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OFFICE OF  
GENERAL COUNSEL

MEMORANDUM

SUBJECT: Use of a Pollution Prevention Rationale to Support an Unreasonable Risk Finding Under TSCA Section 6

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I. INTRODUCTION

The Office of Toxic Substances' Chemical Control Division ("CCD") is currently investigating regulatory strategies under Section 6 of TSCA designed to reduce health and environmental risks from exposure to lead. Among the strategies being considered is a proposal to reduce the introduction of newly-mined lead into the stream of commerce by mandating the recycling of spent lead acid batteries. It is predicted that such recycling will reduce the need for additional lead extraction and significantly reduce the flow of lead into incinerators and landfills.

In connection with CCD's lead investigation, I have been asked to provide an informal written opinion answering the following questions:

Can EPA make an unreasonable risk finding under TSCA without exhaustively quantifying the risks posed by the substance in every stage of the lifecycle of all of its uses? If so, what kinds of arguments and information would be required for such a finding? To what extent do costs need to be quantified?

I conclude that structuring an argument for a regulatory alternative which emphasizes pollution prevention can be consistent with the requirements of Section 6 of TSCA. Pollution prevention is one of TSCA's important goals. Section 6 requires that the Agency have a "reasonable basis" to conclude that activities involving a chemical substance or mixture ("chemical") present an "unreasonable risk of injury" to health or the environment. The

legislative history and judicial interpretation of Section 6 indicate that the "reasonable basis" test is satisfied by a quantum of evidence significantly below the level of demonstrating scientific certainty. Accordingly, the Agency's findings in support of its unreasonable risk determination need not be especially "detailed" or "voluminous", as long as they demonstrate that the regulation's health benefits outweigh its costs to society.

## II. DISCUSSION

### A. Section 6 Requirements

Before the Agency can issue a rule under Section 6 of TSCA, it must find that there is:

- (1) "a reasonable basis to conclude" that activities involving a chemical present
- (2) "an unreasonable risk of injury to health or the environment".

15 U.S.C. § 2605(a). In promulgating any rule under Section 6, the Agency must also consider and publish a statement with respect to:

- (1) the human health effects of the chemical and magnitude of human exposure;
- (2) the environmental effects of the chemical and magnitude of environmental exposure;
- (3) the benefits of the chemical for various uses and availability of substitutes; and
- (4) the reasonably ascertainable economic consequences of the rule.

15 U.S.C. § 2605(c)(1)(A)-(D). Finally, the Agency must ensure that its rule

- (1) "protect[s] adequately" against the identified risk
- (2) "using the least burdensome" of Section 6's regulatory options.

15 U.S.C. § 2605(a).

The fundamental question posed by these statutory requirements in the context of CCD's lead recycling investigation is: What kind of regulatory vehicle do they require the Agency to build? Must every rule issued under Section 6 contain the sort of highly detailed analysis found in the recently issued Asbestos Ban and

Phase-out Rule. wherein the Agency exhaustively quantified the risks posed by the substance in every stage of the lifecycle for all of its uses? Or is it possible for the Agency to issue more "economical" and "affordable" regulations under Section 6 and still comply with the statutory guidelines. In short, does Section 6 contain blueprints for a Cadillac or a Chevrolet?

#### **B. Pollution Prevention Rationale**

It has been suggested that one way to streamline the Section 6 rulemaking process is to view TSCA as a "pollution prevention" statute and justify a Section 6 "unreasonable risk" finding using a "pollution prevention rationale". Such a rationale, as applied to the recycling of lead acid batteries, would proceed as follows:

1. Once mined, lead produces persistent, toxic pollution throughout its lifecycle (i.e., air and water emissions during extraction, smelting, consumer use, and disposal).
2. Lead's persistence means that additional lead mining increases the environmental loading of lead pollutants.
3. This increased environmental loading increases the likelihood of human exposure.
4. Due to lead's extreme toxicity, increased human exposure will result in increased adverse health effects, particularly in children.
5. Recycling lead acid batteries will eliminate the need for the introduction into the environment of a significant amount of newly-mined lead.
6. This reduction in environmentally available lead will result in a reduction of lead emissions, toxic exposures and adverse health effects.

