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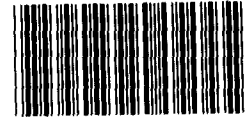


United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-251122

January 8, 1993



148522

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

The Montreal Protocol of 1987--an international agreement--calls for reductions in worldwide production and consumption of chloroflourocarbons (CFCs) and certain other substances because of the danger they pose for the Earth's stratospheric ozone layer.¹ Amendments to the protocol adopted in London during 1990 call for eliminating the production of these substances by the year 2000. In February 1992 the President responded to new evidence of a more dramatic deterioration of the ozone layer by ordering an end to production of these harmful substances in the United States by 1995. Although substitutes for ozone-depleting CFCs are available, their potential health risks and ecological dangers are not well understood. To aid the Subcommittee in evaluating the potential risks associated with the use of these substitutes, you requested that we provide a status report on the Environmental Protection Agency's (EPA) efforts to assess the environmental risks and availability of such substitutes. This letter presents the information you requested.

In summary, EPA began studying the environmental risks and availability of substitutes for ozone-depleting substances in order to implement the phaseout called for by the Montreal Protocol of 1987. These preliminary analyses have laid the foundation for subsequent work by noting that substitutes may pose risks to human health and the

¹Signatories of the Montreal Protocol agreed to control production and consumption of CFC-11, CFC-12, CFC-113, CFC-114, CFC-115, as well as halon-1211, halon-1301, and halon-2402.

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environment, albeit not necessarily ozone depletion. Currently, the agency's analysis of substitutes is focused on the Significant New Alternatives Policy (SNAP), EPA's program to assess the risks and availability of alternatives to ozone-depleting chemicals. Since January 1992 producers and formulators of substitutes have been voluntarily submitting risk and availability data to EPA, laying the groundwork for the final implementation of SNAP. The agency expects the program's final rules to be published by the autumn of 1993, about 1 year later than required by the 1990 amendments. Despite this delay, the phaseout of ozone-depleting substances and the current development and adoption of effective and environmentally safer alternatives do not appear to have been adversely affected. The remainder of this letter provides background information on ozone depletion and discusses EPA's efforts to assess the environmental risks and availability of substitutes for ozone depleting substances.

BACKGROUND

As you are well aware, the Earth's protective shield of stratospheric ozone (O₃) is being rapidly depleted. Ground-based and satellite observations since 1989 show decreases of ozone in winter in the northern hemisphere. These observations also show that, for the first time, there is evidence of significant decreases in spring and summer in both the northern and southern hemispheres at middle and high altitudes. In response to scientific concerns and findings on ozone depletion, the United States and other nations signed the Montreal Protocol on September 16, 1987, which established timetables for reducing the production and consumption of specific ozone-depleting substances. In response to scientific evidence indicating that ozone depletion was greater than expected, the parties to the Montreal Protocol met in London on June 27-29, 1990, and amended the protocol by calling for complete elimination of CFCs, halons, and carbon tetrachloride by the year 2000.

In the United States, the Clean Air Act Amendments of 1990 address the continuing depletion of the stratospheric ozone layer by mandating the phaseout of ozone-depleting substances. Section 614(b) stipulates that title VI of the amendments should be construed as a supplement to the terms and conditions of the Montreal Protocol and that if a conflict between the Protocol and title VI of the amendments

occurs, the more stringent provision should take effect.² The amendments require that production of the worst ozone depleters--known as class I substances--cease by January 1, 2000. These substances, which include all of those slated for elimination by the London agreement, as well as any other substance that EPA finds to be significantly harmful to the ozone layer, have been widely used as refrigerants, foams, solvents, aerosol propellants, adhesives, coatings, and inks. The amendments also mandate that production of less dangerous ozone-depleting substances, such as hydrochloroflourocarbons (HCFC), end by January 1, 2030. HCFCs have been used as interim substitutes for CFCs. In addition, the 1990 amendments also require that EPA establish a program to develop safe substitutes for ozone-depleting substances (section 612).

In February 1992 the President reacted to evidence that ozone depletion had for the first time extended over the northern latitudes of the United States during the summer by accelerating the phaseout schedule for class I substances established in the 1990 amendments. The President also ordered an accelerated review of substitutes that do less harm to the ozone layer than class I substances. EPA's proposed regulation to implement the President's directive is currently under review at the Office of Management and Budget (OMB). EPA officials expect the final rule to be published by early 1993.

