

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

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June 7, 2011

VIA E-MAIL AND FEDERAL EXPRESS

The Honorable Cass R. Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
1650 Pennsylvania Avenue, N.W.
Washington, D.C. 20503

**Re: EPA's Proposal to List Chemicals Under the Toxic Substances
Control Act (TSCA) Section 5(b)(4).**

Dear Administrator Sunstein:

The U.S. Chamber of Commerce, the world's largest business federation representing the interest of more than three million businesses and organizations of every size, sector, and region, is writing to express our deep concern about the U.S. Environmental Protection Agency's (EPA) determination to change long-standing agency policy and exercise its Toxic Substances Control Act (TSCA) § 5(b)(4)¹ authority, without due regard for Executive Order 13563, the Information Quality Act (IQA)² and other controlling law, including the Administrative Procedure Act (APA).³

EPA has proposed eight Chemical Action Plans (CAPs). For five of the eight chemicals subject to a CAP, EPA will initiate, or is considering initiation of, a TSCA § 5(b)(4)(A) listing that will identify each as a substance that presents or may present an unreasonable risk of injury to health or the environment. *See* EPA ACTION PLAN

¹ 15 U.S.C § 2604(b)(4).

² 44 U.S.C. § 3516 note ("IQA").

³ 5 U.S.C § 551 et seq.

FACT SHEET APRIL 2011,

<http://www.epa.gov/opptintr/existingchemicals/pubs/overview.pdf> (Attachment 1).

Section 5(b)(4)(A) conditions a listing on EPA's finding that a chemical "may present" an "unreasonable risk" of harm to health or the environment. 42 U.S.C. § 2604(b)(4)(A)(i). Yet, TSCA does not define these terms.

It is our understanding that EPA submitted certain of the CAPs to your office for review. *See, e.g.*, Steinzor, "Eye on OIRA: President Defied by President's Men; Sunstein and Orszag Violate Obama's Own Directive," <http://www.progressivereform.org/CPRBlog.cfm?idBlog=D871FFE8-C51D-E0BD-9AF3A3ACBA4A9F88>. We believe EPA was correct to do so, in part because its intention to initiate or consider initiating a listing is a tectonic shift in EPA policy. As you may be aware, the Agency has not listed a single chemical under § 5(b)(4)(A) in the thirty-five years since TSCA's enactment.

Although EPA has disclosed its intention to initiate or consider initiation of a listing certain chemicals, it has not promulgated the metrics it will use to determine when a chemical "may present" an "unreasonable risk" and qualify for listing under the statute. The EPA's opacity shields the Agency's scientific and policy bases from public scrutiny and limits the effectiveness of the Congressional oversight and judicial review that check and balance Federal bureaucratic power.

We believe that EPA's consideration or initiation of listing prior to the promulgation of clear, scientifically sound and economically rational listing criteria, and the Agency's apparent non-compliance with applicable Executive Orders, are manifestly improper as a matter of both law and policy.

Therefore, the Chamber asks you to urge the Agency by prompt letter, return letter, or other appropriate action, to promulgate these criteria before any additional consideration is given or action taken to list chemicals under TSCA § 5(b)(4)(A). Additionally, the Chamber requests that you urge the Agency to fully comply with all relevant provisions of Executive Order 13563, including robust benefit-cost analyses, public participation and regulatory flexibility, and the IQA with respect to any listing decision or CAP.

Discussion

TSCA § 5(b)(4)(A)(i) authorizes EPA by rule to compile and keep a list of chemical substances “with respect to which the Administrator finds...presents or may present an unreasonable risk of injury to health or the environment.” Section 5(b)(4)(A)(ii) directs EPA to consider “all relevant factors” including health and environmental effects and the “magnitude of...exposure” before listing a given chemical. Section 5(b)(4)(C) obligates EPA to promulgate a listing pursuant to procedures specified in 5 U.S.C. § 553, provided that “interested persons” may make an oral presentation of data, views or arguments in addition to written comments and that EPA must make a specific finding that a chemical presents or may present an unreasonable risk. TSCA does not define the terms “may present” or “unreasonable risk.”

