

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 264**

[SWH-FRL 1730-61]

Incinerator Standards for Owners and Operators of Hazardous Waste Management Facilities**AGENCY:** Environmental Protection Agency.**ACTION:** Proposed rules.

SUMMARY: The Environmental Protection Agency is proposing to amend the Part 264, Subpart O, general (permit) standards published today in the Federal Register. The proposed amendments apply primarily to the incinerator performance standards (§ 264.343) and include emission limits for hazardous combustion by-products, a variance standard based on an assessment of risk to human health, and a procedure to set emission limits for toxic metals and hydrogen halides based on an assessment of risk. In addition the procedure for designation of POHC's (§ 264.342) is proposed to be amended to include hazardous combustion by-products.

EPA is proposing these additions to the Part 264 general standards because they are major changes from the proposed rules published on December 18, 1978 [43 FR 58982].

DATES: Comments are due on or before April 23, 1981. A public hearing will be held March 19, 1981.

ADDRESS: Comments should be addressed to Deborah Villari, Docket Clerk, Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460. Comments should identify the regulatory docket as follows: "Docket No. 3004, Proposed Amendment, Hazardous Waste Incineration."

The official record for this rulemaking is available at Room 2711, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460 and is available for viewing from 9 a.m. to 4:30 p.m., Monday through Friday excluding holidays.

A public hearing will be held at the Auditorium, Department of Health and Human Services, 330 Independence Ave. SW., Washington, D.C. on March 19, 1981, from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Ed Martin, Office of Solid Waste (WH-565) U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, (202) 755-9203.

SUPPLEMENTARY INFORMATION: A public hearing will be held at the Auditorium,

Department of Health and Human Services, 330 Independence Ave. SW., Washington, D.C. on March 19, 1981, from 9 a.m. to 4 p.m. Anyone wishing to make a statement at the hearing should notify in writing Ms. Geraldine Wyer, Public Participation Officer, Office of Solid Waste (WH-562) U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Oral and written comments may be submitted at the public hearing. Persons who wish to make oral presentations must restrict their presentations to 10 minutes and are encouraged to have written copies of their complete comments for inclusion in the official record.

Preamble Outline

- I. Authority
- II. Background
- III. Summary of Proposed Rules
- IV. Regulatory Analysis
- V. Supporting Documents

I. Authority

This regulation is proposed under the authority of Sections 1008, 2002(a), and 3004 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended [RCRA] 42 U.S.C. 6905, 6912(a), and 6924.

II. Background

Early last year EPA began issuing regulations which comprise the Subtitle C hazardous waste management system and announced that the regulations would be issued in two phases. In January of this year EPA promulgated a large portion of the Phase II technical standards for facilities that treat and store hazardous wastes (Part 264). Elsewhere in today's Federal Register, the Agency promulgated interim final standards for incinerators under Part 264.

However, some of the requirements which the Agency believes may be necessary for adequate control of the incineration of hazardous wastes are substantially different than those proposed in December 18, 1978 [43 FR 58982]. The Agency is therefore proposing these requirements herein, to give the regulated community and the general public the opportunity to comment on them. As a result of the comments received the Agency may abandon these proposed requirements or change them substantially before promulgating them.

III. Summary of Proposed Rules**A. Introduction**

On December 18, 1978, EPA proposed permitting standards for the incineration

of hazardous waste. (43 FR 58946). After consideration of comments the Agency is promulgating those standards on an interim final basis elsewhere in today's Federal Register. At the heart of those interim final standards is the requirement that incinerators must achieve a destruction and removal efficiency (DRE) of 99.99% for each designated principal organic hazardous constituent (POHC) in the waste feed mixture. The principal organic hazardous constituents are to be designated by the permit writer based on the difficulty of incineration and quantity of the hazardous organic constituents in the waste feed mixture. Operating conditions capable of achieving 99.99% destruction and removal of these POHC's will then be incorporated into the permit on the basis of trial burns or equivalent information.

Concurrently with the promulgation of these interim final permitting standards, EPA is today proposing a number of amendments to the standard which are designed to supplement the standards and make them more comprehensive.

The proposed additional requirements in this package include the following: (1) a revision to the designation of POHCs to include hazardous combustion by-products (§ 264.342); (2) an emission limit for the hazardous combustion by-products formed during incineration (§ 264.343(d)); (3) a variance to the 99.99% DRE performance standard for principal organic hazardous constituents and the emission limit on hazardous combustion by-products based on an assessment of risk to human health (§ 264.343(e)); and, (4) a procedure to set emission limits on toxic metals, elemental halogens, and hydrogen halides based on assessment of risk to human health (§ 264.343(f)).

