Analysis, Learning, and Foresight for Assessment and Leadership in Food and Agriculture

A New Agreement for Managing Dietary Contaminants

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May 2014
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Cover: Rice exhibiting symptoms of straighthead disease, which can result from arsenic uptake; from Yan research group, Dale Bumpers National Rice Research Center/Agricultural Research Service, Stuttgart, Arkansas
<http://www.ars.usda.gov/images/docs/7878_8072/straighthead-for-webb.jpg>
Executive Summary

This report to the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA), United States Department of Agriculture (USDA) addresses the question of how to develop an effective interagency agreement for managing dietary contaminants. Case studies of arsenic contamination and subsequent regulatory action related to apple juice, rice, and chicken illustrate the need for better interagency cooperation in this area. The scientific and policy literature, as well as interviews with civil servants and non-governmental experts, corroborate this view.

Key Findings

- Sixteen different agencies, including ORACBA, regulate food and agriculture in the United States.
- Due to poorly harmonized risk assessment techniques, poor data sharing practices, and other organizational barriers, these agencies’ regulations are often confusing, contradictory, and burdensome to those who must comply.
- Differences between food and agriculture agencies in terms of cultures, traditions, and risk analysis methodologies, coupled with statutory requirements for the agencies, contribute to poor regulatory coordination.
- ORACBA possesses significant regulatory oversight authority that could substantially improve the food safety system, but has often avoided using it for historical, political, and other reasons.
- Congressional intent as read from the legislative record, along with statutory language, supports a role for ORACBA in interagency food safety coordination.

Recommendations

- ORACBA should collaborate with other USDA agencies, the Environmental Protection Agency (EPA) National Center for Environmental Assessment, the Food and Drug Administration (FDA), and possibly others to develop and administer an interagency risk policy agreement.
  
  The agreement, called “Analysis, Learning, and Foresight for Leadership and Assessment in Food and Agriculture” (ALFALFA), would combine risk assessment and futures analysis techniques to build a collaborative, systems-based food and agriculture regulatory system.

- To build this initiative, ORACBA should collaborate with officials at USDA Headquarters, and ensure that existing plans under the Food Safety Modernization Act, or other initiatives, are not needlessly duplicated.

- In the long run, further policy study and legislative action will be required to fully reform and improve the food and agriculture regulatory system.
A Broken System & the Promise of Reform

The federal food regulatory system is in dire need of repair.1 Although food risks are very low in the United States compared to those in other countries, many people are still hospitalized or die each year due to food contamination of various kinds. The chemical contamination cases highlighted in this report show that, despite reforms, the national food and agriculture regulation system is highly fragmented, retains its reactionary character, and is poorly equipped to plan for long-term regulatory challenges. Congress created this fragmented system by assigning distinct, but related food and agriculture safety responsibilities to sixteen different agencies, without providing clear guidance for how these agencies should cooperate. This approach may have made sense when food production was less industrialized and complex than it is now. Today, however, food and agriculture are driven by multiple, interacting factors (i.e. complexity) and agency responsibilities often overlap, creating a complicated, confusing regulatory system that burdens industry, hurts consumers, and causes regulatory officials significant consternation.

One of Congress’s early nineties regulatory reforms, and a key to building a better food safety system, is a small office inside the United States Department of Agriculture (USDA) called the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA). Congress created ORACBA in 1994 to serve as a government-wide model for regulatory review and coordination, risk assessment training and outreach, and the use of cost-benefit analysis for writing regulations. ORACBA has completed these tasks well, and can continue to lead by developing a systems-based, interagency agreement for dietary contaminant management. This agreement would primarily coordinate actions between ORACBA, other USDA agencies, and outside agencies such as EPA and FDA. These agencies together comprise most of the food and agriculture regulation system. Other agencies, such as those involved with trade issues, could also be covered by the agreement.

A systems-based approach means that all aspects of the food safety system, from livestock health to the chemistry of food packaging, must be regulated together, and the interactions between these aspects must be accounted for. Therefore, a successful interagency agreement must incorporate a process composed of several steps: collating the various agency risk assessment strategies, and encouraging their harmonization; designing improved organizational, information technology (IT), and research infrastructure for systems-based regulation; and establishing universal methods and training materials for regulatory futures analysis and adaptive regulation. This proposed agreement, called “Analysis, Learning, and Foresight for Assessment and Leadership in Food and Agriculture” (ALFALFA), is described in this report.

Completing these tasks will not be easy, and will require the trust and cooperation of numerous agencies inside and outside of USDA. Given ORACBA’s small size, even basic coordination will require a committed multiagency risk policy team. Additionally, these proposals are not substitutes for legislative action on food safety. Implementing a multiagency cooperative agreement will require reconciling different agency and scientific cultures, as well as creative planning to surmount statutory barriers. Many agency originating statutes require those agencies to address some food safety issues to the exclusion of others. Two examples of such rigidity are

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1 The terms “food safety system”, “food regulatory system”, “food and agriculture safety system”, etc. will be used interchangeably in this report to refer to the collection of food and agriculture regulatory agencies and their accompanying policies.
USDA’s Food Safety and Inspection Service (FSIS), the agency that solely regulates meat, eggs, and poultry, and the Food and Drug Administration (FDA), which regulates most other food, drugs, and cosmetics. One contrasting example is the Environmental Protection Agency (EPA), which has broad authority over environmental hazards, and thus, great influence over the policies of its partner agencies.

Adaptive regulatory approaches will likewise have to strike a balance between the prospective future needs of federal agencies and their more immediate needs. One of the goals of risk assessment is to prioritize food safety concerns given limited resources. Adaptation efforts should be structured so agencies can assess future risks while still addressing short-term problems.

Despite these challenges, ORACBA’s leadership in these areas is sensible and necessary. Other offices, such as EPA’s National Center for Environmental Assessment, conduct risk assessments and are valuable partners for ORACBA, but no other federal office has the statutory mission that ORACBA has. Furthermore, only ORACBA has immediate access to USDA resources. By leveraging these advantages, ORACBA can help construct new guidelines, organizational structures, and ways of thinking that all contribute to a truly integrated food safety system. Such a system will clarify and reinforce existing regulations, assist consumers, and lower costs for industry, while improving the safety of the food supply.

