



**Testimony of Caroline Smith DeWaal  
Director of Food Safety  
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before the  
Subcommittee on Investigations and Oversight of the  
House Committee on Science and Technology  
on “The Role of Science in Regulatory Reform”**

**Washington, DC  
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Good morning Mr. Chairman, Ranking Member Broun and Members of the Subcommittee on Investigations and Oversight. My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). Founded nearly 40 years ago, CSPI is a nonprofit health advocacy and education organization focused on nutrition and food safety. We are supported principally by the 950,000 subscribers to our *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for inviting me to provide testimony today on the role of science in regulatory reform. As my expertise is food safety, I have not had an opportunity to testify before this subcommittee before, largely because issues I am commonly called on to testify on reside within the jurisdiction of the Energy and Commerce and the Agriculture committees. But food safety owes a debt to one of the signature agencies under the Science and Technology Committee’s jurisdiction. The premier process control system, known as Hazard Analysis and Critical Control Points (HACCP), was developed in the 1960s by Pillsbury for the National Aeronautics

and Space Administration (NASA).<sup>1</sup> NASA had an understandable concern over astronauts contracting food-borne illnesses in the confines of a space capsule at zero gravity. Today this space-age program is being used widely to reduce the risks from contaminated food and improve food safety for all Americans, not just astronauts.

### **Advancing the Public Interest Through Regulatory Reform**

As one of the contributors to “Advancing the Public Interest Through Regulatory Reform,” I was privileged to work with a group of diverse regulatory experts on identifying failures and fixes to the regulatory system. In my testimony, I will address some of the issues discussed in that report, together with other issues that we have identified based on long experience working on food safety regulations during the Clinton and Bush presidencies. I will provide case studies of how the failures in our regulatory review system can place the public’s health at risk.

We commend President Obama’s revocation of Executive Order (E.O.) 13422 on January 30, 2009.<sup>2</sup> The rescinded order contained a number of flawed provisions that greatly diminished the deference that should be given to agency experts and scientists in rulemaking decisions. This is a start to implementing the recommendations in “Advancing the Public Interest Through Regulatory Reform.”

But more remains to be done, much of it centered on reforming the regulatory review process at the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). The process and principles governing the review of agency regulations give OIRA undue discretion to override policy decisions that are based on sound

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<sup>1</sup> Pan American Health Organization, HACCP: Essential Tool for Food Safety, 2001.

<sup>2</sup> Letter to Mabel Echols, Office of Management and Budget, from Kirsten Stade, Program Manager, Integrity in Science, and Illene Ringel Heller, Senior Staff Attorney, CSPI, Re: Request for Public Comment on Improving the Process and Principles Governing Regulations; 74 Fed. Reg. 8819, Feb. 26, 2009 (March 19, 2009).

science and the exhaustive work of federal agency experts.<sup>3</sup> The new Administration's commitment to ensuring the integrity of the administrative process is a welcome change.

I have worked with both the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) on identifying effective regulatory approaches to address food safety problems since the early 1990's and have met periodically with the OIRA staff during their consideration of federal regulations, usually at the request of the agencies. Over this period, I have seen the regulatory process extend to a multi-year process – often taking 5 or more years to complete a single regulation. I have also observed the agencies shy away from using regulations at all, and opting for alternative approaches that either don't involve or lessen OIRA review. I will discuss this more during the case studies presented later in my testimony.

If you look at OIRA's function like that of a regulatory agency, the OIRA staff perform a "prior approval" function for most federal actions, even those like voluntary surveys or consumer focus group research.<sup>4</sup> This type of data gathering is often important to help agencies set the parameters for improving their regulatory approach. Conversely, without doing the necessary research and consultation, the agencies may adopt less effective regulatory approaches. Yet the requirement for review by OIRA of even voluntary surveys can trigger long delays. For documents submitted to OMB as a courtesy, agencies have told me that they factor in a 90-day "wait time" for a response.

Cost-benefit analysis has played an overly significant role in rulemaking, an exercise heavily weighted towards the estimation of industry costs. In fact, it can become "mission impossible" for an agency to prove prospectively the benefits that might accrue from a regulation. Instead, federal agencies should be encouraged to identify well-defined public health

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<sup>3</sup> Gary D. Bass, et. al, *Advancing the Public Interest Through Regulatory Reform*, OMB Watch, Nov. 2008.