B. Emissions Limits for Hazardous Combustion By-Products (§ 264.343(d))

An important shortcoming in the incinerator performance standards promulgated today is their failure to address hazardous combustion by-products formed during incineration. If combustion in an incinerator is not complete many hazardous wastes break down and recombine into other forms of hazardous organic compounds. Thus even if the principal organic hazardous constituents (POHC's) in the waste feed are destroyed in accordance with the destruction and removal efficiency standard, the stack gases may contain other hazardous constituents formed during incineration. In some cases the combustion by-products produced may be more toxic than the unburned POHC's.

In order to remedy this problem, the Agency is proposing an amendment to the incinerator regulations which requires that the mass emission rate of hazardous combustion by-products not exceed 0.01% of the total mass feed rate of POHC's feed to the incinerator. This mass emission rate is analogous to the 99.99% DRE based mass emission rate of POHC's. However, the mass emission rate is calculated, not as a percentage of the quantity of combustion products generated, but as a percentage of the quantity of POHC's fed into the incinerator. Consequently, where the DRE for POHC's is 99.99%, this mass emission rate will allow a total emission rate for by-products equal to the mass emission for POHC's. The rationale behind allowing a mass emission of hazardous combustion by-products equal to the mass emission allowed for POHC's is that (1) such hazardous combustion by-products are believed to be as hazardous as POHC's and should thus be equally limited to the extent technologically feasible, and (2) a total mass emission limit for hazardous combustion by-products equal to the total mass emission limit for POHC's is technologically feasible since the chemical constituents of both are the same. EPA specifically solicits comments on the technological feasibility of the proposed emission limit, and on alternate means of setting emission limits on hazardous combustion by-products.

As a supplement to the proposed 0.01 emission limit, the Agency is also proposing to allow more or less stringent mass emission limits for hazardous combustion by-products on a case-by-case basis pursuant to the variance procedure being proposed at § 264.343 (e) and (g).

The Agency intends that the hazardous combustion by-products subject to the proposed emission limit will be designated by the permit writer on the basis of information supplied by the permit applicant. This designation cannot be made until the components of the stack gas have been identified. The identification of stack gas components and designation of hazardous combustion by-products will generally take place following analysis of data from the trial burn, which analysis will encompass only Part 261, Appendix VIII, constituents and will be based on the same considerations upon which POHC designation is based. Where the trial burn data show that the designated hazardous by-products of combustion have not been destroyed in accordance with the required emission limit, the operating conditions will have to be

adjusted to achieve compliance with this limit and the trial burn will have to be repeated to show that the required emission limit could be met.

In some instances, it may be possible for the permit applicant to provide a prediction of hazardous combustion by-products based on data from the literature or from laboratory burns or previous pilot or full scale burns where hazardous combustion by-products have been identified. These data would be included in the trial burn plan, and would allow a tentative designation of hazardous by-products by the permit writer. This would allow the applicant to plan for the destruction of these substances in the trial burn and might obviate the necessity of a second trial burn. In cases where a trial burn waiver is requested, the applicant's prediction of combustion by-products, as described above, would provide the only basis for designation of hazardous combustion by-products by the permit writer and for designation of the operating conditions necessary to achieve the required emission limit. Thus, if a trial burn waiver is requested, the permit writer must be convinced before granting the waiver that the prediction of combustion by-products and their emission rates is accurate.

C. Limits on Toxic Metals, Hydrogen Halides and Elemental Halogens § 264.343(f)

The proposed incineration regulations (43 FR 58946) required incinerators to meet the destruction efficiency requirement for toxic metals and non-organic halogen compounds. Commenters objected to this proposal on the basis that non-organic components cannot be thermally destroyed.

Commenters correctly discerned that the originally proposed destruction efficiency requirement was inapplicable to metals and other non-organics. However, the destruction and removal efficiency approach adopted in today's interim final regulations can be applied to metals and non-organic halogen compounds, because that approach considers removal of waste constituents in the emission control system as well as destruction in the combustion zone. This approach recognizes that metals and non-organic halogens emitted can be controlled through removal and included in a destruction and removal efficiency calculation. However, the Agency elected not to apply a destruction and removal efficiency standard to metals and non-organic halogens in the interim final regulation because the Agency does not now have test data to indicate what specific

removal levels are achievable, except in the case of hydrogen chloride emissions.