Obviously, merely to state such a pollution prevention rationale does not prove its truth. A significant amount of scientific and economic analysis will be needed to support each of its six propositions. However, if the scope and depth of this analysis need not reach Asbestos Ban Rule proportions, a considerable savings in Agency resources may be possible. Recognizing that a pollution prevention rationale does not eliminate the need for "reasonable" proof of its validity, I examine whether it satisfies the rulemaking blueprint contained in Section 6.

#### **C. TSCA is a Pollution Prevention Statute**

The legislative history of TSCA demonstrates that "pollution prevention" is one of its important goals. Both the Senate and

House Reports recognized that existing laws did not provide adequate authority to prevent or regulate the use of dangerous chemicals before human or environmental exposure occurred. (Legislative History, p.158, 414.) The Senate Committee Report, observing that regulation "in the first instance may be a far more effective way of dealing with the hazards", concluded that "the authority to do so ought to be provided" (Id. at 158.) The Senate Committee also recognized that "[t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture" (Id. at 161.) Indeed, Section 6(c) of the statute specifically allows the Administrator to use Section 6(a) to protect against risks if Section 6(a) would do so more cheaply or efficiently than other EPA-administered laws.

The legislative history also indicates that the health and environmental risks posed by heavy metals, and specifically by lead, were carefully considered by the legislators when they passed TSCA. Indeed, the dangers of lead and other heavy metals are mentioned at least 10 times in the House and Senate Reports and in the floor debates. (See, e.g., Legislative History, p 160). Lead was also one of the chemicals whose dangers were highlighted in the 1971 CEQ Toxic Substances Report which was a stimulus for passage of this legislation. Accordingly, we begin our analysis knowing that pollution prevention, with a specific focus on lead and other heavy metals, was one of Congress' primary goals in enacting TSCA.

#### D. The Reasonable Basis Test

Section 6 of TSCA does not specify the precise analytical method the Agency must use to determine whether an "unreasonable risk" of health or environmental injury exists. Nor does it draw a bright line to demarcate the boundary between "enough" and "not enough" proof that such a risk is present.

Courts have not spoken directly to the level of information necessary to show that activities present an unreasonable risk under Section 6. However, in interpreting the less rigorous may present finding in Section 4, the U.S. Court of Appeals for the D.C. Circuit indicated that Section 6 requires only that the Administrator have a "reasonable basis" to conclude that a substance presents an unreasonable risk of injury. Chemical Manufacturers Association v. EPA, 859 F. 2d 977, 986 (D.C. Cir. 1988) (Section 4 test rules authorized where there is a more-than-theoretical basis to suspect an unreasonable risk).

In the CMA case, the D.C. Circuit held that Section 4(a)(1)(A) of TSCA authorized issuance of a test rule on the basis of less than "more-probable-than-not" evidence about a potentially unreasonable risk. 859 F.2d. at 988. CMA had argued for a "more-probable-than-not" standard. The court rejected CMA's argument, in part, because application of such a test to Section 4 would mean that the Agency would have to meet a greater than "more-probable-

than-not" evidence test when issuing Section 6 rules. The court found that "neither Section 6 nor its legislative history indicate any such super-requirement of certainty". Id. at 986. <sup>1</sup>

The court concluded that the Section 6 "reasonable basis" requirement is "certainly no more demanding than a more-probable-than not requirement: indeed the phrase suggests a less demanding standard". Id. The court found support for its interpretation in the House Report, which states that an EPA finding of "unreasonable risk" under Section 6 is not expected to be supported by the same quantum of evidence as is customary in administrative proceedings:

A finding by the Administrator that there is such a reasonable basis must include reasons and explanations for the Administrator's conclusion. It does not, however, require the factual certainty of a "finding of fact" of the sort associated with adjudication.

Id.

Both the House and Senate Reports make it clear that a strictly quantitative cost-benefit analysis is not required to support a finding of unreasonable risk. The Senate Committee noted,

Costs are not to be incurred unless they are offset by benefits of at least the same magnitude. In comparing risks, costs, and benefits, however, it is important to recognize that one is weighing noncommensurates, and it is not feasible to reach a decision just on the basis of quantitative comparisons.

(Legislative History, p. 169).

The House Committee observed,

The balancing process does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with a substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful.