<sup>4</sup> The Paperwork Reduction Act of 1980 gives OIRA authority to review and approve information collection by federal agencies. 44 U.S.C. §3501 et seq.

goals and develop metrics to measure the effectiveness of regulations over time, rather than requiring them to prove with a high degree of confidence that preventative measures will work before initiating the rulemaking process.

In order to increase OIRA's effectiveness and minimize the long-standing delays in the regulatory process, any new executive order on regulatory review should be based on a more narrowly focused role for OIRA in regulatory review, one better suited to its economic expertise. Instead of performing an open-ended review of every "significant" regulation with an economic cost or benefit of \$100 million (a figure not updated for decades),<sup>5</sup> OIRA should issue guidance to the agencies and then audit agencies' compliance with the guidance, focusing primarily on rules with high costs and low benefits. This would allow agencies to develop regulations more easily and quickly and avoid the burden of OIRA review of each action. OIRA audits that disclosed problems with the cost/benefit analysis in specific regulations could be discussed with the agency chiefs and if needed, technical amendments to regulations could be used to make modifications.

A new executive order should update the definition for "significant" rules to narrow the number of regulations requiring prior approval and limit OIRA's review to the economic issues raised in the proposed rules. As OIRA is staffed by economists, it should avoid a scientific and technical review of regulations. Such questions should be deferred to the expertise of the federal agencies. Finally, OIRA should have a rapid time frame for review that balances thoughtful review with the need to produce timely federal agency actions, particularly to protect public health and social welfare.

Recent history has well documented that, as a nation, we are suffering more from the lack

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<sup>5</sup> The very broad definition of "significant" allows OMB to review almost any rule that it chooses. President Ronald Reagan established the \$100 million threshold for determining a proposed regulation is "major" in 1981. E.O. 12291, Feb. 17, 1981.

of appropriate regulation than from too much regulation. Perhaps if OIRA is freed up from this burdensome review of the minutia of agency action, its skilled economists could focus more on the gaps in regulation, such as those that led to major disasters in the financial sector, as well as the continuing crises in health care and food safety, among others.<sup>6</sup> Identifying regulatory gaps or analyzing regulatory approaches in other nations to ensure that our systems are not falling behind could ensure that future crises are averted.

To whatever extent that OIRA retains a role in agency rulemaking, it should operate with greater transparency. Agencies must be instructed more forcefully to document any changes to their draft rules or pre-rule framework made at OIRA's suggestion at whatever point in the rulemaking process those changes occurred. In 2003, the Government Accountability Office (GAO) found that the documentation required by E.O. 12866 was present for only about one quarter of the regulations it reviewed.<sup>7</sup> Documentation of all communications should clearly indicate which regulation is the subject of those communications, as well as the name and affiliations of all parties to the communication.

A complete public docket, which is updated regularly and documents when and by whom all suggestions to modify a rule are made, will be a strong deterrent to the kinds of political and corporate interference in agency rulemaking that have too often prevailed during the previous Administration and which are documented in the case study below.

At its worst, OIRA today is considered a "black box" for regulation, where non-experts review rules and meet with outside parties, often the very industries covered by the regulations, to discuss changes. Public health improvements should not be delayed by a lengthy regulatory oversight process that attempts to second guess agency experts and gives the regulated industries

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<sup>6</sup> OIRA issues prompt letters to suggest areas in which agencies could improve regulation.

<sup>7</sup> Gov. Acct. Off. Rep. No. 03-929, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, Sept. 2003.

an “off the record” opportunity to get provisions changed at OMB.

### **Role of Science in Public Policy: Food Safety Case Studies**

New challenges, such as emerging pathogens or chemical hazards, and new technologies to address them are a fact of life for modern food production. Regulatory systems must be capable of providing the flexibility to allow the rapid recognition of emerging hazards and the rapid implementation of tools to address them. Let me discuss the theory that underpins efforts to modernize today’s food safety regulatory system, which is an antiquated system built on a 1906 legal foundation.

Process control systems managed by the food industry and regularly reviewed by government regulators are at the heart of a modern food safety system. Such systems are designed to be flexible and to adapt to change. The food industry designs and validates its own safety system and monitors its implementation at the processor level. The government sets performance standards and inspects plants to ensure the systems are designed and managed properly.

Performance standards provide a metric for measuring the success of a facility’s food safety controls and allow government inspectors to standardize their evaluation of plants producing similar products. Performance standards can utilize a specific chemical or pathogen limit or a performance measure, such as a standard microbial or “log” reduction. The agency sets the target level, and companies have flexibility in deciding how to reach it. Performance standards allow companies to innovate within the parameters set by the government.

