FINAL ENVIRONMENTAL IMPACT STATEMENT

FLUOROCARBONS: ENVIRONMENTAL AND HEALTH IMPLICATIONS

Prepared in Accordance with Section 102(2)(C) of P.L. 91-190

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FOREWORD

The National Environmental Policy Act of 1969 provides that all agencies of the Federal Government must take environmental considerations into account in their planning and decisionmaking. To that end, it requires that an Environmental Impact Statement (EIS) be prepared for all "major Federal actions significantly affecting the quality of the human environment."

On September 13, 1976, the National Academy of Sciences issued a report which confirmed the risk to the stratosphere of continued chlorofluorocarbon release. The Academy concluded that "selective regulation of CFM (chlorofluoromethane) uses and releases is almost certain to be necessary at some time and to some degree of completeness," but recommended a delay in the decision to regulate of up to two years to reduce the scientific uncertainties.

In evaluating the Academy report and in considering the proper course of action, the Commissioner of Food and Drugs recognized that there are remaining uncertainties and that further studies to reduce the uncertainties would be beneficial. It was his conclusion, however, that the available information indicated an unreasonable risk of long-term biological and climatic impacts and delay to improve estimates was not warranted in view of the risks and the negligible benefit from nonessential uses that primarily serve as conveniences.

Accordingly, on October 12, 1976, the Commissioner sent a letter to the Council on Environmental Quality (CEQ) with copies to the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), the other regulatory agencies, in which he stated his intention to initiate a phaseout of the use of chlorofluorocarbons in products subject to the Federal Food, Drug, and Cosmetic Act. The Commissioner suggested that CEQ coordinate Federal regulatory activity and that CEQ designate EPA as lead agency to supervise the preparation of the environmental impact statement. As a result, CEQ held meetings with the regulatory agencies. All agencies agreed to cooperate in developing the statement with EPA taking the lead in coordinating the preparation of the necessary material. Based on the information, EPA has prepared a problem statement to support its proposed rule, but EPA has not prepared a separate environmental impact statement. FDA used the same information base, and with some revisions, summarization, and supplementation, prepared this draft FDA environmental impact statement. The preparation of this impact statement, therefore, reflects the joint effort by the three regulatory agencies in dealing with a problem where there are interrelated and overlapping responsibilities.

The impact statement considers the environmental impact of fluorocarbons from the perspective that continued release is a global problem. Specifically, the document (1) examines the U.S. contribution to the problem,

(2) evaluates the relative risks of the different types of fluorocarbons, (3) considers regulatory options for reducing and mitigating environmental impacts.

For purposes of review, the impact statement is divided into three parts. The first part (sections 1 and 2) provide history and other background information. The second part (section 3) examines the environmental and health effects resulting from fluorocarbon release. The third part (sections 4, 5, and 6) considers the regulatory alternatives, describes a preferred alternative, and summarizes the environmental effects of the preferred alternative. The reviewer that is not inclined to read the detailed and somewhat technical information presented in section 3 may proceed directly to section 4, which summarizes the effects of the no action alternative and presents regulatory options for reducing the magnitude of the problem. To facilitate the review, we have referenced in section 4 the appropriate parts of section 3 to which the reader may refer for additional information and clarification.

SUMMARY SHEET

I. Draft ( ) Final (X)

II. Administrative (X) Legislative ( )

III. Responsible Federal Agency: Food and Drug Administration; information regarding the action or final environmental impact statement may be obtained from Dr. David Klauder, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4500.

IV. Description of Action

The Commissioner of Food and Drugs has concluded that the continued use of chlorofluorocarbon propellants in self-pressurized containers in products subject to the Federal Food, Drug, and Cosmetic Act (FFD&C) poses an unreasonable risk of long-term biological and climatic impacts.

Accordingly, the Food and Drug Administration is finalizing a prohibition of the nonessential use of chlorofluorocarbons as propellants in self-pressurized (aerosolized) containers in products subject to the FFD&C Act. The products to which the regulation applies are human food, food additives, human drugs, including biological products, animal food, animal drugs, cosmetics, and medical devices.

V. Environmental Impact of Action

A. Beneficial Impacts (Impact 2 provides the major basis for issuing the rule. The remaining potential impacts listed have been taken into account in assessing regulatory action.)

1. Reduce currently predicted steady state ozone depletion levels and resultant increase in DUV (damaging ultraviolet radiation) reaching the Earth;

2. reduce the peak number of new cases of nonmelanoma and probably melanoma skin cancer that would be expected to occur at currently predicted ozone depletion levels;

3. reduce potential for other health effects of increased exposure to DUV radiation, e.g., premature skin aging, increased incidence of sunburn, eye damage;

4. reduce potential for adverse nonhuman biological impacts and possible climatic changes;

5. reduce the hazard of intentional inhalation to the extent that chlorofluorocarbon propellants will be replaced by non-propellant packaging or by less toxic, non-hallucinogenic propellants;

6. possibly reduce other aerosol product-related injuries--explosion, cuts, etc.--to the extent that aerosol products using chlorofluorocarbon propellants are replaced by non-propellant packaging;

7. reduce energy consumption and solid waste volume to the extent that chlorofluorocarbon-containing self-pressurized products are replaced by non-propellant packaging.

B. Adverse Environmental Impacts

There are no anticipated adverse environmental impacts that cannot be avoided when the action is implemented.

VI. Regulatory Alternatives to the Action

A. No Action

B. Ban aerosol propellant uses of chlorofluorocarbons-11 and -12.

C. Ban aerosol propellant uses of all fluorocarbons, e.g., chlorofluorocarbons, hydrofluorocarbons, fluorocarbons containing other halogens, etc.

D. Ban all uses of chlorofluorocarbons, e.g., aerosol propellants, solvents, refrigerants, blowing agents, etc.

E. Require label warning on aerosol products containing chlorofluorocarbon propellants.

VII. Comments on the Draft Environmental Impact Statement were solicited from all interested persons, including the following Federal, State, and local agencies, organizations, and individuals.

A. Consumer and Environmental Groups

National Consumers League
Conference of Consumer Organizations
Consumer Federation of America
National Consumers Congress
American Council on Consumer Interests
Consumer Union of the U.S., Inc.
Consumer Action for Pure Food and Drugs
Health Research Group
League of Women Voters
League of Conservation Voters
Center for the Study on Responsive Law
Environmental Defense Fund, Inc.
Friends of the Earth
Environmental Action Foundation
National Resources Council of America

Sierra Club
Environmental Action, Inc.
Scientists Institute for Public Information
Environmental Law Institute
Center for Science in the Public Interest
Izaak Walton League of America
National Audubon Society
Resources for the Future
National Wildlife Federation
Conservation Foundation
Natural Resources Defense Council
Environmental Action Coalition
Concern, Inc.
Wilderness Society
Environmental Lobby, Inc.
*Action

B. Industry Groups and Associations

Allied Chemical Corp.
*E. I. DuPont de Nemours and Company
Kaiser Aluminum and Chemical Corp.
*Pennwalt Corp.
Racon Inc.
Union Carbide
Chemical Specialties Manufacturers Association
Cosmetic, Toiletry, and Fragrance Association
Manufacturing Chemists Association
Arthur D. Little, Incorporated
Midwest Research Institute

C. Professional and Research Organizations

National Solid Waste Management Association
American Chemical Society
*National Academy of Sciences
National Science Foundation
Smithsonian Institution
American Geophysical Union

D. Federal Agencies

*Central Intelligence Agency
Consumer Product Safety Commission
Department of Agriculture
Department of Commerce
Department of Defense
*Department of Energy (ERDA)
*Department of Housing and Urban Development
*Department of the Interior
*Department of Labor

*Department of State
Department of Transportation
Department of Treasury
Environmental Protection Agency
*Federal Communications Commission
Federal Energy Administration
*National Aeronautics and Space Administration
*Nuclear Regulatory Commission

E. State Agencies

*South Carolina Department of Health and Environmental Control
State Agriculture Officials
State Cosmetic Program Directors
State Food Program Officials
State Health Officials
*State of New Mexico Health and Social Services Dept.

F. Individuals

Honorable Dale Bumpers
Chairman, Ad Hoc Subcommittee on
the Upper Atmosphere
Committee on Aeronautical and
Space Sciences
United States Senate

Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
and Scientific Research
Committee on Human Resources
United States Senate (Attn: David Blumenthal)

Honorable James L. Whitten
Chairman, Subcommittee on Agriculture
and Related Agencies
Committee on Appropriations
House of Representatives (Attn: Chip Harden)

Honorable Robert Dole
Ranking Minority
Committee on Agriculture
and Forestry
United States Senate

Honorable John E. Moss
Chairman, Subcommittee on Oversight
and Investigations
Committee on Interstate and
Foreign Commerce
House of Representatives

Honorable Thomas H. Eagleton
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Committee on Appropriations
United States Senate

Honorable Richard S. Schweiker
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Honorable Tim Lee Carter
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House of Representatives

Honorable Paul G. Rogers
Chairman, Subcommittee on Health
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House of Representatives

Honorable L. H. Fountain
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources
Committee on Government Operations
House of Representatives

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*Commented on the draft environmental impact statement. Comments appear in Appendix C.

This final environmental impact statement was made available to the Office of Federal Activities, Environmental Protection Agency in February 1978.

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SECTION 1. BACKGROUND INFORMATION

In June 1974, Molina and Rowland presented the results of studies which indicated that chlorofluoromethanes[1/] could harm the ozone layer (1). These workers postulated that these chemicals, which are very stable in the lower atmosphere, diffuse very slowly upward into the stratosphere where they undergo photochemical decomposition liberating free chlorine radicals. The chlorine radicals could then act to reduce ozone by means of catalytic chain reactions.

The ozone shield is of great importance in protecting life on earth from shortwave ultraviolet rays of the sun. A reduction of this shield would result in an increase in the amount of damaging, biologically active, ultraviolet light reaching the earth. The consequences of increased ultraviolet radiation might include an increase in human skin cancer and other deleterious effects on man, other animals, and plants. These effects might occur at the cellular, organism, and ecosystem level.

Human activities which could affect stratospheric ozone became a major topic of environmental concern in the early 1970's with the finding that nitrogen oxides emitted from high-flying aircraft, particularly the Supersonic Transport (SST), also catalytically destroy ozone. The Climatic Impact Assessment Program (CIAP) of the Department of Transportation was formed in 1971 to study this problem and their report of December 1974 (2), together with a similar study conducted by the Climatic Impact Committee of the National Academy of Sciences (3), provide a substantial background for the more recent investigations into the stratospheric ozone effects of the chlorofluorocarbons.

On November 24, 1974, the Consumer Product Safety Commission (CPSC) received a petition from the Natural Resources Defense Council (NRDC) requesting a ban on all aerosol products containing certain fluorocarbon compounds.

In December 1974, the FDA contacted the Council on Environmental Quality and requested that they designate a lead agency to coordinate the

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1/ Chlorofluoromethanes (CFMs) refer to chlorofluorocarbons-11 and -12. In this statement the term "chlorofluorocarbons" means fully halogenated chlorofluoroalkanes. These compounds contain only chlorine, fluorine and carbon, and no carbon-carbon double bonds. The term "fluorocarbons" in this document will be used to describe the broad general class of compounds containing at least fluorine and carbon. The different types of fluorocarbons appear to vary in the risk they pose of depleting stratospheric ozone. Therefore, reference to specific compounds will be by the more descriptive chemical terms, such as chlorofluorocarbons, rather than the general term "fluorocarbon."

preparation of an environmental impact statement should regulatory action to restrict the use of chlorofluorocarbons be necessary. A lead agency was not established at that time; however, to assure a unified response by the Federal Government to this hazard, in January 1975, the Council on Environmental Quality and the Federal Council on Science and Technology formed an Interagency Task Force on the Inadvertent Modification of the Stratosphere (IMOS).

The initial report of the Task Force, issued in June 1975 (4), concluded that "fluorocarbon releases to the environment are a legitimate cause for concern. Moreover, unless new scientific evidence is found to remove the cause for concern, it would seem necessary to restrict uses of (chloro)fluorocarbons-11 and -12 to replacement of fluids in existing refrigeration and air-conditioning equipment and to closed recycled systems or other uses not involving release to the atmosphere."

The IMOS report also referred to a National Academy of Sciences' study of man-made impacts on the stratosphere, initiated in March 1975, and concluded that if the National Academy of Sciences confirms the current Task Force assessment, "it is recommended that the Federal regulatory agencies initiate rulemaking procedures for implementing regulations to restrict fluorocarbon uses. Such restrictions could reasonably be effective by January 1978 - a date that, given the concern expressed now, should allow time for consideration of further research results and for the affected industries and consumers to initiate adjustments."

Following issuance of the Task Force report, the Food and Drug Administration published a notice in the FEDERAL REGISTER of July 16, 1975, (40 FR 29914) which called for information on foods, drugs, and cosmetics containing chlorofluorocarbon-11, chlorofluorocarbon-12, and other fluorocarbon propellants. The purposes of this request for information were to: (1) determine more precisely the extent of use of fluorocarbon propellants in products subject to FDA regulatory authority, (2) to obtain the documentation required by the National Environmental Policy Act of 1969 for any subsequent action the Agency may take, (3) to inform industry and the public that such action is under serious consideration.

Also in July 1975, the Natural Resources Defense Council petitioned the Commissioner of FDA to restrict the use of chlorofluorocarbons in self-pressurized (aerosolized) containers (5). The Commissioner denied the petition at that time, stating that it did "not provide a basis for taking immediate action prior to completion of the Academy's current study" (6).

In August 1975, the CPSC published in the FEDERAL REGISTER a Notice of Denial of the November 24, 1974, NRDC petition stating that it could not make a finding of unreasonable risk of injury since, "The information presently available is insufficient for the Commission to determine the

correctness of the hypothesis of ozone depletion by fluorocarbons in the stratosphere, the basic phenomenon from which any risk of death, personal injury, or serious or frequent illness to humans could follow."

On September 13, 1976, the NAS released two reports, one prepared by the Committee on Impacts of Stratospheric Change (7), and the second by the Committee's Panel on Atmospheric Chemistry (8). The Panel report considered the effects of chlorofluoromethanes (CFMs)[2/] on stratospheric ozone. The Committee report contained an assessment of the environmental effects of chlorofluorocarbon release. The NAS Committee found:

(1) Releases of chlorofluorocarbons result in stratospheric ozone reduction, thereby increasing the amount of biologically active ultraviolet radiation (uv) reaching the earth's surface.

(2) The effect of increased uv radiation could result in malignant melanoma, a serious form of skin cancer as well as the less serious but more prevalent nonmelanoma skin cancer. It could also have effects on plants and animals of unknown magnitude.

(3) Accumulation of chlorofluorocarbons in the atmosphere may retard heat loss from the earth and affect the earth's temperature and climate.

The NAS Committee concluded that "Selective regulation of CFM uses and releases is almost certain to be necessary at some time and to some degree of completeness," but added that the costs of a two-year delay in making a decision are small and will result in not more than a fraction of a percent change in ozone depletion. The Committee also concluded that "Measurement programs now underway promise to reduce the uncertainties quite considerably in the near future."

Regarding the need to take regulatory action, the NAS Committee recommended that (1) the decision to regulate be delayed for a year or two, pending the results of ongoing measurement programs which promise to reduce the inadequacies in the bases of present calculations, (2) following this delay, selective regulations for the uses and release of CFMs should be undertaken on the basis of ozone reduction, provided that ultimate ozone reductions of more than a few percentage points

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[2/] Chlorofluoromethanes (CFMs) in the NAS report refer only to chlorofluorocarbons-11 and -12. These terms are used interchangeably in this impact statement.

remain a major possibility, (3) legislation be enacted to require "labeling of all products containing CFMs and not intended to remain under seal during use. (Aerosol cans and refill containers for air-conditioners and refrigerators would then require labels; automobiles and refrigerators themselves would not.)", and (4) "as soon as appropriate legislative authority is in place as well as every three to five years thereafter, our current knowledge of the importance and the certainty and uncertainty of the direct climate effect be reviewed, so that appropriate decisions can be taken about the regulation of CFM uses and release on the basis of this effect."

The IMOS Task Force reviewed the NAS reports and commended the Academy for its "thorough scientific review of this complex study" (9). However, the Task Force did not suggest any delay in the initiation of regulatory action. Instead, the Task Force recommended that "Federal regulatory agencies now commence proposed rulemaking procedures, so that any necessary future restrictions are developed on the basis of thorough and thoughtful consideration." The Task Force viewed this course of action as "not inconsistent" with the conclusion of the NAS Committee.

In evaluating the Academy report and in considering the proper course of action, the regulatory agencies recognized that there are remaining uncertainties about the magnitude of ozone depletion resulting from CFM release and that further studies to reduce these uncertainties would be beneficial. It was the agencies' finding, however, that the available information indicated an unreasonable risk of long-term biological and climatic impacts and delay to improve the estimates was not warranted in view of the risks and the negligible benefit from nonessential uses that primarily serve as conveniences. Accordingly, on October 12, 1976, Russell Train, EPA Administrator, announced that the United States was initiating its regulatory process to phase out the nonessential uses of chlorofluorocarbons.

On the same day, FDA in a letter to Dr. Russell Peterson, Chairman of CEQ, indicated its intent to initiate the regulatory process leading to a phaseout of nonessential uses of chlorofluorocarbon propellants in food, drug, and cosmetic products. This FDA decision was announced to the public in a press release of October 15, 1976.

On October 18, 1976, EPA strongly urged producers, formulators, and registrants of pesticides to voluntarily utilize propellants other than chlorofluorocarbons-11 and -12 in registered pesticide products. In addition to this warning, EPA gave notice that:

(1) labeling would be required after April 15, 1977, for all pesticide products containing chlorofluorocarbons as aerosol propellants; and

(2) during the registration process, EPA would presume that the use of chlorofluorocarbons should be discontinued unless they could be shown to be essential to the safety and efficacy of the product.

In response to two additional petitions from NRDC and others, CPSC preliminarily found on November 22, 1976, that aerosol consumer products which use certain chlorofluorocarbon propellants present an unreasonable risk of injury to consumers from the destruction of ozone in the stratosphere and that no feasible consumer product safety standard would adequately protect the public. The Commission directed its staff to prepare a draft FEDERAL REGISTER notice under section 8 of the Consumer Product Safety Act proposing to declare such aerosol consumer products to be banned hazardous products. In reaching this decision, however, the Commission recognized the regulatory plans of the Environmental Protection Agency under the Toxic Substances Control Act to phase out the nonessential uses of chlorofluorocarbons as propellants in aerosols and stated that it would terminate its proceeding to the extent action by EPA rendered Commission action unnecessary.

On November 26, 1976, a notice was published in the FEDERAL REGISTER (10) indicating the intent of FDA to phase out within a reasonable time period all nonessential uses of at least the chlorofluorocarbons in products regulated by FDA. This included chlorofluorocarbon uses in foods, human drugs, animal drugs, biological products, cosmetics, and medical devices.

Also in the notice, the FDA asked for specific information to guide the Agency in this phaseout and to provide a data base on which to determine whether or not other compounds besides the chlorofluorocarbons (CFCs) should be regulated.

Specifically, information was requested on:

- Uses and amount of all specific halocarbons in FDA-regulated products for 1975;
- Essential uses of chlorofluorocarbons for which there are no substitutes, and essential uses of other halocarbons for which there are no substitutes;
- Projected uses and amounts of substitutes for chlorofluorocarbons including information on economic impacts, time necessary to make substitutions, energy requirements and consumption, and environmental impacts;
- Additional information on environmental effects of any halocarbons in FDA products.

Pending elimination of nonessential uses of chlorofluorocarbons, FDA has proposed (11) that a warning label statement be required on the container of nonessential aerosolized foods, OTC human drugs, animal drugs, non-restricted medical devices, and cosmetics that contain chlorofluoro-carbons.

The label will state - Warning: Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

On January 6, 1977, the CPSC also stated an intention to issue a regulation under section 27(e) of the Consumer Product Safety Act requiring manufacturers of such products to (1) notify the Commission of the consumer products containing these propellants, (2) notify consumers at the point of purchase, by labeling, of the chlorofluorocarbon propellant contained in the product, and (3) include a warning statement on chlorofluorocarbon-containing aerosol consumer products identical to the one proposed by the FDA.

In addition to the proposed Federal regulatory actions, at least 29 states have given consideration to some form of fluorocarbon legislation, i.e. ban, warning label requirements, proposals requesting Federal action. However, Oregon and Minnesota are the only states with laws which ban the sale of aerosols propelled by chlorofluorocarbons.

Until recently, Canada was the only country besides the United States to indicate its intent to restrict the use of chlorofluorocarbons. In a press release of December 15, 1976, it was announced that regulations would be developed requiring the elimination of all nonessential use of chlorofluorocarbons-11 and -12 in aerosol products during 1978. Canadian industry has agreed to reduce by one-half the use of these fluorocarbons by the end of 1977. In January 1978, Sweden enacted legislation to ban chlorofluorocarbons for use as aerosol propellants, effective June 30, 1979. Norway has indicated that they may take a similar action. The Netherlands has proposed a labeling requirement for chlorofluorocarbon-propelled aerosol products.