Congress, through the IQA, directed EPA to comply with the Office of Management and Budget's (OMB) information quality guidelines. *See* 44 U.S.C. § 3516 note (b); *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8452 (Feb. 22, 2002); *see also Prime Time v. Vilsack*, 599 F.3d 678 (D.C. Cir. 2010)(discussing IQA requirements). To comply, EPA must ensure all information disseminated with respect to a listing determination meet OMB's high standards for objectivity, utility, and integrity before it is disseminated and to substantiate information quality “through documentation or other means appropriate to the information.” 67 Fed. Reg. at 8459. Among other things, EPA's analyses of the risks posed by a chemical to human health and the environment must meet the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996, 42 U.S.C. 300g-1(b)(3)(A) & (B).⁴ *Id.*

⁴The law is that EPA must use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices and data collected by accepted methods or best available methods. Also, the Agency must specify, to the extent practicable (i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data. 42 U.S.C. 300g-1(b)(3)(A) & (B).

Executive Order 13563 provides: “Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” Regulatory action must be based on the best available science, promote predictability and reduce uncertainty, and propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs. *See* Executive Order 13563 at §§ 2, 5. EPA must tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account the costs of cumulative regulations, and identify and assess available alternatives to direct regulation. *See id.* at § (1)(b). There must be “an open exchange” of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole. *Id.* at § 2(a). Furthermore, EPA must seek out the views of affected parties, including product manufacturers, prior to the Agency’s determination to consider or initiate a listing. *Id.* at § 2(b). EPA, however, has chosen not to do so.

TSCA § 6(a) empowers EPA to restrict or ban chemical manufacture and use in cases where EPA finds a “reasonable basis,” based on sound scientific evidence, to conclude that a chemical presents or will present an unreasonable risk of health or environmental injury.⁵ However, it appears EPA lacks the sound regulatory science needed to meet the statutory threshold for a restriction or ban of the targeted chemicals. Consequently, it seems to have resorted to other, less scientifically rigorous devices.

Beginning in 2009, EPA began issuing CAPs for a number of chemicals. Although EPA’s website contained (as of September 30, 2009) an assertion that the Agency would “initiate a stakeholder dialogue to address the prioritization of chemicals for future risk management action” and would “formally engage stakeholders and the public in this discussion,” this language was subsequently dropped without explanation. The promised dialogue has apparently never occurred.⁶

⁵ 15 U.S.C § 2605(a).

⁶ *See* Duvall, “Update on EPA’s Recent and Forthcoming Chemical Action Plans” (April 2010) <http://www.bdlaw.com/assets/attachments/Update%20on%20EPAs%20Recent%20and%20Forthcoming%20Chemical%20Action%20Plans%20Under%20TSCA.pdf> (citations omitted)(accessed June 1, 2011).

In 2010, an article in *Politics Daily* quoted an EPA spokesperson as saying: “Although the list is not a legal ban, it does serve as a signal to the marketplace that the agency wants these substances phased out.” EPA lacks the legal authority to “signal to the marketplace that the agency wants these substances phased out” absent sufficient evidence to support a § 6(a) rule. Yet, it appears EPA believes a considered, initiated or actual listing could be the functional equivalent of a ban, causing consumer and other product manufactures to shift away from the listed chemicals due to the wave of tort actions and advocacy group actions that will follow in the wake of the Agency’s announcements and determinations.

EPA’s failure to engage affected stakeholders and, more importantly, its failure to promulgate fixed listing criteria are difficult to understand. For example, EPA admits the targeted chemicals are widely used “in nearly every industry and many consumer products, including food packaging regulated by FDA.” *See* EPA ACTION PLAN SHEET APRIL 2011, *supra*. Consequently, EPA must be aware that these proposed actions are most assuredly economically significant and that the robust benefit-cost, regulatory flexibility and public participation provisions of the applicable Executive Orders must be applied.

