



# Environmental Technology Council

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To: Office of Information and Regulatory Affairs  
Management and Budget

Comments on developing a set of recommendations to the President for a new Executive Order on Federal Regulatory Review

The Environmental Technology Council represents regulated entities under the Resource Conservation and Recovery Act (RCRA). Our companies recycle, destroy, and dispose of hazardous waste, generally at EPA permitted facilities. These comments on Executive Order 12866 are in response to the Request for Comments, printed in the Federal Register, February 26, 2009, 74 FR 8819. We welcome the opportunity to identify some of the problems with the current regulatory review process.

Our overriding concern is that under the current system the regulation of any new toxic waste is virtually impossible. The present requirements of E.O. 12866 have for all practical purposes repealed all provisions of the Resource Conservation and Recovery Act (RCRA) requiring EPA to keep up-to-date the regulated chemicals and compounds that threaten public health and environment. A system that makes it impossible to update 28-year-old regulations of toxic chemicals is surely broken. In these comments we are using RCRA as an example. We believe the scope of the problem is broader and covers many environmental and public health statutes.

Other statutory and internal EPA agency requirements<sup>1</sup> besides E.O. 12886 also have had a debilitating impact on writing of necessary and timely regulations. These additional obstacles to efficient operating government also need to be reviewed.

We agree with many of the early commenters<sup>2</sup> that the Executive Order 12866 is severely flawed and the President needs to alter significantly the relationship between OIRA and the Departments and Agencies. These comments will use the promulgation of the P and U lists of toxic wastes as examples of the obstacles faced by EPA in writing

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<sup>1</sup> Other internal agency policies have stymied regulations or have made the time line so long bureaucrats are loath to start on essentially a small regulatory project that may take up to ten years to complete. These internal Agency policies include the "work group" process, where every office in EPA can comment on every regulation. Another new requirement is a political gatekeeper in the EPA office of Planning and Evaluation who can hold up regulations. Statutory requirements, including the Paperwork Reduction Act, the Regulatory Flexibility Act, Unfunded Mandates Reform Act, and the Congressional Review Act. At least three additional executive orders on environmental justice, energy supply, and federalism also are required to be addressed.

<sup>2</sup> <http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp> March 12, 2009.

needed regulations. [40 CFR 261.33]. Other statutory requirements in RCRA or the Toxics Substances Control Act could just as easily have been used as examples of how the Executive Order has petrified the regulations of hazardous toxics.<sup>3</sup>

In 1980, EPA listed over 600 chemical compounds of Discarded Commercial Chemical Products, Off-Specification Species, Container Residues, and Spill Residues that would be considered hazardous waste if discarded. Some were acutely toxic (the P list) and others were chronically toxic (the U list). The Agency developed the lists with little controversy and for a small cost. Experts in the field developed the list in what today would be considered an informal process.

Despite the fact that many of the compounds including pharmaceuticals are now obsolete (nine generations of toxic cancer drugs have been in the marketplace since that time<sup>4</sup>), and over 15,000 new chemicals have reached the market, the list has not been amended since Bill Gates invented the DOS operating system. This is despite the Congressional requirement in Section 3001(b)(1) that the list "shall be revised from time to time thereafter as may be appropriate."

The main reason for this inability-to-regulate is the substantive requirements of section 1(b) of the Executive Order. Section 1(b) is written with the assumption that regulations are unnecessary and that there is almost always another less-burdensome avenue to influence behavior. Therefore, under the Executive Order, a regulator trying to add a single chemical compound to the P or U list has to make a dizzying number of findings, many of which could easily be challenged by those opposed to regulations.

For instance, what is the significance of the problem that is trying to be addressed? [Section 1(b)(1)] This is a reasonable question in the abstract. However, what specific evidence exists that one particular new cancer drug is polluting waterways? The cost to determine such a finding would be substantial. Water chemistry is complicated. Many compounds have similar chemical constituents. Which cancer drug caused the pollution? Alternatively, is the pollution from a synergistic combination of air and water releases? Such a study would be expensive, time consuming and most likely indeterminate. And that is only one subsection of (b) for one chemical.

The regulator would have "to identify and assess available alternatives to direct regulation." [Section 1(b)(3)] Should EPA just have the industry tell its salespeople how this particular unused drugs should be handled? Is that effective? Should hospices and

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<sup>3</sup> For instance, toxic characteristic chemicals are not toxic under RCRA unless they are promulgated under 40 CFR 261.24. Therefore, of the thousands of toxics chemicals, only the 23 under 261.24 are considered toxic. That list has not been amended since 1989.