Government agencies should regularly update their standards to reflect current conditions. Such a system allows both the food industry and the government programs to achieve continuous improvement.

The government sometimes must rapidly establish a performance standard for an emerging hazard. For example, the findings of melamine in infant formula in China and in some products in global trade provided the immediate need for FDA to set a standard for that chemical in formula quickly, a sensitive issue as this is the single source of nutrition for many infants, who are a high risk group.<sup>8</sup> Clearly the regulatory system must accommodate these circumstances, but the system we have today forces many agencies to operate outside of the rulemaking process in order to set food safety standards.

Unfortunately today more than 10 years into the HACCP era, performance standards are not used effectively. The ones that were developed have become out-dated, and agencies are reticent to develop new ones due to the changing science and the lengthy nature of the regulatory review process. One of the biggest limitations to more effective and responsive regulation is imperfect data. Decision makers often lack the baseline information required to develop new or improve older performance standards. These gaps in data can delay, or even derail, meaningful regulatory efforts. The regulatory system must accommodate these circumstances where meaningful regulatory action must be progressed even in the absence of perfect data.

When it comes to food safety, the goal must be a rapid-paced and flexible regulatory structure that can accommodate constantly changing science and even imperfect science. As regulations and policy evolve, regulators must be allowed to bring new science to bear in preventing food-borne illness outbreaks. Unfortunately, the regulatory review process has become a moribund, time-consuming and daunting barrier to agencies' efforts to rapidly translate new science into better regulation for protecting the health of the public.

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<sup>8</sup> See, FDA, *Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans*, Oct. 3, 2008; followed quickly by FDA, *Update: Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans*, Nov. 28, 2008, in response findings of melamine and cyanuric acid in some U.S. manufactured infant formula.

**Case Study: Meat and Poultry HACCP  
Cumbersome Review Process Means Performance Standards Not Updated;  
Agency Finds Creative Solutions**

An important illustration of the modern food safety system discussed above is USDA's application of HACCP systems for meat and poultry plants. The agency adopted the program by regulation in 1996 and within 3 years it was in use in every meat and poultry facility in the United States. The agency also utilized performance standards based on the frequency of *Salmonella* in the different species and ground products; these standards have been in use since the program started. Under this program, the agency periodically runs a series of tests for *Salmonella* in individual facilities to evaluate their performance against the standard for that sector of the industry.

The performance standards were established on the basis of a series of baseline studies documenting *Salmonella* and other pathogens and indicator organisms on meat in the early-to-mid 1990's. By the time the program was fully implemented (1999), the standards were already largely out-of-date. In fact, to even approach the "limit," many companies would have to double the amount of *Salmonella* in their products.

In 2006, the agency came up with a creative solution to the obsolete standards adopted in the 1996 Pathogen Reduction regulation. The agency published a notice in the Federal Register announcing that it would place meat plants into one of three categories depending on their *Salmonella* testing results.<sup>9</sup> Companies would be placed in category I if their results were 50% or less of the published *Salmonella* performance standard. Companies with results between 50% and 100% of the *Salmonella* performance standard would be placed in Category II. And those plants with results in excess of the *Salmonella* performance standard were placed in Category III,

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<sup>9</sup> *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection, 71 Fed. Reg. 9772, (Feb. 27, 2006).

and faced increased enforcement and compliance checks by USDA.

In August 2007, the Undersecretary of Food Safety at USDA announced that the agency would publish the names of plants in Category II and III on the Internet.<sup>10</sup> The release of plant names started in March 2008. While this new approach was published in the Federal Register, and the agency solicited public comment, it was not a federal regulation because it required no specific action of the industry.<sup>11</sup> This allowed the agency to move from the concept phase to implementation in about one and a half years. If the agency had chosen to update the performance standards, assuming the data was available to do that, it would likely have taken anywhere from 3-7 years from the concept to implementation. So this solution, which effectively reduced the performance standard by 50% through the use of a “name and shame” strategy rather than a more classic regulatory enforcement, was implemented much faster simply by avoiding a full OIRA review.