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<sup>1</sup> The CMA case did not directly involve a Section 6 rule, and we can presume that affected persons are likely to challenge Section 6 rules somewhere other than the D.C. Circuit, as is the case for the Asbestos Ban Rule. However, the reasoning of the D.C. Circuit concerning the Section 6 standard will be helpful.

(Legislative History, p. 422).

The standard for taking action under Section 6(a) recognizes that "factual certainty" respecting the existence of an unreasonable risk of a particular harm may not be possible. As the House Committee observed:

[U]ncertainty is particularly likely to occur when dealing with the long term or chronic effects of a substance or mixture . . . Unless, as here, regulatory action is intended to be taken to prevent the occurrence of harm in the future as well as protect against presently visible harm, such action often must be barred not only on consideration of facts, but also on consideration of scientific theories, projections of trends from currently available data, modeling using reasonable assumptions, and extrapolations from limited data. Further, regulatory action may be taken even though there are uncertainties as to the threshold levels of causation.

(Legislative History, p. 439.)

Nor should the enumeration in Section 6(c) of four factors the Agency must consider in promulgating Section 6(a) rules be read as requiring the Agency to meet an overly-rigorous "reasonable basis" standard. In discussing Section 6(c), the House Committee stated:

By requiring such findings, the Committee is emphasizing that those key considerations enumerated in subparagraphs (A), (B), (C), and (D) of subsection (c)(1) will be addressed in such a statement of basis and purpose. The findings need not be detailed or voluminous, nor does the Committee expect the findings to be based solely on factual evidence. The Committee recognizes that, particularly with respect to such issues as the effects of a substance or mixture on health or the environment, the Administrator's findings may necessarily deal with projections from imperfect data, experiments and simulations, educated predictions, differing assessments of possible risks, etc. (Legislative History, p. 443).

Thus, while Section 6(c) requires that the Agency consider risks, benefits and economic consequences in promulgating Section 6(a) rules, it does not require the Agency's Section 6(c) findings to be "detailed", "voluminous", or scientifically indisputable.

Given the dearth of litigation involving Section 6(a) rules, it is impossible to state with certainty what quantity of proof, in fact, satisfies the "reasonable basis" test. It is clear, however, that such evidence need demonstrate no more (and maybe less) than a "more-probable-than-not" basis to conclude that an

unreasonable risk of injury exists. While the Agency must supply "reasons and explanations" for the rule, its evidence need not reach the level of certainty associated with adjudicatory "findings of fact". Nor does the consideration of risks and benefits require a "formal benefit-cost analysis" supported by "detailed or voluminous" findings. Indeed, the Agency's findings may be based on "projections", "simulations", and "educated predictions". In short, it would appear that TSCA gives the Agency broad discretion to determine what quantum of evidence it will marshal in support of an "unreasonable risk" finding.

#### **E. The Unreasonable Risk Test**

Section 6(a) does not allow the Agency to issue regulations to protect against just any risk of injury to health or the environment. It only permits regulations which prevent "unreasonable risks."

Although asked to do so, Congress consciously decided against putting a precise definition of "unreasonable risk" in the statute:

Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms and is not a factual determination but rather requires the exercise of judgement on the part of the person making it, the Committee did not attempt a definition of such risk.

(Legislative History, p. 421-22.) However, the Committee went on to say that an unreasonable risk determination

involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society. . . . As noted above, the Committee recognizes that risk is measured not solely by the probability of harm, but instead includes elements both of probability of harm and severity of harm and those elements may vary in relation to each other. Thus, the Administrator may properly find that health or the environment are exposed to an unreasonable risk by a lesser probability of a greater harm as well as by a greater probability of a lesser harm.

(Legislative History, p. 422.)

At bottom, the unreasonable risk determination is a "balancing" of the probability, magnitude, and severity of a chemical's harm against the benefits of the chemical's use expected to be lost by the proposed regulation. There is no reason why, on its face, a pollution prevention-based justification for a Section 6 rule requiring the recycling of lead acid batteries could not satisfy Section 6's balancing test.

The battery recycling pollution prevention rationale set forth above certainly appears to present an adequate framework for analyzing the likely adverse health effects of increasing the environmental loading of lead by not recycling. Assuming that the data developed meets the "reasonable basis" evidentiary test discussed above, the Agency should be able to present a sufficiently detailed account of the probability, magnitude, and severity of risk caused by introducing more newly-mined lead into the environment.