Instead, the Agency is proposing at § 264.343(f) to require that emission limits for metals and non-organic halogens (other than HC1) be set on a case-by-case basis by assessing the risk to human health, using the approach established for assessing a variance to the 99.99 percent DRE standard and the proposed hazardous combustion by-products standard. The methodology for these assessments and the manner in which these assessments are to be integrated into the permitting process is discussed in Section E of this preamble.

The Agency anticipates that a risk assessment will be required whenever the permit applicant's waste analysis reveals the presence of toxic metals or non-organic halogens in the waste. Comments on the necessity and feasibility of such a risk assessment and/or the removal efficiencies demonstrated to be technologically feasible are specifically requested.

In proposing the risk assessment based limits for toxic metals, hydrogen halides and elemental halogens, the Agency considered whether metals and non-organic halogens were adequately addressed through standards developed under the Clean Air Act, and determined that they were not. The only existing Federal point source standards applicable to hazardous waste incinerators address beryllium and mercury. These metals are controlled through National Emission Standards for Hazardous Air Pollutants (NESHAPS). However, the NESHAP for mercury applies to sludge incinerators, and thus would not be applicable to all hazardous waste incinerators. Additionally, an ambient standard for lead has been promulgated under the Clean Air Act and is applied through the State Implementation plan (SIP) process. However, some incinerators, due to their small size, may not be covered by this standard.

D. Variance to the Destruction and Removal Efficiency (§ 264.343 (e) and (g))

A number of comments on the December 18, 1978 proposed incineration standards argued for flexibility in the proposed destruction efficiency. The Agency agrees that such flexibility is desirable because the Destruction and Removal Efficiency (DRE) performance standard may be either more or less stringent than necessary to provide assurance of protecting human health and the environment in all circumstances. A basic reason is that destruction and removal efficiency is a percentage

removal standard, and, thus, allows for varying mass emission rates. For any DRE, mass emission rates can vary based on the mass feed rate.

As a result of the comments and EPA's further analysis, EPA is proposing to add a variance procedure to the incinerator regulations providing the permit writer with discretion to alter the basis performance requirements of 99.99 percent destruction and removal efficiency. Under this proposal, the permit writer may establish permit limitations based on an assessment of the risk to human health. If the risk assessment indicates that a more restrictive emission rate is needed to protect human health, the permit writer may strengthen the performance standard either by requiring a higher destruction and removal efficiency or by specifying a lower waste feed rate. In a like manner, the permit writer may reduce the performance standard by approving a lower destruction and removal efficiency (or higher feed rate) if the risk assessment indicates that the lower rate limit will pose no significant hazard to human health. Section d (Estimating risk to human health) of this preamble describes the procedures for conducting these risk assessments.

Although the proposed variance procedure allows the permit writer to either raise or lower the mass emission rate the Agency considered the option of allowing use of the variance only to raise the performance standard. The primary reason for including the variance is to ensure protection of human health in those instances where either a highly toxic stack emission or a very high through-put results in potential risk to humans even at a 99.99% DRE. Although a 99.99% DRE may not be required to protect human health in other instances, the Agency is reluctant to allow incinerators to operate below performance levels that are widely attainable by current technology. The Agency is concerned that until the value of risk assessments is proven and the method of conducting them is perfected, using 99.99% DRE as the minimum acceptable performance, with risk assessment as a tool to increase that standard, provides a more conservative approach which is more certain of protecting human health. On the other hand, the Agency recognizes that there are competing considerations which argue for making the variance flexible in both directions. For example, the 99.99% DRE may not be necessary to protect human health in a location remote from population or where the waste being burned is only marginally hazardous.

Accordingly, the Agency is requesting comment on the question of whether the variance procedure should be used to both raise or lower the destruction and removal efficiency, or only to raise it. If the variance is flexible in both directions, will the variance dominate the standard, in essence making the 99.99% target moot? Is risk assessment sufficiently developed that a relaxed standard based on such an assessment would be acceptable, or should a minimum, i.e. 99.99% DRE, be established?

The Agency recognizes that in some instances it may not be possible, due to lack of data, to conduct a scientifically supportable risk assessment. When a risk assessment is not possible or is not conducted at the behest of the applicant, the public, or permit writer, the performance standard of 99.99% DRE will be the basis for permitting. Over time, data will be developed to expand risk assessment capabilities.