SECTION 2. NATURE OF FLUOROCARBON USE AND RELEASE

2.1. History of Fluorocarbons

Fluorocarbons were invented in the early 1930's by workers at the General Motors Research Laboratory. It was found that these compounds could be readily liquefied and, hence, they became a prime replacement material for the previously used refrigerants, which had serious drawbacks, e.g., ethylene was flammable, sulfur dioxide was toxic and corrosive, and ammonia possessed all three of these drawbacks. Additionally, fluorocarbons had the characteristics of nonflammability, low toxicity, and low chemical reactivity.

The aerosol industry arose after World War II when researchers at the U.S. Department of Agriculture found that the dispersal of insecticides by pressurized refrigerants greatly increased the effectiveness of the chemical through the formation of a fine aerosol dispersion in air. Following the development of low pressure valves in the 1950's, a mixture of chlorofluorocarbons-11 and -12 became the standard propellant for aerosol products.

Listed in table 1 are the major one and two carbon saturated fluorocarbons.

2.2. Physical and Chemical Properties

In general, the fluorocarbons are clear, highly volatile liquids which are nonflammable, have a high vapor pressure, low boiling point, high density, and low surface tension. In addition, most fluorocarbons are nonpolar liquids and are therefore poor solvents in highly polar substances such as water. Also, these compounds have low rates of hydrolysis, usually too low to determine when water alone is used.

The degree of fluorine substitution affects the physical properties. Generally, as the number of fluorine atoms replacing chlorine atoms in the molecule increases, the vapor pressure goes up, while the boiling point, density and the solubility decrease. Bromine atoms tend to increase the density and lower the vapor pressure.

The major commercial applications of the fluorocarbons, as refrigerants and aerosol propellants, are based on their chemical stability rather than their reactivity. This stability is due largely to the strength of the C-F bond and the increase in the C-Cl bond energy associated with increased fluorine substitution. Although they are often referred to as "inert," the fluorocarbons, like other halogenated organic compounds, may react violently with highly reactive materials and should not be exposed to alkali or alkaline earth metals (sodium, potassium, barium, etc.).

The physical characteristics of some of the more common fluorocarbons are presented in tables 2 and 3.

Table 1. Fluorocarbon Numbers and Molecular Formulae of the Major One and Two Carbon Saturated Fluorocarbons

Fluorocarbon Number*	Chemical Name	Molecular Formula
F-11	Trichlorofluoromethane	CCl_3F
F-12	Dichlorodifluoromethane	CCl_2F_2
F-13	Chlorotrifluoromethane	$CClF_3$
F-14	Tetrafluoromethane	CF_4
F-21	Dichlorofluoromethane	$CHCl_2F$
F-22	Chlorodifluoromethane	$CHClF_2$
F-23	Trifluoromethane	CHF_3
F-113	Trichlorotrifluoroethane	$CCl_2F\text{-}CClF_2$
F-114	Dichlorotetrafluoroethane	$CClF_2\text{-}CClF_2$
F-115	Chloropentafluoroethane	$CClF_2\text{-}CF_3$
F-142b	Chlorodifluoroethane	$CClF_2\text{-}CH_3$
F-152a	Difluoroethane	CHF_2CH_3
F-13B1	Bromotrifluoromethane	$CBrF_3$
(Halothane)	Bromochlorotrifluoroethane	$CBrClH\text{-}CF_3$

*The numbering system for fluorocarbons is one used by U.S. industry and indicates the number of each type of atom in the compound. This numerical system consists of a four-digit number, ABCD, where D is the number of fluorine atoms in the molecule, C is the number of hydrogen atoms in the molecule plus 1, B is the number of carbon atoms minus 1, and A equals the number of double bonds in the molecule. Whenever A or A and B are zero, the digits are omitted from the number as in F-11 (CCl_3F). When bromine is substituted for chlorine, a B plus the number of bromine atoms follows the number of fluorine atoms (e.g., $CClF_3$ is 13 whereas $CBrF_3$ is 13B1). The fluorocarbon numbers are often preceded by the letter "F" or, in the refrigeration industry, "R."

Table 2. Physical Properties of Selected Fluorocarbons: Methane Series (After Shepherd, 1961)

Property	F-11	F-12	F-21	F-22	F-30
Chemical formula	CCl_3F	CCl_2F_2	$CHCl_2F$	$CHClF_2$	CH_2Cl_2
Molecular weight	137.4	120.9	102.9	86.5	84.9
Boiling point, ^oF	74.8	-21.6	48.1	-41.4	105.2
Freezing point, ^oF	-168	-252	-211	-256	-142
Vapor pressure, psig					
At 70^oF	[1]13.4	70.2	8.4	122.5	[1]7.1
At 130^oF	24.3	181.0	50.5	300	9.0
Liquid density, g/cm$_3$					
At 70^oF	1.485	1.325	1.323	1.209	1.325
At 130^oF	1.403	1.191	1.193	1.064	--
Vapor density at boiling point, g/l	5.86	6.26	4.57	4.83	3.30
Heat of vaporization at boiling point, Btu/lb	78.31	71.94	104.2	100.7	141.7
Liquid viscosity, centipoise					
At 70^oF	0.439	0.262	0.351	0.238	[2]0.441
At 130^oF	0.336	0.227	0.286	0.211	--
Liquid thermal conductivity at 70^oF, (Btu)(ft)/(ft$_2$)(hr)(^oF)	0.063	0.051	0.072	0.063	[2]0.059
Surface tension at 77^oF, dynes/cm	19	9	19	9	[2]28
Solubility of water at 70^oF, wt%	0.009	0.008	0.13	0.12	[3]0.17
Flammable limits, vol % in air	None	None	None	None	None
Toxicity: Underwriters' Laboratories, Inc. rating system	5A	6	[4](5)	5A	4-5

[1]In pounds per square inch absolute
[2]At 68^oF
[3]At 77^oF
[4]Much less than 4, slightly more than 5

Source: IMOS Task Force Report (4).

Table 3. Physical Properties of Selected Fluorocarbons: Ethane Series (After Shepherd, 1961)

Property	F-114	F-114a	F-142b	F-152a	F-160
Chemical formula ...	$CClF_2CClF_2$	CCl_2FCF_3	CH_3CClF_2	CH_3CHF_2	CH_3CH_2Cl
Molecular weight ...	170.9	170.9	100.5	66.1	64.5
Boiling point, ^oF...	38.4	37.8	15.1	-11.2	12.2
Freezing point, ^oF .	-137	ca. -76	-204	-179	-139
Vapor pressure, psig					
At 70^oF	12.9	13.4	29.1	61.7	5.0
At 130^oF	58.8	60.6	97.2	176	41.3
Liquid density, g/cm_3					
At 70^oF	1.468	1.478	1.119	0.911	0.920
At 130^oF	1.360	1.371	1.028	0.813	--
Heat of vaporization at boiling point, Btu/lb	59.0	58.2	96.0	141	--
Liquid viscosity, centipoise					
At 70^oF	0.386	0.463	0.330	0.243	--
At 130^oF	0.296	0.347	0.250	0.186	--
Solubility of water at 70^oF, wt %	0.008	0.006	0.054	0.17	--
Flammability limit, vol % in air	Nonflam-mable	Nonflam-mable	9.0 to 14.8	5.1 to 19.1	3.7 to 12.0
Toxicity: Underwriters' Laboratories, Inc. rating system	6	1_6	1_{5A}	1_6	4

[1]Probable

Source: IMOS Task Force Report (4).

2.3. Methods of Manufacture

The most commonly used method for the manufacture of fluorocarbons is the replacement of the chlorine atoms on carbon tetrachloride by fluorine using anhydrous hydrogen fluoride with partially fluorinated antimony pentachloride as a catalyst. The degree of fluorination can be varied by changing the temperature, pressure and fluorine concentration. Methods of continuous operation with automatic controls have been developed and the reaction can be conducted in either liquid or vapor phases. A more recent process developed by DuPont in the U.S. and Montecatini Edison in Italy uses the direct reaction of methane with a mixture of chlorine and hydrogen fluoride.

2.4. Uses

The major uses of fluorocarbon compounds are as aerosol propellants, refrigerants, and foaming agents. Certain of the fluorocarbons have major uses as solvents, as fire-extinguishing agents, or as intermediates in the production of fluorocarbon resins and plastics.

The largest commercial use of fluorocarbons is as propellants in aerosol products. Use as refrigerants is the next largest application of fluorocarbons and is the use for which the fluorocarbons were originally commercialized in the 1930's. The fluorocarbons are used for both refrigeration (localized low temperature cooling) and air-conditioning (cooling of rather large volumes of environmental air).

Foaming or blowing agents are used in the plastics industry to produce a finished product in a foamed or expanded form. The fluorocarbons were first used in the production of polyurethane foams, where they impart improved thermal insulation properties because of the fluorocarbon trapped in the cells of the finished product (closed-cell foams). Fluorocarbons are also used to form open-cell foams, in which case they are released to the air. Blowing-agent uses of the fluorocarbons are divided approximately equally between closed and open-cell applications.

Other uses of fluorocarbons include cleaning agents, intermediates in the production of fluorocarbon resins, dielectric fluids, heat-transfer fluids, power fluids, cutting fluids, pressurized leak-testing gases, gases in wind tunnels and bubble chambers, and food freezing agents.

2.5. Fluorocarbon Production Estimates

The two major fluorocarbons, in terms of quantities produced, are chlorofluorocarbons-11 and -12, which in 1973 accounted for about 86 percent of all fluorocarbons produced worldwide (table 4). The worldwide production histories for these two compounds are shown graphically in figures 1 and 2.

Table 4. World Fluorocarbon Production and Production Capacity-1973

Region	Estimated Capacity		Estimated production		Percent of total
	thousand metric tons	millions of pounds	thousand metric tons	millions of pounds	
United States	542	1,203	475	1,055	44
Europe	500	1,110	445	987	41
Japan	100	220	90	199	8
Other	80	177	70	155	7
Total	1,222	2,710	1,080	2,396	100
Fluorocarbon type					
F-11 and F-12	1,050	2,331	930	2,064[1/]	86
Other	172	381	150	333	14

Sources: Chemical Marketing Reporter, European Chemical News, Japan Chemical Week, private communication with industry, and Arthur D. Little, Inc., estimates.

[1/] Worldwide F-11 and F-12 emissions 700 metric tons (1550 million pounds) A. D. Little Report Table I-1.

Modified from A. D. Little Report Table II-4 (12).

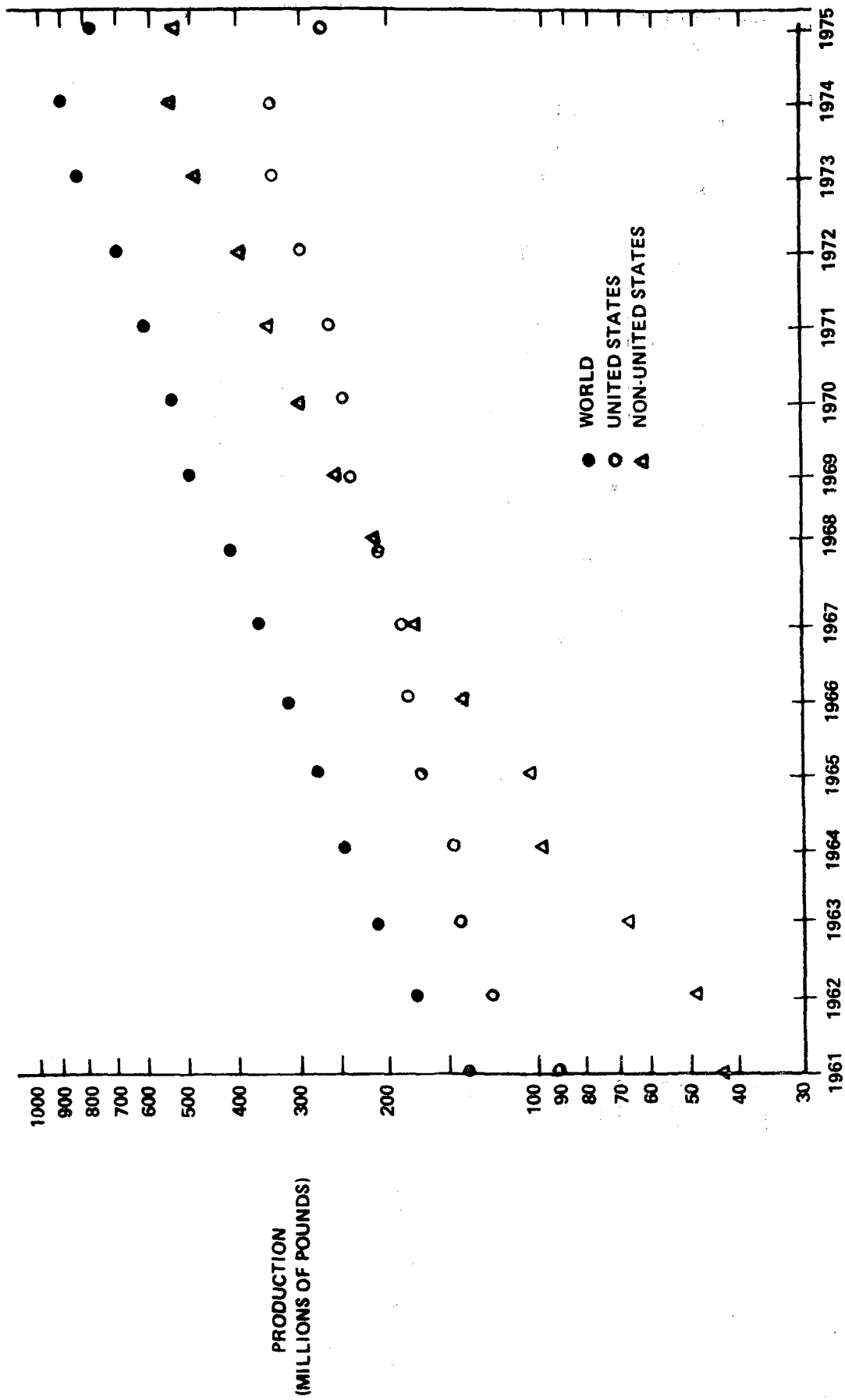


FIGURE 1: ANNUAL PRODUCTION OF F-11, 1961 - 1975

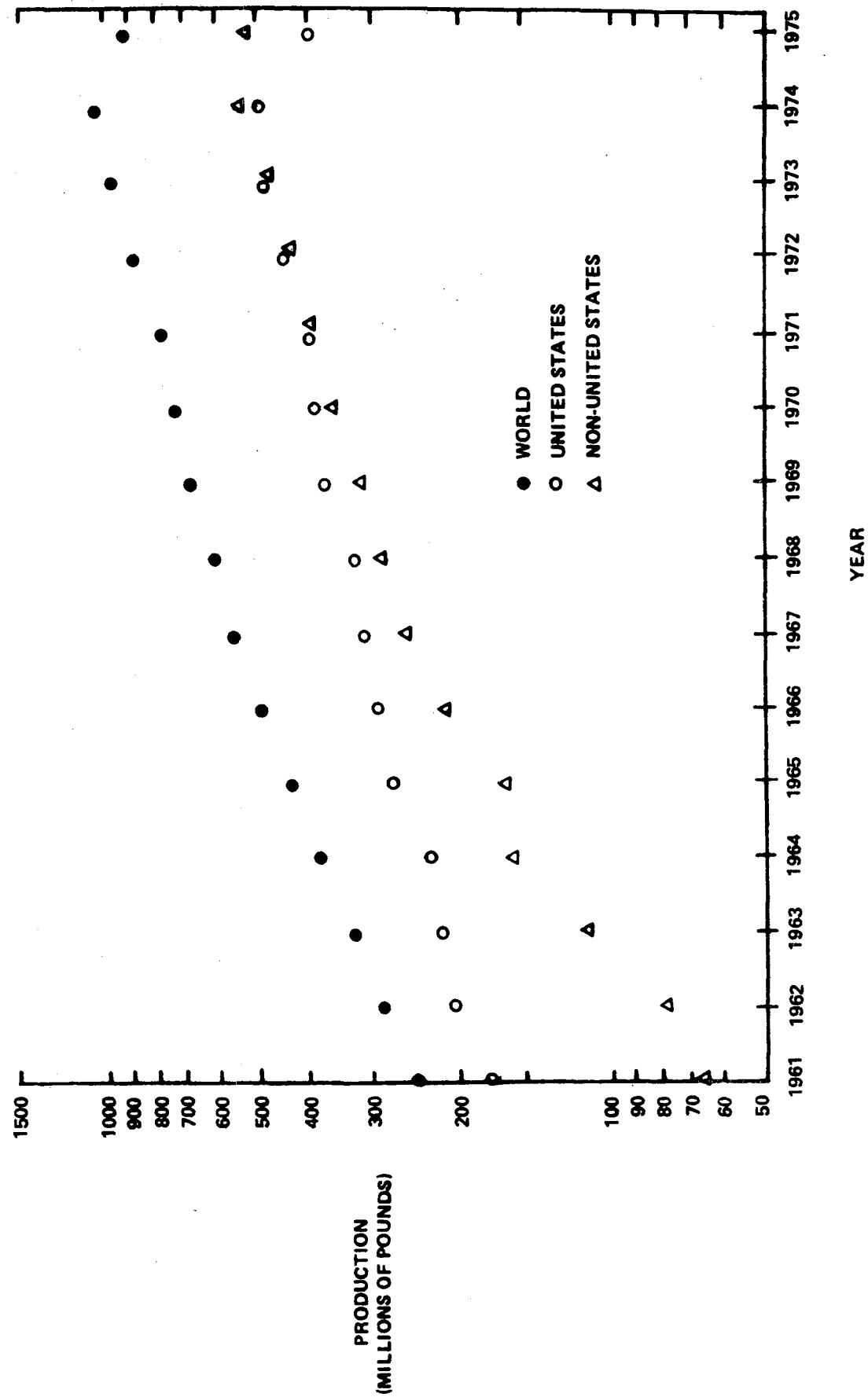


FIGURE 2 ANNUAL PRODUCTION OF F-12, 1961 - 1975

The data in figures 1 and 2 were computed for the Manufacturing Chemists Association (MCA) by Alexander Grant & Company (Certified Public Accountants) from data submitted by producing companies representing over 95 percent of total world production. The data include production estimates of these compounds for the Eastern Bloc countries, which were obtained from estimates given by three producers responding to the survey. This is the least certain component of the data; however, the Eastern Bloc estimate represents only about 4.5 percent of the totals (341 and 461 million pounds for chlorofluorocarbons-11 and -12, respectively). The United States production data in the figures are from the U.S. International Trade Commission (ITC).

Prior to the 1950's, virtually all of the world production of chlorofluorocarbons-11 and -12 occurred in the United States. Since the early to mid-1960's the production of these compounds has been growing at a significantly faster rate among non-United States producers (figures 1 and 2). Through 1975, the United States production has accounted for about 50 percent of worldwide chlorofluorocarbon-11 production and about 60 percent of worldwide chlorofluorocarbon-12 production. For more recent years, the United States has accounted for about 35 percent of worldwide chlorofluorocarbon-11 production and about 50 percent of worldwide chlorofluorocarbon-12 production. It should be noted that worldwide production of chlorofluorocarbon-11 and chlorofluorocarbon-12 declined by about 15 percent in 1975 relative to 1974 and that this decline occurred primarily in the United States (about 20 percent).

World production histories for fluorocarbons other than chlorofluorocarbons-11 and -12 are not available; however, the United States production data from 1960-1974 for chlorofluorocarbons-11, -12, -113, -114, and hydrochlorofluorocarbon-22 are presented in table 5.

2.6. Fluorocarbon Use and Release

In 1973, worldwide fluorocarbon emissions were estimated to be about 1,730 million pounds. Propellant emissions accounted for about 1,076 million pounds, refrigerants about 460 million pounds and other uses (solvents, foaming agents, etc.) about 200 million pounds. These data are presented in tables 6 and 7. The United States emissions were approximately half the worldwide total and Europe contributed an additional third to the total.

Aerosol propellants, solvents, and blowing agents for open-cell plastic foams are considered to be rapid emitters, i.e. there is a short time delay (usually taken as 6 months) between production and release of the material to the atmosphere. Refrigerants and blowing agents for closed-cell foams involve considerably longer time delays between production and release. It should be noted, however, that none of these uses of the chlorofluorocarbons results in decomposition and that eventually almost all of that which is produced reaches the atmosphere.

Table 5. United States Fluorocarbon Production Data
(millions of pounds)

Year	F-11	F-12	F-22	F-113	F-114	Others[a]	Total
1960	72	165	40	Sm.	10	Sm.[b]	> 287
1961	91	174	45	Sm.	Sm.	Sm.	> 310
1962	125	208	49	Sm.	11	Sm.	> 393
1963	140	217	54	Sm.	12	Sm.	> 423
1964	149	228	59	12	13	Sm.	> 461
1965	171	271	64	14	22	Sm.	> 542
1966	170	286	70	16	19	Sm.	> 561
1967	182	310	78	21	23	Sm.	> 614
1968	204	326	86	25	20	Sm.	> 661
1969	239	368	94	30	21	Sm.	> 752
1970	245	375	100	36	22	Sm.	> 778
1971	258	390	112	43	23	Sm.	> 826
1972	300	439	123	50	25	Sm.	> 937
1973[c]	334	489	136	59	26	12	1056
1974[c]	347	509	141	64	27	14	1102
1974 Percent of total	32	46	13	6	2	1	> 9700 / 100

[a]Includes F-13, F-14, F-21, F-115, F-116 and others.
[b]Sm. = less than 10 million pounds.
[c]One industry source believes production of F-11 and F-12 is overstated.