A Brief Introduction to Risk Assessment, Management & Communication

To appreciate why the policies and institutions at the heart of the food and agriculture system do not work well, it is essential to understand the basics of risk assessment, management, and communication; what they can and cannot accomplish; and how these processes, policies, and institutions interact.

To begin, risk policy is about protecting humans, animals, and the environment from hazards — sources of harm. These harms might include a carcinogen or dangerous bacterium. Risk is a measure of the likelihood of harm under certain conditions. Thus, risk assessment is the application of science to the determination of risks. Risk management is the establishment of policies to mitigate those risks. Risk communication is the process of informing the public about particular hazards and the risks they pose to health, safety, or the environment. All three of these processes are key functions of any food regulation scheme. However, this report will focus on risk assessment and management, because they are the major sources of regulatory conflict. (US FDA 2006)

Since risk assessment is about science, it begins with a specific problem involving a hazard and its relationship to a particular system, such as the human body or a forest ecosystem. Risk of harm is always assessed relative to an endpoint — the effect of the hazard — such as death or liver cancer. Once the problem is defined, risk assessors develop exposure models that explain how the hazard harms the relevant system, and dose-response models to understand the effect of a hazard at different exposure levels. (US FDA 2006)
Risk managers use the assessors’ analyses to develop regulations. This requires ethical, rather than scientific judgment. Risk managers must decide the level of harm society can tolerate given limited resources to avoid the harm. Risk communicators, on the other hand, use the assessments to inform the public about how their behavior affects risk levels.

The movement from risk assessment to risk communication and management is not strictly linear, however. Assessors, managers, and communicators often interact, and the lines between these disciplines are not always obvious. The need to distinguish between science and policy raises a number of issues in addition to the institutional questions this report focuses on. The science-policy interactions most critical to interagency cooperation will be highlighted in the subsequent sections.

A Broken System
Understanding and repairing the structure of the current food safety system requires understanding two sets of policies and histories. The first is the set of policies and agencies forming the food regulatory system as most Americans understand it. This system regulates and manages food production, processing, and marketing; agriculture in all of its forms; nutrition programs for schoolchildren and the poor; and many other industry sectors and government programs. The second is the story of ORACBA and its role in food and agriculture policy reform over the past twenty years.

Structure of the United States Food Regulatory System
The American food safety system is complex and fragmented. Numerous agencies and laws regulate food and agriculture at the federal, state, and local levels, including sixteen agencies at the federal level – the focus of this report. (A specific list of fifteen of these agencies can be found in the Appendix. The sixteenth agency is ORACBA.) These sixteen agencies can be broadly categorized as agricultural, public health, environmental, or trade policy agencies, a process that helps conceptualize the current scheme, and provides a framework for organizing a collaborative system.

The agricultural regulators are mostly USDA agencies. Such agencies include food regulators like the Agricultural Marketing Service (AMS), which regulates fruits and vegetables, and the FSIS, which was introduced earlier. Public health agencies are typified by the FDA and the Centers for Disease Control and Prevention (CDC), although some policy areas are handled by departmental agencies such as USDA’s Animal-Plant Health Inspection Service (APHIS). In environmental policy, EPA is the dominant agency, while trade policy is governed by a variety of agencies including Customs and Border Protection (CBP) and the Federal Trade Commission (FTC).

However, these categories are fluid. The originating statutes for the various agencies do not always draw clear lines, and agency roles readily overlap. EPA presents the best example of this overlap and fluidity. As the regulator of chemical hazards, reviewer of environmental impact statements from other agencies, and home of the National Center for Environmental Assessment, EPA’s jurisdiction often collides with that of other risk policy agencies. At the same time, EPA’s
broad authority also offers benefits: EPA maintains the Integrated Risk Information System (IRIS), a database of chemicals and their human health effects widely used by risk assessors.

Thus, the real problem with shared jurisdiction in the food safety system has less to do with the concept of shared jurisdiction and more to do with how that sharing is implemented. If two agencies approach a problem from different perspectives, the combined results might be very useful for policy development. In many cases, however, synthesizing agency perspectives is hard. Risk assessors and managers may tailor their methods to match their agency’s particular mission, or statutes may rigidly define what agencies can or cannot do.

One example of statutory rigidity can be found at FSIS, where inspectors are allowed by law in slaughterhouses, but not on farms, where the hazards of interest to risk assessors often originate. (Kause and Dearfield 2014) The influence of agency culture in regulatory science, meanwhile, is exemplified by the subtle differences between dietary studies conducted at FDA and CDC.

The FDA produces the Total Diet Study (TDS), which estimates per capita nutrient consumption using a standard market basket of foods. (Center for Food Safety and Applied Nutrition 2003) The CDC collaborates with USDA on the What We Eat in America/National Health and Nutrition Examination Survey (NHANES), which relies on both dietary self-reporting and physical examinations for its information. (CDC 2014) Both surveys are informative, and the TDS relies in part on NHANES to produce its results, but the information the surveys provide is not always comparable. Thus, if two risk assessments based on each survey were placed side-by-side, it would be difficult for an oversight office such as ORACBA to quickly compare their conclusions.

A separate problem emerges at the intersection between statutory requirements and agency cultures: agencies may view their missions narrowly. If the result of such narrow-mindedness is data collection solely relevant to the agency’s immediate needs, collaboration can become impossible. Partner agencies statutorily prohibited from collecting certain information may have nowhere to turn for the regulatory data they need.

For a general example of this mission scope problem, consider the distinction between a public health study on cancer risks due to smoking, and a cancer risk assessment aimed at regulating tobacco manufacturing. The public health study is likely to consider both the general population, and a variety of subpopulations, to determine who is at greatest risk for cancer. The risk assessment, on the other hand, may not, unless the law requires it. Since the regulatory agency likely seeks a single manufacturing standard, there is little incentive to collect more data than are required to support the new rule. Such myopic risk policy approaches, however, isolate agencies that ought to work together, and inhibit thoughtful planning for the future.

