



Office of Information and Regulatory Affairs,
Records Management Center,
Office of Management and Budget,
Attn: Mabel Echols
Room 10102, NEOB, 725 17th Street, NW,
Washington, DC 20503.

Re: Food & Water Watch Comments about “Executive Order on Federal Regulatory Review,” 74 Fed. Reg. 8819 (February 26, 2009)

Submitted on March 13, 2009 via email at oira_submission@omb.eop.gov and fax at (202) 395-7245.

Dear Ms. Echols:

Food & Water Watch (FWW), a non-profit consumer organization that advocates for safe food and clean water, is pleased to comment on the administration’s forthcoming Executive Order on federal regulatory review.

As we understand it, the Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) is currently taking public comment in order to provide the President a set of recommendations for a new Executive Order relating to regulatory review. We strongly support this effort. For far too long – and despite attempts at reform in the Clinton administration – OIRA regulatory review has been a star chamber, usurping agency expertise, while sacrificing public health and environmental protection to policy-driven, cost-benefit analysis. We therefore strongly support a dramatic revision of Executive Order 12,866 to improve transparency and public access to the rulemaking process. We strongly support the recommendations made by OMB Watch and others to end the role of OIRA in review of significant rules. Finally, we urge the administration to abandon the requirements that agencies engage in cost-benefit analysis for their public-health-related rulemakings unless the agency is required to do so by statute.

In addition, we offer the following specific comments that should be either incorporated into the new Executive Order or be an immediate outgrowth of such an order.

Transparency and Access

OMB and OIRA should work to improve not only its own transparency, but also the transparency of all agencies with which it works. Specifically, the administrations should drastically change the Regulations.gov website. Previous OIRA guidance has stated that agencies should use this website for its rulemaking because “[t]he site makes the Federal rulemaking process more accessible and enables citizens and small businesses to quickly access and comment on hundreds of open proposed rules from all Federal



agencies.”¹ However, this website – and the way that agencies use it – are ineffective for these purposes. Some of the problems with the website include the following:

- Federal Register notices do not direct the public to specific webpages for rulemakings. Instead, the user is instructed to go to Regulations.gov and submit a site search, using the “Advanced Search Functions” and the docket I.D. number, which can be twelve or more letters and digits long. Requiring users to navigate through numerous pages and engage in site searches means that many users will get lost before they find the appropriate webpage.
- Once one reaches the correct docket page for a rulemaking, submitting comments requires at least four additional steps. One is required to hit the appropriate link to pull up a form for submitting comments, then fill out that form, then attach or write the comments one wishes to make, and then submit them. This can be a daunting and tiresome process for anybody, no less for persons who are not very technologically savvy.
- The web site makes it difficult to read other public comments. Once one finds the appropriate docket page, one can only search by the date that comments were submitted. It is difficult, if not impossible, to search comments by author or subject matter.

In effect, Regulations.gov, and the way that agencies use it, undermines the very purposes of e-government, as laid out in the E-government Act of 2002, which is to make agency rulemaking more accessible. Instead of the current system, each rulemaking should have its own page, with its own easy-to-remember domain name, by which people should be able to directly access the docket and submit comments. The link to this page should be provided in the Federal Register notice for the rulemaking and its contents should be searchable through major search engines such as Google.com. The web address of this page should remain the same until after the rule has finalized, removing people’s ability to comment only after the comment period has closed. When the page needs to be moved or archived, it should still be easy to find through minimal linking. Further, people should be able to search within each docket page for terms used in public comments.

Finally, and very importantly, people should not be required to submit comments solely through the website. Instead, the agency should provide numerous ways by which people can submit comments, including fax and email, so as to make it as easy as possible. The agency should then make these comments part of the electronic docket.