Sources: U.S. International Trade Commission and Arthur D. Little, Inc. estimates, based on industry contacts.

Source of Table: Arthur D. Little Report Table II-1 (12).

Table 6. World Emissions of Fluorocarbon Aerosol Propellants-1973
(units as indicated below)

Region	Estimated emissions		Percent of total
	(thousand metric tons)	(millions of pounds)	
United States	232	511	48
Europe	170	375	34
Other	86	190	18
Total	488	1076	100

Source: Arthur D. Little, Inc., estimates.

Table Source: Arthur D. Little Report Table III-6 (12).

Table 7. World Emissions of Fluorocarbon Refrigerants-1973
(units as indicated below)

Region	Estimated emissions		Percent of total
	(thousand metric tons)	(millions of pounds)	
United States	96	212	47
Europe	81	179	39
Other	30	66	14
Total	207	457	100

Source: Arthur D. Little, Inc. estimates.

Table Source: Arthur D. Little Report Table III-7 (12).

Table 8 presents estimated U.S. fluorocarbon production and emissions (by end use) for 1973. This table reveals the following facts.

- The release of chlorofluorocarbons-11 and -12 to the atmosphere was about 83 percent and 80 percent of that year's production values, respectively.
- Chlorofluorocarbons-11 and -12 accounted for over 80 percent of total fluorocarbon emissions.
- Hydrochlorofluorocarbon-22 accounted for 7 percent of total fluorocarbon emissions.
- Chlorofluorocarbons-113 and -114 and other nonspecific fluorocarbons accounted for about 11 percent of total fluorocarbon emissions.
- Aerosol propellants accounted for 62 percent of total U.S. fluorocarbon emissions.
- Refrigerants comprised about 26 percent of total U.S. fluorocarbon emissions; solvents about 6 percent and blowing agents about 5 percent.

Arthur D. Little, Inc. has estimated the 1973 U.S. aerosol propellant emissions of fluorocarbons by product type (table 9). This table presents the contribution of these various products to the U.S. aerosol propellant source of chlorofluorocarbons-11, -12, and -114. The data in the table show the following:

- Chlorofluorocarbons-11 and -12 comprise about 95 percent of fluorocarbon aerosol propellant emissions; the remaining percentage is contributed by chlorofluorocarbon-114.
- Hair care, antiperspirant and deodorant products contribute 75 percent of total fluorocarbon aerosol propellant emissions.
- Other personal products (medicinals, pharmaceuticals, colognes, shaving lathers) contribute an additional 8 percent of total fluorocarbon aerosol propellant emissions.
- 6 percent of fluorocarbon aerosol propellant emissions is from household products, i.e. room deodorants, cleaners, laundry products, waxes.

Table 8. Estimated U.S. Fluorocarbon Emissions-1973
(millions of pounds)

Fluorocarbon	Production transport and storage emissions		Annual emissions from use and disposal						
	Production (million lbs)	Emissions[a] (1 percent)	Propellant	Refrigerant	Solvent	Blowing agent	Plastic resin	Total[b]	Percent of total
F-11	334	3.3	236.9	11	sm.	29.3	-	280.5	34.0
F-12	489	4.9	249.4	130.5	-	7.5	-	392.3	47.6
F-22	136	1.4	sm.	59.5	-	-	sm.	60.9	7.4
F-113	59	0.6	-		50		sm.		
F-114	26	0.3	24.7	11	-	3.7	sm.	90.4	11.0
Other	12	0.1	sm.		-		-		
Total[b]	1056	10.6	511.0	212.0	50	40.5	sm.	824.1	-
Percent of total	--	1.3	62.0	25.7	6.1	4.9	--	--	100.0

'sm' = less than 5 million pounds; '-' = none or negligible.
[a]Emissions from production transport and storage are judged to be approximately 1 percent of total production.
[b]Does not include 'sm.'

Source: Arthur D. Little, Inc., estimates based on industry contacts.

Table Source: Arthur D. Little Report Table III-5 (12).

Table 9. Estimated U.S. Fluorocarbon Emissions as Aerosol Propellant[a] By Product Type-1973

Aerosol Type		Fluorocarbon propellant emission estimates (millions of pounds) F-11 emissions	F-12 emissions	F-114 emissions	Total F.C. emissions	Percent of total
Personal						
Hair care		103.0	72.0	3.4	178.4	35.0
Antiperspirants and deodorants	Subtotal	85.5 / 188.5	114.3 / 186.3	7.0 / 10.4	206.8 / 385.2	40.4 / 75.4
Medicinal and pharmaceutical		11.0	5.5	3.0	19.5	3.8
Colognes and perfumes		-	1.0	6.7	7.7	1.5
Shave lathers		-	0.4	0.6	1.0	0.2
Others		7.5	7.5	1.0	16.0	3.1
	Subtotal	18.5	14.4	11.3	44.2	8.6
Household						
Room deodorants		2.7	5.0	-	7.7	1.5
Cleaners		2.1	2.1	-	4.2	0.8
Laundry products		4.2	6.0	-	10.2	2.0
Waxes and polishes		1.5	2.5	-	4.0	0.8
Others		2.0	2.0	-	4.0	0.8
	Subtotal	12.5	17.6	0.0	30.1	5.9
All Other Products						
Insecticides		5.5	9.0	-	14.5	2.8
Coatings		3.4	6.6	-	10.0	2.0
Industrial		6.0	11.0	-	17.0	3.3
Foods and pan spray		-	-	3.0	3.0	0.6
Automotive		1.0	2.5	-	3.5	0.7
Vet. and pet		0.5	0.5	-	1.0	0.2
Others		1.0	1.5	-	2.5	0.5
	Subtotal	17.4	31.1	3.0	51.5	10.1
Total Emissions (millions of pounds)		236.9	249.4	24.7	511.0	100.0
Percent of F.C. Propellant Emissions		46.4	48.8	4.8	100.0	

[a]Use and filling emissions for products produced in 1973; emission lag averages 6 months for most products.

Sources: Chemical Specialties Manufacturers Association and Arthur D. Little, Inc. estimates based on industry contacts.

Modified from A. D. Little Report Table IV-2 (12).

- Other products such as pesticides, coatings, food and pan sprays contribute 10 percent of total fluorocarbon aerosol propellant emissions.

In summary, the major points regarding fluorocarbon emissions outlined above are presented as follows:

a. Worldwide fluorocarbon emissions for 1973 were estimated to be about 1730 million pounds.

b. Worldwide chlorofluorocarbon-11 and -12 emissions for 1973 were estimated to be about 1550 million pounds or 89 percent of total worldwide fluorocarbon emissions. (A. D. Little Report, table I-1)

c. U.S. fluorocarbon emissions (824 million pounds) in 1973 were estimated to be about 47 percent of worldwide release.

d. U.S. chlorofluorocarbon-11 and -12 emissions in 1973 were estimated to be 673 million pounds (43 percent of worldwide chlorofluorocarbon-11 and -12 emissions).

e. 62 percent (511 million pounds) of U.S. fluorocarbon emissions in 1973 was aerosol propellants.

f. In 1973, U.S. fluorocarbon aerosol propellants accounted for about 30 percent of worldwide fluorocarbon emissions. (95 percent of U.S. aerosol propellant emissions is chloro-fluorocarbons-11 and -12.)

g. U.S. chlorofluorocarbon-11 and -12 aerosol propellant use is about 486 million pounds (31 percent of worldwide chlorofluorocarbon-11 and -12 emissions).

h. In 1973, U.S. fluorocarbon aerosol propellant use in personal products contributed about 25 percent of worldwide fluorocarbon emissions.

i. In 1973, U.S. fluorocarbon aerosol propellant use in household products contributed less than 2 percent of worldwide fluorocarbon emissions.

j. In 1973, U.S. fluorocarbon aerosol propellant use in all other products comprised about 3 percent of worldwide fluorocarbon emissions.

k. In 1973, U.S. refrigerant uses contributed about 12 percent of worldwide fluorocarbon emissions; solvent uses about 3 percent; blowing agents about 2 percent.

2.7. Chlorofluorocarbons Produced for Aerosol Propellant Uses in 1977

The manufacturers of chlorofluorocarbons have recently reported a 40 percent drop in their sales of these compounds for propellant uses over the past three years. Therefore, 1977 emissions of chlorofluorocarbons resulting from their use as propellants in aerosol containers were closer to 300 million pounds as compared to the 511 million pounds reported for 1973 in Table 8. This reduction in the use of chlorofluorocarbon-propelled products is likely the result of (a) public concern for the potential adverse health and environmental effects resulting from chlorofluorocarbon releases and (b) an intensive industry-initiated advertising program during 1977 to promote alternate delivery systems.

For the purposes of this document, the estimates of potential effects have been based upon the assumption that chlorofluorocarbon release rates will remain constant at 1973 levels. Therefore, the fact that the use of chlorofluorocarbon propellants has declined by 40 percent since 1973 must be kept in mind when evaluating subsequent efforts to quantify the impacts of these compounds on stratospheric ozone (subsection 3.1) and on human health (subsection 3.3).

2.8. Production and Release of Other Chlorofluorocarbons

The production histories and commercial distribution of the other completely halogenated chlorofluorocarbons (F-13, F-111, F-112, F-112a, F-113a, F-114a, and F-115) are not known to the same degree of detail as those of chlorofluorocarbons-11, -12, -113, and -114. A discussion of the former chlorofluorocarbons along with additional information regarding chlorofluorocarbons-113 and -114 is presented below.

Chlorofluorocarbon-13 production, which has been estimated to be less than 0.5 million pounds/year worldwide for 1973-1975, is used as a refrigerant in low-temperature specialty applications using reciprocal compressors and in the low-temperature segment of cascade refrigeration units.

Chlorofluorocarbon-111 is apparently not produced in any significant quantities.

Chlorofluorocarbon-112 production is not known. It is used as a solvent, and the Midwest Research Institute estimated that the combined consumption of chlorofluorocarbons-11 and -112 for solvent uses in 1975 was 5.5-6.0 million pounds, which was primarily chlorofluorocarbon-11 (13).

Chlorofluorocarbon-113 is currently produced in the United States in quantities of about 50-60 million pounds/year; worldwide production is unknown. It is estimated that more than 99 percent of the chlorofluorocarbon-113 produced in the United States is used as a solvent, with the remainder used in refrigeration and foam-blowing applications. Chlorofluorocarbon-113a is apparently not produced for commercial use, though it may be present to some extent in commercial chlorofluorocarbon-113.

Chlorofluorocarbon-114 is currently produced in the United States in quantities of 25-30 million pounds/year; worldwide production is unknown. About 95 percent of the chlorofluorocarbon-114 produced in the United States is used as an aerosol propellant and after chlorofluorocarbons-11 and -12, it is the most commonly used fluorocarbon propellant. The remaining 5 percent of chlorofluorocarbon-114 production is used as a refrigerant, with possibly some minor use as a foam-blowing agent. Thus almost all of the chlorofluorocarbon-114 produced in the United States is released to the atmosphere within a short time after production and releases to date are probably only slightly less than cumulative production.

Chlorofluorocarbon-114a is apparently not produced for commercial use, though it may be present in commercial chlorofluorocarbon-114.

Chlorofluorocarbon-115 production is not known, but based on estimates in the Arthur D. Little report, it is less than 10 million pounds/year in the United States. The major use of chlorofluorocarbon-115 is as a refrigerant (~90 percent) and the remainder is used as an aerosol propellant. Chlorofluorocarbon-115 is approved by the FDA for use as a propellant and stabilizer in aerosol food products, and these products are, according to Midwest Research Institute (1975), the only propellant application of chlorofluorocarbon-115 (13).

2.9. Bromofluorocarbons and Bromochlorofluorocarbons

The only compounds in this group with current commercial significance are the fully halogenated bromofluorocarbon-13B1 and bromochlorofluorocarbon-12B1, both used primarily as fire-extinguishing agents, with some minor use of bromofluorocarbon-13B1 as a specialty refrigerant. Bromofluorocarbon-13B1 is used primarily in the United States and consumption for 1972 was estimated to have been 4 million pounds for fire-extinguishing purposes and 0.2 million pounds for refrigeration. Currently, bromochlorofluorocarbon-12B1 is used primarily in Europe.

SECTION 3. STATEMENT OF PROBLEM--EFFECTS OF FLUOROCARBON RELEASE

3.1. Impact on Stratospheric Ozone

3.1.1. Impacts Resulting from Chlorofluoromethane Release

3.1.1.1. Introduction

The stratosphere is the region of the atmosphere that extends from about 16-50 kilometers above the earth's surface at low latitudes and from 8-50 kilometers at high latitudes. In contrast to the troposphere where there is turbulence and rapid mixing, the stratosphere is relatively quiescent. As a consequence it is particularly susceptible to contamination because pollutants introduced there tend to remain for long periods--several years or more. Ozone (O_3) is present in the stratosphere in very small amounts (a few parts per million). Though it exists throughout the atmosphere, ozone is concentrated primarily in the stratosphere where, even in its very small concentration, it results in effective shielding of the earth's surface from harmful solar ultraviolet radiation.

The amount of ozone present in the stratosphere is maintained in a dynamic equilibrium by natural processes through which it is continually being formed and destroyed. Ozone formation occurs through a photochemical process wherein molecular oxygen (O_2) is dissociated by high energy ultraviolet radiation into oxygen atoms (O). These oxygen atoms then react with other O_2 molecules in the presence of another molecule (M) which stabilizes the ozone formed by removing its excess energy.

Ozone can be destroyed by absorbing ultraviolet radiation to yield the molecular oxygen and atomic oxygen species. It is the absorption of ultraviolet radiation by ozone in this process which "shields" the earth, and in addition, converts the solar energy to heat, producing a characteristic temperature profile of the stratosphere. This process is not a true destruction mechanism since the products formed can rapidly recombine to produce ozone again. The important natural destruction mechanisms for stratospheric ozone are catalytic chemical reactions involving nitrogen oxides and hydrogen-containing species, a reaction between ozone and oxygen atoms, and physical transport of ozone to the troposphere. Of these, the nitrogen oxide reaction is the most important, accounting for about 50-60 percent of the ozone destruction rate, and proceeds as:

$$NO_2 + O \longrightarrow NO + O_2$$

$$NO + O_3 \rightarrow NO_2 + O_2$$

$$\text{Net} \quad O + O_3 \longrightarrow O_2 + O_2$$

This sequence is catalytic since the nitrogen oxide species (collectively referred to as NO_x) are not consumed in the process and can affect the cycle many times over. The nitrogen oxide species enter the stratosphere primarily by bacterial production of N_2O at the earth's surface which is slowly transported upward to the stratosphere where it is oxidized to NO_x (about 1 percent of the time). The similar catalytic cycle involving the hydrogen-containing species HO_2 and OH accounts for about 10 percent of the ozone destruction rate; the reaction between O_3 and O, and transport combined account for about 20 percent of the destruction rate.

Although the concentration of ozone in the stratosphere varies, both regularly and irregularly, with time of day, season of the year, latitude, and with the eleven-year sunspot cycle, it is nevertheless held in relative equilibrium by these counterbalancing processes of formation and destruction. The Climatic Impact Assessment Program (CIAP) of the Department of Transportation focused on the possible effects of upsetting this balancing process toward an increased rate of destruction by the introduction of an additional ozone destroying NO_x catalyst into the stratosphere from the exhaust of high-flying aircraft. While investigating this problem, it was recognized that chlorine species were also capable of destroying ozone catalytically by the following chain:

$$Cl + O_3 \longrightarrow ClO + O_2$$

$$ClO + O \longrightarrow Cl + O_2$$

$$\text{Net} \quad O_3 + O \longrightarrow O_2 + O_2$$

This ClO_x (chlorine oxide species) cycle repeats with the chlorine that is regenerated, and ozone destruction continues until the chlorine species react with other substances in the stratosphere to produce temporary reservoirs such as hydrogen chloride and chlorine nitrate ($ClONO_2$). These reservoirs can either release the chlorine to enter the ClO_x cycle again, or they can be transported out of the stratosphere to terminate the cycle.

At first, this "ClO_x" cycle was not considered to be important, at least as a natural ozone sink, because no natural source of stratospheric chlorine was identified, nor had any chlorine species been detected in the stratosphere. Though such natural sources, particularly methyl chloride produced in oceans, are now believed to account for a small, yet still uncertain percent of the ozone destruction rate, it is the artificial, man-made sources introducing the ClO_x catalyst to the stratosphere in addition to that from any natural sources (and over and above the other natural catalysts, NO_x and HO_x, as well) that has been the focus of concern.

3.1.1.2. Rowland-Molina Theory

In June 1974, Drs. F. S. Rowland and M. J. Molina presented a theory proposing that the two widely used chlorofluorocarbons-11 and -12, posed a serious threat to the integrity of the earth's protective stratospheric ozone (1). The fundamental concepts of the theory are these:

Man-made chlorofluorocarbons-11 and -12 are released to the atmosphere in large quantities each year as a direct or eventual consequence of their commercial applications as aerosol propellants, refrigerants, foam-blowing agents, solvents, and miscellaneous others. Because of their chemical inertness, low water solubility, and volatility, these compounds remain in the atmosphere for a long time. In the turbulent troposophere (the portion of the atmosphere extending from the ground to about 8-16 kilometers altitude--higher at low latitudes; lower at high latitudes), they accumulate and become widely dispersed. Chlorofluorocarbons-11 and -12 are slowly transported upward by atmospheric motions across the tropopause, the boundary between the troposphere and the stratosphere, and on into the stratosphere where they reach the portion of the stratosphere where the short wavelength solar ultraviolet radiation (which does not penetrate to the troposphere) photolyzes them, resulting in release of chlorine atoms. These chlorine atoms then react with the ozone (O_3) present in the stratosphere in a catalytic cycle whereby they convert ozone to molecular oxygen (O_2). The chlorine atoms are regenerated in the process, making them available to affect this sequence many times before they are removed by being transported back down to the troposphere. The predicted consequence of this sequence of events is that the amount of stratospheric ozone will eventually be reduced by some significant amount, with attendant effects on human health and the environment, as discussed elsewhere in this document.

3.1.1.3. Magnitude of Ozone Depletion

Placing a numerical value on the amount of ozone reduction to be expected from past and future releases of chlorofluorocarbons, or any other chlorine source, requires that the several key features of the problem be considered in numerical terms. These include the rate of release of the compounds to the atmosphere, the rate at which they, and other important species, are transported by atmospheric motions, the amount of the compound reaching the stratosphere (a function of both transport and the rate of processes leading to their destruction before they can reach the stratosphere), the various photochemical and chemical processes by which chlorine atoms are produced in the stratosphere, interact with ozone through the ClO_x cycle, and are ultimately removed from the ClO_x cycle, and the numerous related photochemical and chemical processes which influence stratospheric ozone and other important stratospheric species.

To accomplish this, models are used which reduce many of the complex processes of the real atmosphere to a set of mathematical equations incorporating the above factors. Such models were used in the CIAP studies on NO_x emissions, and have been relied on extensively for assessing the stratospheric ozone impact of chlorofluorocarbons-11 and -12.

At the foundation of predicting the extent of ozone depletion resulting from chlorofluorocarbons is the amount of chlorine that they can be expected to introduce into the stratosphere. This, of course, is dependent upon the amounts of chlorofluorocarbons that have been released to the atmosphere to date and the amounts that will be released in the future. The past releases are quite well known; the future releases are, of course, unknown and dependent on many factors. It is nevertheless necessary to make some reasonable assumptions about future release schedules. Three such scenarios are commonly used: (1) continued constant release at approximately the rate estimated for a recent year; (2) continued release at an increasing rate similar to the historical growth rate for their production and release; and (3) continued increasing release rates as in (2) for a few years followed by complete termination thereafter. None of these scenarios is to be viewed as the expected or desired release rates. They are "what ifs" useful in arriving at conclusions, recommendations, and decisions regarding the problem.

IMOS Task Force Report

In June 1975, the Federal Interagency Task Force on Inadvertent Modification of the Stratosphere (IMOS), which was formed in January of that year with the initial charge of conducting an intensive study of the impact of chlorofluorocarbons-11 and -12 on stratospheric ozone, published a report stating that the ozone depletion problem was a legitimate cause for concern (4). Based on model calculations available at that time, the Task Force found that if release of chlorofluorocarbons-11 and -12 was to continue at the 1972 release rate, a maximum reduction of about 7 percent in the equilibrium ozone concentration would be expected after several decades.

NAS Reports

In March 1975, the Panel of Atmospheric Chemistry of the National Academy of Sciences was appointed and charged with assessing the extent of the impact of chlorofluoromethanes (chlorofluorocarbons-11 and -12), other halocarbons, and the potential emissions from the proposed space shuttle on stratospheric ozone.

On September 13, 1976, the National Academy of Sciences released two reports prepared by the Committee on Impacts of Stratospheric Change (7) and its Panel on Atmospheric Chemistry (8). The Panel report considered

the effects of chlorofluorocarbons-11 and -12 on stratospheric ozone. The Committee report contained an assessment of the environmental effects of chlorofluorocarbon-11 and -12 release.