E. Implementation of the Agency's Proposed Risk Assessment Provisions

1. *Procedures for developing a permit requirements based on a human health "risk assessment."* The manner in which the risk assessment-based variance procedure should be integrated with the permitting process has deliberately been left somewhat flexible in the proposed regulations. Before discussing the many ways in which these two can be integrated, some overview of the permitting process should be provided.

There are basically two routes by which a permit applicant can obtain an incinerator permit according to the regulations promulgated today under Parts 264 and 122. In one, the permit applicant submits to the permit writer a trial burn plan which contains an analysis of his waste feed, a description of the operating conditions believed to be capable of achieving a 99.99% DRE of POHC's, and a description of the test protocol he intends to employ in demonstrating achievement of this DRE. On the basis of this submission, the permit writer tentatively designates the POHC's in the applicant's waste and issues a trial burn permit allowing the applicant to conduct a trial burn. The purpose of the trial burn is to demonstrate that the operating conditions specified in the trial burn plan are indeed sufficient to achieve the desired DRE. After the trial burn is completed the applicant submits data to the permit writer containing the results of the trial burn. The permit writer then reviews this data, and issues a draft permit which is subject to public review and comment before being finalized.

The other route, is essentially the same as the first, but the permit applicant does not conduct a trial burn. Instead, he secures a trial burn waiver. Such a waiver will only be granted where the applicant can supply data demonstrating that particular operating conditions for his incinerator will achieve the desired DRE.

The Agency believes that the risk assessment procedure can be effectively integrated into the permit process described above. The integration could occur several possible ways, depending on whether the risk assessment is initiated by the permit writer, the permit applicant or the public. It can also be carried out at several different points of the process—either prior to the trial burn, following the trial burn but before issuance of a draft permit for public comment, or after public comment. These are discussed below.

A risk assessment variance analysis will in most instances be performed by the applicant prior to conduct of a trial burn. This would be advantageous in that the applicant would know prior to the trial burn whether he would need to demonstrate a performance other than 99.99% DRE. Thus, he may be able to avoid having to repeat a trial burn, although the POHC's and hazardous combustion by-products will not be finally determined until the trial burn is complete. In most instances, the trial POHC's, designated by the permit writer from waste analysis data included with the trial burn plan, will also be the final POHC's. Thus the permit applicant, on the basis of waste analysis data in his possession, will be able to compute stack POHC emissions at the 99.99% DRE and at other destruction and removal efficiencies and to compute the risks associated with those DRE's. Hazardous combustion by-products present a more difficult problem. While a prediction can be made, the trial burn may indicate different or additional by-products than those predicted. Should this occur, a risk assessment for those new hazardous by-products would have to be performed after the trial burn.

In cases where the applicant requests that a risk assessment for a variance be performed, this request would be included in a "variance assessment plan" submitted as a part of the trial burn plan. It would include a description of the proposed methodology to be used in the assessment. In reviewing the variance assessment plan, the permit writer would accept or, require modification of, the risk assessment methodology, and would designate the trial POHC's and trial hazardous combustion by-products to be included

in the risk assessment. The risk assessment would then be performed and the results submitted to the permit writer for incorporation into the trial burn plan.

In cases where the applicant does not request a variance assessment, but instead it is required by the permit writer, upon review of the trial burn plan, the applicant would be requested to amend the plan with a methodology for the risk assessment. Then the process would proceed as described above. In either case, the performance of the risk assessment prior to conduct of a trial burn would add a step to the trial burn application process. That step would require that a new part be added to the trial burn plan, that the permit writer approve that part of the plan, and that the applicant complete the assessment and submit it to the permit writer to complete the trial burn plan. In addition, the applicant or permit writer might decide to provide opportunity for public comment on the results of the risk assessment and the variances determined by the permit writer prior to conduct of the trial burn.

In cases where a waiver of the trial burn is requested in Part B of the permit application, the same procedure would be followed regarding a risk assessment variance. Part B would not be considered final until a determination of the need for, and, where appropriate, completion of, a risk assessment was made.

