EPA 450/5-84-001

RESPONSE TO PUBLIC COMMENTS ON EPA'S LISTING AND REGULATION OF BENZENE UNDER SECTION 112: COMMENTS OF A GENERAL POLICY NATURE

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NOTE: Commenters are identified by the rulemaking docket numbers assigned their submissions. The relevant dockets are as follows:

OAQPS-79-3	Benzene Listing and Maleic Anhydride Standard
A-79-27	Benzene Fugitive Emissions Standard
A-79-49	Ethylbenzene/Styrene Standard
A-80-14	Benzene Storage Vessel Standard
OAQPS-79-14	Airborne Carcinogen Policy

A number of commenters submitted multiple or duplicate comments to several of the dockets. While EPA has made an effort to reference representative comment sources, the citations should not be considered an exhaustive record of the docket items addressing a particular issue.

1.0 INTRODUCTION

In addition to comments on the decision to list benzene, addressed in "Response to Public Comments on EPA's Listing of Benzene Under Section 112" (EPA 450/5-82-003), EPA received a number of oral and written submissions addressing the procedures followed by EPA in evaluating the public health hazard posed by benzene, selecting sources for regulation, and determining appropriate levels of control. Many of the procedural comments referenced statements made by the Agency in a related rulemaking proposal (44FR58642, October 10, 1979) to establish an EPA policy for the identification, assessment, and regulation of airborne carcinogens.[1] EPA has not, at this time, published a final policy. Relevant comments from the carcinogen policy record, however, are included in the discussion below and EPA's responses reflect consideration of the comments from both sources.

2.0 COMMENTS OF A GENERAL POLICY NATURE

The comments are divided into four major policy issues: 1) the role of quantitative risk estimation in the regulatory process; 2) the appropriate criteria for listing an airborne carcinogen under Section 112; 3) the appropriate criteria for assigning regulatory priorities to emitting sources; and 4) the requirement of best available technology (BAT) for selected source categories and the evaluation of residual risks in determining the appropriate level of control under section 112.

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[1]U.S. Environmental Protection Agency "Policy and Procedures for Identifying Assessing, and Regulating Airborne Substances Posing a Risk of Cancer; Notice of Proposed Rulemaking" 44 FR 58642, October 10, 1979.

2.1 The Role of Quantitative Risk Estimation in the Regulatory Process

Commenters were significantly divided on the general issues of the accuracy and reliability of quantitative risk assessment (QRA) for carcinogens as well as on the utility of such estimates in the regulatory decision process. Proponents of quantitative risk assessment (QRA), primarily industry and trade association commenters, held that such assessments, when based on reliable data, should play an important role at all stages of decisionmaking on potential airborne carcinogens (OAQPS-79-3(Part II)-IV-D-23, IV-F-1, IV-F-9; OAQPS-79-14-IV-D-65,73,74,78,79,88,90a,94,97,102,104,110,116,117,119a,128,129, 130-133,135,195). Comments largely from public interest groups, State air pollution control agencies, and private individuals, expressed concern that the underlying uncertainties in attempting to quantify cancer risks greatly reduces the reliability of such estimates and argues for limiting or avoiding their use in the regulatory process (OAQPS-79-3(Part II)-IV-F-4;OAQPS-79-14-IV-D-52,118,120,179a,184,194,G-8) and that such use is not required by the language of the Clean Air Act (A-79-25-IV-D-31).

Commenters skeptical of the utility of QRA cited a number of reasons for discounting the reliability of numerical risk estimates. These included: uncertainties in dose extrapolation and scaling factors; differing sensitivities and metabolic pathways in humans versus laboratory animals; confounding variables, potential interactions, and synergism; latency and unknown exposure levels in epidemiological studies; and the general unreliability of exposure monitoring and modeling techniques (OAQPS 79-3(Part II)-IV-F-4; OAQPS-79-14-IV-D-118, IV-G-8). Organizations taking this view suggested that EPA place less emphasis on QRA (OAQPS-79-14-IV-D-120), attempt to characterize the uncertainty in such estimates by presenting them as ranges (OAQPS-79-14IV-D-120,IV-D-194), and limit

their role in the decision process to a rough indicator of relative risk for use in the assignment of regulatory priorities (OAQPS-79-3(Part II)-IV-F4; OAQPS-79-14-IV-D-118,120,179a,194).

Of the role of risk estimates in cost/benefit analysis, two commenters argued that EPA lacked authority to engage in such practices under section 112. The commenters stated further that Congress recognized the difficulties, given the current state of scientific knowledge, with attempting to quantify an "ample margin of safety." Congress did not require EPA to delay regulation in the absence of such quantification or to undertake "sham quantitative risk analysis." (A-79-27-IV-D-27; A-80-14-IV-D-19).