The NAS Committee found that:

> CFMs, after release at the surface of the earth, mix with the atmosphere and rise slowly into the stratosphere, where they are decomposed by the sun's ultraviolet radiation. Chlorine atoms (Cl) and chlorine oxide (ClO), produced directly or indirectly by this decomposition, then react to remove ozone (catalytically), reducing the total amount of ozone and somewhat shifting the distribution of ozone toward lower altitudes. As a consequence, more biologically active ultraviolet (DUV) reaches the earth's surface and the temperature distribution in the stratosphere is somewhat altered. . . .
>
> At the moment, the ozone reduction and consequent DUV increase corresponding to a given CFM release is uncertain by a larger factor. Continued release at the 1973 level, the usual example, is calculated to give an ultimate reduction in ozone of about 7 percent, where "about 7 percent" is relatively certain to be between 2 percent and 20 percent. This range does not allow for possible inadequacies of the bases of the calculation. Three of the possible kinds of inadequacies may be cited as examples: (1) essential chemical reactions not so far recognized as such, (2) the possibility of unexpected effects of tropospheric sinks (many possible sinks have been studied carefully), (3) possible important inadequacies in the one-dimensional transport models. . . .
>
> If CFM uses and releases were to continue at a constant rate, the ozone reduction and consequent DUV increase would gradually flatten out, approaching a steady state. To reach half of this value would take roughly 50 years. In particular, if constant CFM releases at the 1973 rate are to give 7 percent ultimate reduction of ozone, this reduction will initially increase at about 0.1 percent a year, reaching 3.5 percent after roughly 50 years.

> If the rate of CFM release, after continuing at a constant rate, were drastically reduced at any time in the next decade, say halved or eliminated, and then continued at the drastically reduced rate, ozone reduction and consequent DUV increase would continue to increase for at least a decade after the drastic reduction. It would then decrease, if releases had been nearly eliminated, by roughly 1/70 of its current value each year, taking roughly 50 years to fall back to half its peak value.

The results of the constant release scenarios were examined in detail by NAS for sources of error and overall uncertainty in the predicted ozone depletion. Uncertainties were expected owing to: the many approximations used in the simplified atmospheric transport models; the experimental uncertainty in the values of the rate constants for the chemical and photochemical reactions; and the probable error in the 1973 release rate values. Uncertainty factors placed on these sources by NAS were 1.05 for release rates, 1.7 for transport and 2.5 for atmospheric chemistry. Applying these uncertainty factors to the 7.5 percent figure gives an overall range of 2 percent to 20 percent for ozone reduction. These upper and lower bounds were believed by NAS to bracket the 95 percent confidence range; that is, there is 1 chance in 20 that the actual value of ozone depletion would lie outside this range.

These NAS estimates refer to the amount of ozone reduction relative to the total column of ozone overhead. In addition to the overall reduction of ozone, local stratospheric changes much larger or smaller than the average for the total column are predicted. Maximum destruction of ozone by CFMs is expected to occur at about 30-45 km (upper stratosphere). Ozone depletion at this altitude would allow uv radiation normally absorbed by ozone to pass through this region. Some of this radiation would photolyze molecular oxygen at lower altitudes making available more odd oxygen to combine with oxygen to produce an increase in ozone at about 20-25 km (lower stratosphere). Present models predict that this increase in ozone will not completely counteract the decrease in ozone at higher altitudes so that there will be an ultimate net decrease of column ozone with continued CFM release of about 7 percent. With or without an effect of CFMs on column ozone, this alteration in the distribution of stratospheric ozone would remain as an impact of CFMs.

The time frame for the predicted effects on stratospheric ozone to occur is also an important factor to consider. For the constant CFM release scenario, the predicted annual reductions in ozone are relatively small, about 0.1 percent per year to reach half the maximum depletion level (about 7 percent), and less thereafter in approaching the maximum. The maximum depletion is not expected until well into the next century. As indicated by the scenario where releases are terminated completely at some future time, the ozone level depletion would continue for about a

decade afterward reaching a value of about 1.5 times that at cutoff (this lag is largely due to CFM vertical transport time), and subsequent recovery would be a slow process, requiring some 50 to 75 years after the peak perturbation for the ozone level to return to its value at the time of cutoff. Thus, while the impact of continued release of these compounds may not be felt until many years in the future, these impacts will, even if the most drastic measures are then taken to eliminate them, persist for many more years beyond that time.

NASA Studies: The Chlorofluoromethane Workshop and Assessment Reports

In 1976, the National Aeronautics and Space Administration (NASA) made a commitment to Congress to provide an assessment by September 1977, of the effects of chlorofluoromethane releases on stratospheric ozone. A preliminary report (14), issued in March 1977, evaluated: (a) position papers on selected topics of research written for the purpose of generating the NASA report, and (b) the results of a NASA workshop on the subject held in January 1977. This report will be referred to as the preliminary NASA report.

The preliminary NASA report concluded that, "As noted in the NAS report, there is little doubt that ozone in the stratosphere will be destroyed by the release of chlorofluoromethanes into the troposphere." The major concern of the report is "how well one can evaluate the effect (of CFM releases) on the total column ozone."

For the purpose of evaluating the effects of CFM releases on stratospheric ozone, NASA formed five working groups--a laboratory measurements group, a measurements and analysis of ozone group, a minor species and aerosols group, a one-dimensional (1-D) modeling group, and a multidimensional modeling group. The preliminary NASA report consisted of a summary of the inputs from the participants within each work group.

Each of the 1-D modelers was asked to generate a curve for percent ozone depletion at steady state (using 1975 CFM release rates and a NASA reference data set) as a function of altitude. Very close agreement was seen among most model predictions, all showing a maximum ozone depletion effect of about 60 percent near 40 km and a maximum ozone increase (the "self-healing" effect, a positive feedback) of about 10 percent near 25 km. Total column ozone reduction (the sum of ozone decreases and increases) varied between values of 5 and 9 percent.

In September of 1977, the final NASA workshop report was issued (77) along with a NASA assessment report (78). Since the release of the preliminary NASA report, Howard has measured directly the $HO_2 + NO$ reaction rate and "obtained a result nearly 30 times higher than the earlier recommendation" (77, pp. 17-18). This revision resulted in an increase in the NASA estimate of ultimate ozone depletion from continuous releases of chlorofluorocarbons at 1975 release rates from the 5-9 percent

reported in the preliminary report to 10.8-16.5 percent (77, pp. 189-195). In addition, the currently projected curve for percent ozone depletion at steady state as a function of altitude no longer shows an increase in the level of ozone at about 25 km ("self-healing" effect). Although present models still predict an increase in the rate of production of ozone in this region of the stratosphere, the ozone levels at 25 km are also expected to be slightly decreased.

The assessment of the uncertainties associated with this estimate were subdivided into those associated with radiation processes, chemical processes, and dynamic processes. An uncertainty analysis was performed on the chemistry incorporated into the assessment of ozone depletion (e.g., uncertainties in reaction rates). The error bars were "a factor of 2.8 on the low side, and a factor of 1.8 on the high side." (78) The differences between the uncertainty ranges quoted in the NAS and NASA reports are within the expected variations among 1-D models of the stratosphere. For all practical purposes they are in excellent agreement even though they are derived from two very different and independent analyses.

The uncertainty in the assessment due to the approximation of dynamics implied by the use of one-dimensional models is more difficult to assess. The NASA assessment report concludes that it "is at least the factor of 1.7 quoted in the NAS report." (78). The uncertainty in the assessment associated with radiative process was not evaluated quantitatively. These processes are considered under discussions of feedback mechanisms. A few of these feedback mechanisms have been included in one-dimensional models but most have been neglected.

"The one-dimensional (1-D) model is a particular simplification of the atmospheric radiative/chemical/dynamic system in which chemistry is treated in greater detail than radiation or dynamics." (77, p. 133). Latitudinal and seasonal dependencies of transport, temperature, and the polar flux are better described by multi-dimensional models. However, ". . . a generally applicable model of interactive RCD (radiation, chemistry, and dynamics) will not be available in the near future." (77, p. 197). NASA concludes that "The results of these models (1-D models) provide the best available estimate of the CFM effects on ozone that depends on the anticipated CFM-release scenario." (77, p. 226).

A notable difference between the reaction rates recommended in the NAS report and those adopted by the NASA workshop is that for the formation of chlorine nitrate ($ClONO_2$). The NASA recommended reaction rate for the formation of $ClONO_2$ included less pressure dependence, a factor tending to reduce estimates of ultimate ozone depletion. Analyses by Murcray have placed an upper limit on the levels of chlorine nitrate in the stratosphere (77, p. 176). Chlorine nitrate is not present in the stratosphere in the amounts which would be predicted from the NASA working group calculations of January 1977. The Murcray observation

is still only an upper limit, and is using the more conservative (i.e. predicts more chlorine nitrate and less ozone depletion) absorption coefficients for chlorine nitrate (79).

The newly recommended reaction rate for $ClONO_2$ did not reduce the NAS estimates of ultimate ozone reduction primarily because of the inclusion of more accurate diurnal and multiple scattering effects in the models used by the NASA workshop than were included in the NAS predictions.

With regard to possible sinks which could lead to the inactive removal of CFMs in the troposphere, the NASA workshop report states that only two possible 70-year sinks for chlorofluorocarbon-11 (none for chlorofluorocarbon-12), dissolution in the ocean and ion-molecular reactions, could significantly reduce ozone depletion estimates. The combined effects of these two possible sinks could reduce the steady state concentration of chlorofluorocarbon-11 by 60 percent which would result in "only approximately 20 percent reduction in predicted ozone depletion." (77, p. 184-5). In other words, the maximum effect from hypothesized sinks might lower a central value estimate of 7.5 percent ozone depletion to 6 percent.

Of course, the ultimate proof of the theory that constant CFM releases would result in a redistribution of stratospheric ozone and a reduction in column ozone levels resides in the ability to measure such changes in stratospheric ozone. With regard to ozone measurements the preliminary NASA report concludes: "Although presently available statistical techniques appear to be adequate to filter the various 'natural' periodicities in the ozone records and to give estimates of the variance of the residual data, work now in progress gives promise that statistical analysis of long-term ozone trends can be improved to give more definitive results of possible interruptions (or moderation) of the present patterns by CFM inputs to the atmosphere." The January NASA workshop concluded that ". . . it is clear that a larger data set (based on more precise observational techniques) than is currently available is needed to verify the rate of ozone destruction by CFMs postulated by the models discussed in this document." (77, p. 87).

Acknowledging all the uncertainties, lacking much of the data needed to verify model predictions, and without many ozone measurements to confirm the theory, NASA concludes their assessment report with the following summary: "With the new rate set, predictions by the various modeling groups cover a range of ozone depletions from 10.8 percent to 16.5 percent. This range is the current best estimate for ozone depletion from continued CFM releases at the 1975 release rates." (78, p. 6).

A more detailed discussion of the NASA workshop and assessment reports is provided in section IIIA of the preamble to the final regulation to prohibit the nonessential propellant uses of chlorofluorocarbons in FDA-regulated aerosol products.

3.1.2. Impacts Other than Those from Chlorofluoromethanes on Stratospheric Ozone

The greatest amount of attention has been given to the study of the stratospheric effects of chlorofluoromethanes. As a result, much less data are available which describe the potential impacts associated with other compounds which may enter into the stratosphere. The attempt of this section will be to briefly review the potential impacts on stratospheric ozone from sources other than chlorofluoromethanes.

3.1.2.1. Impacts from Fluorocarbons Other than Chlorofluoromethanes

a. Other Fully Halogenated Halofluorocarbons

(1) Other Chlorofluorocarbons

The chlorofluorocarbons, as a group, are the most stable of all halocarbon compounds containing a reactive halogen atom (12). Included in this group are chlorofluorocarbons-13, -113, -114, and -115. Data available indicate that these compounds, like chlorofluorocarbons-11 and -12, react slowly with hydroxyl radicals (15,16), and, therefore, have long tropospheric lifetimes (17). Once released into the troposphere, they would diffuse upward into the stratosphere to be broken down by ultraviolet radiation. Upon photolysis, reactive chlorine atoms would be released which could catalytically destroy ozone as previously described for the chlorofluoromethanes. The potential impact from any chlorofluorocarbon in a gaseous phase at ambient temperature and pressure would be directly related to the number of chlorine atoms per molecule and the amount of the chlorofluorocarbon emitted.

(2) Those Containing Bromine or Iodine

As discussed previously (section 2.9), the only fully halogenated bromofluorocarbons with current commercial significance are F-13B1 and F-12B1, both used primarily as fire-extinguishing agents.

Unfortunately, there are very little data on the potential stratospheric impacts associated with these compounds. Determinations of tropospheric lifetimes for these compounds are needed. Unpublished data indicate that fully halogenated bromofluorocarbons have tropospheric lifetimes in the same range as those of the chlorofluorocarbons (80). For those brominated fluorocarbons which reach the stratosphere, it has been shown that the bromine released upon photolysis would be at least as efficient as chlorine in its ability to act as a catalyst in the destruction of ozone (18).

Little information is available on iodofluorocarbons. Aliphatic iodine compounds are typically more susceptible to photolytic, thermal, and hydrolytic decomposition than the bromine, chlorine, and fluorine analogs. There is some doubt, therefore, that iodoalkanes will survive sufficiently long in the troposphere to be transported into the stratosphere.

(3) Perfluorocarbons

Perfluorocarbons are fluorocarbons containing only fluorine and carbon, such as F-14 and F-116. Since the carbon-fluorine bond is the strongest of the carbon-halogen bonds, perfluorocarbons are highly stable in the troposphere. The carbon-fluorine bond may be broken by ultraviolet radiation in the stratosphere. The fluorine atoms thus formed do not appear to be a significant threat to ozone because the steps leading to inactive HF formation are fast, and, once formed, HF is not readily converted to active FO_x species (19). To the extent that perfluorocarbons absorb in the 8-12 μm region of the infrared radiation spectra, they would prevent natural heat losses from Earth into space. The magnitude and significance of this potential effect on climate are not yet known.

b. Fluorocarbons Not Fully Substituted with Halogen Atoms

(1) Alkenes and Alkynes

Up to this point the discussion of fluorocarbon compounds has been limited to those in the alkane series, those with single bonds between adjacent carbon atoms. Fluorocarbons with double and triple carbon-carbon bonds, alkenes and alkynes respectively, are also possible. Compounds with alkene and alkyne linkages are far more reactive than those of the alkane series. Reaction rates with hydroxyl radical are much faster (20) and thus tropospheric lifetimes would be far shorter. The breakdown products, including HCl and HF, would be rained out of the troposphere. The use and release of these compounds will probably not contribute significantly to the stratospheric halogen load.

(2) Hydrochlorofluorocarbons

Hydrochlorofluorocarbons, such as F-21, F-22, and F-142b, react more rapidly with hydroxyl radicals in the troposphere than do chlorofluorocarbons (15,16). Relative to chlorofluorocarbon-12, F-21 and F-22 (on a molecule for molecule basis) have been estimated to be factors of 50-200 and 20-50 less hazardous to stratospheric ozone, respectively (21).

The exact margin of safety, however, is still the subject of considerable uncertainty. The NASA preliminary report (14) points out that methyl chloroform has been measured in the troposphere at levels which are a

factor of 5 greater than the lifetime inferred from mid-troposphere OH concentrations and the rate constant for OH + CH_3CCl_3. Aware of these measurements, Singh (22) concludes that tropospheric hydroxyl radical concentrations must be 1/5 the levels currently used to predict tropospheric lifetimes. If this were so, all tropospheric lifetime estimates would be revised upward. This would be particularly significant in the case of the hydrochlorofluorocarbons and raises new questions regarding the troposphere's ability to remove these moderately active compounds.

However, the accuracy of the measurements used to calculate OH concentrations by this indirect method (from measurements of methyl chloroform) is currently in question. It is concluded that until direct measurements are available or until consistent estimates are obtained by several indirect methods such as that of Singh (22), estimates of tropospheric lifetimes for hydrochlorofluorocarbons based on OH reactions cannot be established with confidence.

3.1.2.2. Impacts from Halocarbons Other than Fluorocarbons

a. Chlorocarbons

A number of natural sources of stratospheric chlorine have been identified including volcanic emissions and sea salt spray (both considered to be minor sources), methyl chloride from sea water, and possibly, some naturally produced carbon tetrachloride. Man-made releases of chlorocarbons which may contribute to the stratospheric chlorine load include those resulting from the production and use of methyl chloride, methylene chloride, methyl chloroform, carbon tetrachloride, ethyl chloride, ethylene dichloride, perchloroethylene, trichloroethylene, vinyl chloride, and others.

As with the fluorocarbons, the presence of hydrogen atoms and carbon-carbon double bonds increases the reactivity of the compound and, therefore, decreases the potential threat of such compounds to stratospheric ozone. Most carbon tetrachloride is converted into other compounds before use or release. The manufacture of chlorofluoromethanes takes up 95 percent of carbon tetrachloride production. Thus only a few percent of present reported carbon tetrachloride production can directly participate in or contribute to ozone reduction. The total amount (not the percent) of this direct participation would not be likely to be altered by changes in chlorofluorocarbon use and production.

b. Bromocarbons and Iodocarbons

The lower atmosphere contains small amounts of bromine produced in part by marine activity, in part by the volatilization of particulate material

released during the combustion of leaded gasoline, and an additional contribution from the use of methyl bromide as an agricultural fumigant (18). Except for that reported under 3.1.2.1.a(2) above, little is known about the potential impacts to stratospheric ozone which might result from the use and release of bromo- and iodocarbons.

3.1.2.3. Impacts from Other Man-Made Activities

In December 1975, the Interdepartmental Committee on Atmospheric Sciences (ICAS) issued a report on possible hazards to the stratosphere other than fluorocarbons (23). In addition to the potential impacts from the release of other halocarbons, ICAS briefly considered the possible effects on stratospheric ozone resulting from nitrogen fertilizers, particles (e.g., sulfate particles formed from the photodissociation of carbonyl sulfide), the space shuttle, and carbon monoxide. The significant contribution to stratospheric NO_x resulting from increasing nitrogen fertilizer uses appears to be cause for concern and additional research. Present estimates of ultimate ozone depletion resulting from continued use of nitrogen fertilizers at current rates vary from 2 to 30 percent.

Other potential modifiers of the stratosphere not considered by ICAS include the emissions from supersonic and subsonic aircraft and nuclear testing.

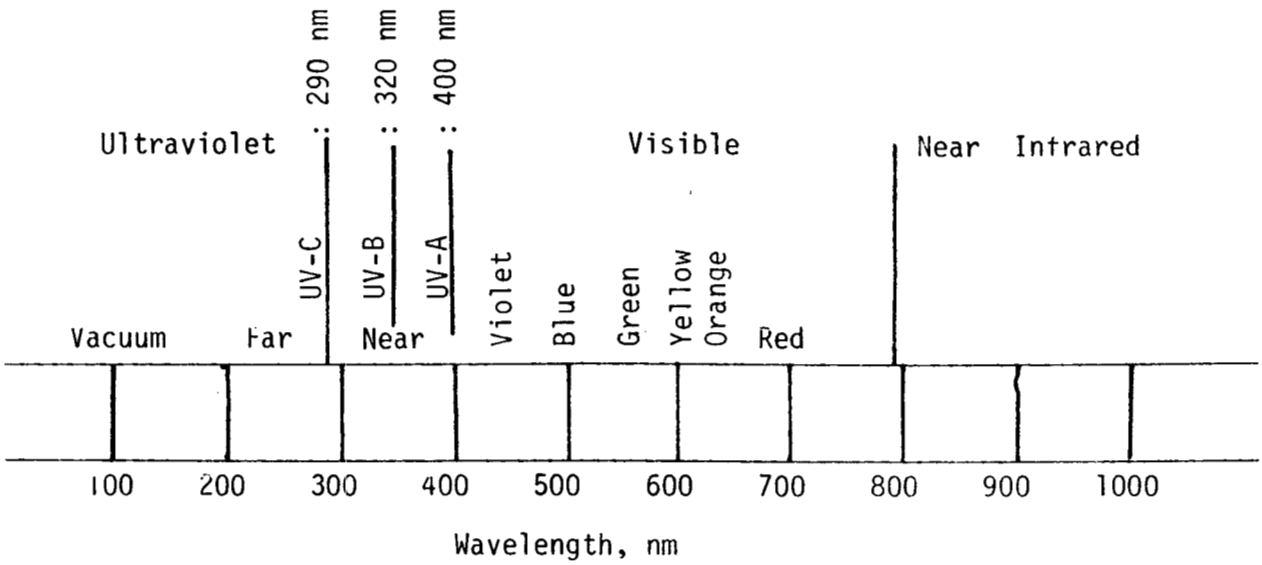
3.2. Potential Biological (Nonhuman) Effects of Increased UV-B

The following discussion of the potential biological (nonhuman) effects of increased UV-B represents a condensed, edited and modified version of a more detailed unpublished report (Rundel and Nachtwey report on "Biological (Nonhuman) and Human Effects of Increased UV-B") on file at the Office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

In sections to follow, terrestrial agricultural plants, natural terrestrial plants and ecosystems, terrestrial animals--both domestic and wild--and aquatic organisms and ecosystems, will be specifically addressed. In section 3.3, potential effects of increased UV-B on human health will be considered. However, there are common elements for all these different organisms and ecosystems. Prior to the discussions of these effects, some background information on ultraviolet radiation (uv), UV-B, and DUV[1/] is provided.