The second option for integrating a risk assessment into the permit process is to conduct the assessment following the trial burn. A probable basis for requiring a risk assessment at this time would be that the data from the trial burn revealed hazardous by-products which were not predicted. A risk assessment at this juncture might be requested by the applicant in his submitta¹ of trial burn results in Part B of the permit application, required by the permit writer upon review of those results prior to issuance of a draft permit, or requested by the public as a part of their review of the permit application or draft permit. In any of these cases the applicant may be requested (at the permit writer's discretion) to submit a methodology for the risk assessment, and upon approval, to conduct the assessment and submit the results to the permit writer, essentially as a modification of Part B of the permit. If review of the results causes the permit writer to use the variance and alter the performance standard, a repeat of the trial burn may be necessary. If so, a new trial burn plan

will be required, thereby forcing a repeat of the permit application process.

2. *Calculation of the human health "risk assessment."* Section 264.343(g) proposes four elements which must be considered in performing any risk assessment. These elements include (1) data on the mass and concentrations of POHC's, hazardous combustion by-products, metals and hydrogen halides which may be omitted from the stack; (2) air dispersion estimates of these substances for determining ground level ambient concentrations of emitted pollutants; (3) expected human and environmental exposure; and (4) the consequences of exposure, including dose response curves for carcinogens and or estimated toxic effects for noncarcinogens. Based on this data, the Regional Administrator must determine the maximum level of pollutants which may be emitted without posing an unacceptable risk to human health or the environment. Operating conditions necessary to ensure that these levels are not exceeded would be included in the incinerator permit.

These regulations do not specify any one methodology for performing the risk assessment. Permit writers may, as long as they address the factors identified in the regulation, develop risk assessments in the manner most appropriate to the nature of the incinerator and waste feeds in question. The Agency has, however, identified approaches to risk assessment which it believes can feasibly be employed by permit writers and which satisfy the requirements of today's proposal. These approaches are discussed in detail in "Background Document: Hazardous Waste Incineration Proposal."

One major issue on which comment is requested is whether the regulations should specify a methodology, including (as discussed below) an acceptable risk level to be employed by the permit writer in developing permit limitations based on a risk assessment. The following discussion identifies one approach which could be used by permit writers. EPA requests comments on the appropriateness of the method and the assumptions which are used.

a. *Emission rate estimates.* Emission rates can be determined from sampling and analysis during trial burns or they can be calculated based on feed rates, POHC concentrations in the food, and assumed DRE's. In order to conduct a risk assessment prior to a trial burn, the latter approach would be required, and is straight-forward using the equation for DRE in § 264.343(a).

b. *Air dispersion modeling.* The role of air dispersion modeling is to estimate the ground level concentrations of

hazardous wastes emitted by incinerators. This data is used, along with health effects data discussed below to calculate human health risks from exposure to the emissions, and, ultimately, the levels of emissions which will be allowed by the permit writer.

One appropriate source of information in developing air dispersion models is the *Guideline on Air Quality Models* (EPA publication 450/2-78-027). The Guideline recommends specific air dispersion models appropriate for various situations. The guideline also makes recommendations concerning the source and meteorological data to be used in these models. This document has undergone extensive review by the scientific community and is incorporated into regulations under the Clean Air Act.

The *Guideline on Air Quality Models* discusses both screening and refined modeling techniques. The screening techniques involve simple calculation and are based on generally conservative assumptions. Thus, if screening shows that an allowable concentration is not exceeded, more detailed modeling need not be performed. If, however, screening indicates that allowable concentrations are exceeded, it is desirable to use a more refined technique to confirm these results.

In performing air quality modeling for purposes of risk assessments, two factors should be noted. First, assessments of impact on human health are generally based on long-term exposure to emissions. Thus, there will usually be no need to estimate daily or hourly fluctuations. For some substances which demonstrate acute effects, shorter averaging times may, however, be necessary. Second, hazardous pollutants should generally be considered chemically unreactive in the atmosphere. Unless applicants can demonstrate that the hazardous emissions are degraded to non-hazardous substances in the atmosphere, an inert pollutant model should be used.

c. *Exposure estimates.* An approach to risk assessment which the Agency believes can most simply be applied is a determination of incremental individual risks at the point of maximum ground level concentration of emissions from the incinerator. The actual presence of individuals at this point, or the number of individuals, would not be considered.