According to EPA, class I substances are, in fact, being phased out faster than required to meet the President's 1995 milestone. EPA officials estimated that total current production of class I substances is only about 40 percent of 1986 levels and that the rate of current reductions can meet the 1995 milestone. Officials emphasize, however, that the availability of safe and effective substitutes is crucial to the continued success of the accelerated phaseout. According to these officials, unless effective substitutes are available and competitively priced, the momentum of the phaseout could stall.

Section 612 of the amendments required that EPA promulgate regulations by November 15, 1992, prohibiting the replacement of any ozone-depleting substance with any

²Title VI of the Clean Air Act of 1990 repealed Part B of title I of the Clean Air Act, sections 150 through 159, which represented previous authority for ozone protection.

substance the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that reduces the overall risk to human health and the environment. Section 612 further requires EPA to publish lists of prohibited and accepted substitutes for specific uses. The law also directs the Administrator to require producers of chemical substitutes for class I substances to (1) notify the Administrator not less than 90 days before new or existing chemicals are introduced into commerce as class I substitutes and (2) provide the Administrator with unpublished health and safety studies on such substitutes.

EPA'S EFFORTS TO ASSESS THE ENVIRONMENTAL RISKS AND AVAILABILITY OF CLASS I SUBSTITUTES

EPA has assisted the United Nations Environment Programme (UNEP) in producing technical reports assessing the effectiveness of CFC substitutes. EPA officials stated that the agency's studies of substitutes completed before the 1990 amendments focused more on the performance of substitutes, rather than on their environmental risks, because of EPA's belief that the development of effective substitutes is critical to a timely phaseout of ozone-depleting substances. EPA did, however, conclude in a January 1990 report that the use of some CFC substitutes could have adverse effects on air quality. The agency found that, to varying degrees, CFC replacements could contribute to global warming and that carbon dioxide, methane, and nitrogen oxide emissions could increase.³

EPA's overall plan for assessing the environmental risks and availability of substitutes, as required by section 612 of the amendments, is concentrated in the agency's proposed Significant New Alternatives Policy program. SNAP, which EPA initiated as part of an advance notice of proposed rulemaking on January 16, 1992, is designed to evaluate the overall effects of substitutes on human health and the environment. EPA's strategy is to use the results of SNAP risk assessments to guide the agency in deciding which substitutes it will list as acceptable and as prohibited. According to the chief of the stratospheric ozone branch, final SNAP rules will require that substitutes pose a lower

³Analysis of the Environmental Implications of the Future Growth in Demand for Partially Halogenated Chlorinated Compounds (EPA 400/1-90-001, Jan. 1990).

overall risk than the class I products they replace. SNAP's final rules will also emphasize the importance of substitutes' availability. EPA officials maintain that allaying industry concerns about the environmental risks and availability of substitute products through the SNAP program is a key component of the agency's accelerated phaseout of class I ozone depleters. EPA's premise is that the more confident class I users are that effective substitutes are available, the more willing users will be to give up products containing ozone-depleting substances in favor of products made with safer substitutes.

EPA anticipates that, under SNAP's final rules, manufacturers will be required to submit applications to EPA to have their products listed as acceptable substitutes. In support of their applications, manufacturers will have to submit unpublished health and safety studies, including estimates of their product's environmental risk, and notify the agency at least 90 days before the substitute's introduction into interstate commerce. It will be EPA's responsibility to assess substitutes' safety and availability. After the 90-day notification period, manufacturers will be allowed to market their products, even during EPA's assessment, unless the agency concludes that a product is unacceptable. EPA officials noted that the reporting burden on the regulated community will be relatively small because many substitute products have already been evaluated.