[1/] DUV - The sum of the irradiances of ultraviolet light in the wavelength range of 290-320 nm, with each wavelength interval weighted according to its biological effectiveness. UV radiation below 290 nm does not reach the ground and uv radiation above 320 nm does not affect DNA seriously.

below is a diagram of the electromagnetic spectrum showing where the uv region lies with respect to the visible and infrared spectra:



Source: Rundel and Nachtwey report on "Biological (Nonhuman) and Human Effects of Increased UV-B.

For clarification purposes the following background discussion on ultraviolet light (uv), UV-B, and DUV taken from the NAS Committee report is included:

> Ultraviolet light is invisible, and each of its units (photons) is more energetic than the photons of visible light. Starting near the edge of the visible, we can usefully define the following wavelength ranges (where the visible extends between 400 and 750 nm):

320 to 400 nm--uv-A

290 to 320 nm--uv-B, largely responsible for sunburn, skin cancer, and other biological effects

240 to 290 nm--does not reach the earth's surface mainly because of the shielding effect of ozone (O_3)

180 to 240 nm--absorbed by molecular oxygen (mainly with formation of ozone) or by ozone and does not reach the lower stratosphere

below 180 nm--does not reach even the high stratosphere in appreciable quantities

The shorter the wavelength of uv-B light, the greater its biological effects. Relative effectiveness of one quantum for altering DNA, the material carrying the genetic information of all living cells, is roughly as follows:

320 nm	0.03
315 nm	0.1
310 nm	0.6
305 nm	2.6
300 nm	15
295 nm	60
290 nm	160

(These define the action spectrum of uv-B light for DNA, which is here normalized to a value of 1000 at 265 nm, the wavelength for peak sensitivity. At still shorter wavelengths the sensitivity drops off.)

We shall refer to the total amount of DNA-altering light, weighed by its relative effectiveness, as the damaging uv, or DUV intensity.

> Either normal or reduced amounts of ozone in the stratosphere absorb rapidly increasing amounts of light as we pass from 320 to 290 nm, where absorption is almost complete. As a result of the combination of the action spectrum and the ozone absorption, wavelengths near the middle of the uv-B contribute most to DUV intensity and to biological effects.
>
> A reduction in the total ozone from any cause allows more ultraviolet light to reach the earth's surface. The corresponding increase in DUV is even greater than the increase in total uv-B, because the increase is proportionally greater at shorter wavelengths.

The NAS estimates of increased DUV resulting from a given decrease in stratospheric ozone (physical amplification factor) have been updated by Rundel and Nachtwey as follows. The UV-B irradiances as a function of solar zenith angle and ozone layer thickness were calculated using the method of Green et al. (24). The UV-B irradiances were weighted with the DNA-damage action spectrum to obtain DUV irradiances. The DUV irradiances were diurnally and seasonally averaged, using values for initial and reduced average ozone thicknesses based on latitude and season as reported by Bener (25). (This averaging procedure takes into account the daily and seasonal variability of the amplification factor at any particular latitude).

Increases in DUV resulting from a 7.5 percent ultimate ozone reduction were calculated for various latitudes as shown below:

Latitude (^{o})	Percent DUV Increase (at 7.5 percent ozone reduction)
0	14.3
10	14.6
20	15.0
30	15.8
40	17.0
50	17.7
60	18.0

If there is no cutoff and release of CFMs continues at 1973 release rates, which the NAS calculates would reduce ozone by 7.5 percent at equilibrium, then half of the maximum increase in DUV will occur by about 2025, 3/4 of maximum by 2070, and the ultimate maximum (17 percent at 40^{o}N latitude) will not be reached until well into the 22nd century.

3.2.1. Biosphere in General

3.2.1.1. Statement of the Potential Problem

A large extant literature documents the fact that ultraviolet radiation can affect a wide variety of organisms and this information forms the basis for our concern about ozone reduction/increased UV-B. Most of the information, however, has been obtained with UV-C under laboratory conditions. Analyses have shown that these data cannot be readily extrapolated to a quantitative assessment of the biospheric impact of increased UV-B (26). Similar studies of the effects of UV-B per se are relatively rare. Nonetheless, qualitatively, many of the effects demonstrated in the laboratory with UV-C are found to occur with UV-B. Much of what we know about uv photobiology can be generalized, on a qualitative basis, for a first approach to assessment of impact of increased UV-B.

From basic photobiological knowledge, we can generalize that organisms are currently living in, and apparently coping with, a radiation field of damaging solar DUV. The key question for an assessment of the impact of increased UV-B is whether organisms can cope with more of it and, if so, how much more.

3.2.1.2. Available Information

With very few exceptions, the studies to date do not allow accurate answers to the above fundamental questions for any specific organism in nature. This ignorance should not be surprising given that almost all of our information was obtained from the short-term (18-month) biological studies portion of the Climatic Impact Assessment Program effort plus a few subsequent NASA-supported studies. Moreover, these initial pilot studies were designed not to answer the fundamental questions but to ascertain if UV-B could have effects. The NAS reports on stratospheric flight (3) and on halocarbons (7,8) did not add any new information. The initial studies did show that DUV at high doses could have effects in many cases but not all; other studies showed that current levels of DUV could have effects, but it is not known if such effects will occur in nature.

Nonetheless, from our general photobiological knowledge, we can reasonably assume that organisms in nature are coping with current levels of DUV by a combination of the following mechanisms:

a. Avoidance

Many organisms live almost permanently underground or under rocks, or in litter, or inside fruits and vegetation. Others live in the dark depths of water where essentially no UV-B penetrates. Some terrestrial organisms have nocturnal habits and avoid the sun in the daytime. Obviously,

effects on organisms that totally avoid sunlight are not a source of concern. However, many organisms only partially avoid DUV, being exposed to various levels of solar radiation at least at some time in their life cycles: many plants are fixed in an exposed condition; many animals are exposed to direct solar UV-B during much or all of the day; other organisms are directly exposed only part of the day, seeking shade during midday. Aquatic organisms live in a variable solar UV-B field depending upon their depth in the water.

b. Protective Screening

As protection against the solar UV-B to which exposed animals are subjected, there are a variety of organismal screening agents: (1) nonliving materials like fur, or hair, feathers, horny layers of epidermis in vertebrates; chitinous exoskeletons in arthropods; calcareous or siliceous shells in other invertebrates; bark, waxy cuticles, and cellulose walls in plants, etc., (2) pigments within living cells, e.g., melanin, xanthophylls, anthocyanins, etc., (3) noncritical, i.e. replaceable substances within living cells such as chlorophyll, proteins, and ribonucleic acid.

The above screening agents can absorb UV-B photons and thus shield critical cellular targets such as the hereditary materials of cells, DNA. The energy of the photon absorbed by these screens is usually degraded to harmless molecular motion (heat), but some chemical damage can occur. However, most damaged molecules can be broken down and recycled, or the damaged structure, e.g., horny epidermis, can be sloughed and replaced with new horny epidermis. Such consequences have a cost in energy but they protect against permanent damage to the organism.

c. Redundancy of Information

Despite the above protective measures, some solar UV-B may penetrate through to critical target molecules such as DNA. DNA is probably not the only critical target molecule within all cells, but it is probably the most important one in most cells because DNA contains the genetic information for making all of the constituents of cells and combining them into ordered cellular structures, organs, and organisms. Since DNA is so important to living organisms, there is frequently a redundancy of genetic information within the cells. Thus, effects to DNA are not necessarily detrimental if a redundant section of undamaged DNA can take over.

d. DNA Repair Systems

Even though some photons get through the screens and are absorbed and damage DNA, almost all cells have enzymatic mechanisms for repairing damaged portions of DNA.

e. Cell Division Delay, Possibly for Repair Time

A prominent feature in the response of almost all cells to uv radiation is a delay of cell division. Certain evidence (27,28) indicates that cell division delay may represent an evolved mechanism by which organisms are allowed time for repair of uv-induced damage before it is "fixed" by cell division to become lethal.

f. Miscellaneous Mechanisms

In addition to the above general mechanisms, some organisms have evolved other ways to cope with solar UV-B damage. For example, (1) many cell types are more sensitive to the lethal effects of uv radiation during cell division than at any other time in their cell cycle (progression from one cell division to the next). Such extra sensitivity may result from the damage being "fixed" in some way before it can be repaired. Some cells in some organisms show cyclic daily patterns with cell division at night. Their complex pattern of reproduction may have evolved as a mechanism for coping with the increased sensitivity to uv prior to and during cell division; (2) Calkins (29) has pointed out that in nature reproduction by surviving unicellular organisms could replace those killed by UV-B. As long as the dose of UV-B does not exceed a certain "replacement limiting dose" (RLD) for each species of organism, then, according to his model, populations could survive.

3.2.1.3. Projections of Effects of Increased UV-B

If all UV-B radiation is currently producing damage in exposed parts of organisms and the organisms are coping with this damage by a constant expenditure of energy for repair or replacement of damaged molecules, cells, or nonliving structures, then any increase in DUV will likely increase this expenditure of energy. A diversion of input energy to such coping activity and away from productive activity may be considered detrimental. If the amount of energy expended for coping activity is large compared to that for productive activity, then the effect of increased DUV could be large; if the amount is small, the effect could be small. At present we have no information for any organism on the fraction of its energy flow used in coping with DUV.

There are two experiments that suggest that in some organisms the diversion might be substantial: Sisson and Caldwell (in press) found that simulated solar UV-B significantly inhibited photosynthesis in a moderately UV-B-sensitive plant, Rumex patientia (a biennial herb), at all doses and dose-rates tested, even at those less than currently irradiating Earth at the plant's natural location. Worrest and Van Dyke (unpublished) irradiated microcosms of some marine algae with various doses, including some less than those currently reaching Earth, and found

a reduction of growth rate varying with increased dose. Neither of these experiments, however, was conducted in the presence of high visible light irradiances, as would occur in nature, so the results may not be totally applicable to what might happen in nature. (High visible light is necessary for repair of DNA by an enzymatic mechanism called photoreactivation.)

It is not unreasonable to expect some level of tolerance in many, if not most, organisms or populations of organisms. The energy flow into repair of damage to, say, cows' eyes and unpigmented skin is doubtlessly a very small fraction of the total energy flow, so a moderate increase in DUV would not likely decrease production. Similarly, this concept likely holds for other partially protected vertebrates and invertebrates. In the case of populations of photosynthetic organisms, damage to the photosynthetic apparatus in individual leaves and a reduction in plant size, could be compensated in a population of organisms by decreased competition from smaller plants for soil nutrients and water, thereby allowing more plants to grow per unit area. Thus, other factors in nature besides DUV may limit the amount of total biomass production.

Nonetheless, a comprehensive analysis of existing knowledge indicates that a 17 percent increase in DUV has a potential for altering the normal situation even though the sensitivities and limits of tolerance of most organisms are not known. (See Rundel & Nachtwey report on "Biological (Nonhuman) and Human Effects of Increased UV-B" on file with the FDA Hearing Clerk.) The analysis assumes for worst-case assessment purposes that the limit of DUV tolerance by a particular species is constant for the species throughout its geographic range and assumes that the lower latitude limit for the range is set by the maximum DUV irradiance. Thus an increase in DUV will subject organisms at high latitudes to DUV irradiances exceeding their tolerance limits. The "zone of potential impact," in miles, resulting from a particular ozone reduction can be calculated: for mid-latitudes the zone of potential impact amounts to a worst-case estimate of several hundreds of miles for a 7.5 percent ozone reduction. However, the analysis also considers that DUV is not likely to be the lower latitude limiting factor for all organisms. The analysis also takes into account that various types of organisms live competitively in ecological niches which are determined by a large number of interacting physical, chemical, and biological factors. DUV is one such factor. An increase in DUV will subject organisms to additional DUV over normal exposures. Sensitive organisms may become less competitive leading to a community structure shift; that is the change in types and numbers of species in a given ecosystem. Our understanding of ecology is insufficient to allow prediction of DUV-induced community structure shifts but it has been demonstrated to occur and therefore is a definite possibility in nature.

3.2.1.4. Uncertainties and Ameliorating Circumstances

Although we cannot accurately predict DUV-induced community structure shifts or which ones might be detrimental, we can have some faith that the wide diversity of types of organisms in many ecosystems tends to stabilize the ecosystem against catastrophic change resulting from variations in physical factors. A decline in or loss of the population of one type of organism in an ecosystem is sometimes made up by an increase in the population of some other type with no significant change in total productivity or noticeable detrimental effect.

On the other hand, there are some species-poor ecosystems that might be quite susceptible to alteration, for example, at the margins of deserts. Impact of UV-B on some organisms at such locations may not be easily stabilized. An encroachment of desert with increased sedimentation of rivers, sand storms, microclimate changes, and other consequences might result. At present, we have no information on the potential for increased UV-B inducing such an effect; we can only speculate that the thick cuticles and waxy layers of many desert plants, which protect them from water loss, may also protect them from UV-B.

3.2.1.5. Summary on Effects of Increased UV-B on the Biosphere in General

Although a considerable amount of information regarding the effects of uv at the molecular and cellular levels exists, there is a paucity of information for assessment at the organismal and ecosystem level. However, on the basis of the little that is known, we can conclude that organisms are currently living in and apparently tolerating a radiation field of harmful solar UV-B. Organisms cope with this stress by a combination of mechanisms. If we assume that there is no reserve capacity to cope with more than the maximum DUV doses to which they are currently subjected, then increased DUV has the potential for affecting organisms in the lower latitude limits of their geographical ranges. The approximate extent of the potentially affected areas may be calculated for various situations of ozone reduction/increased UV-B. However, it should be emphasized that the calculated zones are for <u>potential</u> impact. Theoretical arguments can be made that organisms may be indifferent to DUV at the lower latitude limit of their geographic range, a limit more likely set by other more pervasive environmental factors such as temperature and moisture. Thus, the zone of potential impact can be viewed as a worst-case estimate.

The potential for detrimental community structure shifts does exist. At present it is not possible to project quantitatively or qualitatively the occurrence of characteristics of any community structure shift.

3.2.2. Agricultural Plants

3.2.2.1. Statement of the Potential Problem

The obvious importance of agricultural plants (including forage crops) as sources of human food makes any potential impact of ozone reduction/ increased UV-B, even a small one, a cause of great concern, especially considering the world's burgeoning population. The global extent of agriculture is so vast that even a 1 percent reduction in productivity is a large amount. Potential impacts of increased DUV on fiber-producing, medicinal (including tobacco), horticultural, and ornamental plant species are also of concern.

The potential effects that might occur from increased UV-B are as follows:

- decreased photosynthesis
- decreased rate of biomass accumulation and development
- decreased fruit or grain yield
- decreased reproductive ability (pollen and seed germination)
- altered morphology (structure)
- altered competitive ability (e.g., weeds vs. agricultural species, resistance to plant pathogens such as fungi and viruses)
- decreased resistance to other physical and chemical stress (e.g., drought, temperature, nutrient deficiencies, etc.)

Depending on the quantitative extent of these potential effects, increased UV-B may significantly affect global food supply or lead to increased costs of production.

3.2.2.2. Available Information

Studies were initiated during the CIAP effort to assess the potential effects of increased UV-B on selected species of domesticated plants. Prior to that time very little research on the effects of UV-B had been performed. A few subsequent studies have been conducted, but the main source of information continues to be the CIAP studies; the NAS Committee report (7) based its conclusions on those studies. The following subsection presents an abridged and edited version of the summary section by Biggs, Sisson, and Caldwell regarding the results of the CIAP studies on terrestrial plants. It is taken from chapter 4 of CIAP monograph 5, part 1, which should be consulted for details (30).

a. CIAP Studies

Most plants, especially those that grow in full sunlight, possess natural defense mechanisms that minimize the uv-radiation insult under present day conditions. These include absorption of UV-B radiation in epidermal waxes, cell wall materials, and cellular compounds such as flavonoids; enzymatic repair mechanisms such as photoreactivation; and induced photoprotection such as protective pigment synthesis and nastic movements (31). The key question for an assessment of impact is whether or not plants can cope with the increased levels of UV-B radiation anticipated in the biosphere in the event of partial ozone destruction. From the available data summarized here we cannot at present answer this key question with any confidence. We do have results from a limited number of studies, however, which will be discussed.

(1) Biomass Accumulation

The effects of DUV radiation on biomass accumulation were studied at three locations. Results of these studies reflect many of the physiological activities of plants. Twenty-three cultivated crops were tested at the University of Florida under growth-chamber, greenhouse, and solarium conditions. Of the 23 plants tested under growth-chamber conditions, 13 exhibited biomass accumulations that were less than the controls (exposed to no UV-B radiation). Under greenhouse conditions, 11 of the 17 plants tested had significantly less dry matter than controls exposed to no UV-B radiation. In the case of plants tested in the solarium, a greenhouse without a roof, 4 of the 10 had dry weight totals less than the controls, which were exposed to normal solar UV-B irradiance.

In the field tests at Utah State University, the plant species tested under elevated UV-B irradiance also responded differentially. Of the 5 agricultural species tested under UV-B radiation supplementation, 3 species (corn, pepper, and barley) exhibited significant reductions of biomass of either the shoot or root component, or both. Control plants were exposed to normal UV-B radiation.

One study approached the question of effects of UV-B by using filters to attenuate the natural levels of UV-B irradiance in the field and to evaluate changes in agricultural productivity. The field test location was Gainesville, Florida (29°N, 82°W), where the UV-B radiation flux density was expected to be greater during the spring than in areas farther north. During the course of the experiment, the natural ozone level in the stratosphere varied between 0.265 and 0.33 atm. cm.[2/] The average ozone column during the course of the field tests was 0.29 atm. cm.

[2/] atmosphere-centimeters (atm. cm.). An atmosphere-centimeter is a unit of ozone concentration expressed in terms of the thickness (in centimeters) that the entire ozone column above the earth would occupy if it were compressed at standard surface atmospheric pressure at 0°C.

From the plant measurements taken at Gainesville, there were some statistically significant changes observed in a few growth characteristics and in certain yield categories, but total yield was not significantly altered for the three crops on the basis of comparison between the two filter treatments. This indicated either that these tests with small plots of plants in the field under filters lacked the sensitivity needed to detect significant differences between the treatments or that these crops were not stressed by normal solar UV-B radiation under the conditions of the tests, i.e. they are not currently existing at UV-B levels exceeding their tolerance limits.

(2) Photosynthesis

Photosynthesis is of paramount importance to growth and development of most higher plants. It is directly coupled to biomass production and to crop yield.

Net photosynthetic studies using a variety of agricultural and nonagricultural plants have shown that an enhanced uv-radiation regime does effectively repress photosynthetic rates, and that over a several day period, deleterious effects upon the photosynthetic mechanisms accumulate.

(3) Plant Morphological Changes

Plant morphological changes consisting of shortened internodes, decreased apical dominance, and decreased leaf size seem to be the general reaction to high dose UV-B irradiation in controlled studies. Of the plants tested under growth-chamber, greenhouse, or full-sun conditions, 15 of 23, 1 of 16, 3 of 7 species, respectively, exhibited reduced height when exposed to UV-B irradiation. Nonagricultural plants show similar reduced height effects (32). The earlier stages of growth and development, whether of individual plant organs or of whole plants seem to be more sensitive to UV-B radiation. However, the overall effect of chronic UV-B irradiation seems to be an accumulative inhibition. This is in general agreement with the observed reactions of higher plants to other stresses, such as suboptimal visible light, temperature, moisture, and nutrient conditions (33,34).

(4) Other Plant Responses

Apart from the basic responses of plants to elevated UV-B irradiance, such as reductions in photosynthesis, height, and biomass accumulation,

and induction of morphological alterations, other potentially important responses should not be overlooked. For example, the significant depression of pollen germination observed in preliminary experiments (35) might have far-reaching implications if this holds true for species with windborne pollen.

Mutation rates were increased by as much as 300-fold in preliminary studies of stamen hair cells of Tradescantia clones by Campbell (35). Increased mutation rates are generally considered to lead to detrimental consequences in biological systems, even though the impact might not always be immediately felt by the organisms in question. However, in a plant population subjected to natural selection, an increased level of mutant individuals would probably not occur because they would be eliminated by natural selection.

(5) Summary

Although the 18 months of research on higher plants conducted under CIAP auspices have laid a valuable foundation for further research with UV-B radiation, results thus far must be interpreted with caution. These preliminary studies on whole-plant response to UV-B irradiance suggest three important conclusions:

- High doses of UV-B radiation can be a decidedly detrimental stress on higher plant growth and productivity;
- Beneficial effects or growth stimulation by UV-B irradiation is apparently not to be generally expected;
- Plant species vary considerably in their sensitivity to this stress.

The preliminary experiments also indicate that some plants (e.g., some varieties of bean, peanut, tobacco) have considerable capacity to resist increased UV-B. Some data suggest that part of the resistance involves photorepair processes. It is tempting to speculate that the increased incidence and expression of significant UV-B radiation growth depression in growth-chamber and greenhouse experiments, as opposed to field experiments, are due to lessened photorepair in the chambers or greenhouse because visible irradiance is much less intense than in the field. It must, however, be remembered that many other environmental conditions differed in these various experimental regimes. Also, in the greenhouse and most of the growth-chamber experiments, the control plants were exposed to essentially no UV-B radiation; whereas, in the field, the control plants were exposed to normal ambient solar UV-B irradiance. Hence, the UV-B radiation increment between the UV-B radiation supplement treatment and the control plants was much less in the field.