This is a relatively simplified and conservative approach to risk assessment. It assumes, in essence, that an individual is exposed to the greatest ambient concentration of hazardous constituents, regardless of where that may be. An alternative approach would

be to assess the aggregate risk to total exposed populations. The determination of individual risk at the point of maximum concentration avoids the difficult and often disputed estimates of actual total population exposure to different concentrations. Nothing in the regulation, of course, precludes the permit applicant or other interested persons from preparing such estimates for consideration by the permit writer.

d. Estimating risk to human health. Numerous models exist for predicting the human health effects of exposure to various concentrations of pollutants. The fundamental question in selecting the appropriate model is whether the pollutant has a threshold below which no adverse effects to human health are expected. Carcinogens are generally considered to be non-threshold substances; pollutants displaying other toxic effects may have a threshold. In calculating the risk from several pollutants with both threshold and non-threshold effects, the lowest safe levels should be employed in setting emission limits.

Non-threshold pollutants (Carcinogens). An appropriate methodology for estimating the risk to human health from carcinogens is the Linearized Multistage Model for Cancer Induction employed by EPA's Cancer Assessment Group. The general formula for this model is $P = q_1 \cdot x$, in which P represents the lifetime risk to an individual of cancer due to an average daily exposure, x , to the substance. q_1 is a value representing the carcinogenic potency of the carcinogen from inhalation exposure. Currently q_1 values for inhalation exposure have been developed for 21 carcinogens; these values are listed in the background document for this proposal. Additional values will be prepared by the Agency in the near future.

In estimating the daily average exposure assumptions which must be employed include the weight of the exposed individual, the amount of air inhaled on a daily basis and the amount of pollutant retained by the individual. Values which have been developed, and which could be used by the permit writer, include a reference weight of 70 kg, inhalation of 20 m³/day of air, and retention of 50% of inhaled pollutants. The last value may vary with particulate size. A detailed discussion on this methodology and these assumptions is contained in the background document.

To derive permit limitations based on a risk assessment, permit writers must determine an acceptable level of risk. Two qualitative measures of risk have been used by the Agency in evaluating carcinogenic hazards to populations

exposed to an agent. These are: (1) individual lifetime cancer risk, which is defined as the probability that an exposed person will die of cancer, as opposed to other causes, as a result of exposure, and (2) the number of cancer cases per year which can be attributed to the exposure. The individual risk depends on the carcinogenic potency of the compound and the concentration of the agent in the exposure medium, whereas the number of cases depends on the individual risk and the size of the exposed population.

In deciding what risk is acceptable from a public health protection point of view the Environmental Protection Agency regulatory offices have concentrated on the individual risk. For example, EPA's Office of Pesticides and Toxic Substances is considering a lifetime risk of less than 10^{-6} as acceptably low in the case of nitrosamine contamination of pesticide products. EPA's Water Quality Office is requiring the reporting of hazardous material spills into navigable water that could be used as a source of drinking water if the risks are greater than 10^{-6} . In the Food and Drug Administration regulations of animal feed additives that could cause residues of carcinogenic substances in edible meat, a risk of less than 10^{-6} is considered safe enough to require no use restriction. The Agency's recently promulgated Water Quality Criteria for the protection of human health present values based on a risk range of 10^{-7} to 10^{-5} .

The attitude of many scientists and policy makers seems to be that risk of less than 10^{-7} is too small to justify the resources required to issue and enforce a regulation. However, a risk of above 10^{-4} is usually considered serious enough either to take regulatory action or to require a determination that the costs of control are prohibitively large. Within the range of roughly 10^{-7} to 10^{-4} the acceptability of a risk is usually a result of cost-benefit balancing.

Under the regulation proposed today, the determination of acceptable risk has been left to the permit writer. This determination will be made on a case-by-case basis as a part of the permitting process. However, to ensure reasonable consistency from one case to another, the Agency anticipates establishing a "Risk Review Board" to review individual risk decisions.

The Agency considered establishing an acceptable risk level in the regulation, but has determined that such a risk determination, affecting a local area, can best be made on a case-by-case basis after reviewing the local circumstances associated with the incinerator. However, the Agency is

requesting comment on the issue of how acceptable risk levels can be established, and whether that should be done in the regulation or as part of the permit process.

Threshold Pollutants (Non-carcinogens) For pollutants which display threshold effects, risk assessment calculations require development of an acceptable daily intake from inhalation of the pollutant. Unlike risk assessments for carcinogens, no social judgment need be made as to acceptable levels of risk. Rather, the issue involves a scientific determination of safe levels of exposure.

