ATTACHMENT E

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UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY WASHINGTON, D.C.
20460

May 23, 1996

The Honorable David M. McIntosh
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of April 19, 1996 to Administrator Browner regarding the Environmental Protection Agency's (EPA's) implementation of the Hazardous Waste Minimization and Combustion Strategy and related combustion matters. We appreciate your continued interest in this most important area. Following are our responses to your questions:

1) What is the legal and scientific justification for requiring interim combustion facilities to perform indirect exposure risk assessments in view of the fact that the protocols recommended by EPA for conducting these assessments have not been peer reviewed?

The Agency's policy that the permitting process for hazardous waste combustion facilities should include, in many cases, a site-specific risk assessment is based primarily on information which became available since the time that the current regulations for incinerators and BIFs (boilers and industrial furnaces) were issued (1981 and 1991, respectively). Specifically, the Agency concluded that the regulatory requirements do not fully address potentially significant risks via indirect pathways of exposure. Many recent studies, including the Agency's draft Dioxin Reassessment, indicate there can be significant risks from indirect exposure pathways (i.e., pathways other than direct inhalation). The food chain pathway appears to be particularly important for pollutants from hazardous waste combustion sources. In many cases, risk from indirect exposure constitutes the majority of the risk from a hazardous waste combustor. This key portion of the risk from hazardous waste combustor emissions was not fully taken into account when the hazardous waste combustion emissions standards were developed.

It is important to evaluate whether indirect pathway risks may pose risks to human health and the environment not fully addressed by the promulgated regulations. Therefore, it is EPA's general policy -- as stated in the

preamble to the proposed revision to the hazardous waste combustion standards (April 19,1996) -- to evaluate site-specific factors to determine whether to require a risk assessment at a particular site.

Where risks are identified, permit writers will consider the imposition of additional conditions pursuant to RCRA Section 3005(c)(3) (the "omnibus" provision). The omnibus provision is implemented in EPA regulations at 40 CFR 270.32(b)(2). Under the omnibus authority, permit writers determine on a site-specific basis what, if any, additional permit conditions are necessary to assure protection of human health and the environment. For combustion facilities, in many-cases, multipathway site-specific risk assessments provide information needed to make such determinations.

Although the Office of Solid Waste (OSW) risk assessment guidance has not been subjected to an external peer review, it was internally peer reviewed by risk assessment experts in EPA
headquarters and regional offices. It was also discussed in an informal consultation with some members of the EPA's Science Advisory Board (SAB). Furthermore, its parent document, the Agency's "Addendum to Methodology for Assessing Health Risks from Indirect Exposures to Combustor Emissions," was reviewed by the SAB. The Agency is considering the SAB comments as part of its effort to revise the indirect exposure methodology and we will make any appropriate revisions to the OSW guidance once that process has been completed. There are some difficult issues regarding indirect exposure assessment. Nevertheless, EPA is using the best science available considering the need in the near term for the Agency to issue permits that protect human health and the environment.

2) Has the EPA issued three different risk assessment/deposition models since June 1992 and/or within the last 24 months? Please explain the rationale for the changes in each model, what defects the changes sought to address and whether the Agency plans to make further changes. Have any of these models been reviewed by independent scientific panels? If not, why not?

The Agency has been working to improve the models it uses to evaluate dispersion and deposition from combustion sources. The Agency convened an interoffice working group in 1992 to make recommendations with regard to the Agency's indirect exposure methodology. The working group recommended that COMPDEP, the model that had been developed for use with the indirect exposure methodology, be replaced. The working group also recommended that as an interim measure the COMPDEP model be further tested and corrections made as necessary. Subsequently, COMPDEP was revised for public release for use on an interim basis. At the same time the Agency began work on revisions to

the widely-used ISC (Industrial Source Complex) model that would serve as the replacement for COMPDEP. Thus, in 1994, EPA released to the user community for comment a draft version of the ISC model which included an improved dry deposition algorithm, a wet deposition algorithm, a complex terrain screening algorithm, and an enhanced area source algorithm. Allowing the user community to test important software components as part of the development process has become standard practice in the field, and therefore, is also practiced by EPA. The revised ISC model was officially adopted as a Guideline model in August 1995.