ORACBA’s Role in the Regulatory System

When Congress created ORACBA in 1994, they saw risk assessment as a way to ease the regulatory burden on farmers, and also hoped that risk assessment would be more widely used throughout USDA and the rest of the federal government. Thus, they gave ORACBA dual authority: on one hand, ORACBA was to educate agencies on the value of risk assessment; on the other hand, ORACBA was to regulate its fellow agricultural agencies, and ensure they
produced consistent and high-quality risk assessments. (United States. Congress. House. Committee on Agriculture. Subcommittee on Department Operations 1995) In practice, since its inception, ORACBA has had to compete for funding with the very agencies it is supposed to regulate. Thus, the agency has tended to take educational and collaborative approaches to its mission, rather than engaging in the kind of thorough oversight that would require more money and personnel. This educational approach has eroded ORACBA’s informal authority within USDA, hampering the Office’s ability to push for policy changes. (Anderson et al. 1999)

This weakened authority notwithstanding, ORACBA plays an important part in the food and agriculture regulation system. The Office reviews all “major” USDA regulations (those with an economic cost greater than $100 million in 1994 dollars) addressing risks to human health, human safety, the environment, and “any combination thereof.” (“7 U.S. Code § 2204e - Office of Risk Assessment and Cost-Benefit Analysis | LII / Legal Information Institute”) Additionally, ORACBA provides risk assessment expertise to agencies outside of USDA, including the White House Office of Management and Budget. (Linda Abbott 2014) As noted in a 1999 Society for Risk Analysis report on the agency, ORACBA is not statutorily required to review outside regulations, but it is often asked to do so. In the present, such requests remain a significant part of the Office’s work. (Anderson et al. 1999)

In many ways, therefore, ORACBA is representative both of the problems in the current regulatory system and the promise of reforms. When the agency was created, risk assessment was a new addition to federal regulatory science that was not widely practiced at USDA or in other agencies. Today, risk assessment forms an important part of food and agriculture regulation, in no small part because of the agency’s visibility. By the same token, ORACBA’s history of inhibited authority illustrates how even simple attempts to harmonize regulatory practices can go astray when they are poorly implemented.

Fire Ants & Arsenic: Science Policy, Agency Self-Interest & Regulatory Failure

If jurisdictional arguments and poor collaboration among agencies were the only problems facing the food safety system, better regulatory processes might already be in place. However, the apparently simple demarcation between science and policy in food safety obscures two serious problems for both policymakers and scientists. First, even though risk assessment is conducted scientifically, this guarantees neither that assessors can provide a completely objective and accurate analysis, nor that they can answer every toxicological question. Second, although risk management answers social and political questions science alone cannot, risk managers are still called upon to “rely on the science” to make these decisions. The inexorable linkages between these two problems form the basis for the broader challenge of regulatory integration. (C. D. Carrington 2014; C. D. Carrington and Bolger 2010)

The first problem is typically due to either imperfect information, or adherence to professional principles in experimental design. For example, determining what kinds of food Americans eat and in what quantities is very difficult without resorting to statistically-derived estimates. Likewise, experimentation to determine lethal dosages of chemicals in humans is outside the boundaries of scientific ethics. In both cases, scientists must rely on models to draw even the
simplest conclusions. Thus, “sound science” does not always produce a single answer, because risk assessments based “only on facts” do not exist.

The second problem – the use and interpretation of scientific results by risk managers – compounds the first problem. As one example, lead and many other chemical compounds have effects at the molecular level that translate into adverse effects at the organismal level. From a toxicological viewpoint, there is no level at which lead does not poison a living thing, because the molecular effects are the same regardless of the dose. The question for the risk manager, however, is one of magnitude: at what dose will the poison seriously harm the human, non-human animal, or plant? (C. D. Carrington and Bolger 2010). The problem in this situation is not only that molecular science cannot answer the question, but that scientifically-based statistics are often used to answer it. Indeed, there are few other ways to resolve such a question. The result is a blurring of the line between what is science, what is policy, and whether the judgments of scientists or policymakers ought to receive greater weight in risk management decisions. Because different people and different agencies may resolve this problem differently, collaborative risk policy is inherently complex.

In fact, for all the discussions of objective toxicological studies, the primary driver for food safety regulations in the United States is political action. Well before the passage of the Food and Drug Act, the interests of trade regulators and merchants led to USDA studies of numerous foods and drugs in the late nineteenth century. (Janssen 1981) Likewise, FDA’s recent investigations of arsenic in apple juice and rice might not have happened but for consumer advocacy and media attention. (Consumer Reports 2014) The same holds true for other regulators, which means food safety, environmental, and public health agencies are all put in the position of refereeing competing political claims. In the process, agencies develop their own methods, cultures, and traditions, and prioritize their constituencies over those of other agencies and interest groups.

This regulatory self-interest is illustrated by the “fire ant wars” between the USDA and environmentalists such as Rachel Carson, which took place from the 1950s into the 1970s. USDA’s primary concern at the time was curtailing the population of fire ants in the agricultural lands of the South. Farmers, the agency said, complained of crop damage, ant attacks on livestock, and ant mounds that hindered farm equipment, among other problems. The response was decisive: the Department would use DDT to eradicate the ants. (Buhs 2002)

From USDA’s perspective, it did not initially matter that DDT could poison entire ecosystems, that the ant problem was itself a symptom of local ecology disturbed by urban sprawl, or that the program might place human health at risk. Rather, the agency had a mandate to promote agricultural production, and fire ant eradication served that mandate. Two decades later, the eradication program was a convenient target for environmentalists, who wanted to abolish the use of toxic pesticides. (Buhs 2002) Thus, there is a long history in food and agriculture policy of singular interests taking priority over a systematic, big-picture approach to regulation. The continuation of this history can be seen today in the arsenic debates. (Blum 2013)

Further examples of agency self-interest and ineffective or contradictory regulations abound. In correspondence and interviews, civil servants from different agencies highlighted very different
concerns. One FDA risk assessor pointed to protracted disagreements with EPA officials over methylmercury in fish, while officials at FSIS raised the issue of new FDA foodborne pathogen authority under the Food Safety Modernization Act of 2010 (FSMA). (C. D. Carrington 2014; Kause and Dearfield 2014) These coordination challenges cause very real problems for regulators, and should not be diminished.