**Case Study: Shell Egg Rule  
Multiple Risk Assessments and 10 Years is Still Not Sufficient to Achieve Needed  
Regulations**

The efforts to finalize a regulation to control *Salmonella* Enteritidis (SE) in shell eggs shows that even when sound science supports regulation and cost-benefit analysis favors action, the lack of a clear food safety agency that is “in charge” may allow OMB to throw up roadblocks to implementation. Thus OMB can block a regulation that might prevent thousands of illnesses and possibly hundreds of deaths each year,<sup>12</sup> just because it can’t decide which federal agency

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<sup>10</sup> Transcript, USDA, Public Health Based Inspection in Slaughter to Address *Campylobacter*, *Salmonella*, and Other Public Health Concerns (August 7, 2007) at [http://www.fsis.usda.gov/PDF/Transcript\\_080707\\_Slaughter\\_Inspection.pdf](http://www.fsis.usda.gov/PDF/Transcript_080707_Slaughter_Inspection.pdf).

<sup>11</sup> *Salmonella* Verification Sampling Program: Response to Comments and New Agency Policies, 73 Fed. Reg. 4767 (Jan. 28, 2008).

<sup>12</sup> *Salmonella* is estimated to cause 1.3 million illnesses and 500 deaths each year. *Salmonella* Enteritidis is the most common serotype, according to the Centers for Disease Control and Prevention. CDC, Preliminary FoodNet Data

should manage the problem.

In 1997, on the basis of a pilot study conducted in Pennsylvania that showed that on-farm controls could greatly reduce the incidence of SE in eggs and laying flocks, CSPI petitioned the government to require egg producers to implement on-farm process control programs. The approach supported by CSPI's petition was also recommended in the first SE risk assessment. In 1996, after watching an increasing incidence of SE in eggs, the Food Safety Inspection Service (FSIS) and FDA initiated a risk assessment to assess the interventions needed to reduce the risk of illnesses from SE.<sup>13</sup> Published by FSIS in 1998, it provided further support for the need for on-farm controls to address SE in live hens, thereby reducing the incidence of illnesses from SE.<sup>14</sup>

FDA and FSIS issued a joint advanced notice of proposed rulemaking in 1998<sup>15</sup> and the issue even merited a Presidential announcement in 1999 by President Bill Clinton, which clearly indicated FDA would take the lead on the food safety regulation.<sup>16</sup> But after that, the issue sat under the Bush Administration while it re-debated internally which agency should handle this issue. FDA did not publish a proposed rule until 2004.<sup>17</sup> At approximately the same time, FSIS released a second risk assessment further documenting the need for regulatory action.<sup>18</sup> After accepting comments in 2004, and in a second extended comment period in 2005, the rule continued to languish. It was not sent to OIRA for final review until 2008.

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on Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, 2008, MMWR Weekly, April 10, 2009, 58(13); 333-337.

<sup>13</sup> FSIS, *Salmonella* Enteritidis Risk Assessment: Shell Eggs and Egg Products, June 12, 1998.

<sup>14</sup> Id.

<sup>15</sup> *Salmonella* Enteritidis in Eggs; Advanced Notice of Proposed Rulemaking, 63 Fed. Reg. 27502 (May 19, 1998).

<sup>16</sup> Press Release, USDA & FDA, Clinton Administration Announces Ambitious New Plan to Improve Egg Safety, Reduce *Salmonella* Illnesses (Dec. 11, 1999) at <http://www.usda.gov/news/releases/1999/12/0483>.

<sup>17</sup> Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule, 69 Fed. Reg. 56824 (Sept. 22, 2004).

<sup>18</sup> FSIS, Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products, Oct. 2005 (Assessing risk of SE contamination in processed eggs for the purpose of establishing science-based performance standards).

FDA had cited its intention to finish the Shell Egg rule in numerous documents including the budget<sup>19</sup> and the Food Protection Plan.<sup>20</sup> But it could never seem to get it finalized at OMB. What happened at OIRA once the rule was forwarded to OMB is anyone's guess, though we know OIRA met with industry and consumer groups on the rule in August 2008. All we know is that on Nov. 19, 2008, FDA withdrew a well-vetted final rule citing the need to address comments received during interagency review.<sup>21</sup> Because OIRA's comments were made through an interagency exchange, the public has no way of challenging the decision to withdraw the rule.

So the rule fully supported by science-based risk assessments as being needed to protect public health from an avoidable problem in shell eggs is back at FDA with the start of the Obama Administration, no change from 10 years ago when President Clinton made it the topic of a Presidential radio address.