EPA's Guideline models are supported by many years of research, including demonstration and evaluation studies. The models are subject to review at Congressionally mandated triennial conferences on Air Quality Modeling, the last of which was held in August 1995. Organizations such as the National Academy of Sciences, the National Science Foundation, the American Meteorological Society, the Air and Waste Management Association, the Chemical Manufacturers Association, and the Natural Resources Defense Council participate in these conferences. The revisions to the ISC model were formally proposed in the Federal Register on November 28, 1994 (59 FR 60740). All significant public comments received were summarized and evaluated (Summary of Public Comments and EPA Responses on the Proposal for Supplement C to the Guideline on Air Quality Models). In the final rule promulgated in August 1995 (60 FR 40465), all significant public comments were addressed and the revised model was adopted.

We understand there may be some frustration with changes to the models used for risk assessments. However, the Agency believes it is important to continuously seek ways to improve its air quality models and to make improved modeling tools available to the public. EPA recognizes that frequent changes to methods recommended for routine use makes the regulatory process more
complex. Hence, with respect to air quality Guideline models, as stated in the Guideline's introduction, EPA always provides ample opportunity for public review and comment before formally updating the models recommended for routine use. For risk assessments, it is not the Agency's policy to require that a particular model be used. Instead, that decision is generally made on a case-by-case basis by the permit applicant in consultation with the permitting authority. This approach allows flexibility to decide, for example, that once the risk assessment protocol for a site is approved by the permitting authority, no further changes will be made unless agreed to by the applicant and the permitting authority.

3) Please provide the number and location of interim status facilities that have

been required to conduct indirect risk assessments, the number of risk assessments that were completed, the length of time to complete each risk assessment, and the total cost of each risk assessment.

The information you requested is not available at EPA Headquarters. We are collecting the information from our Regional offices and will respond as soon as complete data are received.

4) Does the omnibus permitting authority allow the Agency to implement proposed regulations in certain permit actions, or to incorporate new requirements in permits where EPA intends to add such requirements to the regulations but has not yet issued a final or proposed rule? Please explain.

As a general rule, the Agency's position is that EPA's regulations are protective of human health and the environment and that permits implementing these regulatory standards will also be protective. There may, however, be site-specific circumstances in which it may be necessary to supplement regulatory permitting requirements in order to protect human health and the environment (e.g., where there is a sensitive subpopulation). In such cases, use of the omnibus provision may be appropriate. The decision to invoke omnibus authority must be made on a case-by-case basis and only when the Agency, after examining all relevant data supplied during the permitting process, determines that additional conditions are necessary to ensure protection.

One use of the omnibus authority would be to impose additional permit conditions reflecting standards that EPA has proposed but has not yet finalized. (Conditions that have been proposed for national application by EPA have gone through extensive Agency review and generally represent the Agency's best thinking on an issue.) In the legislative history for RCRA, Congress recognized that it may be appropriate to add certain provisions to permits under the omnibus provision even where those provisions are not yet contained in final regulations:

"[The omnibus authority] can also be used to incorporate new or better technologies or other new requirements in permits, where EPA intends to add such technologies or requirements to the regulations but has not yet issued a final regulatory amendment."

S. Rep. No. 284, 98th Cong., 1st Sess. 31 (1983). Another use of the omnibus authority might be to impose permit provisions that are not contained in either proposed or final regulations but which EPA has detailed in guidance documents.

EPA does not apply these provisions, however, to permits as if they were

final regulatory requirements. Rather, EPA's view is that the proposed regulations or guidances have specifically identified particular areas where the current generic regulations
might need to be supplemented. Procedurally, EPA would still propose to add these supplemental conditions to permits on a case-by-case basis based on a finding in each case that the specific conditions at issue are necessary to protect human health and the environment. Permit applicants would be free to comment on those findings and to challenge these supplemental conditions both administratively within EPA and in the courts, as explained below.

5) With regard to EPA's permitting authority, can the Agency simply claim an intention to issue a regulation and go no further? If not, what prevents the Agency from doing so? Are there any administrative checks and balances on the Agency's use of omnibus authority? Please explain.

There are a number of administrative checks and balances on EPA's use of rulemaking authority and its use of the omnibus authority. With regard to the omnibus provision, the Agency's authority is broad but is not unlimited. To invoke the omnibus authority to add conditions to an RCRA permit, EPA must show that the additional conditions are necessary to ensure protection of human health and the environment. Specifically, the permit writer must explain and document why the Agency believes that human health or the environment is not fully protected under the regulations and must provide a sound technical basis for the need to include additional permit conditions to ensure protection. Under RCRA and EPA's regulations, the Agency must provide an opportunity for public comment and if requested, hold a public hearing on the permit. EPA must respond to the public comments and include the responses in the administrative record of the permit. If the permit is issued by EPA, applicants and other interested parties have the option of appealing the final permit decision to EPA's Environmental Appeals Board. Finally, once the Agency's administrative appeal process is completed, parties may challenge the final decision through the courts. Authorized States may or may not have similar administrative and judicial appeal processes.