However, the prominent debates over arsenic contamination in food best illustrate how the broken regulatory system can affect ordinary people. In addition to the broad press coverage this issue has received, the FDA’s very different responses to three recent food contamination cases raise questions about how regulators make decisions. The foundations for these decisions – at times in harmony and at times in conflict with EPA risk assessment models – also cut to the heart of the interagency regulation problem, and when and how regulatory agencies ought to work together.

The three cases addressed here are arsenic contamination in apple juice, for which a regulation was proposed in 2013; arsenic in rice, which the FDA investigated in 2012; and arsenic in chicken feed, which the agency also addressed in 2012. These cases are important for four reasons. First, they represent foods Americans consume in high quantities. Cooked white rice is the fifteenth most consumed food item (by aggregate grams consumed per day) of 286 standard market basket items in the FDA’s Total Diet Study. Bottled apple juice ranks 23rd, and chicken is included in 14 categories, 8 of which fall in the top 100. (Center for Food Safety and Applied Nutrition 2003)

Second, these cases show the range of FDA’s regulatory responses to the arsenic question. In the case of rice, the agency has advised consumers to be cautious, but has not proposed new limits. (Center for Food Safety and Applied Nutrition 2014) In the case of chicken, after advocates’ outcries over arsenic found in meat, three out of four prominent anti-parasitic and weight-gain-inducing feed additives were banned from the market. (Strom 2013) In the case of apple juice, the agency has proposed an “action level”, which sets the maximum inorganic arsenic concentration allowed in apple juice. (F. D. A. Voice 2014)

Third, these cases contain numerous examples of the deep ecological and commercial interconnections within the agricultural system. Rice is often grown on arsenical pesticide-contaminated land left behind from cotton production. (Meador 2013) Chicken manure, which contains any excreted arsenic, is regularly used to fertilize crops of all kinds. Apple juice sold in the United States, sixty percent of which is imported from China, is easily contaminated since international manufacturing is difficult to monitor. (Timmerman 2013)

Finally, the debates over arsenic toxicology and regulation illustrate the complexity of the science behind the policies even in the absence of other complications. The apple juice case shows the choice of risk models and data, as well as the determination of the mode of action for arsenic toxicity, presents challenges for risk assessment. These factors show why food risk assessment and management are so difficult, and how a linear, case-by-case approach to food regulation is inadequate to meet this difficulty.
The FDA’s proposed action level for arsenic in apple juice illustrates three main points. (Carrington, Murray, and Tao 2013; Center for Food Safety and Applied Nutrition 2013) First, the way a regulation is drafted is strongly influenced by the agency that wrote the regulation. Second, agency-specific regulatory techniques can make analyses incomparable with other agencies’ reports, or entirely opaque to an average, objective reader. Third, the FDA in particular uses a case-by-case regulatory approach. Examination of the action level and its accompanying risk assessment reveals: the subject is strictly confined to inorganic arsenic in apple juice, rather than more general categories of food or drink; scientific and policy-oriented assumptions are not clearly distinguished; and disagreements with similar risk assessments by other agencies (most notably EPA) are either not mentioned (as in the proposed action level) or only briefly discussed (as in the risk assessment). These regulatory features reflect agency-specific attitudes toward science and policy, as well as the FDA’s attitude toward its fellow regulators.

Industry and advocacy group comments on the action level show how this institutional behavior can be problematic. For example, The Chief Scientist at Consumer’s Union noted that while the FDA’s risk assessors claimed their apple juice models largely agreed with EPA drinking water models, EPA’s data could have supported stronger regulations than those the FDA ultimately proposed for apple juice. (Hansen 2014) Meanwhile, the Union’s official comments on the proposal stated that their statisticians found potentially serious health risks from arsenic in apple juice using NHANES data. (Consumer Reports 2013)

Other commenters questioned the agency’s limited focus on apple juice, or argued the FDA’s risk model was inappropriate for examining the carcinogenic effects of inorganic arsenic. The Juice Products Association, for example, contended FDA toxicologists made bad assumptions about arsenic biochemistry. (Juice Products Association 2013) The American Beverage Association (ABA) was more concerned with regulatory consistency, stating, “[FDA] has taken inconsistent positions with regard to action levels for inorganic arsenic in different commodities. For example, the Guidance proposes to reduce the action level to 10 PPB for apple juice while refraining from similar action with regard to rice.” (American Beverage Association 2013) The National Academy of Sciences has noted, however, that these debates are more about policy than science, suggesting a need for institutional change. (National Research Council (U.S.))

The preceding apple juice case study focused on the limits of toxicological science and the challenge of administratively addressing those limits. The FDA’s experiences with chicken and rice, on the other hand, demonstrate the limits of agency-by-agency and case-by-case risk policy. The chicken contamination case shows how a single, specialized agency can react very well to a single hazard, but is ill-equipped to address systemic problems. (Lasky 2013; Nachman et al. 2013) Conversely, the case of arsenic in rice shows how, without incentives to look beyond immediate agency needs and overcome outside criticism, agencies such as FDA tend toward myopia and inertia. (Blum 2013)

The FDA’s decision to remove three arsenical chicken feed additives from the market, for instance, was probably wise. However, this policy shift is insufficient to address the effects of arsenic-laden chicken manure already applied to crops as fertilizer. Since such application is common, the effect of feed additives becomes closer to say, the problem of heavy metal
contamination in tobacco, than to say, the regulation of a patent medicine. (Rego 2009) Thus, multiple forms of expertise – such as FDA’s and USDA’s veterinary and EPA’s remediation knowledge – are essential. A collaborative regulatory model would enable such a response.

On the other hand, the FDA’s limited action on rice contamination illustrates the reverse problem from the chicken case. Agencies without broad, external bureaucratic support are forced to be risk-averse, since outside criticism is harder to absorb. Thus, there is no advantage to introducing rice regulations unless popular support outweighs likely industry criticism. If instead, agencies coordinated their risk policies, calculated risk-taking would be less necessary, and more thorough examinations of cases like that in rice might be more likely.