One possible weakness of the pollution prevention approach, however, is that it does not appear to invite comparably rigorous or extensive scrutiny of the costs to society of promulgating a regulation. Indeed, the pollution prevention rationale, as articulated with respect to lead, appears to assume that recycling will cost society nothing. It may be true that recycling's costs are generally going to be less than the costs of other Section 6 regulatory options, e.g., banning or limiting use of a chemical where there are unavailable or very expensive substitutes. Nevertheless, even recycling regulations are bound to impose some costs, and, under Sections 6's "unreasonable risk" test, those costs must be identified and weighed against the rule's benefits.

For example, one of the costs to society of requiring battery recycling will be the increase in toxic air emissions, and human exposure to those emissions, around secondary smelters. According to preliminary CCD figures, mandating battery recycling will divert approximately 105,000 tons of lead from incinerators and landfills to secondary smelters. This increase in secondary smelter throughput is predicted to increase secondary smelter lead emissions by approximately 76 tons a year, leading to as much as a 7 point increase in the worst-case blood lead levels of 2 years olds in the vicinity of those facilities. It is unclear how those costs are weighed under the pollution prevention rationale.

In addition to health costs, increased recycling of batteries may impose other economic or administrative costs on society. For example, recycling distribution networks may have to be set up to ensure the proper collection and sorting of wastes. Moreover, publicity and enforcement costs will be incurred to ensure the system functions as intended. The purpose of identifying these (and other) costs is not to suggest that their existence invalidates a pollution prevention approach to Section 6 rulemaking. I merely wish to observe that, at some point in the



pollution prevention rationale, these and any other societal costs must be identified and balanced against the benefits to be achieved from recycling.

### III. CONCLUSION

A pollution prevention approach to justifying Agency regulation is consistent with Section 6 requirements, provided that such an approach gives the Administrator a "reasonable basis" to conclude that the benefits of a proposed regulation outweigh its costs. The Administrator's findings in support of this conclusion need not be especially "detailed", or "voluminous" or equivalent to "findings of fact" in administrative proceedings. However, in focusing on the benefits to be derived from the pollution prevention effects of a regulation, the Agency must not forget to identify the costs of a particular regulatory option and weigh those costs against the benefits. While pollution prevention options may often be, as Congress indicated, the most cost-effective alternatives, Section 6 does not permit the Agency to assume that will always be the case.

## VI. REGULATORY ALTERNATIVES TO ACTIONS UNDER TSCA

### Introduction

The decision to initiate a regulatory investigation under TSCA will rest in part upon the relative merits of alternative remedies. Section VI reviews Federal and State legislation and regulations that bear on the issue of controlling Pb in MSW. Some of the alternatives are existing authorities, and some are proposed legislation. The section is in three parts: (1) Federal regulations, (2) proposed Federal legislation, and (3) State legislation and regulations.

### Federal Regulations

#### Clean Air Act (CAA)

##### §109: National Ambient Air Quality Standards (40 CFR Part 50)

NAAQS, promulgated under §109, establish a single national health-based permissible ambient air concentration for each of the six air pollutants ("Criteria" Pollutants) listed by EPA under CAA §108. Air concentrations are not supposed to exceed these standards, measured as a quarterly average, at the fence line of any plant. Plants may choose any means they wish to meet the standards. The current Pb NAAQS is  $1.5 \text{ ug/m}^3$ .

As noted in Section II, all primary smelters and most secondary smelters currently exceed this standard. We have no reason to believe that any MWC is out of compliance.

OAR will propose a lower Pb NAAQS in mid-1990. Levels under consideration range from  $0.5$  to  $1.25 \text{ ug/m}^3$ , measured as a monthly average, with  $0.75 \text{ ug/m}^3$  a likely choice. Unless smelters are brought into compliance, however, the lower NAAQS will not affect the issues of concern in this paper.

This will not be easy. OAQPS estimates<sup>1</sup> that the capital and annual operating costs of bringing three of the four primary smelters into compliance with the existing NAAQS standard would be \$44 and \$14.7 million, respectively, and that the fourth