One basis for calculating these values is by use of the "Threshold Limit Values" ("TLV") developed by the American Conference of Governmental Hygienists. TLV's represent 8-hour, and industrial time-weighted average concentrations in air that are intended to protect workers from various adverse health effects over a normal working lifetime. For purposes of the risk assessment associated with today's proposal, TLV's would have to be reduced by an appropriate factor to reflect the fact that exposure would not be limited to a healthy population and for a limited period during the day.

Additionally, acceptable intake levels may be derived from toxicological data defining "No Observed Adverse Effect Levels" ("NOAELs") or similar appropriate concepts. Derivation of acceptable intake values in this case would require application of "safety factors" to account for extrapolation from animal data to man. Guidelines for applying such safety factors have been developed by the National Academy of Science.

IV. Regulatory Analysis

Under Executive Order 12044, the Agency is required to prepare a regulatory analysis for all new significant regulations. This analysis includes a comprehensive economic impact analysis and a discussion of the regulatory alternatives considered. The Agency has not yet prepared the economic impact analysis for this proposal. However, the Agency plans to complete it and make it available for public review and comment before a final rule is promulgated. In addition, EPA plans to prepare and allow public comment on a full Regulatory Analysis before promulgation of this rule which will include both the economic impact analysis and summary of approaches considered.

The Federal Report Acts of 1942 requires federal agencies to minimize the reporting burden created by their regulations. For all new regulations,

agencies must estimate the size of the reporting burden, describe who must report and apply to OMR for a clearance. Accordingly EPA is estimating the reporting burden of this rule and will submit a clearance package to OMB as soon as possible. Congress has recently amended this Act with the Paperwork Reduction Act of 1980. After the effective date of this new Act (April 1, 1980) all Agencies must have OMB's approval of the reporting burden before any regulation is published as a proposal or promulgation.

The Regulatory Flexibility Act requires all Federal agencies to consider the effects of their regulations on "small entities", i.e., small businesses, small organizations, and small governmental jurisdictions. It requires agencies to propose for public comment a "Regulatory Flexibility Analysis" for any regulations proposed after January 1, 1981 which will cause a significant impact on a substantial number of small entities.

The analysis should include primarily a description of the impact of the rule on small entities, an estimate of the number of small entities affected, a description of the reporting and other compliance requirements, and a description of any alternatives considered to minimize the impacts.

Although EPA has not yet prepared a Regulatory Flexibility Analysis of the small entity impacts of the rules it is proposing today, it believes that a significant portion of the potential impact of these rules on small entities has already been substantially reduced by the small quantity generator exemption contained in EPA's May 19, 1980, regulations; an exemption granted primarily for administrative reasons. (See 40 CFR § 261.5.) EPA intends to analyze the impact of these rules on small entities more thoroughly in the future, and publish its analysis for public comment. In the meantime, the Agency expressly invites the public to address the impact of this rule on small entities in their comments.

V. Supporting Documents

A. Background Documents

Two background documents have been prepared to support these regulations, providing rationale for the need to supplement the interim final regulations, and the rationale for the proposals as written. In conjunction with the references listed in them, these documents provide most of the basis for and defense of the proposed regulations. However, the background document in support of the interim final Part 264, Subpart O regulations also provides

background information that may help in understanding the proposed regulations. Finally, the guidance documents that EPA is developing for the Subpart O regulations provide useful background information.

Thus, the following documents and others referenced in them support the Subpart O regulations proposed today: (1) "Background Document, 40 CFR Part 264 Subpart O, and 40 CFR Part 265 Subpart O: Incineration"; (2) "Background Document, 40 CFR Part 264 Subpart O: Incineration—Proposed Standards"; (3) "Engineering Handbook on Hazardous Waste Incineration"; and (4) "Permit Writer's Guidance Document for Hazardous Waste Incineration".

Copies of these documents are available for review in the EPA regional office libraries and at the EPA headquarters library, Room 2404, Wasterville Mall, 401 M Street, S.W., Washington, D.C. 20460.

B. Guidance Documents

Reliance on performance standards and the incorporation of case-by-case consideration of many factors provide considerable flexibility to accommodate new technologies, special needs of specific locations, and variations in waste characteristics. To assist both owners and operators of facilities and regulatory officials, EPA is preparing guidance manuals. These will not have the effect of regulations, but will provide guidance on how facilities may be designed and operated to meet the standards. Future manuals will also provide guidance on what modifications and variations are likely to be effective under the variance procedures. They will be organized to correspond closely to the regulations and will be based on the collective knowledge of the Agency, the literature, and experts throughout the world.