**Recent Food Safety Reforms**

In addition to the formation of ORACBA, both the Clinton and Obama administrations have attempted to streamline food and agriculture regulations. While Clinton’s expansion of the FoodNet foodborne pathogen surveillance network has made the regulatory system more responsive to crises, and Obama’s Food Safety Modernization Act of 2010 (FSMA) promises a systems-based approach to legal enforcement, the desperate need for interoperability among food and agriculture agencies remains unfulfilled.

Both the expansion of FoodNet, based at the CDC, and FSMA, which primarily concerns the FDA, have their origins in a 1998 National Academy of Sciences report entitled *Ensuring Safe Food*. That report identifies key features of a model food safety system, including: risk analyses based on science; a collaborative, adaptive, and unified system that connects industry, consumers, and all levels of government; and adequate funding for partnerships and training at all levels. (Committee to Ensure Safe Food from Production to Consumption and Council 1998)

Agencies such as ORACBA played key roles throughout the nineties as the Clinton administration attempted to meet these ideals, and in some respects, succeeded. In particular, the expansion of government risk assessment helped address the need for science-based analyses, while the expansion of FoodNet improved the government’s adaptability. Nevertheless, the resulting food system was not truly adaptive, collaborative, or unified.

FSMA builds on the Clinton era initiatives, and gives FDA new abilities to force product recalls, mandate testing and preventive controls at food processing facilities, and share its authority and information with other federal agencies. The law also identifies key partners for food safety collaboration at the federal level, including FDA, USDA, and DHS, and explicitly encourages collaboration between federal, state, and local governments. Finally, the law provides for new food safety performance measures, information technology systems that enable information sharing, and increased funding for field investigations.

These reforms are positive, but there are two major shortcomings. First, the statutory charges that separate key agencies and bring them into conflict remain in place, and existing cooperative agreements fail to acknowledge this reality. While it is unlikely that the United States will ever have a single food regulatory agency, merely sharing resources is not enough to create a systems-based regulatory structure. Agencies must agree to follow inoperable procedures, which no
current law requires. FSMA also focuses on the FDA, which continues to leave the other food regulators without any guidance for collaboration.

Second, most of the reforms have been focused either on enforcement or private sector preventive controls. Although prevention and enforcement reforms are invaluable, they do not address current and future deficiencies in regulatory and scientific capacity. [Error! Reference source not found.] Even if the FSMA reforms make the regulatory system more proactive, it does not follow that the system will be adaptive. An adaptive regulatory system must be able to anticipate new hazards and risks, changes in workforce requirements, and more.

In short, the food safety reforms to date have made some progress toward a more cohesive regulatory system, but further reforms are needed to prepare regulators to collaboratively address tomorrow’s hazards as well as today’s.

The ALFALFA Agreement Explained

Toward an Integrated, Adaptive Food & Agriculture Regulatory System

The ALFALFA Agreement aims to transform the present group of food and agriculture regulators into a cohesive, robust, and adaptive food and agriculture regulation system. As with the current approach, the Agreement is focused on risk assessment and leadership (i.e. effective response to crises.) The major distinction is that the Agreement incorporates the ideas of learning and foresight into the regulatory system. Unlike most reforms, this proposal does not assume the reforms of today will be adequate tomorrow. Instead, it assumes that regulations themselves will need to respond to future changes in food, agriculture, technology, and the natural environment, among other factors.

In brief, the Agreement must address the following needs:

- Market-based design principles for food and agriculture policy
- Better integration of regulatory oversight in the executive branch
- Sustainable and adaptive regulatory infrastructure

The first point is a bedrock principle of the American regulatory system, and considered central to international best practice (OECD 2010). To the extent possible, farmers and food producers are encouraged to self-regulate; ideally, regulators identify specific public health, environmental, and performance goals for themselves and for the firms they oversee; and most important, the regulatory cost-to-benefit ratio is kept as small as possible.

The second and third points are the foundations for the Agreement. In addition to building food safety infrastructure outside of government—whether through preventive controls, industry cooperative agreements, or other measures—infrastructure must also be built inside of government. This means agencies must share expertise, develop risk assessment procedures that account for differing agency missions, and take regulatory oversight and coordination seriously.

Additionally, food and agriculture agencies must ensure they have adequate research competencies in economics, policy, and the natural sciences. Regulators must be able to respond not only to problems they expect, but also to problems they may not expect. By maintaining multidisciplinary research capabilities, agencies can quickly draft policy proposals that adapt or
create new regulatory structures to respond to agricultural, environmental, public health, or commercial concerns.

Organizational coordination and adaptation must also be matched by employee flexibility and collaboration. Agencies must coordinate long-term workforce planning, interagency training exercises should become routine, and employees should be cross-trained as much as possible to facilitate interagency linkages.

Most importantly, employees must be trained to understand and apply adaptive thinking and futures analysis. The majority of the principles at work in the ALFALFA Agreement depend on the efforts of agencies, but agencies and policies only function well if people administer them well. Since this proposal crosses interagency boundaries, successful implementation of these policies on a human level is extremely important.

Finally, as a brief note, the proposal outline that follows provides a list of basic questions that allows agencies to begin thinking about adaptability. In practice, numerous systems for adaptive planning and analysis exist, some of which are already in use in federal, state, or local government agencies. One such system that could be useful for an interagency working group, is the Forward Engagement proposal written by Leon Fuerth. (Fuerth and Faber 2012) Originally designed for defense policy, it incorporates many useful concepts. In the end, however, cooperating officials and agencies should choose adaptation and futures analysis techniques best suited to the policies with which they are working.

Parties to the Agreement
Ideally, all fifteen agencies involved in food and agriculture regulation will join the Agreement with ORACBA, including the eight major agencies at USDA. Such broad membership is not practical initially, however. The initiative must be organized and tested before it can be fully expanded. At the same time, ORACBA is a small office without the resources to coordinate a large project alone.