There may be cases in which permit writers may find a need under the omnibus authority to add certain permit conditions to conform to requirements that EPA has proposed to issue, but has not issued (and ultimately may not issue), in final regulations. It is important to understand that the Agency's stated intention to issue regulations or proposal of regulations establishing further permit conditions does not have legally binding status. As in any other case involving the omnibus authority, the permit writer would need to justify its decision to impose those additional conditions each time the permit writer sought to impose them in a permit. Therefore, the right to bring administrative and

judicial challenges, and the other procedural checks and balances described above, would apply.

Finally, there are also checks and balances on the Agency's ability to propose a regulation and to go no further. Were the Agency to follow such a course, a party could seek redress from the courts for "agency action unlawfully withheld",(see section 706 of the Administrative Procedure Act (APA), 5 U.S.C. 706). A party could also petition EPA to issue a regulation (see section 553(e) of the APA, 5 U.S.C. 553(e)) and could bring a judicial challenge if EPA declines to do so (see 7006 of RCRA).

6) Is the EPA's implementation of its Combustion Strategy policy initiative and its use of indirect exposure risk assessments consistent with the rulemaking process required under the Administrative Procedures Act? Please explain.

Yes. The Strategy itself does not impose regulatory requirements, but is a policy statement expressing how the Agency plans to exercise its discretionary authorities under RCRA in the future. Specifically, the Strategy recommends procedures for ensuring that individual permits meet RCRA's mandate to protect human health and the environment. As such, the Strategy is not subject to the notice and comment rulemaking provisions of the APA (see APA Sec. 553(b)(3)(A)). However, each independent activity undertaken as part of the overall Strategy (e.g., the promulgation of updated technical standards, individual permitting decisions) has followed and will continue to follow all legal requirements in RCRA and all appropriate procedural requirements under the APA (including public notice and comment for all rulemakings and for each individual permit action).

7) If the Agency requires a regulated facility, as part of a "site specific determination," to conduct extensive trial burns and indirect exposure risk assessments based solely on the Agency's assertion that it is " necessary to preserve health and human safety," does the regulated facility have any recourse to challenge the decision?

Yes, a facility can challenge a request for more data. Under 40 CFR section 270.10(k), EPA may require the applicant to submit additional information (e.g., trial burn data or a risk assessment) that the Agency needs to make required determinations under the omnibus provision. During the application process, the applicant may informally provide technical information to the permitting authority to justify its position that the additional information being requested is not needed to assure permit conditions that will protect human health and the environment at the applicant's facility. If the applicant disagrees with the

Agency's determination under 270.10(k) (or the authorized State's analogous determination), it may refuse to provide the requested information. The permitting authority would then evaluate the reasons offered, if any, for the failure to obtain and provide the requested information and may either decide to proceed without the information or propose to deny the permit.

In the case of a permit denial, the facility has a number of opportunities for recourse, as described above in the response to item 5, starting with commenting during the public comment period on the draft permit (or here, the draft permit denial) and followed by the opportunity for administrative review within EPA and then judicial review.

In certain cases, the Agency also may seek additional testing or data under the authority of RCRA section 3013 (i.e., where the Agency believes that hazardous waste activity "may present a substantial hazard to human health or the environment") and may issue an order for testing. The facility owner or operator may refuse to perform the work; however, EPA either may then seek to enforce its order in court or may perform the work itself and seek to recover its costs. In both cases, of course, the owner or operator can raise any appropriate defenses or explanations.

Ultimately, it is important to ensure that EPA's permit decisions are supported by an adequate level of data in the record. The lack of adequate supporting data can leave permits vulnerable to legal challenges by other interested parties.

8) How much does EPA spend on implementing the Combustion Strategy annually, including outreach activities, commitment of regional resources, the OSW newsletter, and other management resources? Please provide a breakdown of such costs.