EPA Response

EPA has considered the comments on the role of quantitative risk assessment in the regulatory decision process for airborne carcinogens and concludes that, while numerical estimates of risk offer a clear appeal over non-quantitative data in regulatory decisionmaking, the importance ascribed to such information must be in proportion to its reliability. EPA agrees that QRA can provide meaningful information to the decision process but disagrees with comments suggesting that risk assessments should be the sole criterion for decisionmaking.

Where risk estimation is feasible and some measure of confidence is obtainable, EPA will perform quantitative assessments for use in the appropriate stages of the regulatory process. For potential airborne carcinogens, these stages could include: comparisons between pollutants; comparisons among source categories of a pollutant; selection of appropriate control levels; and the evaluation of residual risks.

EPA does not agree that the Agency lacks authority to consider risk estimation or other social and economic factors in the determination of whether an "ample margin of safety" is provided by a given control level. First, the primary purpose of section 112 is to improve public health and QRA, despite its limitations, is the best tool available for evaluating the health consequences of environmental pollution. Second, EPA believes that the Congress' direction that standards under section 112 provide an "ample margin of safety" does not require the total elimination of risk. Given the serious economic consequences of total elimination of risk for the control of non-threshold pollutants such as carcinogens, EPA feels that, had this been the intent, Congress would have spoken more explicitly, as it did in the Delaney Clause of the Food and Drug Act[2], prohibiting the use of any food additive found to induce cancer.

In this interpretation, EPA is following the approach enunciated by the U.S. Suprement Court in Industrial Union Department AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980), in which it stated that:

> "By empowering the Secretary to promulgate standards that are 'reasonably necessary or appropriate to provide safe or healthful employment and places for employment,' the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day--such as driving a car . . .--that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' Similarly, a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm.
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> Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe--in the sense that significant risks are present . . ."

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221 U.S.C. 348(c)(3)(A)

Where the presence of some residual risk is likely, EPA believes that it is appropriate and necessary to attempt to characterize this risk and to consider it along with other factors in the determinations of the appropriate level of control. EPA does not agree that such consideration, appropriately tempered by an awareness of the uncertainties in such analysis, would delay regulation or represent "sham quantitative risk analysis."

2.2 The Appropriate Criteria for Listing an Airborne Carcinogen Under Section 112

A number of commenters expressed concern over the criteria for listing a substance under section 112 as described in EPA's proposed airborne carcinogen policy (44 FR 58642). The criteria provided that EPA would list under section 112 substances that 1) had a high probability of being human carcinogens, and 2) were emitted into the ambient air from one or more categories of stationary sources in amounts sufficient to significantly expose human populations. The listing decision would be based on preliminary assessments of carcinogenicity and human exposure. Several commenters objected to the listing criteria on the grounds that a "low hurdle" based on preliminary studies was unwarranted and unrealistic (OAQPS-79-3(Part II)-IV-F-1,IV-F-9; OAQPS-79-14-IV-D-26, 90a,106,110,135). One commenter argued that EPA must conduct more than a risk assessment to justify listing (OAQPS-79-3(Part II)-IV-F-9). A number of commenters felt that EPA had underestimated the impact of the listing decision itself, and should avoid listing until such time as a reasoned and supported judgment could be made (OAQPS-79-3(Part II)-IV-F-9; OAQPS-79-14,IV-D-77,79,97,112,116,179a,192).

It was the view of five commenters that EPA should publish, and take public comment on, the basis for listing prior to a listing decision (OAQPS-79-14-IV-D-51,55,60,73,199). Six commenters suggested that EPA make public the list of pollutants under assessment as candidates for listing (OAQPS-79-14-IV-D-60,75,77,86,90a,157).

Commenters were divided on the use of quantitative risk assessment (QRA) in the listing decision, with positions ranging from the use of QRA as the listing basis (OAQPS-79-14-IV-D-94), to use as a factor in the decision (OAQPS-79-3(Part II)-IV-F-9; OAQPS-79-14-IV-D-67,97,116,139,199), to the establishment of a risk "benchmark" for listing (OAQPS-79-14-IV-D-79), and finally, to having no appropriate role in the listing decision (OAQPS-79-14-IV-D-100).

Two commenters requested more guidance on and a definition of "significant" as applied to the human exposure criterion (OAQPS-79-14-IV-D-63,IV-D-118). One commenter felt the listing decision format was not clear (OAQPS-79-14-IV-D-104).

Two commenters suggested that the final policy should include specific criteria for delisting as well as listing substances (OAQPS-79-14-IV-D-94, IV-D-199).

One commenter recommended that EPA proceed to list all substances currently regulated as carcinogens by other agencies (OAQPS-79-14-IV-D-140).