<sup>4</sup> Polovich, M. (September 30, 2004). "Safe Handling of Hazardous Drugs". *Online Journal of Issues in Nursing*. Vol. 9 No. 3, Manuscript 5. [www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol92004/No3Sept04/HazardousDrugs.aspx](http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol92004/No3Sept04/HazardousDrugs.aspx). The article notes that many hospital employees make think a new compound is safer because it is not regulated as a P or U waste. In actuality it could easily be more toxic.

hospitals be sent a letter from the head of EPA? Should a new voluntary program be instituted? How would that program be measured? This analysis could go on endlessly.

The risk assessment and cost benefit analysis are additional burdens that on a chemical-by-chemical basis are expensive and, for most compounds are unlikely to have the critical data needed to make useful conclusions. The risk assessment requires a complete, usually peer-reviewed analysis consisting of four steps:

1. Hazard identification;
2. Dose-response assessment;
3. Exposure assessment; and
4. Risk characterization.

EPA has tried, so far unsuccessfully for ten years, to do acceptable risk assessments for asbestos and dioxin. Risk assessments are good tools if you have underlying facts. However, research into specific compounds requires underlying data does not exist or is very expensive to develop. Since it is unlikely a college doctoral student did a study on the disposal characteristics of a particular new compound, the risk assessment process may require EPA to undertake such a study. The cost of one study of one prospective P or U chemical would cost more than it took to do the research for the original 600 chemicals listed in the P and U lists. Section 1(b)(7) directs that decisions be based "on the best reasonably obtainable scientific, technical, economic, and other information. . ." Historically, this section has been ignored if powerful forces were likely to oppose such regulation.<sup>5</sup>

These are just a few of the hurdles in section (b) that have made RCRA's requirements for regulating new harmful chemicals a dead letter. As other commenters have noted,<sup>6</sup> the other subsections of (b) are also difficult to meet. It should be underscored the problem of the Executive Order 12866 essentially repealing the statutory RCRA requirements to regulate new chemicals and compounds is not a problem of policies of the last Administration. The Office of Solid Waste for at least three administrations realized the futility of such an undertaking. Instead, the office has opted to ignore the law and address waste problems with questionable voluntary programs.

There are possible fixes. One solution is to remove the ability of OMB to bring regulations under \$100 million under the requirements of E.O. 12866. Section 3(f)(4) has, for all practical respects repealed the \$100 million floor for every attempt to strengthen environmental regulation under the catchall "Raise novel legal or policy issues

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<sup>5</sup> In addition, synergistic impacts of multiple chemicals in the environment are generally ignored, not because synergistic impacts are not a risk to public health or the environment but the science is too immature. Therefore, this important risk is ignored and under regulation is the result.

<sup>6</sup> Ibid, fn1.

arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order." This subsection should be deleted. In addition, the \$100 million floor should be adjusted for inflation.

A better alternative is to remove OMB's power to review each regulation. The President has chosen the head of the Departments and Agencies and he should trust his team to follow the law and his policies. Requiring a handful of bureaucrats in OIRA to second guess and hold up virtually each regulation for as long as they want<sup>7</sup> has undercut the Congressional requirements to enforce the laws. Regulating toxics requires a combination of experts that OMB cannot duplicate. OIRA has less than 45 staff and is required to review a myriad of regulations of which environmental ones are a small percentage. Therefore, it has relied on industry groups, generally opposed to regulation, to help direct the course of their review. The President should give Agency heads greater authority to carry out their Agency's mission based on principles and guidelines developed by OIRA. OIRA should continue its very important interagency coordination.<sup>8</sup>

In the opening paragraph to Executive Order 12866, President Clinton wrote:

"The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable."

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<sup>7</sup> Under the Executive Order, OMB has half a year to review regulations; 90 days on the proposal and 90 days on the final. However, the OIRA has learned how to circumvent this rule. OIRA tells agencies that they will reject the rule if the agency does not ask for an extension for OMB review.

<sup>8</sup> The interagency review needs to be changed too. Some of the largest polluters who are regulated by EPA are other agencies of the federal government. The Department of Defense, Department of Energy, Department of Commerce, and the Small Business Administration all participate in the Interagency Review Process. Their impact in weakening and slowing down regulations cannot be underestimated. This review needs to be streamlined with specific deadlines and some institutional barriers so that the self-interest of the departments who do not want to be regulated are not given undue weight.

At this time, the balance has sacrificed protecting the public to easing regulatory burdens. It is time to right the balance.

Thank you for considering our comments.

Very truly yours,



Scott Slesinger  
Vice-President for Government Affairs