Furthermore, plant-to-plant variability under field culture usually greatly exceeds the variability in greenhouse or growth-chamber conditions--hence statistical detectability of treatment effects is also lessened in the field.

b. Post-CIAP Studies

A few additional pieces of information have become available since the CIAP summary was written. Unequivocal data now exist showing that photoreactivation and excision repair of UV-B-induced damage to DNA does occur in cells from several plants species (36). Fox and Caldwell (unpublished) have obtained preliminary evidence that high doses of UV-B can alter competitive ability between agricultural species and their associated weeds but in some cases the shift favored the agricultural species and in other cases no effect was seen. Caldwell and co-workers have demonstrated an increase in flavonoid pigments in one plant in response to UV-B exposure. They have not yet established the limit of such screening pigment production but the results suggest some ability to adapt to changing levels of UV-B.

Krizek (37) has studied the influence of high doses of UV-B radiation on germination and early seedling growth of tomato, radish, cucumber, lettuce, bean, wheat, cotton, soybean, and millet. Continuous exposure of seeds for 3 days to unfiltered lamps had a slight effect on fresh weight of seedlings but no appreciable influence on germination percentage or dry weight of seedlings. Extending the duration of continuous exposure to 6 days resulted in abnormal seedling growth in all species but wheat.

Two very significant studies have been performed by Sisson and Caldwell (38,39). These studies, although involving a nonagricultural species, Rumex patientia, have demonstrated a significant effect on photosynthesis by DUV doses that might be expected with current and moderately reduced ozone levels. Another finding of the Sisson and Caldwell studies is a UV-B-induced inhibition of leaf elongation. They concluded that this effect is not attributable to the reduced photosynthesis per unit area of individual leaves, but point out that the DUV-induced leaf size reduction further reduces the whole plant's ability to assimilate carbon and increase in biomass. Moreover, DUV caused a reduced leaf longevity, i.e. premature aging. Although leaf longevity was reduced, there was no evidence for an acceleration of whole-plant aging and death even at the highest doses. If the results of their studies, with a moderately DUV-sensitive plant, are generally applicable to many other species, then there is a definite potential that any increase in average DUV doses will over a long period cause accumulative damage.

3.2.2.3. Projections of Impact of Increased DUV on Agricultural Plants

It has been repeatedly emphasized that the present available data on UV-B effects on plants are inadequate for projecting what may occur if the NAS report scenario is valid and a 7.5 percent ozone reduction ultimately occurs. Nonetheless, working with the available data and surrounding the estimates with numerous caveats and emphasis of uncertainties, P. E. Stevenson (contract with EPA) has attempted to assess the potential impact of a 10 percent ozone reduction on the increase in dry weight. Out of necessity, he had to make a number of assumptions to calculate the potential effects of a 10 percent ozone reduction on plants in the field, i.e. in nature, from results of disparate studies conducted mainly in growth-chambers and greenhouses using enhanced DUV from simulated 40-50 percent ozone reductions.

Despite the many assumptions and questionable extrapolations, his analysis suggests that in most cases studied, a 10 percent ozone reduction will produce less than a 10 percent reduction in biomass even if any of his numerical assumptions is incorrect by a factor of 2.

Although Stevenson's analysis and the examination of relative sensitivities suggest that a 10 percent increase in DUV might not affect biomass production by more than a few percent, it should be emphasized that this conclusion should not be generalized to agriculture as a whole. His analysis only considers effects on biomass for a relatively few plants. It does not consider fruit or grain yields and quality, nor does it consider mutations and reproductive ability, water relations, interactions with other chemical, physical, or biological factors (e.g., insects, weeds, viruses) that may affect the end products of agriculture.

In the absence of sufficient experimental data on agricultural plants, one might examine "nature's experiments." Looked at simplistically for purposes of illustration, individual agricultural plant species are currently growing in, and apparently tolerating a wide range of DUV doses over a wide range of latitudes. If DUV is the only factor to consider, then it is reasonable to expect that plant species which tolerate the current level of UV-B at say 30^{o} latitude in some fairly homogeneous longitudinal area, e.g. the Great Plains area, will be able to tolerate those same UV-B levels at higher latitudes. The direct effects of increased UV-B may then be expected to affect only the lower latitude portion of the plants' range. If one ignores the "fuzzy" imprecise nature of the range boundary, one can calculate the zone of potential impact in which increased UV-B will exceed that currently experienced at the lower latitude limit of the range. For a 17 percent increase in DUV, this zone of potential impact amounts to several hundreds of miles. The actual zone of impact, if any, may be less or it may be more, even ignoring the "fuzzy" boundary. It may be less if DUV is not the factor that

currently sets the lower latitude limit of a plant's range. Extensive studies in the Northern Hemisphere have shown that given sufficient water by natural means or irrigation and adequate nutrients, the factor that usually limits the southern extent of growing regions for particular crops is temperature.

Yields of some plants decrease at lower latitudes partly because of water shortage and partly because of higher rates of respiration (and therefore less storage of photosynthate) at the higher summer temperatures. Some plant species are also limited by too much light. In these species, it is primarily the visible and near-uv components that are responsible; the high-intensity visible light causes photo-oxidation of plant constituents. Usually these plants are adapted to live under canopies of trees. Reproduction of some plants is limited by photoperiod (the number of hours of sunlight per day) so they will not grow properly except at certain latitudes. Decreased ozone will not change these limits, which are set by the sun-earth geometry. Therefore, the real zone of potential impact is decreased by the difference between the actual lower limit set by some factor and the lower limit that would be set by DUV if plants could grow there.

On the other hand, the zone of potential impact could be greater than that calculated. Other factors also vary with latitude and location (e.g., soil nutrients and soil physics and chemistry, moisture, competing weed types, pests, and pathogens). Plants adapted to grow under a given set of conditions under current levels of UV-B interacting with all of these factors may be subtly affected by increased UV-B at every location or over a significant part of their entire range. Insufficient data exist to assess the probability of such an interactive effect but it remains a possibility.

On the basis of current knowledge, one may infer that the impact of a 7.5 percent ozone reduction on agricultural plants will not be catastrophic but may cause subtle effects that result in decreased productivity and/or a decrease in the range a plant might be profitably grown. The effect of a 7.5 percent ozone layer reduction may not be detectable against the effects produced by the changing climate and other factors. However, lack of detectability should not be equated with acceptability; a few percent reduction in productivity is still a serious cause for concern given the vastness and importance of agriculture.

3.2.2.4. Uncertainties and Ameliorating Circumstances

The uncertainties in the available data upon which to base any immediate assessment are extremely large. Technical problems in simulating solar UV-B, insufficient replications of experiments, large statistical variability under control conditions, and the limited number of plants and plant parameters studied, make projection from experimental data very

uncertain. Moreover, the projections have considered only changes in biomass for a few plants; it has not considered fruit yields, mutations and reproductive ability, water relations, and other physiological processes that may affect the end-products of agricultural plants.

Furthermore, most of the plants used in these experiments were not under particular duress from other abiotic or biotic environmental factors. When plants are under stress from other factors such as moisture deficits or low temperatures, or in competition with other plants, the additional impact of enhanced (DUV) irradiance, though subtle, might be expected to be more significant in some cases. The competitive balance between plants, whether in agricultural or natural communities, might well be expected to be influenced by increased intensities of UV-B radiation that might not be detected when growth parameters of plants grown in isolation are measured.

Should the increase in DUV be shown to cause significant harm to any or all agricultural species, ameliorating mechanisms are conceivable. First of all, one must consider that the time course of ozone reduction/ increased DUV will be long. The changes will be slow so a well planned research effort over the next decade should be able to identify areas and plant species of greatest concern. Phased redistribution of crop growing areas might be required. Shielding of sensitive crops by UV-B absorbing plastic sheets may be a "technological fix" possible in some cases but impractical in others. The breeding of UV-B resistance into crops has also been suggested as a possible solution. Should weed competition or pest infestation prove to be a problem, increased cultivation or increased use of pesticides may be needed.

3.2.2.5. Summary - Agricultural Plants

The available data are inadequate for a quantitative estimate of the potential impact of increased DUV, but they suggest that a 17 percent increase (section 3.2) as might result from an equilibrium level of 7.5 percent ozone reduction is unlikely to have a catastrophic effect on agricultural plants, but could have subtle effects that reduce productivity and/or decrease the range a plant might be profitably grown, and/or increase the cost of production. Because of the great normal variation in crop yields resulting from the vicissitudes of weather and improved agricultural practices, an effect of increased DUV may not be detectable. However, lack of detectability should not be equated with acceptability, and undetectable small percentage reduction in crop yield may have significant impact on the world's food supply in the 21st century.

3.2.3. Natural Plant Communities

Although the aesthetic qualities of "Nature," the importance of forest products to commerce, and the value of rangeland to food production, are all well-recognized, the greatest importance of natural vegetation is

its global stabilizing influence. For example, forest ecosystems are of great importance to climatic stabilization in that they remove and fix the CO_2 that man has introduced into the atmosphere by burning fossil fuels.[2] It has been estimated that about 40 percent of the CO_2 removed from the atmosphere each year occurs in the humid and semi-arid tropical regions--an area comprising only 8.3 percent of the global surface (40). Grasslands and other natural vegetation stands also have a stabilizing influence, particularly on soil.

3.2.3.1. Statement of Potential Problem

Effects of UV-B on natural plant communities are even more difficult to predict than those on agricultural plants because of the high level of interdependence among different species. Effects on dominant members of the natural plant community may easily cause secondary effects on other plant species by altering the control that the dominant species exert in dampening climatic extremes. For example, a UV-B-induced decrease in leaf size could result in a decreased canopy leaf area of a forest which would allow more light/temperature to pass through to shade-adapted plants on the forest floor. This could provide a selective advantage for competitive species of plants and/or invasion by other organisms such as insects, fungi, and viruses. Thus, an increase in DUV might well change the species composition of a forest or rangeland. Even though these lands might still have a reasonable plant cover, the quality of these plants for forage or timber production might be reduced if the shift favored less desirable plants (41).

In regions under severe stress, such as at the margins of deserts, the diversity of plant types is frequently limited by unfavorable chemical or physical factors. An added stress of DUV could perhaps depopulate such regions with serious consequences. For example, Caldwell (41) has stated that "some of the salt desert range areas of Colorado and Utah, while constituting only 5 percent of the Colorado River drainage, contribute over 35 percent of the total sediment load to the Colorado River. If this rather small proportion of the drainage area of the Colorado River possessed an even less stable plant cover, then the extra contributions of sediment to the Colorado River could bear substantial ecological costs in reducing water quality with ramifying effects on fish and other aquatic biota. Economic costs of increased sediment loads in the dams . . . are also readily calculable." He does not predict that decreased ground cover will occur with any particular ozone reduction but uses the illustration as an example of the potentially serious consequences resulting from subtle changes.

Another potential effect of increased DUV on desert margins is exemplified by the recent experience in the Sahel region of Africa. In this case it has been postulated (42) that overgrazing reduced plant cover, which in turn altered solar reflectivity of the ground, which altered microclimate and thus reduced rainfall and exacerbated the overgrazing

effect in a chain reaction manner. Skylab observations also implicate extensive field burning in the desertification phenomenon. A consequence of desert encroachment was an increase in dust clouds over the Sahel and the Atlantic Ocean, which some climatologists claim may be affecting global weather character. DUV was not implicated in this situation, but it is conceivable that similar consequences might result from some UV-B-induced alteration of ground cover.

These "ecological horror stories" are presented not because there are sufficient data to conclude that they will occur with ozone reduction but they are possible consequences that should be considered.

3.2.3.2. Available Information

Only a very few of the 300,000 species of higher plants have been tested for susceptibility to damage by DUV. The natural plants that have been studied show responses to UV-B radiation similar to those of agricultural plants. In addition, UV-B has been shown to affect competition between plant species, which suggests that community structure shifts in nature may occur as a consequence of increased DUV.

A particularly important lack of information involves trees. Technical difficulties involved in irradiating large trees almost precludes direct experimentation. Observations of chlorosis (yellowing) in Engelman spruce at high altitudes (43,44) have been attributed to solar irradiation. It is not clear, however, whether the effect involves the UV-B, UV-A, and/or visible component of solar radiation.

3.2.3.3. Projections - Natural Plants and Ecosystems

Projections other than the estimates of zones of potential impact are not possible from the available data.

3.2.3.4. Uncertainties and Ameliorating Circumstances

The uncertainties and ameliorating circumstances for natural plant communities are as discussed for agricultural plants.

3.2.3.5. Summary

There is a potential for an increase in DUV to seriously affect natural plant communities, especially those under stress from other unfavorable factors such as high temperature, low moisture, poor nutrient supply. The probability of occurrence of such potential effects cannot be assessed because the available data are insufficient.

3.2.4. Terrestrial Animals, Domestic and Wild

The importance of domesticated animals to man is obvious. In addition, however, wild animals, including insects and other invertebrates, are also very important parts of ecosystems. They play an important role in the nutrient cycle: food from grazing, predation, scavenging goes to feces which is decomposed by bacteria and recycled through plant life and back into animals. They also play roles in the dissemination of plant pollen and seed, culling of weak animals and stabilization of populations by predation.

3.2.4.1. Statement of Potential Problem

Generally, animals that are exposed to the sun are protected from solar UV-B by fur, feathers, or thick pigmented skin. Their eyes, however, may be vulnerable. Many animals do not usually expose themselves to the sun; they either have nocturnal habits, live underground or under rocks, or stay in the shade, at least during the middle of the day. In those cases where organisms seek shade during midday, they likely rely on cues other than UV-B, e.g., temperature, visible or UV-A radiation, or perhaps position of the sun. These cues are not expected to change with an ozone reduction, so increased shade seeking will not likely occur and thus animals may be exposed to greater amounts of DUV than they currently experience. In those cases where they seek the shadow of rocks or trees, they will still be exposed to an enhanced diffuse component of solar UV-B (the diffuse component is frequently about half of the total UV-B irradiance). In those cases where they seek the shade of forests, they will still be exposed to increased UV-B that does penetrate through gaps and/or is scattered (reflected) from leaves; thus, increased DUV has the potential to affect animals which might not otherwise be expected to be vulnerable.

3.2.4.2. Available Information

Very little information on the effects of uv radiation on domesticated or wild vertebrates exists. UV-B can cause photokeratitis and cataracts in experimental animals (45). The only available and applicable photobiological data on animals concern four conditions found in domesticated livestock: pinkeye, sunburn in swine, photosensitization, and carcinogenesis.

The effect of solar radiation on pinkeye is one of exacerbation of a disease caused in cattle by a bacterium, Moraxella bovis. Some investigators suggest that the exacerbating effect seen in summer may result as much from high temperatures and increases in insect populations as from ultraviolet radiation. If uv radiation is the cause of exacerbation, then an increase in UV-B may increase the severity of the pinkeye but should not increase the incidence of the disease which is controlled by

the presence of the bacterium. The potential for sunburn in swine is well-recognized and ranchers usually provide shade for their animals. The diffuse component of any increased UV-B may require the provisions of more shade than is currently needed.

The photosensitization effect involves the action of solar uv and visible light on ingested photodynamic agents, which circulate to the skin, with skin damage as a consequence. (A wide variety of plants contain photosensitizing agents during part or all of their growth cycles. The most common plants of this type in the U.S. are rye, buckwheat, clover, alfalfa, and weeds such as St. John's Wort.) The impact of increased UV-B on this condition will likely be small because the amount of the agent reaching the sensitive site is the limiting factor, not the amount of radiation. Moreover, most of the radiation causing the effect is UV-A, which will not change appreciably with an ozone reduction.

Carcinogenesis in cattle is the most serious presently known potential effect of increased DUV on animals. In 90 percent of the cases, it consists of ocular squamous cell carcinoma (cancer eye) involving the unpigmented skin of the eyelid and eyeball, mainly in white-faced herefords. It is most frequently found in older breeding stock rather than in young marketable-age steers. It is rare before age 4 years, but the incidence increases rapidly after age 7. The incidence of cancer eye has been found to be correlated with geographic location; the highest incidence occurs in the regions of the U.S. with the greatest amount of high natural solar radiation.

Effects of DUV on insects were studied during the CIAP effort. Some attention was paid to the effect of UV-B on pollination activity by bees. The rationale for such studies is that insect eyes transmit into the UV-B and insects used uv cues in pattern recognition of flowers. It might be expected that flowers under enhanced UV-B would have different "hues" than normal. The effects of enhanced UV-B on pollination activity was not significant (46). More studies are needed to rule out possible effects on pollinating activity by other insects visiting different types of flowers. Moreover, UV-B effects on navigation require study.

3.2.4.3. Projections of Effects of Increased DUV on Animals

The experimental data are inadequate for projecting potential adverse effects on animals of a 17 percent increase in DUV within reasonable limits of uncertainty. The zone of potential impact may amount to several hundreds of miles, but it is doubtful that DUV is a range-limiting factor for animals. The available data suggest that insects may tolerate 17 percent increase in DUV, but many more species and developmental stages need to be tested. The effects on birds' eyes are unknown, but the exposure-prone behavior of soaring and marine birds plus the capacity

of UV-B to induce photokeratitis and cataracts (known from studies on mammalian eyes) suggest that a potential for detrimental effects of enhanced UV-B exists. The consequences of photokeratitis or cataracts may be a reduction in food gathering and competitive ability.

3.2.4.4. Summary - Animals

The insufficiency of the available data precludes accurate assessment of the impact of increased DUV on domestic and wild animals. Given the shade-seeking behavior of most wild animals, and the protective hair, feathers, and pigmented skin, about the only potentially vulnerable site for DUV damage is the eye. High doses of monochromatic UV-B can cause photokeratitis and even higher doses can cause cataracts. Whether increased DUV doses in nature will cause such effects is unknown. An accumulation of DUV damage to eyes, if it occurs, may shorten the lifetimes of individual animals, which are thus removed from competition with younger survivors.

3.2.5. Aquatic Organisms and Ecosystems

The major importance of marine organisms to man is as a source of food. Secondarily, the marine environment provides for sport fishing and recreational fishing. The human food and sport fish from the sea are but part of an intricate food web of primary producers and primary-, secondary-, and tertiary-consumers, plus bacterial decomposers. All of these organisms contribute in one way or another to the production of food from the sea. The regions of productivity vary: 90 percent of productivity occurs in coastal upwelling areas, 99 percent in coastal areas in general, and only 1 percent occurs in the open ocean.

Organisms in the sea also serve other functions: aquatic plants are responsible for producing a portion of the oxygen utilized by living organisms on earth; phytoplankton in the oceans serve to convert carbon dioxide and microorganisms degrade pollutants that run off from land or are dumped at sea. The marine ecosystem as a whole is a vital and necessary element in the complex environment that makes life as we know it possible.

Fresh water ecosystems are also important to man in that they provide a human food source. In addition, organisms in fresh water ecosystems aid in purifying (depolluting) water for human and terrestrial animal consumption.

3.2.5.1. Statement of Potential Problem

Ozone reduction leading to increased DUV may affect aquatic ecosystems by inhibition of photosynthesis of phytoplankton, by killing phytoplankton and zooplankton, by killing eggs and larvae of finfish and shellfish or

causing abnormal development. As pointed out in the NAS report on halocarbons, "in their early life stages, certain fishes and crustaceae tend to frequent shallow waters, where solar UV radiation can penetrate to the bottom. In some cases, egg clusters actually float on the water surface. We may reasonably infer some solar UV radiation damage to DNA, even at present radiation levels, from the existence of very active photorepair systems in cells of marine forms." In addition, solar DUV may have an impact on eyes and skin of fishes and marine mammals.

3.2.5.2. Available Information

a. Penetration of UV-B into Natural Waters

The penetration of UV-B into aquatic environments is not well known (47); even the absorption of UV-B by distilled water is not well-characterized. The presence of biota, which is also highly variable, greatly affects the amount and wavelengths of UV-B that penetrate. Most of the measurements that have been taken in natural waters do not include wavelengths below 310 nm, the wavelengths expected to be most effective in producing biological effects.

On the basis of present knowledge, all we can do is state qualitatively that increased UV-B at the surface will increase the DUV irradiances at every level in the water column and a portion of the water column will be subjected to higher fluxes than currently received at the surface with maximum insolation.

b. Effects of DUV on Aquatic Organisms

A large amount of information indicates that uv can have detrimental effects on aquatic organisms and these studies form the basis of concern. Most of these studies were performed with UV-C (primarily 254 nm) under laboratory conditions and cannot be readily extrapolated to an assessment of the impact of increased UV-B (26).

Studies of the effects of simulated solar UV-B on aquatic organisms, which might be applicable to an assessment, did not really commence until the CIAP effort. Neither the CIAP studies nor the few more recent studies have examined the sensitivities of surface floating organisms (neuston), of eggs and larvae of finfish and shellfish, or of larger organisms to sunburn and eye damage. (There are reports that current levels of solar irradiance can cause sunburn and eye damage in hatchery-reared fish. In nature it may be expected that fish might avoid such damage by going deeper or seeking shade.)

The CIAP and subsequent studies have shown that solar UV-B at present surface irradiance levels can inhibit photosynthesis in phytoplankton and can kill a wide variety of small aquatic organisms with a few hours'

exposure (48,49,50). Daily irradiation of amphibian tadpoles can lead to developmental abnormalities (51). A single dose of UV-B comparable to present surface levels can induce developmental abnormalities in 100 percent of early fish embryos (Nachtwey and Boyd, unpublished).