EPA Response:

In consideration of comments on the nature of the "significance" criterion for human exposure, it remains EPA's opinion that the test of significance is largely judgmental and does not lend itself to rigid quantification. A judgment of significance depends not only on the magnitude of

emissions and consequent exposure levels, but also on the distribution of emissions including the number and nature of emitting sources.

Delisting procedures are adequately described in section 112(b)(1)(B). EPA does not see a need for further discussion or interpretation of the delisting process.

EPA does not consider the wholesale listing of all substances currently regulated as carcinogens by other agencies as a feasible or warranted action. First, listing under section 112 requires a finding that a substance "contributes to air pollution." Moreover, in EPA's judgment only substances having a significant effect on public health should be listed. The mere fact that a substance is regulated as a carcinogen in pharmaceuticals, cosmetics or food does not show that it meets these criteria.

Second, section 112 directs that the Administrator should list only those pollutants "for which he intends to establish an emission standard." In the absence of an assessment of the emitting sources, such intent would not be established.

2.3 The Appropriate Criteria for Assigning Regulatory Priorities to Emitting Sources

Most commenters supported a mechanism for assigning regulatory priorities to categories of stationary sources emitting a hazardous air pollutant. Some saw such a process as a means of diverting attention away from "small cancer risks" (OAQPS-79-3(Part I)-IV-D-13), others as a means of focusing regulatory attention on the "worst offenders" (OAQPS-79-14-IV-G-6).

Commenters were generally supportive of the use of risk estimates in priority assignment as a measure of health hazard. Three commenters felt that risk estimates should weigh equally with the non-risk criteria (feasibility,

ease of control) in the determination (OAQPS-79-14-IV-D-90a,190a,191). One commenter suggested that only the extent of the health hazard be used to make distinction (OAQPS-79-14-IV-D-115). One commenter approved the use of risk estimates but only as a "rough measure" (OAQPS-79-14-IV-D-118).

Two commenters suggested that the risk estimates be combined with projected control costs to permit measures of cost-effectiveness to be factored into the priority process (OAQPS-79-3(Part I)-IV-D-23; OAQPS-79-14-IV-D-26).

One commenter maintained that EPA should develop priorities across pollutants as well as across source categories of a particular pollutant (OAQPS-79-14-IV-D-79).

EPA Response:

EPA envisioned the priority assignment process as serving two purposes: first, the identification of those categories of sources which presented potentially the greatest hazards to public health; and, second, the identification of those sources for which the regulatory and control dollar would go furthest in reducing the hazards. In combination, these aims would ensure that the most important and tractable problems would be addressed on a priority basis.

EPA agrees that non-risk criteria are important in the assignment of priorities. Setting priorities based on estimates of health hazard alone could result in resource-intensive regulations with little health benefit.

EPA recognizes the advantages of combining risk estimates with proposed emission reduction and control costs in the derivation of "cost effectiveness" figures. Such estimates would be, however, preliminary since the extent and cost of possible control would not be well enough known at this stage to permit firm estimates.

EPA has considered expanding the priority process to include other pollutants. There are difficulties with such an approach, however. The staggered timing of listings would make it difficult to coordinate priorities, but to the extent possible, EPA does attempt to set priorities for regulation development across pollutants.

The availability of resources for regulatory development will influence the assignment of priorities for source categories of a listed substance. Actions planned or underway for source categories of previously listed pollutants will be considered in the priority assignment process. While it is possible that an ongoing action could be suspended to divert resources to a higher priority project, EPA anticipates that such redirections would be infrequent.

2.4 The Requirement of Best Available Technology (BAT) as the Minimum Level of Control for Selected Source Categories

Although most commenters endorsed EPA's proposed procedure for consideration of economic and technological feasibility in the development of emission standards under section 112, the automatic requirement of best available technology (BAT) was often criticized as unnecessarily rigid and not reflective of Congressional intent. A number of commenters argued that a level of control less stringent than BAT could be appropriate where the health risks are low (OAQPS-79-3(Part II)-IV-D-22; OAQPS-79-14-IV-D-132, IV-D-155). Similarly, several commenters argued that the imposition of BAT could result in excessive control (OAQPS-79-14-IV-D-29), arbitrarily chosen (OAQPS-79-14-IV-D-65), with no statutory support (OAQPS-79-3(Part I)-IV-D-5), and no evidence that the avoidable risks were unreasonable (OAQPS-79-14-IV-D-87).

Several commenters suggested that health risks should be considered in establishing BAT (OAQPS-79-14-IV-D-73,90a,155) or that cost benefit analysis should be performed (OAQPS-79-14-IV-D-29-90a,97). One commenter recommended EPA determine acceptable risk levels in place of a BAT minimum control level (OAQPS-79-14-IV-D-135).