It is difficult to isolate the specific costs of implementing the Combustion Strategy since it is an integral part of overall implementation of the RCRA program for combustion facilities. Therefore, the following budget information identifies the Agency expenditures that are targeted for implementing the combustion program in general, not just the Combustion Strategy. Many of these activities would be necessary even in absence of the Combustion Strategy. The three major portions of the combustion budget are rulemaking and analysis, technical assistance and outreach, and permitting activities. In fiscal year 1995, the agency budgeted a total of $3,419,000 and 12.8 FTE for rulemaking and analysis. Note that the Agency is obligated to pursue this rulemaking due to a settlement agreement and Clean Air Act rulemaking requirements. Outreach and technical assistance were funded at $1,394,000 and 5.8 FTE. Regional offices

were provided with $1,539,000 and 8.7 FTE for combustion-related permit activities above the base permitting allocation for permitting of these units. The fiscal year 1996 operating plan is not yet finalized but the budget is estimated at $3,414,000 and 11.7 FTE for rulemaking and analysis, $952,000 and 5.0 FTE for outreach and technical assistance, and $1,562,000 and 8.7 FTE to cover the additional regional expenses of combustion permitting. The President's Budget for fiscal 1997 includes $4,009,000 and 12.8 FTE for rulemaking and analysis activities, and $1,540,400 and 5.6 FTE is allocated for outreach and technical assistance costs. Regional budgets for fiscal year 1997 include $1,586,000 and 8.7 FTE for supplementary combustion permitting costs. The dollars cited here include both salary and contract costs, in line with the Agency's new appropriation structure. The figures for fiscal year 1995 show the sum of what were separate appropriations at the time, in order to facilitate comparison.

9) Can the Agency cite specific scientific studies, or peerreviewed agency-sponsored research, which show that hazardous waste combustors are the major source of direct and indirect human exposures to dioxins/furans, mercury and other contaminants and the major contributor (as claimed by the Agency) to "relatively high" background levels?

As indicated in the preamble to the proposed rule "Revised Standards for Hazardous Waste Combustors," 61 FR 13758, April 19, 1996, the Agency estimates that hazardous waste combustion accounts for approximately 9 - 10% of known current dioxin emissions. As concerns the dioxin estimates, as well as those for other hazardous air pollutants, the estimates for emissions from hazardous waste combustion are presented in the engineering background documents for the rule. These documents are currently undergoing both independent technical peer review and public review and comment. To the extent your question asks about dioxin estimates from other sources, the estimates for emissions from other known sources are from the 1994 draft dioxin reassessment document "Estimating Exposure to Dioxin-Like Compounds," which has undergone extensive scientific peer review and is now being revised.

With respect to mercury, the Agency estimates that hazardous waste combustion accounts for approximately 4% of known current anthropogenic mercury emissions. The mercury emissions estimates for hazardous waste combustors are also contained in the engineering background documents for the April 1996 proposed combustion rule, and those for other sources are from EPA air program emissions data.

10) If hazardous waste combustors are a potentially minor source of direct and indirect exposures, and the Agency has focused on them through the Combustion Strategy, has the Agency directed

resources to the other major sources?

By placing hazardous waste combustors under the RCRA program, Congress has required EPA to place special emphasis on hazardous waste combustors. We do not believe the Agency is focusing unduly on hazardous waste combustors, and in fact the Agency is also putting a great deal of resources into regulation of other air emissions sources. The Agency has directed resources to study emissions of mercury and dioxins/furans, and to develop Clean Air Act standards pursuant to Section 112-Hazardous Air Pollutants and Section 129-Solid Waste Combustion to reduce air emissions of mercury and/or dioxins/furans, from numerous sources in addition to hazardous waste combustors. These activities include the development of standards for the following source categories that are either included on the list (published by the Administrator pursuant to Section 112(c) of the Clean Air Act) of all source categories of listed hazardous air pollutants; or that are specified in Section 129: municipal waste combustors (rule promulgated in December 1995), medical waste incinerators (rule proposed in February 1995), non-hazardous waste burning cement kilns, secondary aluminum smelters, chlor-alkali production, primary copper smelters, industrial/commercial waste incinerators, and lime production. The Agency has also directed resources to developing the list of categories and subcategories of dioxin/furan emissions and of mercury emissions as required in Section 112(c)(6) of the Clean Air Act. This section directs the Administrator to list sources that account for at least 90 percent of the national emissions of each of these pollutants and to promulgate standards for these sources by November 2000. The source categories of municipal waste combustors and medical waste incinerators, for which standards have been promulgated or proposed as stated above, are among the largest sources of mercury and dioxins/furans emissions.

11) Please indicate the total cost of the Agency's overall efforts related to all major sources of dioxins/furans, mercury and other contaminants, and indicate the amount spent on each major source. If there are sources of dioxin and contaminants other than hazardous waste combustors, what is the Agency doing to manage and prevent emissions at those sources? What are major natural sources of dioxins?

We are pulling together the information you have requested from various EPA offices and will provide it to you as soon as it is compiled.

Thank you for your interest in this important area. If you have any questions regarding this response, please have your staff call Sonya Sasseville or Val de la Fuente at (703) 308-8648 and (703) 308-7245 respectively.