Not only is it important that the OIRA and other agencies improve the manner in which they conduct electronic rulemaking, it is important that the docket is complete and

¹Memorandum from John D. Graham and Karen S. Evans to the President's Management Council on “Regulations.Gov.” (March 1, 2004)



publicly accessible. All documents that are relied upon by the agency in proposing and finalizing rules need to be made accessible to the public. While this is seemingly commonsensical, agencies often do not follow this basic principal. For example, recently FWW attempted to review a food additive petition that had been approved by the U.S. Food & Drug Administration (FDA). Despite the fact that the petition had been previously pending for several years, FDA refused FWW's request to review the petition and supporting material on the grounds that the agency had yet to evaluate which material was confidential business information. This blatantly contradicts the recommendations of the Administrative Conference of the United States that all rulemaking files be managed to so that maximum disclosure to the public is achieved.²

Likewise, all OIRA "post-review" documents should be made part of the record and available to the public in its docket. This would include the draft regulation as originally submitted; any agency analyses and other material submitted by the agency during the review; pages of the draft where changes have occurred in the course of review; correspondence between OIRA and the agency exchanged during the review; and correspondence OIRA received from outside parties while the rule was under review. This information is not routinely made publicly available through either Regulations.gov or Reginfo.gov.

It should be underscored that post-review documents include *all* comments made by OIRA. Right now, OIRA engages in far more review and comment of agencies' rules than what is made public in formal review and return letters. All of the OIRA's comments, regardless of whether they are formalized in such letters, should be made available to the public.

Finally, this information should be available, even if the agency withdraws the rule. After all, a decision to withdraw a rule should be considered a final agency decision. In the past, OIRA has refused to release post-review materials when the agency had proposed a rule but then subsequently withdrew it.

OIRA Review of Agency Rulemaking

While FWW does not believe that the proper role for OIRA is to review and oversee agency rulemaking on a rule-by-rule basis, to the extent that OIRA will continue this practice in some form, FWW recommends that OIRA make the following changes to the way that it does its review:

- OIRA should disclose its timeline for reviewing rules and meet its deadlines. Currently Reginfo.gov only discloses the date that the rule was submitted; no estimates are provided for when OIRA will likely finish this review. This stands in contrast to almost every agency's rulemakings, in

² Administrative Conference of the United States Recommendation 93-4 Improving the Environment for Agency Rulemaking, Recommendation V.E, 59 Fed. Reg. 4670 (Feb. 1, 1994)



which officials openly discuss when they think proposed rules and finalized rules will be published. Further, rules often are inappropriately delayed at OIRA beyond the 120 days specified in E.O. 12,866.

- OIRA and agencies should clarify when and why rules are subject to review. E.O. 12,866 is clear that OIRA is to review rules that are “economically significant,” which includes those that have a \$100 million effect on the economy. But this designation also includes those rules that raise novel legal and policy issues. Because it is often times unknown what raises novel legal and policy issues or otherwise makes a rule economically significant, OIRA and agencies should disclose what has triggered regulatory review for each rulemaking. Similarly, OIRA should disclose what agencies do and do not have to get pre-clearance for legislative proposals and testimony.
- E.O. 12,866 should be revised so as to not exclude independent agencies, like the Nuclear Regulatory Commission.

Cost-Benefit Analysis

As mentioned above, agencies should not be required to engage in cost-benefit analysis for rulemakings involving public health unless required by statute. After all, agencies are often not permitted by statute to consider costs in designing such rules, so cost-benefit analysis becomes, at best, an exercise in futility, and, at worst, an exercise that serves to undermine legislative mandates. Also, when a statute is silent on the matter, the agency should be given discretion, regardless of OIRA mandates, to use the tools it deems are best to carry out its functions, which might or might not include cost-effectiveness and cost-benefit analysis.