Information required as part of the notification will serve as criteria in SNAP's risk assessments, including information on each substitute's ozone-depleting potential, global-warming potential, flammability, cost per kilogram, and replacement ratio (the quantity of substitute required relative to the ozone-depleting substance being replaced); the changes in technology required to use the substitute and costs associated with these changes; and availability. The 1990 amendments require that EPA publish lists of accepted and prohibited substitutes in the Federal Register. EPA

plans to update these lists regularly as information becomes available through the 90-day notification process.⁴

EPA, which submitted the SNAP program's notice of proposed rulemaking to OMB for review in October 1992, estimates that final SNAP rules should be published by November 1993. Agency officials attributed the delay in issuing final rules--by November 1993 instead of November 1992--to the complexity of EPA's risk evaluations and to the lengthy list of potential substitutes that remain to be assessed before final lists of prohibited and acceptable alternatives are prepared.

In January 1992, as a prelude to the promulgation of the SNAP program's final rules, EPA requested that producers and formulators of class I substitutes voluntarily provide the agency with information to evaluate the risks and availability of substitutes. EPA began this early data call-in for two reasons. First, EPA believed that in order to meet the statutory deadline of November 15, 1992, for issuing the regulations called for in section 612, it was essential to conduct risk assessments of substitutes before the deadline. Second, EPA sought to provide producers, formulators, and users with information on the acceptability of substitutes as soon as possible to reduce market uncertainties. EPA officials expressed optimism that a quick, widespread dissemination of accepted substitutes would ease many of the doubts and fears that industry may have had about the availability and/or safety of substitutes.

The SNAP program director noted that between January and November 1992 the agency received about 120 responses to its request for data. The information contained in these responses covers about 66 percent of the known substitutes. The agency used these data submissions to supplement previously collected data as the basis for preliminary risk assessments on these substitutes. In addition, EPA

⁴For new chemicals--substances not currently on the Toxic Substances Control Act (TSCA) inventory--the regulatory requirements under section 5 of TSCA will remain in effect. Thus these substitutes will be subject to review under section 5 of TSCA and section 612 of the Clean Air Act. To expedite these reviews, EPA is developing a joint review process.

initiated preliminary risk assessments on potential substitutes for which the agency believed there would be a commercial interest, but whose manufacturers did not respond to the agency's request for data. According to EPA officials, preliminary risk analyses took into account not only substitutes' human health risks and ozone-depleting potential, but also other environmental risks, such as global-warming potential, toxicity to ecosystems, and contributions to ground-level ozone. EPA used the results of these risk evaluations to develop preliminary lists of prohibited and accepted substitutes, which are subject to OMB and final agency review.

According to agency officials, EPA had analyzed about half of the 120 responses as of November 1992; it has listed about 50 different alternatives as "acceptable" and about 10 different alternatives as "unacceptable." The remaining 60 or so responses are still being analyzed. EPA determined that voluntary data submissions did not contain sufficient information to characterize the risks or the availability of particular alternatives in about six cases. For example, one solvent producer provided the ingredients and toxicity of its substitute mixture but failed to provide the mixture's specific formulation, i.e., the percentages of each ingredient in the mixture. Agency officials said that they would not approve a substitute without first analyzing its specific formulation. In another case, the producer filed adequate information on toxicity and formulation but neglected to include estimates of exposure to humans and the environment. Agency analysts noted that risks to humans and the environment cannot be estimated without good information on how they will be exposed to the substitute. According to EPA's advance notice of proposed rulemaking, any substitute not reviewed before the promulgation of the final rules implementing the SNAP program, will have to be reviewed under the program once it becomes effective.

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The information contained in this letter was obtained through interviews with EPA officials in the Stratospheric Ozone Branch of the Global Change Division. In addition, we examined a number of documents from EPA, including agency risk assessment guidance and specific risk assessments, studies on ozone depletion, and agency plans and proposed rules for implementing section 612.

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We discussed the facts contained in this correspondence with EPA officials, including the chief of the stratospheric ozone branch. The agency generally agreed with our presentation of the facts, although we clarified some language on the basis of EPA's comments. As requested, however, we did not obtain written agency comments.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this correspondence until 30 days from the date of this letter. At that time we will send copies to the Administrator of EPA.

We hope that this information will assist you in your continuing effort to ensure that CFC substitutes are available and environmentally safe. If you have any further questions about this matter, please contact me on (202) 275-6111 or William McGee, Assistant Director for Air Quality Issues, on (919) 829-3500.

Sincerely yours,



Richard L. Hembra
Director, Environmental
Protection Issues

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