Two commenters suggested as alternatives to BAT: "reasonably available control technology" (OAQPS-79-14-IV-D-187), and "best available retrofit technology" (OAQPS-79-14-IV-D-195).

One commenter argued that section 112 contained the presumption of a zero-emission standard, and contended that an evaluation of "residual risk" goes farther than EPA is authorized in the consideration of technical and economic factors, and argued that BAT was inadequate to address the hazardous posed by substances for which no level of exposure could be considered safe (A-79-27-IV-D31;A-80-14-IV-D-19).

EPA Response:

Section 112 provides that standards must be set so as to protect public health with an ample margin of safety.[3] Historically, EPA has responded to this mandate by requiring for source categories determined to pose significant cancer risks, the application of best available technology (BAT), considering costs, non-air quality health and environmental, and energy impacts, and then evaluating the residual risks to determine the need for further controls.

Where a health effects threshold can be determined, the margin of safety requirement can be met by establishing the standard at a level that insures that the exposure threshold is highly unlikely to be exceeded.

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3 Clean Air Act as amended August, 1977, Section 112(b)(1)(B),p.38.

Cases may also arise where the reductions in the estimated health risks obtainable with the application of BAT are so small that little health benefit would be realized.

In establishing the appropriate level of control for carcinogens, EPA views the objective as a judgment of the extent to which the estimated risk of cancer must be reduced before the degree of control can be considered amply protective. Two choices are available: either the emission standards must be set at zero to eliminate the risk of cancer altogether, or some residual risk must be permitted. In the absence of specific direction on this choice in section 112 and in recognition of the drastic economic consequences that could follow a requirement to eliminate all risk from carcinogenic emissions, EPA believes that it is not the intent of this section to eliminate totally all risks and that section 112 standards which permit some level of residual risk, therefore, provide an ample margin of safety to protect public health.

Over the past several years, the Agency has explored a number of approaches to the evaluation of residual risks and the determination of what constitutes an amply protective standard under section 112. In EPA's judgment, the decision that a particular residual risk is not unreasonable cannot be based solely on the level of risk. Other factors which influence society's ability to estimate and to mitigate such risks must also be considered. These include the uncertainties inherent in the estimation of carcinogenic risk as well as the social and economic impacts of further emission reductions.

In determining BAT for source categories regulated under section 112, the Agency first identifies alternative levels of control which have

control may have actually been achieved by representative plants in the source categories. The Agency determines the costs and associated impacts of the various alternatives. The Administrator selects that alternative which achieves the most emission reduction and/or risk reduction without incurring unreasonably adverse impacts of one type or another. As suggested by one of the commenters, retrofit costs are considered when determining the appropriate control level for existing source categories. A particular regulatory alternative may be rejected for a variety of reasons, among them that: it is judged to result in a price increase that adversely affects consumers to an unreasonable extent; it will result in plant closures or unreasonably discourage the construction of new plants due to reduced return on investment or capital inavailability; or it has reasonably high costs for the amount of emission or risk achieved.

After selecting BAT for each source category to be regulated, EPA evaluates the incremental reductions in health risks obtainable against the incremental costs and economic impacts estimated to result from the application of more stringent control alternatives. Based on this evaluation of the risks remaining after the application of the control technology and the impacts of further control, EPA determines whether the residual risks are unreasonable. If not, BAT represents an appropriate level of control that provides an ample margin of safety to protect human health. If the residual risks are unreasonable, the standard will be set at a more stringent level.

Although the BAT approach has been used in recent benzene rulemakings, EPA has come to recognize that it may give limited and indirect weight to information on exposure and health risks in determining BAT and more direct

weight to the amount of emissions reduced. For example, in determining BAT for emission sources, the Agency relies on estimates of the total emissions reduced and on estimates of the average and incremental cost of reducing those emissions. However, the Agency recognizes that emission estimates along can sometimes be poor measures of public health risks because they do not account for the carcinogenic potency or exposure potential of hazardous air pollutant emissions.

In order to more directly consider health risks, the Agency is considering changing the approach for selecting the appropriate control levels for hazardous air pollutants. The alternative approach would combine the current two-step process into one step. In selecting the appropriate control technique, EPA would consider in one step the before- and societal costs of achieving those risk reductions. The major change in this approach would be the greater consideration of public health risks over emission estimates in selecting controls.

EPA has considered the adoption of acceptable risk levels and cost per life saved targets, but considers such goals less desirable than an approach which considers not only the health risks but other economic, energy, and environmental impacts of regualtory alternatives. Risk targets are difficult to establish and give no weight to the feasibility of risk reduction or other benefits of regulation.