Unfortunately, under the Bush administration, cost-benefit analysis became more entrenched and enshrined than under previous administrations, displacing other valid values and tools that agencies can employ in designing regulations. This is evident in John Graham’s Circular A-4 Memorandum on Regulatory Analysis (September 13, 2003).³

We urge this administration to reverse this trend. Agencies’ regulatory analyses of rules need to consider other, equally important values besides monetary costs and benefits. For example, the precautionary principle, while not easy to monetize, is recognized around the world in designing regulations to protect the environment and public health. OMB’s A-4 Circular, in contrast, mentions “precaution” only once, and refers to it as “precautionary instincts,” counterpoising it with “science” based considerations.⁴

³ <http://www.whitehouse.gov/omb/asset.aspx?AssetId=206>.

⁴ *Id.* at p. 40.

The prior administration's disregard for using the values of precaution in regulatory analysis was evident, as an example, in the National Marine Fisheries Service's (NMFS) rule to protect the krill in the Pacific. In 2008, OIRA sent a return letter to NMFS for this rule on the grounds that the agency had insufficient evidence for regulation. OIRA stated that the agency had not specified why such a prohibition was needed given the fact that there was currently no known or planned exploitation of the fishery. But this position overlooked the fact that NMFS foresaw commercial fishing of krill (regardless of whether it was planned), had considered other alternatives, and concluded that the best alternative was to prevent the activity before it was planned and started. While it is vitally important to ensure that agencies are being as clear as possible in both their rationale and alternatives for regulation, OIRA's return letter in this case seemed to be grounded upon skepticism of the need for the rule, as opposed to a genuine concern related to transparency. After all, all of the material that NMFS eventually used to justify its rule was already part of the record.

Further, and more importantly, OIRA's return letter reflected a strong bias against implementation of the precautionary principle. OIRA was overly skeptical of a rule designed to prevent potential harm, distinguishing it from rules designed to mitigate harms from planned or existing activities. We urge the Obama administration to reject this view of regulation and to fully support the precautionary principle, which undergirds many federal environmental and public health laws.

In addition to underestimating the value of precaution, regulatory analysis under the Obama administration should avoid undervaluing any innovation- and technology-forcing benefits of regulations. Instead of evaluating a regulation based on whether industry can comply, the agency should recognize that a regulation can oftentimes force the most-sustainable industry to excel, thus incentivizing the development of this technology.

The krill example also demonstrates a key principle that should underlie all federal regulations. Regulatory assessment should be performed uniformly within and between agencies and not in a way that simply supports desired policy outcomes. For example, OIRA guidance is very clear that when doing cost-benefit analysis, the agency should be explicit about its assumptions and any uncertainty in those assumptions.⁵ But past agency analyses have directly contradicted this guidance, especially when doing so comported with pre-ordained policy preferences. For example, the U.S. Department of Agriculture's (USDA) Country of Origin Labeling (COOL) guidelines were premised on the assumption that COOL would yield a \$1.9 billion dollar cost and no benefits. Numerous commenters noted that these costs were overstated because, among other things, they did not consider the consolidation in the industry. The agency also overlooked the benefits that were estimated to come from the public's willingness to pay for American goods. Despite numerous public comments addressing these issues, USDA has now finalized mandatory COOL rules but continues to apply this flawed cost-benefit analysis.

⁵ *Id.*



Finally, the Bush administration's A-4 Circular put a premium on market-based regulatory solutions. We urge the Obama administration to abandon such reverence. Often times market solutions result in severe inequities, reward bad actors, encourage industry consolidation, and can simply mean a solution that the regulated industry supports – as opposed to a solution that actually works.

In summary, we urge this administration to issue an executive order that dramatically changes the manner in which it engages in rulemaking. The new executive order should increase the transparency in e-rulemaking. It should end OIRA's current role of rule-by-rule review. In the alternative, it should dramatically increase the transparency of this process. Finally, it should reject cost-benefit analysis as part of its requirements for regulatory assessments, unless mandated by statute. Agencies should be required to consider other, equally important values such as precaution in their rulemaking.

FWW appreciates this opportunity to comment and looks forward to working with you on this very important matter.

Sincerely,

Wenonah Hauter
Executive Director
Food& Water Watch