Nevertheless, there is no evidence that EPA has considered economic cost and jobs impact of its actions, developed a reasoned balance of benefits and costs, evaluated a range of lesser burdensome alternatives, determined whether there are viable alternatives to the subject chemical or evaluated how a listing might affect the quality, performance and safety of various products. There is no evidence that EPA has accounted for or balanced the increased compliance costs for manufacturers and users of a listed chemical or attempted to evaluate the direct and indirect impact of market disruptions and litigation due to “blacklisting” as a result of EPA action. There is no evidence that EPA has estimated or accounted for rising costs due to the need for potentially significant formulation and equipment changes and or for the potential substitution of alternatives that may not be “safer.” And there is no evidence EPA has accounted for the admitted impact of its actions on small businesses through a regulatory flexibility analysis as required by law. *See* <http://www.epa.gov/opptintr/existingchemicals/pubs/sect5b4.html> (accessed May 23, 2011); *see also* 5 U.S.C. § 603.

Furthermore, there is no evidence that EPA has complied with the IQA and developed risk assessments in accordance with 42 U.S.C. 300g-1(b)(3)(A) & (B) for each chemical subject to a considered or initiated listing, or disclosed all of the studies,

human dose-response assumptions and peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data for each chemical. Absent clear and fixed listing criteria it is simply impossible for the Chamber, or anyone else, to determine whether the scientific studies cited by EPA are relevant, accurate or appropriate to support a listing determination in a given case. This, in turn, allows EPA to shield itself from critical review and to neutralize the checks and balances of Congressional oversight and judicial review.⁷

Conclusion

The Chamber believes all Federal agencies, including EPA, ought to affirm and implement all of the relevant principles of Executive Order 13563 and comply with the relevant provisions of the IQA to ensure our regulatory system is transparent, balanced, effective and scientifically sound. Therefore, the Chamber requests that you urge EPA, by prompt letter,⁸ return letter or other appropriate actions, to take the following steps with respect to the EPA's CAPs and considered or initiated TSCA § 5(b)(4) listings:

⁷ TSCA §5(b)(4) listing decisions are by an informal notice and comment rulemaking under 5 U.S.C. § 553, and not by adjudication. Therefore, EPA arguably is required to first promulgate fixed criteria and then make listing decisions. *See generally International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991)(holding that a statute, as interpreted by the agency, violated the non-delegation doctrine by conferring unfettered discretion).

⁸The approach taken by OIRA in 2002 with respect to the Office of Federal Housing Enterprise Oversight (OFHEO), in which a prompt letter was sent asking OFHEO to consider a rulemaking to strengthen the corporate governance of Fannie Mae and Freddie Mac and to require public disclosures, is arguably appropriate in this case as well. There, OIRA rightly emphasized the benefits and value of transparency and accountability associated with the promulgation of clear standards. *See generally* OIRA LETTER TO THE OFFICE OF FEDERAL HOUSING ENTERPRISE OVERSIGHT (OFHEO) REGARDING CORPORATE GOVERNANCE AND DISCLOSURE BY FANNIE MAE AND FREDDIE MAC (May 29, 2002), http://www.reginfo.gov/public/prompt/prompt_ofheo052902.html (accessed June 1, 2011). Here also there is a critical need for transparency and accountability, particularly given the scientific uncertainties and the economic impact associated with EPA's intended or considered listing decisions.

- Suspend the consideration and initiation of all TSCA § 5(b)(4) listings until after fixed and scientifically sound listing criteria have been properly promulgated.
- Suspend the consideration and initiation of all TSCA § 5(b)(4) listings until after EPA has carried out all the benefit-cost analyses, identified the best, most innovative, and least burdensome tools for achieving regulatory ends, appropriately provided for public participation, and the other applicable measures required under Executive Order 13563 for each CAP.
- Recommend EPA comply in all respects with the IQA, including the provisions of 42 U.S.C. 300g-1(b)(3)(A) & (B) with respect to the human health and environmental risk assessments and information used to justify each CAP.

Thank you in advance for your cooperation. Please contact me if you have any questions or require additional information.

Sincerely,



William L. Kovacs

Cc: EPA Administrator Lisa Jackson