Thus, ORACBA should initially coordinate with a core group of agencies, to include:

- The eight major USDA agencies, plus relevant Headquarters offices (e.g. Office of Environmental Services)
- The National Center for Environmental Assessment at EPA
- Other EPA offices as appropriate
- FDA

Additionally, the United States Forest Service, as well as other natural resource management agencies, are likely to have substantial and useful expertise in futures analysis and long-range planning; ORACBA should strongly consider inviting these agencies to participate.

Representatives from committed agencies should establish an advisory committee, both for the purposes of coordinating the initiative, and for integrating the initiative with existing departmental and government-wide reform efforts. As a practical matter, initial implementation success should be judged by the extent to which ORACBA is a party to the kinds of policy discussions addressed in this report.
Harmonization of Agency Risk Assessment & Management Strategies

Key to any collaborative venture is a universal point of reference for the collaborators. Drivers on a highway must understand and follow the same rules to prevent car accidents. The same is true for food and agriculture regulation. Agencies must have a common understanding of what the food safety system as a whole intends to accomplish. Individual agency processes, data collection strategies, reporting requirements, and other policies must be clear to all agency stakeholders. Most importantly, this information must be presented in a way that makes collaboration possible.

Thus, ORACBA’s first task in cooperation with its partners is to compile a standard regulatory reference book. This reference must not only describe various agency processes, but it must describe these processes as part of the broader food regulatory system. The guide must also have interpretive value: a risk assessor or manager must be able to identify the statutes that control a given agency’s analyses, and to understand how each agency’s products can or cannot be used by the other agencies.

Once the reference has been established, the real work of harmonization can begin. Two major kinds of regulatory gaps are likely to arise: science policy gaps and statutory gaps. In the first case, risk assessors and managers from different agencies will need to find ways to bridge different scientific concepts and policy approaches from disparate disciplines. In the second case, officials will need to determine whether work can be divided between agencies, or how coordination or data transfer can be accomplished without violating statutory demands. In the past, agency-to-agency memoranda of understanding would likely have been the first solution to such problems. The concept under this agreement is to generalize such memoranda as much as possible. A single, long-term, multi-agency agreement is greatly preferred to numerous, bilateral agreements under this framework.

Design of Improved IT, Organizational, and Research Frameworks

When ORACBA was created, one of the first acts of the inaugural Director was to implement a database of USDA risk assessment experts. Building on that tradition, ORACBA should facilitate the use of IT to share methods, protocols, statutory mandates, and other scientific and organizational information central to ALFALFA procedures. In fact, despite their limitations, one fortunate aspect of FSMA and other reforms is their emphasis on information infrastructure. As a matter of policy and implementation, ORACBA and the other ALFALFA partners should, as much as possible, build this initiative into or on top of existing efforts at USDA and elsewhere.

In addition to IT development, ORACBA and its partners will need to assess the present adaptability of agency internal structures and policies. The parties will also need to assess policy and scientific research capacity across government, whether on their own or through a request to a third party research agency. The information collation/policy harmonization phase should lay much of the groundwork for these assessments.

Some pertinent questions to ask include:

- What needs to be done to ensure our agencies can collaborate quickly and easily?
- Review requirements notwithstanding, how difficult is it for each agency to design a new regulation?
• Which interagency relationships are the strongest? The weakest? How can they be strengthened?
• What kind of scientific research capacity does each agency have? Policy research capacity?
• What are the top research competencies in each agency? How can we facilitate cross-pollination?
• What does the workforce plan look like for our agencies in terms of risk assessment and management? Should expertise be drawn from industry or state and local government?
• How often do we consider the interaction between policies or regulations?
• How do/can/should we address unintended policy consequences now and in the future?

Once these questions have been answered, performance metrics can be designed. Such metrics in government are often quantitative, but no agency should be compelled the use a quantitative metric if computing it would be too cumbersome. The most important point is to choose metrics that reflect the risk policy outcomes of interest. One simple example might be the ability of an agency to conduct adaptive policy research. A positive outcome in that case might be fulfilled using internal policy analysts, or through cooperation with a dedicated research agency.

Lastly, the parties will need to consider the question of research, and how it ought to be structured. The organizational model for risk assessment, for instance, is for expertise to be distributed. In the case of research, some non-research agencies with internal scientific or policy research expertise could build on this model. On the other hand, there are several agencies throughout the federal government and beyond dedicated to research alone. How these agencies should be incorporated into the new Agreement – or not – should be discussed thoroughly.

Establishment of Universal Methods & Training Materials for Adaptive Regulation
During its twenty years of existence, education and training have been ORACBA’s greatest strengths. Its Risk Forums helped propel risk assessment into the mainstream through USDA and beyond. ORACBA should expand this mission to include rigorous training at the intersection of risk assessment, management, and futures analysis. In doing so, the Office should explain how a systems-based approach to policy can complement the risk assessment and cost-benefit analysis policies already in place.

Furthermore, ORACBA should establish a series of practical, integrative training exercises that build on real needs for risk assessors and policymakers. For example, ORACBA could offer a collaborative planning session for risk assessors from FSIS and EPA, alongside rangeland and natural resources assessors from the Forest Service, Interior, or other agencies. The training sessions could build on existing cooperative agreements, or address long-range concerns such as the impact of climate change on food safety, grazing practices, and ecological conservation.

Most importantly, ORACBA should develop a standard set of guidelines for futures analysis, scenario planning, and other adaptive techniques, so individual employees may be trained, whether through live sessions or a training system such as AgLearn.

The Promise of Reform
Over the short and long runs, ALFALFA addresses the central problems with the food and agriculture system today. It strives for true consistency in risk assessments, comparability of
analyses between agencies, and systems approaches to science policy that facilitate consistent regulations.

The greatest advantage of the ALFALFA Agreement over any similar policy currently implemented or proposed is its emphasis on planning and assessment. Other major policies, including FSMA, emphasize enforcement and monitoring actions as a direct response to political and commercial concerns and complaints. There is no doubt that stakeholders and their concerns matter greatly; yet, the philosophy behind ALFALFA is such complaints cannot be addressed without a strong scientific and organizational foundation. Risk assessment, cost-benefit analysis, and adaptive policy planning provide that foundation.

