizes of industry**: There are some potential conflicts that both sides should be aware of in working groups. These include ensuring that working groups:
    - Have a balance of viewpoints.
    - Have a balance of industry participants so that individual companies cannot use the process to negatively impact their competition, or that a group of firms of a similar size do not steer the process toward an outcome that is unworkable for those of any other size or configuration.
    - Can freely share internal procedures or industry food safety practices that serve as information sharing, gauge performance status, and seek evaluations for quality improvement. Voluntary information exchange regarding industry practices should not result in punitive actions during non-emergency workgroup meetings, but rather promote education opportunities and foster environments for regulatory feedback to improve food regulatory compliance. Using the workgroup meetings as a platform, regulators can serve as the key advocate to encourage voluntary information exchange from industry partners, communicate the goals of information sharing from the initial phases when regulatory-industry group was formed, and continue to provide assurance regularly through workgroup meetings.
    - Identify and recruit members from different-sized entities within an industry or industry sector. Large and medium-sized entities may have staff that can more easily participate in working groups or be represented by industry trade associations. In some cases, smaller entities including cottage industries may be affected by the outcomes of the working group but not have been aware of or invited to participate in the working group. Also, smaller entities may not be as likely to belong to trade associations. Including individuals representing entities of a smaller size may help to ensure that the concerns of smaller entities are brought forth and included in the discussion.
    - Create a mechanism or process to let all members, and potentially the public, submit and openly discuss all proposals.

8.2.7. Keeping working group members engaged

This is an issue for on-going working groups. Both industry and the regulatory agencies have limited staff time, and both must make decisions about how much time to commit to these groups. The regulators, due to their public service mission, may have more flexibility to spend time and energy on these kinds of projects. Industry representatives may have to evaluate how serving on a working group, especially a long-term one, will benefit both the individual company and the industry. If the working group is coordinated out of a regulatory agency, the agency should regularly ask industry if the working group is meeting their needs, to keep the private sector at the table and engaged.

8.2.8. Building and maintaining trust among all members

There may be certain topics addressed in working groups that are contentious or require a level of trust to resolve. For contentious issues, it may be advisable to use third-party facilitators without a stake in the outcome to help a working group understand all perspectives and reach consensus. This may be very useful for temporary/ad-hoc groups working on issues like creating a new type of licensed activity or setting fees, and for long-term working groups where there has been a history of poor communication or distrust.

8.3. Issues to Consider During Outbreak Investigations and Crisis Response

The language below covers two types of crises. The first identifies where the firm/industry is at the center of an outbreak investigation and potential recall; and the second focuses on when the firm/industry is involved in a response to a natural disaster or criminal action.

8.3.1. Outbreak investigations and recalls

The following are considerations for industry-regulatory relations when the crisis is related to an outbreak investigation and recall:

- **Sharing information during the investigation:** The firm and/or industry is generally very interested in all actions being taken by the regulators and will want to know what steps are being taken and being planned. In some cases, the firm/industry can be a very useful partner and can act quickly to address the situation, thereby protecting the public health and reducing exposure and their liability.
- **Balancing multiple interests:** There are often multiple aims and interests among those involved in an outbreak investigation. The regulatory agency may be concerned with taking sufficient time to conduct a thorough investigation. The firm may be concerned with recovering as quickly and inexpensively as possible. In some cases, the regulatory agency may be considering penalties against the firm during an investigation, and this can lead to a lack of information sharing by both the agency and the firm. Both parties should be aware of the pros and cons when an agency or firm

withholds information. For example, a firm may destroy product when they believe their involvement is over, but the regulatory agency may still have need of that product. Or a regulatory agency may have product under seizure or embargo at a firm. The firm may take legal action like suing the agency to try to get the seizure lifted so they could recondition and sell the product. The balance here is between the firm's desire to get rid of implicated product to stop paying storage costs and to try to regain customer trust versus the regulatory agency's desire of having more with which to perform laboratory analyses to best ensure public health.

- **Describing the process and what to expect:** There can be a lot of confusion during an outbreak or food contamination investigation at a food facility. These investigations can last several days to weeks, and require collection of many different types of information. While there are situations when the regulatory personnel cannot predict next steps, often the general framework of the investigatory process is known. Communicating to industry the process and what to expect will often improve how well the firm and the regulatory agency work together during an outbreak or crisis. Tools that assist this communication can be developed in working groups, tested in exercises and real-world responses, and then taken back to working groups for additional discussion.