Lorenzen's studies suggest that current levels of UV-B can affect photosynthesis which is fundamental to the growth of phytoplankton and the food web based upon the phytoplankton. The phenomenon demonstrated, however, can also be interpreted as an increase over normal when the natural UV-B is removed; that is a demonstration of the excess capacity for photosynthesis by organisms adapted to UV-B in nature. The study does not address the extent to which phytoplankton can adapt to enhanced UV-B, so does not allow an assessment of the impact of ozone reduction/ increased UV-B.

In another study, Van Dyke and Thomson (52) showed effects on gross photosynthesis during the first few days in microcosms irradiated with UV-B relative to control microcosms given no UV-B. However, the productivity in the UV-B irradiated microcosms later essentially caught up with that of the unirradiated ones suggesting a form of adaptation. More definitive studies on UV-B effects on photosynthesis of phytoplankton are needed for an accurate quantitative assessment of the energy cost and ecosystem effect of any given increase in UV-B.

A few hours' exposure to surface levels of DUV can kill between 50-90 percent of the population of a wide variety of small organisms (53). However, Calkins (29) has pointed out that in nature reproduction by survivors could replace organisms killed by UV-B. As long as the dose of UV-B does not exceed a certain "replacement limiting dose" (RLD) for each species of organism, then, according to his model, populations could survive.

Even when all of the above mechanisms for coping with UV-B are operating, the basic sensitivities or RLD's are still such that a few hours of direct solar UV-B can kill most of a population of unicellular organisms; yet populations of organisms survive in nature. They must, therefore, rely on additional means to cope with UV-B. The most important is probably avoidance. Some organisms hide during the day and are active only at night. Large populations of zooplankton remain in the darker depths of the ocean during the day and rise to the surface at dusk to feed. Natural waters attenuate UV-B more than visible light.

Phytoplankton, of course, need light for photosynthesis, and so must remain nearer the surface than zooplankton. But phytoplankton probably use the attenuation of natural waters to some extent to avoid UV-B. Many mobile phytoplankton show a well-developed behaviorial response

to light: they swim toward a low-to-moderate-intensity light source (positive phototaxis) and away from a high-intensity light source (negative phototaxis), thus exposing themselves to solar DUV at a lower dose rate.

If these mobile organisms survive current DUV irradiances as a result of a complex behavior pattern that has evolved over eons in response to many factors, the key question for assessment of the effect of an increase in DUV irradiance is: Will organisms adapted to a particular zone of depths be able to move deeper in response to a change in one of the factors, DUV? No one knows. If organisms cannot for some reason alter the zone in which they live (most phytoplankton cannot), they might suffer from the disproportionate increase of the killing effect with increase of uv even at the attenuated levels of UV-B expected under water. Those organisms which can move to lower depths in response to increased levels of DUV might suffer decreased productivity due to the attenuation of visible light at lower depths.

Another concern is competition. Certain species of organisms may predominate in a particular ecosystem. If the conditions are changed--even slightly--the competitive edge may be shifted to another species, which can result in a shift in the structure of the phytoplankton and zooplankton community. For example, one study by Van Dyke and Thomson (52) caused a shift in predominance from single-celled diatoms to filamentous blue-green algae. The consequence of such a shift in nature could be that the number of small zooplankton will be reduced because they are not able to eat the large filamentous algae and the larger animal organisms would be reduced because they generally find blue-green algae less palatable. Thus a shift in community structure could have consequences that transcend the initial effect.

3.2.5.3. Projections of Impact of Increased DUV on Aquatic Organisms

From the little experimental information available, it is not possible to project the impact on aquatic ecosystems of any particular ozone reduction/increased DUV. It has been demonstrated that UV-B at current surface levels can affect organisms under experimental conditions, yet these organisms thrive in nature. All that can be said is that there is a potential for affecting basic food organisms (phytoplankton and zooplankton) near the top few meters and perhaps below this if organisms are highly restricted to where they may exist in the water column.

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3.2.5.4. Uncertainties and Ameliorating Circumstances

Most of the sensitivity studies mentioned were performed in the laboratory under unnatural conditions such as reduced visible light. Since visible light frequently affects the pigmentation of organisms and is also involved in photoreactivation-repair, the laboratory-obtained sensitivities may be too high for application to organisms under nature's higher visible light conditions.

In addition, the above considerations do not take into account possible ameliorating circumstances. Lorenzen (48) discusses the possibility of negative feedback situations that may ameliorate the killing effects on phytoplankton; in clear ocean waters, plant production is nutrient-limited. Loss of a production layer near the surface could have a minimal effect on the total water column productivity because release of nutrient from killed phytoplankton by bacterial degradation near the base of the euphotic zone (the zone with enough photosynthetically active visible light to yield a net gain in organic matter) will allow increased reproduction and growth of the surviving phytoplankton. On the other hand, in more turbid waters such as in coastal upwelling areas, the nutrient is adequately supplied and photosynthetically active light (PAL) is the growth-limiting factor. A reduction of phytoplankton growth near the surface and the accompanying decrease in biomass will likely produce a deepening of the euphotic zone because the phytoplankton are the major factors in attenuating PAL in these regions. DUV would not necessarily penetrate more deeply because its attenuation is more affected by dissolved organic substances (called "yellow substances") primarily from terrestrial runoff, which are not expected to change appreciably. Thus, the end result in these two cases would be about the same total photosynthesis per square meter of surface as in the unperturbed situation; in open ocean the zone of production would be somewhat compressed in the water column, while in the coastal region the zone of production would be displaced downwards. This feedback situation does not preclude community structure shifts and ignores the possibility of complications from currents and temperature discontinuities, but it provides a different perspective for assessing the potential for an impact on aquatic ecosystems.

An additional ameliorating circumstance is the possibility that DUV is not a major limiting factor in the productivity of the ocean. For example, Tont (54) has analyzed weekly averages of diatom biomass off the coast of Southern California and found that 85 percent of the annual biomass is associated with major blooms following upwelling of nutrient-laden water. Superimposed on the upwelling factor is the influence of associated movement of subtropical or tropical water masses which affect

temperature and salinity. He was not able to establish a correlation between biomass changes and changes in total solar irradiance which presumably reflects DUV intensities.

3.2.5.5. Summary - Aquatic Organisms and Ecosystems

Studies to date have demonstrated that small aquatic organisms are the most sensitive to the lethal effects of DUV of any organisms tested; current levels of solar DUV at the surface can kill 50-90 percent of a population with a few hours exposure. Yet these organisms can thrive in nature. Therefore, in addition to demonstrated basic tolerance mechanisms (screening pigment, DNA-damage repair mechanisms, etc.) the attenuation of DUV by natural waters must play a major role. There are few measurements of the penetration of UV-B into natural waters. This lack of information precludes quantitative projections of the effects of ozone reduction/increased DUV.

Despite the inability to project effects, the available data indicate a potential for detrimental effects. By the same token, the available data suggest the possibility of negative feedback effects that might ameliorate increased killing by DUV. Such feedback effects might lead to no change in productivity, but subtle changes in community structure cannot be ruled out.

It must be concluded that the following question is still an open one. "Will increased DUV overwhelm the coping mechanisms for aquatic organisms and ecosystems?"

3.3. Human Health Effects of Increased UV-B

The following discussion of the potential human effects of increased UV-B represents a condensed, edited, and modified version of a more detailed unpublished report (Rundel and Nachtwey report on "Biological (Nonhuman) and Human Effects of Increased UV-B") on file at the Office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

3.3.1. Statement of the Potential Problem

Increased UV-B can be expected to increase those pathological conditions in man already known or suspected of being caused by current levels of exposure to solar UV-B:

- Skin Cancer
- Sunburn
- Skin Aging
- Eye Damage

Of the above listed conditions, sunburn and photokeratitis are temporary, reversible conditions, which although uncomfortable, are not serious; therefore, they will not be considered further. The potential for increased UV-B to increase the serious effects on the eyes (pterygium and cataracts) is not well characterized. It is a possible effect only, which should be studied further before concluding that it is a potential hazard of increased UV-B.

An increase in all types of skin cancer is recognized in the CIAP report and in the NAS reports on stratospheric flight and halocarbons to be a definite possibility, although the quantitative extent of the increase is still open to question. The quantitative extent of increase in melanoma is particularly open to question. In previous reports, a 2 percent increase in nonmelanoma skin cancer is generally projected to occur with a 2 percent increase in DUV resulting from a 1 percent reduction in ozone thickness if all other factors (lifestyle, ethnic mix, etc.) remain constant (3,4,7,8,30). More recent analyses based on the same data indicate the percentage increase in nonmelanoma skin cancer may be greater than 2 percent for a 2 percent increase in DUV, whereas it is still generally accepted that about a 2 percent decrease in DUV will result from a 1 percent ozone reduction (physical amplification factor of 2). Currently, this physical amplification factor ($\Delta UV/\Delta O_3$) varies with latitude, initial ozone level, and solar zenith angle, but a value of 2 is still representative for the center of population of the U.S. (viz. $40^{o}N$ latitude).

Nonmelanoma Skin Cancer. CIAP monograph 5 and the NAS report on stratospheric flight discuss extensively the available information on nonmelanoma skin cancer (NMSC) in humans. The available evidence supporting the concept that solar UV-B plays a major role in the induction of NMSC is summarized in table 10. No new epidemiological data have become available since the CIAP and NAS reports, but new analyses (see section 3.3.2.2) and some relevant animal experiments have.

New experimental data using hairless mice exposed to xenon arc irradiation through various cutoff filters (Forbes and Urbach, unpublished) support the idea that it is the shorter wavelengths in the UV-B which are most effective in inducing NMSC, a finding consistent with an action spectrum resembling that of DNA.

Recent studies by Fry and Ley (unpublished) suggest a relationship between uv-induced DNA damage and NMSC-induction in hairless mice, but their studies using two strains of mice also show that genetically controlled factors also play a role in the time to appearance of a diagnosable tumor. Their studies plus a number of others (55) indicate that at least two factors are involved in NMSC induction: initiation and promotion. Boutwell (56) has discussed extensively the evidence for both

Table 10. Summary of Evidence for Solar UV-B Playing a Major Role in Nonmelanoma Skin Cancer Induction

Pigmented races, which sunburn much less readily than people with white skin, have very much less skin cancer and when it does occur, it most frequently affects areas not exposed to sunlight but areas associated with trauma.

Among Caucasians there appears to be much greater incidence of skin cancer in those who spend more time outdoors than those who work predominantly indoors.

Skin cancer is more common in white skinned people living in areas where insolation is greater. The logarithm of incidence is inversely related to latitude and directly related to flux of UV-B.

It is clearly established that superficial skin cancers occur most frequently on the head, neck, arms, and hands -- parts of the body habitually exposed to sunlight (80-90 percent of nonmelanoma skin cancers are on exposed parts).

Superficial skin cancers, particularly squamous cell carcinoma of the skin, occur predominantly on the areas of the face receiving the maximum amounts of solar uv radiation and where histologic changes of chronic uv damage are most severe.

Genetic diseases resulting in greater sensitivity of skin to the effect of solar uv radiation are associated with marked increases and premature skin cancer development (albinism, xeroderma pigmentosum).

Skin cancer can be produced readily on the skin of mice and rats with repeated doses of uv radiation and the upper wavelength limit of the most effective cancer producing radiation is about 320 nm, that is the same spectral range that produces erythema solare in human skin.

initiation and promotion being involved in many kinds of tumor induction. Initiation involves some change in a cell or focus of cells that alters it in some way (perhaps by inducing a mutation or a constellation of mutations by misrepair of DNA) so that it becomes a precancerous cell or small group of cells. Promotion involves the precancerous lesion growing into a frank tumor, perhaps by escaping immunological or other cellular or whole body defense mechanisms. The available evidence (55) suggests that uv can act as both initiator and promotor. The mechanisms of action are not clear but may involve a uv-induced stimulation of skin cell proliferation coupled with some systemic effect on the body (57).

The mortality from nonmelanoma skin cancer is very low. The American Cancer Society (58) roughly estimates that in the U.S. there are about 1500 deaths and 300,000 new cases per year. Deaths accompanied by nonmelanoma skin cancer thus represent 0.5 percent of new cases.

Because of the very low mortality and because of the difficulty in distinguishing from death certificates whether a person died of basal cell carcinoma or just with it, some countries (Puerto Rico, Russia) do not classify it as a malignancy but as a benign tumor (Urbach, personal communication). Death "of" basal cell carcinoma should be extremely rare, occurring only in cases of extreme neglect.

Malignant Melanoma. The incidence of malignant melanoma of all types in the U.S. ranges from about 4/100,000 in the north to about 8/100,000 in the south (59). The U.S. annual age-adjusted rate (1969-71) is 4.6 for white males and 4.4 for white females (Third National Cancer Survey (TNCS), 1975). In 1975, the American Cancer Society roughly estimated there were going to be about 9300 new cases/year in the U.S. in 1976 (4,400 in males and 4,900 in females) and about 3500 deaths. The NAS report (7) estimates 8400 new cases/year. Because the age-adjusted 5-year survival rate in recent years (1965-69) is about 67 percent, the NAS report concludes that about 2800 of the new cases will die within 5 years in the absence of any ozone reduction.

The NAS report on halocarbons (7) concludes that increased DUV may increase the incidence of this rare but serious disease. Lee (60), Urbach et al. (55), and the NAS report on halocarbons have reviewed the evidence for a connection between solar radiation and the etiology of malignant melanoma. The following discussion on malignant melanoma has been extracted from these papers. The influence of latitude of residence on the incidence of and mortality from melanoma is the original and strongest evidence of importance of exposure to sunlight by white people as a cause of malignant melanoma. The gradient of incidence of malignant melanoma vs. latitude is not as great as for nonmelanoma skin cancers, but it is substantial. Where exposure of particular anatomical sites is different between the sexes because of conventional dress and hair styles (ears and

neck in males; lower limbs in females), the exposed site has higher incidence and mortality rates than the unexposed site in the opposite sex.

In spite of this evidence, the importance of solar radiation as an etiological factor in malignant melanoma has only been recognized in recent years and tends to be minimized in the older literature. Malignant melanomas are not common tumors and, until the sixth revision of the International Statistical Classification of Diseases (61), were not separated from other skin tumors. This effectively prevented recognition of their variation from population to population. However, a more important factor in observing the relationship to solar radiation was the lack of concentration of malignant melanoma on the face and neck, in obvious contrast to squamous and basal cell carcinomas.

The NAS report on halocarbons analyzed recent data on the anatomical sites of malignant melanomas. These data, although still showing a large percentage of occurrence on sites not usually exposed to solar radiation, indicate that the locations of most tumors are consistent with sites that are either usually (face, neck, hands) or occasionally (trunks of men and backs of women) exposed. There is a very small incidence at sites that are rarely exposed, the areas of the body usually covered with bathing suits. The NAS report also points out that British studies show malignant melanoma to be more common in indoor workers than outdoor workers and cite the "clinical impression that a majority of cases of melanoma are seen in younger middle and upper-class males and females who pursue active outdoor recreational activities but spend their working hours indoors." The NAS report suggests that the etiology of malignant melanoma may predominantly involve acute exposures, such as might occur during weekend or vacation/recreation, rather than chronic exposures, such as occurs in outdoor workers. The NAS report goes on to conclude "while we need much more information to understand why melanomas are in some way associated with a middle-class way of life and with modest and moderate exposure to sunlight, the weight of evidence is consistent with their being in some way a consequence of exposure to uv-light."

Both the incidence and the mortality rates from malignant melanoma are rising rapidly in all countries in which they have been studied. Mortality rates are rising by around 3-9 percent per year, so that the rates have doubled in about the last 15 years. In some countries, e.g., Canada, the rate of increase is greater than that of any other tumor except male lung cancer. The changes have been shown to be independent of improved diagnosis or certification. There is some indication that incidence rates have risen more rapidly than mortality, showing that improved diagnosis and treatment has reduced case fatality -- but not to a great extent. All these relationships are most unlikely to be due to chance. These increases in incidence and mortality over the past decades support an influence of solar uv exposure on melanoma incidence. To quote Lee (60): "There seems no reasonable doubt that, as industrial

societies develop, the exposure of the population to sunlight becomes greater, hours of work become less, vacations become longer, the opportunities for vacation travel become greater, and clothing becomes lighter. There is, at present, no reason to associate the increasing melanoma rates with anything but this. The proportion of rural workers declines as societies industrialize, but this may not make much difference, as in general, white people living a traditional country life -- whether as peasant farmers in Europe or herding cattle in the American West -- tend to be fairly shy of the sun and to dress accordingly."

Although the correlation of malignant melanoma rates with factors associated with solar radiation exposure (latitude gradient of incidence and mortality, degree of pigmentation, degree of outdoor exposure, and predilection for occurrence on exposed anatomical sites) may seem to implicate accumulated solar radiation dose as the sole or major cause of the disease, the relatively large number of tumors occurring on anatomical sites only occasionally exposed is at variance with the accumulated dose postulate. A simple hypothesis to account for the broad distribution of tumors would be that malignant melanomas have two origins -- one independent of solar radiation and occurring wherever there are melanocytes to undergo malignant change (perhaps related to pre-existing naevi (moles)) and the other related to exposure (60). The data are inadequate for specifying what fraction is associated with solar radiation. Moreover, the association between melanoma incidence and lifestyle (greater in recreationally exposed indoor workers) suggests that one or a number of acute exposures to above-threshold levels of irradiation may play more of a role in melanoma induction than does the lifetime accumulated dose.

Photosensitivity. An additional influencing factor for which no adequate quantitative values exist is that of photosensitive populations. Table 10 referred to genetic predisposition, but there is also concern over chemical phototoxicity and photoallergy (81). Both contact and systemic photosensitizers are known (82) including the common tranquilizer, chlorpromazine.

Adverse reactions in photosensitive populations (81) include those that result from three general "causes": (1) The loss or absence of pigment. This includes albinism, vitiligo, and the light-complexioned, light-haired individual. (2) The presence of topical or systemic photosensitizers. (3) Human conditions that do not appear to involve either (1) or (2) above. These include lupus erythematosus, solar urticaria and the common polymorphous light eruption syndrome. Although such qualitative information is available, other factors limit the determination of quantitative impact. While a great deal is understood about the action spectrum of photosensitizers in the UV-A region, the influence of increased UV-B is not clear. In addition, photosensitizers may cause other adverse reactions independent of exposure to solar radiation. Because of

these uncertainties, the existence of photosensitive populations cannot impact greatly on the projections of increased human health effects that follow. What can be said is that such projections are likely to be low for sub-populations with genetic or chemically induced photosensitivity. The magnitude of those sub-populations is not known and, hence, neither is the magnitude of the underestimate.

3.3.2. Projections of Increased Human Health Effects Resulting from Increased DUV

3.3.2.1. Eye Damage and Skin Aging

There is insufficient quantitative information to project any increase in eye damage (pterygium, cataracts) or skin aging from increased DUV. It is not clear what fraction of cataracts might be caused by solar uv radiation and what fraction can be attributable to other factors (e.g., diabetes, nutrition, or simply aging).

3.3.2.2. Projections of Increased Nonmelanoma Skin Cancer Resulting from Increased DUV

There is no question in the research community among those most knowledgeable that there is a relationship between nonmelanoma skin cancer and ultraviolet radiation. However, because there are many variables and uncertainties concerning this relationship, any attempts at quantification must, of necessity, use certain assumptions. These uncertainties, assumptions, and ameliorating circumstances are discussed in Section 3.3.3.

Nonetheless, recognizing the uncertainties extant, the inadequacies of the data available, and the assumptions that must be made at this time, in a following subsection we attempt to quantify and project the incidence of nonmelanoma skin cancer that might occur in the future following ozone reduction. Such a quantitative estimate of impact, even if uncertain by a factor of 2-4, is useful in order to assess whether the impact is potentially important or trivial.

The CIAP report and the NAS report on stratospheric flight (3) both project that basal and squamous cell carcinomas (collectively called nonmelanoma skin cancer, NMSC) would increase at equilibrium about 2 percent for every 1 percent ozone reduction. The NAS Committee report (7) found no reason to change the projections presented in the NAS report on stratospheric flight. The specific projections in the latter NAS report are as follows:

- A 1 percent decrease in stratospheric ozone will cause roughly a 2 percent increase in skin cancer;

- A 10 percent decrease in stratospheric ozone appears to give more than 20, possibly a 30 percent increase in the incidence of skin cancer.

The projections on nonmelanoma skin cancer above are subject to large uncertainty factors. Urbach et al. (55) summarized the underlying amplification factors and their uncertainties as follows:

- physical (radiation) amplification factor $\Delta uv/\Delta O_3$)[3/] is 2 with a range from 1.4 to 2.5
- biological amplification factor (ΔIncid./Δuv) is 1 with a range from 0.5 to 2
- total amplification factor (ΔIncid./ΔO_3) is 2 with a range from 0.7 to 5.

These factors imply a constant relation of NMSC to DUV which is modified somewhat at higher percentage increases in DUV. These estimates are derived from exponential and power function models relating epidemiological data on NMSC incidence to estimated exposure to DUV based on meter readings and/or calculated DUV related to geographical latitude. Most projections to date have relied on the latitudinal gradient of skin cancer incidence found in the Supplemental Study to the Third National Cancer Survey (TNCS), which was conducted for purposes other than predicting the incidences of nonmelanoma skin cancer. The potentially large errors in these estimates are due to the small number of sites where the epidemiological data were collected; to deficiencies in exposure data for prior years; to insufficient knowledge of the etiology of skin cancer; and to inadequate data in demographic, ethnic, and other factors which modify individual exposure to sunlight.

