36

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Subject: 2004 Draft Report to Congress

Document attached.

- OMB.Draft Report.doc

May 12, 2004

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PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Re: OMB Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations - Request for Comments published at 69 Fed. Reg. 7987.

Dear Ms. Hunt:

I am in-house Legal Counsel in the Research and Investigations Department of People for the Ethical Treatment of Animals ("PETA"). I am writing on behalf of our 800,000 members and supporters and in response to the Office of Management and Budget's notice in the Federal Register seeking comments to the Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations (the "Draft Report"). Our purpose in commenting is to offer five concrete suggestions for reforms to rules and guidance documents that would reduce unnecessary costs, increase effectiveness, reduce uncertainty, and increase flexibility.

By way of background information, PETA has been an active and acknowledged stakeholder in connection with various chemical testing and assessment programs being undertaken by the Environmental Protection Agency ("EPA"). Specifically, PETA has been involved with programs emanating from the Agency's Office of Pollution Prevention and Toxics ("OPPT"), Office of Pesticide Programs ("OPP"), and Office of Science Coordination and Policy ("OSCP"). We are fully acquainted with the Toxic Substances Control Act, the Federal Insecticide, Fungicide and Rodenticide Act, the Federal Food, Drug and Cosmetics Act, the Food Quality Protection Act, and the various implementing regulations and guidance documents relating to those statutes. We are also conversant in the protections afforded the public by the Administrative Procedure Act and the Federal Advisory Committee Act.

PETA has been the leading voice on behalf of the animal protection community with respect to the OPPT's High Production Volume ("HPV") Chemical Challenge Program. PETA has reviewed every test plan submitted to the Agency in the HPV program and provided detailed comments on most. When the EPA announced the formation of the National Pollution Prevention and Toxics Advisory Committee, a central focus of which is the HPV program, two PETA staffers who are thoroughly acquainted with the HPV program were nominated to the Committee. They were not simply nominated by PETA, they were nominated by a coalition of animal welfare groups with a collective membership of over 10 million members and supporters. The EPA ignored those nominations, even though the most active stakeholders

representing environmental and industry interests were seated on the Committee. The EPA's disregard for the animal protection community violated the Federal Advisory Committee Act, and resulted in litigation.[1]

PETA has been a stakeholder with respect to the EPA's Endocrine Disruptor Screening Program, the architecture of which is being designed by the Agency's OSCP. The Food Quality Protection Act requires that the EPA develop an "estrogenic substances screening program," to determine whether certain substances have "an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such endocrine effect as the Administrator may designate." The statute requires the EPA to develop a screening program "using appropriate validated test systems …" 21 U.S.C.A. § 346a. Not only has the EPA not developed appropriate validated test systems, it has expanded the screening program to include testing on wildlife even though the statute clearly applies exclusively to humans. Again, the EPA's actions have transgressed the letter and spirit of the law.

PETA has been vitally concerned with the EPA's actions relating to developmental neurotoxicity ("DNT") testing. The DNT guidelines promulgated as a final rule by the EPA in December 2000, failed to comply with the Administrative Procedure Act. Additionally, the EPA's pesticide Data Call-Ins are requiring certain pesticide registrants to conduct DNT testing to reregister their products, and in order for tolerance levels to be set. The DNT guidelines have never been subject to notice and comment rulemaking, and have never been validated. DNT testing is not only poor and unreliable science, but extremely costly to perform.

Unfortunately, the EPA's activities in connection with each of the programs described above have more than a few negatives. First, the EPA's conduct has lacked transparency. Second, the EPA's various testing requirements have imposed financial burdens on industry and manufacturing, not to mention the toll on the animals subject to testing. And third, the EPA's approach with respect to stakeholders such as PETA has resulted in costly lawsuits. Those suits could potentially have been avoided had the EPA conducted its activities with transparency and inclusiveness, rather than creating federal policy in private negotiations with special interests, and excluding the animal protection community.