8.3.2. Examples of the kinds of information and tools that can be used:

- **Guidance documents:** Several federal, academic, and trade organizations have written food safety, HACCP, environmental sampling, and sanitation guidance documents for specific foods and processes.
- **On-site investigation daily timelines:** Lists of what parts of the investigations are going on that day and how the firm can facilitate these actions. For example, by compiling the records that regulators will need, or making available the employees a regulator will need to interview that day.
- **Laboratory analysis timelines:** Turn-around times and information that describe how long different types of laboratory tests take.
- **Regulatory authority:** Materials that explain the legal basis for actions and the thresholds for action. This helps ensure that regulatory actions are predictable and implemented uniformly.
- **Discussion of potential outcomes:** What are the possible outcomes and what would be expected actions in each of those outcomes? For example, if food contact surface or finished product samples test positive for a pathogen (outcome), the regulatory authority may expect to issue a Consumer Advisory and recommend that product be recalled.
- **Describing the process for "appeal":** What if the firm doesn't like what a regulatory agency is doing and vice versa?

8.3.3. All-hazards crisis response

When a firm, industry, or food sector is involved in a crisis response such as a natural disaster or terrorist event, the relationship may be very different because of

differences in how enforcement and litigation are considered. However, other contributions are still very relevant, including information sharing, public and risk communication, and coordinated response.

8.4. Issues to Consider for Training and Educational Events or Materials

There is a need for establishing a common understanding of food safety among regulatory agencies and industry and for a common format for providing training and education. There is also a need to develop a consistent means to educate and communicate information to industry and the public.

8.4.1. Seek input from industry and academia

When creating training and educational events or materials, regardless of audience, consider seeking input from industry and academia. These sources may help define training needs and offer expert information. For in-person trainings or workshops, consider having trainers or speakers from a variety of backgrounds. Industry and academic partners can also help advertise the events or circulate published materials.

8.4.2. When joint training is a good idea

Working relationship between private sector and regulatory agencies can be improved by having staff members participate in training together. While some of the same concerns as noted in the working group issues above can also exist in a training situation, the dissemination of good information as widely as possible benefits all players within the sector. Further, both sides can benefit from learning the same information through the course material. For state, local, and tribal entities, it can be helpful to host a course developed by a third party, particularly a federal agency or university.

8.4.3. Considerations when posting information to an agency website

As noted above, each jurisdiction has its own requirements under open records and disclosure laws, which can impact what an agency may have on its website. In some jurisdictions, there are prohibitions on content or links to private sector information or entities to avoid any suggestion of bias. Other jurisdictions routinely share content developed by the private sector on their websites and through social media as a means of disseminating information, particularly on recalls initiated by the private sector itself. Check with your public information officer and legal counsel for additional information about online posting of information.

9.0. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

9.1. Achievement Levels

Level	Description
1	Little or no engagement with the industry
2	Medium engagement with the industry
3	High degree of engagement with the industry

9.2. Process Overview

Use the descriptions of the levels below to help assess an agency's level of engagement. The heads of organizations have a strong influence on the tone and expectations for industry-regulatory partnerships. Therefore, it is important to re-assess the engagement level as leadership at the state and local levels change through elections and other departures and agency perspectives on engagement may vary. For additional resources, refer to Working with Other Agencies chapter of the RRT Best Practices Manual.

Level 1: **Little or no engagement with the industry**

The regulatory agency does not attend industry conferences or trade shows; the agency gets bills sponsored in the legislative body that have not been shared with the industry; there is a food protection task force but it does not contain representatives from the private sector; there are no or very few working groups with public and private sector representation.

Level 2: Medium engagement with the industry

The regulatory agency's staff occasionally attends industry conferences or trade shows; the agency tells the industry when they get bills sponsored in the legislative body; the food protection task force includes some representatives from the private sector but not many attend; there are some working groups with public and private sector representation.

Level 3: **High degree of engagement with the industry**

The regulatory agency's staff attends industry conferences or trade shows and is asked to present or speak; the agency forms working groups that include industry to work on proposed legislation before approaching the legislative body; there is a food protection task force that includes many members from the private sector and many attend; there are many working groups with public and private sector representation.

10.0. RELATED DOCUMENTS

Related RRT Best Practices Manual Chapters, Topics, and References:

- Working with Other Agencies
- Communication Standard Operation Procedures (SOPs)
- Recalls
- Tracebacks
- Environmental Sampling
- Training
- Joint Inspections & Investigations

11.0. REFERENCES AND OTHER RESOURCES

N/A

12.0. ATTACHMENTS

N/A

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