EPA has already prepared the following manuals in support of the hazardous waste incinerator regulations:

- (1) Engineering Handbook on Hazardous Waste Incineration;
- (2) Permit Writer's Guidance Manual on Hazardous Waste Incineration.

For a more complete list of guidance manuals that EPA is preparing in support of the entire hazardous waste regulatory program see the preamble discussion in the January 12, 1981 regulation.

(Section 1006, 2002(a), 3004, 3005, and 3007 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. §§ 6905, 6912(a), 6924, 6925 and 6927.)

Dated: January 13, 1981
Douglas M. Costle,
Administrator.

For the reasons set out in the preamble, it is proposed to amend 40 CFR Part 264, Subpart O as set forth below:

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. In § 264.342; the section heading and paragraphs (a) and (b) are revised to read as follows:

§ 264.342 Designation of principal organic hazardous constituents and hazardous combustion by-products.

(a) Principal organic hazardous constituents (POHCs) and hazardous combustion by-products must be treated to the extent required by the performance standards specified in § 264.343. (b)(i) For each waste feed to be burned, one or more POHCs and hazardous combustion by-products will be specified from among those constituents listed in Part 261, Appendix VIII of this Chapter. This specification will be based on the degree of difficulty of incineration of the organic constituents of the waste feed and its combustion by-products, their concentration or mass, considering the results of waste analyses and trial burns or alternative data submitted with Part B of the facility's permit application. Organic constituents or by-products which represent the greatest degree of difficulty of incineration will be those most likely to be designated as POHCs or hazardous combustion by-products. Constituents are more likely to be designated as POHCs or hazardous combustion by-products if they are present in large quantities or concentrations. (ii) Trial POHCs will be designated for performance of trial burns in accordance with the procedure specified in § 122.27(b) for obtaining trial burn permits. Trial hazardous combustion by-products may be designated under the same procedures.

2. Section 264.343 is amended by redesignating paragraph (d) as paragraph (h) and adding new paragraphs (d), (e), (f), and (g) as follows:

§ 264.343 Performance standards.

(d) Incinerators burning hazardous waste must destroy hazardous combustion by-products designated under § 264.342 so that the total mass emission rate of these by-products

emitted from the stack is no more than .01% of the total mass feed rate of POHCs fed into the incinerator.

(e) After consideration of the factors listed in paragraph (g) of this Section, the Regional Administrator may, on a case-by-case basis, establish performance standards which are either more or less stringent than those required by paragraphs (a) and (d) of this Section based on a finding that:

(1) More stringent standards are necessary because the emission rates achieved by the application of the performance standards otherwise required by this Section may pose an unacceptable risk to human health and the environment, or

(2) Less stringent standards will achieve emission rates which do not pose an unacceptable risk to human health and the environment.

(f) After consideration of the factors listed in paragraph (g) of this section, the Regional Administrator may, on a case-by-case basis, stipulate performance standards for metals, hydrogen halides, and elemental halogens, based on a finding that such standards are necessary to limit the emission rates of these constituents to levels which do not pose an unacceptable risk to human health and the environment.

(g) The findings under paragraphs (e) and (f) of this Section will be made after evaluating the following data, which the Regional Administrator may require from the permit applicant:

(1) Emissions of POHC's, hazardous combustion by-products, metals, and hydrogen halides, including:

(i) Mass emission rates from the stack, and

(ii) Concentration in the gas stream exiting the stack;

(2) Air dispersion estimates for these substances, including:

(i) Meteorological data,
(ii) Description of the air dispersion models,

(iii) Assumptions underlying the air dispersion models used;

(3) Expected human and environmental exposure, including:

(i) Topographic considerations,
(ii) Population distributions,
(iii) Population activities, and
(iv) Modes, intensity and duration of exposure;

(4) Consequences of exposure, including:

(i) Dose-response curves for carcinogens,

(ii) Health effects based on human or animal studies for other toxic constituents,

(iii) Potential for accumulation of toxic constituents in the human body, and

(iv) Statements of expected risk to individuals or populations.

(h) For purposes of permit enforcement, compliance with the operating requirements specified in the permit (under § 264.345) will be regarded as compliance with this Section.

However, evidence that compliance with those permit conditions is insufficient to ensure compliance with the performance requirements of this Section may be "information" justifying modification, revocation, or reissuance of a permit under § 122.15 of this Chapter.

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