### **Case Study: Bioterrorism Act Interference in Agency Determinations Results in Weak Regulations**

In June 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Act gave FDA four new authorities: FDA could detain potentially contaminated foods; register foreign and domestic food facilities; require record keeping in the food industry; and give prior notice of food imports. Congress set an 18-month time frame for FDA to adopt regulations under the new law.

FDA did publish four proposed rules between February and May 2003, with intentions to

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<sup>19</sup> FDA, Foods, FY2008 Budget Justification Documents located at <http://www.fda.gov/oc/oms/ofm/budget/2008/1-BudgetNarrativeCFSAN.pdf>.

<sup>20</sup> FDA, Food Protection Plan, Nov. 2007 (Proposing to issue a final regulation on *Salmonella* in shell eggs by Spring 2008).

<sup>21</sup> Joan Murphy, *FDA Withdraws Salmonella Enteritidis Shell Egg Rule From OMB Review*, Food and Chemical News, Dec. 1, 2008.

push forward to get the regulations finalized to meet the deadlines in the Act. But things slowed when the rules arrived at OMB.

Documents reviewed by CSPI showed that during the comment periods, OMB hosted a steady stream of meetings with over 30 food industry representatives who we believe were seeking to influence the final outcome on four proposed anti-bioterrorism rules.<sup>22</sup> While these meetings provide an opportunity for OIRA staff to ask questions of outside experts, they are not formally within the notice and comment rulemaking process under the Administrative Procedure Act (APA).<sup>23</sup> Therefore, the meetings produce few of the hallmarks of transparency that are part of the APA process. OIRA lists participants at the meetings and publishes documents it receives on its website, but does not follow a public comment process, make a transcript or provide any response to comments it receives. And these meetings with industry seemed to have an impact.

Because FDA does not have inspectors at every port of entry, the purpose of the prior-notice requirement for shipments of imported food was to allow the FDA to dispatch its inspectors to check the riskiest incoming food shipments. FDA proposed a rule on prior notice of food imports that required importers to notify the Agency by noon on the day before a food shipment arrives. However, in July and September 2003, OMB held four meetings with the food industry on this proposed regulation. The regulation that emerged in October 2003 had significantly shorter notice requirements—just two hours notice for trucks, four hours for trains or planes, and eight hours for ships transporting food. Additionally, under the interim final rule

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<sup>22</sup> According to participant lists on OMB's web site, agency officials met with officials from Kraft, ConAgra, Procter & Gamble, the Food Marketing Institute, the Grocery Manufacturers of America, the National Food Processors Association, and the National Coalition of Food Importing Associations, as well as several food packaging and transportation groups. In response to a Freedom of Information Act (FOIA) request, CSPI obtained additional information, including handouts and meeting agendas supplied by the industry representatives. There was no evidence that OMB met with any independent food-safety experts or consumer groups during this time. <http://www.cspinet.org/new/200409291.html>

<sup>23</sup> A similar meeting of industry representatives at the agency level would require, at a minimum, a taped transcript.

importers are permitted to make last minute changes to their notifications. The final rule on prior notice that was required to be completed in late 2003, is slated to go into effect next week, nearly six years past its Congressionally-mandated “due date.”<sup>24</sup>

These time frames were clearly not adequate to meet the intention of the statute. FDA could not move inspectors to ports to check high-risk products identified under the shortened notice requirements. While they could potentially hold suspect products on site until an FDA inspector could get there, it clearly undercut the intent and efficacy of the new law.

In another of the proposed rules, FDA sought to require companies to keep records on food shipments and ingredients. Known as “one up/one down,” this traceability provision was intended to allow FDA to quickly track food back to its source in an emergency

During consideration of this regulation, OMB held meetings with 14 food industry representatives, including three meetings in February and March 2004. The industry agenda for one meeting included such topics as “Lot code tracking is unnecessary and costly,” and “Four hour record keeping retrieval—Unreasonable and unnecessary.” The impact: The lot code tracking provision was revised to exempt transporters and distributors and the record retrieval provisions were changed in the final rule from 4 hours to 24 hours. These changes significantly weakened the final record keeping provisions, and may have contributed to the long investigative delays in recent outbreaks linked to *Salmonella* in the United States.<sup>25</sup>

As the Bioterrorism Act specified that the regulation be finalized within 18 months, the first deadline expired in December 2003. Though FDA announced that it would finalize the rule

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<sup>24</sup> Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Draft Compliance Policy Guide; “Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;” Availability; Final Rule and Notice, 73 Fed. Reg. 66294, (Nov 7, 2008).