ALFALFA also directly addresses Congress’s intent that regulatory agencies should coordinate, as well as reduce burdens on those they regulate. Although the introduction and spread of risk assessment throughout government has realized much of that intent, the full potential of an efficient regulatory system has not been realized. The ALFALFA Agreement brings that intent to fruition without creating new agencies or demanding that ORACBA receive new statutory authority. Although in the long run, ORACBA will almost certainly need an expanded staff and a larger budget, ALFALFA is structured to share resources and distribute costs among agencies as long as that is feasible.

Lastly, ALFALFA introduces new emphases on future planning and policy research to the risk policy community. These aspects of the policy are rooted in the reality that there would be no FSMA if the contemporary food system were the same as it was in the early days of the Republic. Put another way, there are few complex policies that are not subject to change over time. Therefore, ALFALFA aims to anticipate that change by asking government agencies to integrate strategic planning with their usual risk analysis activities. By addressing future, as well as present hazards, agencies and policies will hopefully be more resilient.

Thus, ALFALFA attempts to create a food and agriculture regulation scheme that is simultaneously responsive to the needs of a democracy, and to the practical needs of the regulators themselves. In meeting these needs, the Agreement creates a robust regulatory system that serves the public, ensures prosperity, and protects the natural environment.

Limitations of the Agreement
Although the ALFALFA Agreement promises great flexibility, adaptability, and efficiency in regulation, critics will point out – rightly – that it is not a panacea. No interagency agreement can replace a complete Congressional overhaul of the food safety system, and no adaptive approach to analysis and research can replace statutorily-supported interoperability standards. Both of these arguments have merit.

Anticipatory frameworks, for instance, provide ways to conceptualize and design better legislation, regulations, and institutions. Long run flexibility of anticipatory systems, however, depends on flexible agencies to implement them. If statutes and agency cultures combine to create agencies that are too rigid, no cooperative agreement can fix that rigidity. Similarly, frameworks that demand responsiveness to change require benchmarks for measuring an
institution’s short- and long-term success. Yet, if agencies cannot even agree on analytical methods, it is unlikely they would reach an agreement on benchmarks.

Fortunately, this is not the system the United States has. Agencies are bound by statutes in inconvenient ways and agency cultures do make collaboration unnecessarily difficult. There is, however, sufficient legal room for benevolent agencies to maneuver.

Likewise, given sufficient context, most agencies will see that coordination and adaptation are in their long-term interests. Unlike plans that call for a unified food safety agency, no agencies need lose all their authority under this plan. To be sure, agencies will need to decide where they are willing to cede authority to others, but in light of the significant shortcomings of the current system, this concern is a detail.

A different set of criticisms rests on questions about implementation. Current approaches to collaboration both inside and outside of government, for example, rely heavily on information technology – an area in which the federal government has had mixed success. Apart from IT, if the program is not properly implemented, a focus on future regulatory needs could draw resources and attention away from present risks and hazards. While a need to examine future trends might exist, these critics say, such a need cannot justify placing strain on an already stretched regulatory system.

The response to these concerns is two-fold. First, strained as the regulatory system might be, the system’s rigidity is a large source of that strain. The goal of an adaptive system is to generate ideas, making the system more nimble than it would otherwise be. Second, funding and manpower are always going to be limited, and there is no doubt that asking ORACBA and several other agencies to take on new tasks would draw resources away from regular operations. The question is whether these activities reduce costs that would be incurred without them. The argument here is they serve an important function that can be fulfilled no other way. Likewise, the information technology implementation question is an important one, but it is a question little different from that posed about any other policy. Implementations can fail as much as they can succeed. Should implementation fail in this case, it will more likely be a failure of administration than a failure of the policy itself.

Last but not least, some might question the wisdom of coordinating all of these resources rather than simply consolidating these agencies into a single food department. The response is the efficiency of a single department must be weighed against the advantages of multiple, smaller offices with a variety of functions and expertise. In the European Union, for example, one agency conducts food risk assessments, but it also has no regulatory power. (European Food Safety Authority 2006) Thus, the agency is free to assess risks without the political calculations that accompany the office of a regulator. A similar setup in the United States would be very unlikely: most federal agencies that regulate also have research or education departments. From this vantage point, it makes the most sense to work with agencies as they exist.

**Future Directions**

The ALFALFA Agreement is a small step on the path to a better food regulatory system. To be successful, this policy, and any policies derived from it, must be implemented with the greatest care. Done right, however, the returns will far outweigh the potential costs. Government will be
more responsive to technological, economic, and social change; citizens will be happier; and farms will be more productive. This is only the beginning.

To be sure, legislative action and further policy study will be needed to improve the food safety system, regardless of this policy’s performance. Future research in particular could take a more rigorous and quantitative approach to complexity and adaptation than that taken here, and with the rapid developments evident in the life sciences, such research may be essential. More thorough examinations of management practices in the United States government and abroad could also be useful for future policies. A strong understanding of the optimal balance between scientists and economists in regulatory settings, for example, could be valuable for risk policy design.

Finally, a full review of how federal food and agriculture agencies can fully connect to farmers, consumers, and agencies at the city, town, and county levels of government – where production and consumption actually happen – is critical.

These research paths are simple examples of how agencies and policy analysts can expand the frontiers of risk assessment policy beyond statutory requirements. Indeed, if there is a central tenet of the ALFALFA Agreement, it is that such expansion is vital for food and agricultural safety today and tomorrow.
Appendix

The GAO listing of food safety agencies is contained in the pages that follow, after which References are provided.