It is telling that in March 2004, the EPA issued a Staff Paper entitled "*An Examination of EPA Risk Assessment Principles and Practices*." In part, the Staff Paper was in response to the comments the OMB received about the EPA's risk assessment principles and practices for its 2003 Final Report to Congress. As described in the Staff Paper, the comments the OMB received focused on "issues of conservatism in risk assessment, use of rigid default assumptions, poor transparency in the risk assessments [EPA produces], and unacknowledged uncertainty."

Sadly, nothing appears to have changed. Instead of exercising common sense by regulating chemicals and pesticides based on known hazards, the EPA calls for rounds and rounds of animal-based testing data for risk assessment – data which are easily manipulated and challenged

[1] It is noteworthy that the HPV program was developed behind closed doors by the EPA in conjunction with the environmental group, Environmental Defense, and the industry group, the American Chemistry Council. Representatives from both organizations have seats on NPPTAC.

by industry or environmental organizations as the case may be. Instead of genuinely pursing *in vitro* alternatives to live-animal testing guidelines, the EPA embraces a "check-the-box" mentality to chemical and pesticide safety testing. Instead of conducting its operations with transparency, the EPA entertains and is influenced by the views of special interests, and shuns conscientious stakeholders from whom it does not wish to hear, such as PETA.

The OMB has asked for specific reforms to rules and guidance documents that would reduce unnecessary costs, increase effectiveness, reduce uncertainty, and increase flexibility. Our suggested reforms are as follows:

1. Require that the EPA submit new and revised testing procedures to notice and comment rulemaking instead of characterizing rules as "guidelines" so as to avoid compliance with the Administrative Procedure Act. For example, the EPA issued Toxic Substances Control Act Test Guidelines on December 15, 2000. 65 Fed. Reg. 78746. These guidelines were described as a "Final Rule." However, they were never subject to notice and comment rulemaking, nor were they scientifically validated for reliability, reproducibility, and relevance, as set forth by international consensus.

2. Require that all major government programs be subject to public notice and comment. It transgresses every notion of open and participatory government that a program of the magnitude of the EPA's HPV chemical testing program was developed behind closed-doors with special interest groups, and never noticed in the Federal Register until *after* its implementation.

3. Require that the EPA apply the same validation standards to *in vivo* testing assays as it applies to *in vitro* assays. For example, the HPV program involves using the Screening Information Data Set ("SIDS") endpoints established by the Organization for Economic Cooperation and Development. A number of the SIDS endpoints entail animal-based testing protocols, none of which has ever been validated. In contrast, before the EPA will accept *in vitro* methods, it requires that they undergo rigorous validation, peer review, and acceptance by the scientific community. The same standard should apply to *in vivo* methods.

4. Require the EPA to comply with the letter of the Food Quality Protection Act, 21 U.S.C.A §346a(p). Subsection (p) is captioned "Estrogenic Substances Screening Program." That subsection requires the EPA to develop a screening program using validated test systems, to determine whether certain substances may have "an effect in ***humans*** that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate." (Emphasis supplied.) The EPA has broadened this screening program, without statutory authority, to include testing for estrogenic and other endocrine effects on wildlife.

5. Revise or amend the regulations issued pursuant to the Federal Advisory Committee Act to ensure that advisory committees are truly balanced and not

stacked with Agency favorites and special interests. 41 C.F.R. 102-3.60(b)(3) currently addresses a fairly balanced membership but it is more honored in the breach. Were the EPA following the letter and the spirit of the law, PETA would be representing the animal protection community on the National Pollution Prevention and Toxics Advisory Committee, among other relevant Agency advisory committees.

These are some concrete actions that can be taken. They will increase Agency transparency, increase flexibility, increase public participation in agency programs, reduce costs to industry, reduce litigation, and increase the effectiveness of the administrative branch. I can be reached at (757) 962-1809 or by e-mail at SusanH@peta.org, should you have any questions.

Very truly yours,

Susan L. Hall
Legal Counsel

SLH/pc
cc: Mary Beth Sweetland
Jessica Sandler
Troy Seidle