<sup>25</sup> Julie Schmit, Tracing Tainted Produce Isn’t Easy; Salmonella Case Highlights Complex Distribution System, USA Today, Aug. 14, 2008, at 1B; See, HHS Office of Inspector General Rep. No. OEI-02-06-00210, Traceability in the Food Supply Chain, March 2009 (revealing poor compliance by industry and recommending stronger traceability laws).

by the end of March 2004, the final rule was instead published nine months beyond that target date, in December 2004. Compliance with the rule was not required until June 2005 for large companies. Small businesses (fewer than 500 employees) had an additional year to comply.

The two other regulations were finalized as required by the law. In October 2003, FDA issued a final rule requiring domestic food processors and importers to register with the agency. In June 2004, it finalized a rule covering administrative detention procedures for food.

### **Conclusion**

This testimony has identified and illustrated a number of problems with the OIRA review of regulations. The meat and poultry HACCP regulation showed how science is not well advanced and public health improvements can be thwarted when regulations are tied up in a multi-year regulatory review process. The case showed that OIRA's burdensome review has provided incentives for the agencies to find creative ways to avoid going through the OMB process. For meat and poultry products, it means that USDA has kept outdated performance standards in place by using newer guidance benchmarked to the old performance standards.

The proposed egg regulation illustrated the problem inherent in unlimited reviews that can add years to the development of regulations. It also illustrates the confusion of having multiple agencies in charge of food safety.

The bioterrorism rules showed that OIRA reviews can open the door for industry to lobby for changes to regulations without the transparency requirements of the APA and also how OIRA can override policy decisions best left to the agencies. We have also heard from agencies about the long delays inherent in trying to do a voluntary survey and how agencies are sometimes asked to predict future benefits with specificity before a rule can progress.

These problems did not originate in the Bush administration, nor will they necessarily

disappear just by having different people in charge. Fundamental changes are needed to reduce the breadth of oversight and the time lags that result from such broad oversight.

The role of science in the regulatory process is very important; however, for the reasons discussed above, OIRA review has diminished the role of science in crafting federal regulations. CSPI recommends that a new executive order rewrite the OIRA mandate to give it more targeted review along with responsibility for identifying gaps in regulatory oversight. A new executive order should update the definition for “significant” rules to narrow the number of regulations requiring prior approval and limit OIRA’s review to the economic issues raised in the proposed rules. As OIRA is staffed by economists, they should defer to the federal agencies on scientific and technical questions. OIRA should have a rapid time frame for review that balances thoughtful review with the need to produce timely federal agency actions, particularly to protect public health and social welfare. Finally, to whatever extent that OIRA retains a role in agency rulemaking, it should operate with greater transparency. Agencies must be instructed more forcefully to document any changes to their draft rules or pre-rule framework made at OIRA’s suggestion at whatever point in the rulemaking process those changes occurred.

The real costs of regulatory delay are felt by everyday American’s when they experience an avoidable food borne illness. The food industry can improve, but it needs a level-playing field to do it. Our nation’s food safety program can and will improve, I am confident. But it won’t happen without reform of the OIRA review process as well.

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Biographical Sketch

Caroline Smith DeWaal is the director of the food safety program for the Center for Science in the Public Interest and co-author of *Is Our Food Safe? A Consumer's Guide to Protecting Your Health and the Environment* (Three Rivers Press, 2002). She represents CSPI in the media, in Congress and in the regulatory arena on a broad range of food safety issues. Ms. DeWaal is the leading consumer analyst on reform of laws and regulations governing food safety. Since 1999, she has maintained and annually published a listing of foodborne illness outbreaks organized by food source that now contains over fifteen years of outbreaks reports. She has presented CSPI's outbreak database at numerous scientific conferences, including the American Public Health Association, International Association for Food Protection and the American Society for Microbiology. She has presented papers on food safety at over 50 scientific and public policy conferences. She has participated in a number of World Health Organization consultations on food safety and is currently an expert advisor on its Intergrated Surveillance of Antibiotic Resistance project. She represents the International Association of Consumer Food Organizations at the Codex Committee on Food Hygiene. She has participated in several national advisory committees to USDA and FDA. She chaired the Editorial Board of the Food and Drug Law Journal and is a member of the International Association of Food Protection. DeWaal graduated from the University of Vermont and Antioch School of Law.