The reference for the report from which the figure is taken is:

Appendix II: Federal Agencies with Food Safety Responsibilities

<table>
<thead>
<tr>
<th>Agency</th>
<th>Programs</th>
<th>Program Type</th>
<th>Responsibilities and main authorizing statutes</th>
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<tbody>
<tr>
<td>1 USDA Food Safety and</td>
<td>Meat, Poultry, Egg Products, and Catfish</td>
<td>Regulation</td>
<td>• Responsible for: Ensuring that the nation’s domestic and imported commercial supply of meat, poultry, egg products, and catfish is safe, wholesome, and correctly labeled and packaged, and for enforcing the Humane Methods of Slaughter Act of 1978, as amended. Responsible for providing voluntary fee-for-service inspections for exotic and other edible animals.</td>
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<tr>
<td>Inspection Service</td>
<td>Inspection; Voluntary Fee for Service Inspections</td>
<td>Inspection</td>
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<td></td>
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<td>Enforcement</td>
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<td>Grain &amp; Coop. Admin.</td>
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<td>Other</td>
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<tr>
<td>Inspection Service</td>
<td>Veterinary Services</td>
<td>Inspection</td>
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<td>Enforcement</td>
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<td>Research</td>
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<td></td>
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<td>Grain &amp; Coop. Admin.</td>
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<td>Other</td>
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<tr>
<td>3 USDA Grain Inspection, Packers</td>
<td>Federal Grain Inspection Service</td>
<td>Regulation</td>
<td>• Responsible for: Establishing quality standards, inspection procedures, and marketing of grain and other related products.</td>
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<tr>
<td>and Stockyards Administration</td>
<td></td>
<td>Inspection</td>
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<td>Enforcement</td>
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<td>Research</td>
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<td>Grain &amp; Coop. Admin.</td>
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<td>Other</td>
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</table>
| **4** USDA Agricultural Marketing Service | Commodity Programs; Science and Technology Programs; School Lunch Commodity Purchases | ![ ](image) ![ ](image) ![ ](image) ![ ](image) ![ ](image) | - Responsible for: Establishing quality and condition standards for, among other things, dairy, fruit and vegetables, livestock.  
| **5** USDA Agricultural Research Service | Nutrition, Food Safety, and Quality          | ![ ](image) ![ ](image) ![ ](image) ![ ](image) ![ ](image) | - Responsible for: Providing the scientific research to help ensure that the food supply is safe and secure and that foods meet foreign and domestic regulatory requirements.  
- Main authorizing statutes: 7 U.S.C. ss. 1622, 2204, 3101, 3121, 3318, 3319a; also e.g., 7 U.S.C. ss. 136i-2, 391, 7654. |
| **6** USDA Economic Research Service | Food Safety Research                          | ![ ](image) ![ ](image) ![ ](image) ![ ](image) ![ ](image) | - Responsible for: Providing analyses of the economic issues affecting the safety of the U.S. food supply.  
- Main authorizing statutes: 7 U.S.C. ss. 1622, 2204, 3101, 3121, 3318, 3319a; also e.g., 7 U.S.C. ss. 136i-2, 391, 7654. |
| **7** USDA National Agricultural Statistics Service | Statistical Program on Food Safety            | ![ ](image) ![ ](image) ![ ](image) ![ ](image) ![ ](image) | - Responsible for: Providing statistical data, including agricultural chemical usage data, related to the safety of the food supply.  
- Main authorizing statutes: 7 U.S.C. ss. 1622, 2204, 3101, 3121, 3318, 3319a; also e.g., 7 U.S.C. ss. 136i-2, 391, 7654. |
| **8** USDA National Institute of Food and Agriculture | National Integrated Food Safety Research Initiative | ![ ](image) ![ ](image) ![ ](image) ![ ](image) ![ ](image) | - Responsible for: Supporting food safety projects in the land-grant university system and other partner organizations that demonstrate an integrated approach to solving problems in applied food safety research, education, or extension.  
- Main authorizing statutes: 7 U.S.C. ss. 361a-361l, 3121, 3151, 3155, 3318, 3319a, 6971(f); also e.g., 7 U.S.C. ss. 450h, 3902. |
| **9** HHS Food and Drug Administration | Foods Program; Animal Drugs and Feeds Program; Regional Operations and Enforcement | ![ ](image) ![ ](image) ![ ](image) ![ ](image) ![ ](image) | - Responsible for: Ensuring that all domestic and imported foods, excluding meat and poultry products, are safe, wholesome, sanitary, and properly labeled.  

Figure continued
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<tbody>
<tr>
<td>10</td>
<td>HHS</td>
<td>• Responsible for: Preventing the transmission, dissemination, and spread of foodborne illness to protect the public health.</td>
</tr>
<tr>
<td></td>
<td>Centers for Disease Control and Prevention</td>
<td>• Main authorizing statutes: Public Health Service Act, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. ss. 201-300bcb),</td>
</tr>
<tr>
<td>11</td>
<td>Commerce</td>
<td>• Responsible for: Providing voluntary, fee-for-service examinations of seafood for safety and quality</td>
</tr>
<tr>
<td>12</td>
<td>EPA</td>
<td>• Responsible for: Regulating the use of certain chemicals and substances that present an unreasonable risk of injury to health or the environment. Responsible for issuing regulations to establish, modify, or revoke tolerances for pesticide chemical residues. Responsible for setting national drinking water standard of quality and consulting with FDA before FDA promulgates regulations for standard of quality for bottled water.</td>
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<tr>
<th>Agency</th>
<th>Programs</th>
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</tr>
</thead>
</table>
| 13 Treasury                   | Alcohol                         | • Responsible for: Regulating, enforcing, and issuing permits for the production, labeling, and distribution of alcoholic beverages.  
| 14 Department of Homeland Security | Customs and Border Protection | • Responsible for: Inspecting imports, including food products, plants, and live animals, for compliance with U.S. law and assisting all federal agencies in enforcing their regulations at the border.  
| 15 Federal Trade Commission   |                                 | • Responsible for: Enforcing prohibitions against false advertising for, among other things, food products.  

Source: GAO analysis.

*The 2008 Farm Bill amended the Federal Meat Inspection Act to give USDA responsibility for the inspection of catfish. The amendments specified that they would not apply until USDA issues final regulations implementing them, a process that was not yet complete as of February 2011.*
References


Hansen, Michael. 2014. “Interview with Consumer’s Union Chief Scientist.”


Linda Abbott. 2014. “Interview with ORACBA Director Linda Abbott.”