Since the NAS report on halocarbons was completed, a number of new analyses has been reported: Scotto et al. (62) used an exponential relation between the data for NMSC incidence in four areas and exposure in those areas as measured by a "sunburning uv meter" to obtain a biological amplification factor, B, of 1.6 for males with a standard error of 0.9. If the physical amplification factor is 2, then the total amplification would be 3.2.

Fears et al. (59) also used an exponential model as above, but related NMSC incidence to DUV dose calculated from the wavelengths of sunburning uv reaching the earth's surface through various ozone levels at 35 locations (63). Their model suggests that the biological amplification factor

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[3/] Δ means "change in."

varies from 1.6 to 4.1 for increases in DUV from 10-30 percent. Therefore, if the physical amplification factor is 2, the total amplification factor would vary from about 3 to 8.

Green et al. (64) correlated annual ultraviolet dose estimates with age-specific and age-adjusted incidence data for nonmelanoma skin cancer in the United States, United Kingdom, Canada, and Australia. They examined five different models with different logical assumptions about the human dose-response characteristics for NMSC induction. All models lead to biological amplification factors greater than unity. For the U.S. they found the biological amplification to be approximately 1.8 for the population center but greater in regions of higher uv annual dose, and less in regions of lower annual uv dose. The range was 1.5-2.5 for a total amplification factor of 3-5, assuming a physical amplification factor of 2.

Rundel and Nachtwey (Appendix B) derived an age-response distribution for first and subsequent occurrences of nonmelanoma skin cancer and, assuming reciprocity to hold[4/], calculated the effect of a fractional increase in DUV as equivalent to increasing the chronological age by the same fraction to yield an effective age. The probability of contracting skin cancer was then taken as the current probability at the chronological age corresponding to the calculated effective age. The result is that with increased DUV the cancer that would have appeared anyway if the person lives appears at an earlier age where there are more individuals at risk, effectively causing an increase in cancer incidence. They calculate the biological amplification factor for the four geographical sites in the TNCS study as varying from 3.5 to 4.4 for a total amplification factor varying from 7.0 to 8.8, assuming a physical amplification factor of 2. However, contrary to some of the models of Green et al. (64) or of Fears et al. (65), their model yields biological amplification factors that are lower at lower latitudes and higher at higher latitudes. By weighting the latitude-dependent biological amplification factors by the U.S. population in each latitude band, they calculate an average biological amplification factor of 4.0 for the U.S. at equilibrium after the ozone reduction has reached steady state and after all of the population has been exposed for a lifetime to the steady state increased DUV. With a physical amplification factor of 2, the total average amplification is thus 8.0.

[4/] Reciprocity holding means that dose rate and duration of exposure to produce a given biological effect bear a reciprocal relation to one another (i.e. a short exposure at a high dose rate produces the same effect for the same dose given as a long exposure at a low dose rate).

It is important to note that all authors use the same incidence data but various methods of estimating dose and that the models chosen all indicate a total amplification factor greater than 2 that is used in the NAS report.

The Rundel and Nachtwey (R&N) model is the only one which is not based on incidence with latitude and estimated exposure, but only assumes that an increase in cumulative DUV dose will decrease the age of appearance of a diagnosable skin cancer. Their model is based on extensive experimental data on uv-induced skin cancer in mice (66). As is the case for all toxicity testing in animals, the degree to which animal studies can be extrapolated to man is uncertain. The use of this model allows the computation of the increased numbers of cases that might occur through time for the various ozone reduction scenarios. In tables 11-13, the results of their time dependencies are shown.

Tables 11-13 show the projected cases of skin cancer assuming continued release of chlorofluorocarbons at the 1973 release rates. The ultimate ozone decrease is taken in table 11 as 7.5 percent, the centerline NAS value. Tables 12 and 13 present the results for the NAS lower and upper limits for ultimate ozone reduction, 2 percent and 20 percent. The baseline incidence figures represent the expected number of cases with no ozone reduction at all; thus it ignores chlorofluorocarbons already released into the atmosphere. The percentage increase in new cases by the year 2100 is about 52 percent (lower limit 12 percent, upper limit 184 percent); the number of additional cases in that year is about 344,000 (table 11) (lower limit 81,000, upper limit 1,200,000).

Tables 14 and 15 show the projected NMSC cases assuming all CFM release to be stopped in 1978 and 1980, respectively. For both cases, the maximum percentage increase in NMSC incidence occurs in 2035, and is 6.0 percent for 1978 cutoff and 6.6 percent for 1980 cutoff. The difference in the number of new cases per year for the two cutoff years reaches a maximum of about 3300 cases per year in the year 2035. Even with the 1978 cutoff, it takes so long for the ozone layer to recover, and for the skin cancer incidence to re-equilibrate, that there are still about 17,000 additional cases per year in the year 2100, 122 years after cutoff. The total number of additional cases resulting from a two-year delay in banning is 0.43 percent of the total number of cases that are projected to occur (52.8 million) in the next century (to 2078) with a ban in 1978.

An independent set of projections for the impact of a two-year delay (1978 vs. 1980) in banning certain uses of CFMs has been calculated by Energy and Environmental Analysis, Inc. (EEA). Their study employed an approach and model that differed in several respects from that using the R&N model; in particular, the EEA study employed the dose-response model of Fears et al. (65), which is based upon the latitudinal gradients of

Table 11. NMSC Cases for 7.5% Ozone Reduction at Equilibrium Worst-Case Estimates

Year	White Population ($X\ 10^{-3}$)	O_3 Decr.	Normal + Inc. DUV*	Cases/yr with Inc. UV-B	Cases/yr without Inc. UV-B	Additional cases/yr	% Inc. in cases
1975	185576	0.49	1.01	328946	328341	605	0.18
1980	192165	0.95	1.02	350445	347926	2519	0.72
1985	200548	1.38	1.02	373859	367944	5915	1.60
1990	208685	1.78	1.03	399909	388879	11031	2.83
1995	215396	2.16	1.04	429233	411100	18132	4.41
2000	220784	2.51	1.05	462960	435511	27450	6.30
2005	225663	2.84	1.06	501146	462129	39018	8.44
2010	230940	3.14	1.06	543476	490700	52776	10.75
2015	236511	3.43	1.07	588342	519844	68498	13.17
2020	241456	3.70	1.08	633414	547609	85805	15.66
2025	245119	3.95	1.08	674719	570654	104065	18.23
2030	247577	4.18	1.09	708026	585545	122481	20.91
2035	249469	4.40	1.09	732291	591802	140488	23.73
2040	251447	4.60	1.10	750813	592773	158040	26.66
2045	253622	4.79	1.10	767610	592296	175314	29.59
2050	255904	4.97	1.10	786848	594183	192666	32.42
2055	258275	5.14	1.11	810519	600289	210230	35.02
2060	260716	5.29	1.11	836238	608681	227557	37.38
2065	263173	5.44	1.12	859667	615707	243960	39.62
2070	265629	5.57	1.12	879384	620063	259321	41.82
2075	268143	5.70	1.12	898220	623999	274221	43.94
2080	270703	5.82	1.12	918759	629672	289086	45.91
2085	273247	5.93	1.13	940707	636926	303781	47.69
2090	275756	6.03	1.13	962084	644185	317898	49.34
2095	278258	6.13	1.13	981487	650269	331219	50.93
2100	280779	6.22	1.13	999275	655374	343901	52.47

*DUV calculated for 40^{o}N latitude (demographic center of U.S.) using DNA-damage action spectrum.

Reporting the results to six significant figures should not be construed as indicating such a degree of accuracy.

Table 12. NMSC Cases for 2% Ozone Reduction at Equilibrium Worst-Case Estimates

Year	White Population ($\times 10^{-3}$)	O_3 Decr.	Normal + Inc. DUV*	Cases/yr with Inc. UV-B	Cases/yr without Inc. UV-B	Additional cases/yr	% Inc. in cases
1975	185576	0.13	1.00	328502	328341	161	0.04
1980	192165	0.25	1.00	348593	347926	667	0.19
1985	200548	0.36	1.00	369502	367944	1558	0.42
1990	208685	0.47	1.01	391767	388879	2889	0.74
1995	215396	0.57	1.01	415818	411100	4717	1.14
2000	220784	0.67	1.01	442602	435511	7091	1.62
2005	225663	0.75	1.01	472136	462129	10007	2.16
2010	230940	0.83	1.01	504139	490700	13439	2.73
2015	236511	0.91	1.01	537164	519844	17319	3.33
2020	241456	0.98	1.02	569154	547609	21546	3.93
2025	245119	1.05	1.02	596613	570654	25959	4.54
2030	247577	1.11	1.02	615907	585545	30362	5.18
2035	249469	1.17	1.02	626425	591802	34623	5.85
2040	251447	1.22	1.02	631509	592773	38736	6.53
2045	253622	1.27	1.02	635048	592296	42752	7.21
2050	255904	1.32	1.02	640949	594183	46766	7.87
2055	258275	1.37	1.02	651108	600289	50819	8.46
2060	260716	1.41	1.03	663483	608681	54801	9.00
2065	263173	1.45	1.03	674250	615707	58543	9.50
2070	265629	1.48	1.03	682076	620063	62012	10.00
2075	268143	1.52	1.03	689357	623999	65358	10.47
2080	270703	1.55	1.03	698366	629672	68694	10.90
2085	273247	1.58	1.03	708917	636926	71990	11.30
2090	275756	1.60	1.03	719333	644185	75148	11.66
2095	278258	1.63	1.03	728378	650269	78109	12.01
2100	280779	1.65	1.03	736286	655374	80912	12.34

*DUV calculated for 40°N latitude (demographic center of U.S.) using DNA-damage action spectrum.

Reporting the results to six significant figures should not be construed as indicating such a degree of accuracy.

Table 13. NMSC Cases for 20% Ozone Reduction at Equilibrium Worst-Case Estimates

Year	White Population ($X\ 10^{-3}$)	O_3 Decr.	Normal + Inc. DUV*	Cases/yr with Inc. UV-B	Cases/yr without Inc. UV-B	Additional cases/yr	% Inc. in cases
1975	185576	1.31	1.02	329970	328341	1628	0.49
1980	192165	2.54	1.05	354761	347926	6835	1.96
1985	200548	3.69	1.08	384174	367944	16230	4.41
1990	208685	4.76	1.10	419564	388879	30685	7.89
1995	215396	5.76	1.12	462343	411100	51242	12.46
2000	220784	6.70	1.15	514409	435511	78898	18.11
2005	225663	7.57	1.17	576239	462129	114110	24.69
2010	230940	8.39	1.19	647756	490700	157056	32.00
2015	236511	9.15	1.21	727224	519844	207380	39.89
2020	241456	9.87	1.22	811722	547609	264114	48.23
2025	245119	10.53	1.24	895969	570654	325314	57.00
2030	247577	11.15	1.26	973904	585545	388359	66.32
2035	249469	11.74	1.27	1043059	591802	451257	76.25
2040	251447	12.28	1.29	1106414	592773	513641	86.65
2045	253622	12.79	1.30	1168179	592296	575882	97.22
2050	255904	13.26	1.32	1233043	594183	638860	107.51
2055	258275	13.70	1.33	1303034	600289	702745	117.06
2060	260716	14.12	1.34	1374684	608681	766003	125.84
2065	263173	14.50	1.35	1442286	615707	826579	134.24
2070	265629	14.86	1.36	1504224	620063	884160	142.59
2075	268143	15.20	1.37	1564442	623999	940443	150.71
2080	270703	15.52	1.38	1626163	629672	996491	158.25
2085	273247	15.81	1.39	1688626	636926	1051700	165.12
2090	275756	16.09	1.40	1749024	644185	1104838	171.50
2095	278258	16.34	1.41	1805639	650269	1155370	177.67
2100	280779	16.58	1.41	1859232	655374	1203858	183.69

*DUV calculated for 40°N latitude (demographic center of U.S.) using DNA-damage action spectrum.

Reporting the results to six significant figures should not be construed as indicating such a degree of accuracy.

Table 14. NMSC Cases for Ban on CFMs in 1978[+] Worst-Case Estimates

Year	White Population ($X\ 10^{-3}$)	O_3 Decr.	Normal + Inc. DUV*	Cases/yr with Inc. UV-B	Cases/yr without Inc. UV-B	Additional cases/yr	% Inc. in cases
1975	185576	0.49	1.01	328946	328341	605	0.18
1980	192165	0.87	1.01	350336	347926	2410	0.69
1985	200548	1.00	1.02	373095	367944	5151	1.39
1990	208685	1.03	1.02	397379	388879	8500	2.18
1995	215396	0.99	1.02	423381	411100	12280	2.98
2000	220784	0.92	1.01	451829	435511	16318	3.74
2005	225663	0.85	1.01	482534	462129	20406	4.41
2010	230940	0.78	1.01	515080	490700	24380	4.96
2015	236511	0.72	1.01	547891	519844	28047	5.39
2020	241456	0.66	1.01	578806	547609	31198	5.69
2025	245119	0.61	1.01	604253	570654	33599	5.88
2030	247577	0.56	1.01	620603	585545	35058	5.98
2035	249469	0.52	1.01	627346	591802	35544	6.00
2040	251447	0.48	1.01	627902	592773	35208	5.93
2045	253622	0.44	1.00	626556	592296	34259	5.78
2050	255904	0.40	1.00	627112	594183	32929	5.54
2055	258275	0.37	1.00	631673	600289	31384	5.22
2060	260716	0.34	1.00	638350	608681	29669	4.87
2065	263173	0.32	1.00	643489	615707	27783	4.51
2070	265629	0.29	1.00	645899	620063	25835	4.16
2075	268143	0.27	1.00	647983	623999	23984	3.84
2080	270703	0.25	1.00	651973	629672	22301	3.54
2085	273247	0.23	1.00	657693	636926	20766	3.26
2090	275756	0.21	1.00	663515	644185	19329	3.00
2095	278258	0.19	1.00	668232	650269	17964	2.76
2100	280779	0.18	1.00	672052	655374	16678	2.54

+ Ozone reduction without ban would be 7.5%.

*DUV calculated for 40^{o}N latitude (demographic center of U.S.) using DNA-damage action spectrum.

Reporting the results to six significant figures should not be construed as indicating such a degree of accuracy.

Table 15. NMSC Cases for Ban on CFMs in 1980+ Worst-Case Estimates

Year	White Population ($\times 10^{-3}$)	O_3 Decr.	Normal + Inc. DUV*	Cases/yr with Inc. UV-B	Cases/yr without Inc. UV-B	Additional cases/yr	% Inc. in cases
1975	185576	0.49	1.01	328946	328341	605	0.18
1980	192165	0.95	1.02	350445	347926	2519	0.72
1985	200548	1.10	1.02	373462	367944	5518	1.49
1990	208685	1.13	1.02	398065	388879	9186	2.36
1995	215396	1.09	1.02	424428	411100	13327	3.24
2000	220784	1.01	1.02	453261	435511	17750	4.07
2005	225663	0.93	1.01	484355	462129	22227	4.80
2010	230940	0.86	1.01	517283	490700	26583	5.41
2015	236511	0.79	1.01	550452	519844	30608	5.88
2020	241456	0.73	1.01	581680	547609	34072	6.22
2025	245119	0.67	1.01	607372	570654	36717	6.43
2030	247577	0.62	1.01	623878	585545	38333	6.54
2035	249469	0.57	1.01	630684	591802	38882	6.57
2040	251447	0.52	1.01	631302	592773	38529	6.49
2045	253622	0.48	1.01	629795	592296	37499	6.33
2050	255904	0.44	1.00	630230	594183	36047	6.06
2055	258275	0.41	1.00	634646	600289	34357	5.72
2060	260716	0.38	1.00	641158	608681	32477	5.33
2065	263173	0.35	1.00	646117	615707	30411	4.93
2070	265629	0.32	1.00	648338	620063	28274	4.55
2075	268143	0.29	1.00	650243	623999	26244	4.20
2080	270703	0.27	1.00	654073	629672	24400	3.87
2085	273247	0.25	1.00	659646	636926	22719	3.56
2090	275756	0.23	1.00	665331	644185	21146	3.28
2095	278258	0.21	1.00	669919	650269	19651	3.02
2100	280779	0.19	1.00	673617	655374	18243	2.78

+ Ozone reduction without ban would be 7.5%.

*DUV calculated for 40^{o}N latitude (demographic center of U.S.) using DNA-damage action spectrum.

Reporting the results to six significant figures should not be construed as indicating such a degree of accuracy.

NMSC incidence for ten-year age groups. EEA estimated that a two-year delay in a U.S. ban of just those CFMs used as aerosol propellants would "cost" 764 cases/year (averaged over the period 1977-2050) in the U.S. This figure is based upon the fact that aerosol propellant usage of CFMs in the U.S. amounts to about 30 percent of the world total CFM release. The projected increased skin cancer cases/year resulting from ozone reduction/increased DUV were calculated for the scenario where there is a ban of 30 percent of the worldwide CFM releases in 1978. These cases/year were subtracted from the cases/year following a similar ban in 1980. The differences were then averaged for the period from 1977-2050 to obtain the 764 cases/year figure.

A comparable figure can be calculated from the values in tables 14 and 15: the difference between the cumulative additional cases in the two tables over the period 1978 to 2048 is about 147,000 cases (taking into account the five-year age groupings). The average over this 70-year period is 2100 cases/year avoided by a worldwide ban on all CFM release in 1978 relative to a ban in 1980. If one takes 30 percent as reflecting the contribution of the U.S. aerosol propellant CFMs to the total ozone reduction resulting from worldwide CFM releases, then the number of cases avoided by banning such U.S. CFM release is approximately 30 percent of the 2100 cases/year mentioned above or 630 cases/year. The small difference between 630 and 764 cases/year, calculated by the two different approaches using different models, might become even smaller if the same ozone reduction scenarios were to be used (the EEA value is based upon a somewhat higher worldwide CFM release rate than that included in the NAS report, which was used in the R&N approach).

3.3.2.3. Projections of Increased Malignant Melanoma Incidence Resulting from Increased DUV

The extent of the relationship between melanoma skin cancer and ultraviolet radiation is uncertain, and at this time should only be discussed qualitatively. As pointed out earlier, there may be causes of malignant melanoma other than solar radiation, and the unknown fraction of melanoma incidence that is solar radiation-induced may not be related to accumulated dose as much as it may be related to lifestyle. A biomodal distribution of melanoma incidence with age indicates that a fraction of the population is more sensitive to melanoma induction than is the majority of the population; a small fraction of the population contracts melanoma during middle-age whereas a larger fraction contracts it in old age. The biomodality plus other differences preclude the use of a model similar to that developed for NMSC for projecting increases in melanoma incidence.

Despite the great uncertainty in projecting increases in melanoma, the NAS report on halocarbons states that "a 7% ultimate reduction in ozone, with a consequent 14% ultimate increase in DUV accumulation rate, might

be expected, if most melanoma deaths are solar UV radiation related, to produce a somewhat smaller percentage increase (less than 15%) in melanoma deaths. Thus, a few hundred deaths per year would be expected after all delays have taken place."

The NAS position assumes that malignant melanoma is a response to total accumulated lifetime dose. If, however, the latitude gradient indicates that melanoma induction is a matter of latitude-dependent differences in lifestyle and reflects opportunities for sensitive individuals to obtain acute above-threshold exposures, then an increase in DUV should be examined not from the total accumulated dose standpoint but from the increased opportunities standpoint. The number of days with any particular high solar DUV dose increases nonlinearly with an increase in average DUV. Therefore, the number of opportunities increases nonlinearly and so might melanoma incidence.

With all of the unknowns concerning malignant melanoma, it appears unwise to make any projection at this time.

3.3.3. Uncertainties and Ameliorating Circumstances Regarding NMSC

One major uncertainty in the projections involves the degree to which solar ultraviolet radiation is the predominant cause of NMSC. Not all tumors occur on exposed sites of the body; perhaps 10-20 percent do not. Moreover, other factors, such as ionizing radiation from x-ray sources or radioactive materials, exposures to polycyclic aromatic hydrocarbons, and chronic irritations and burns, are known to contribute to NMSC induction (67). The extent to which these other factors contribute to the overall present-day incidence of human skin cancer should be determined and subtracted before employing the R&N model for estimating increases in skin cancer incidence. If 20 percent of skin cancers are non-uv related, then only 80 percent of the total distribution might be shifted to an earlier age and contribute to an increased incidence. In this regard, the projections tend to provide an upper bound to the increase in cases resulting from ozone reduction.

The R&N model assumes that effective DUV doses accumulated during any period in the life of an individual are equivalent and additive to the accumulated lifetime dose. This assumption at present has no adequate experimental or epidemiological verification or refutation. Animal experiments to test the influence of age on tumor induction by given doses of DUV are in progress.

Despite these uncertainties and others, even if the projected numbers are incorrect by a factor of say 2-4, the very large base number for the current incidence of NMSC leads to large numbers of additional cases resulting from increased DUV. Because such numbers are sensationally

large, and because we are dealing with a type of cancer, a term that has frightening connotations to many or most Americans, it is important to put the NMSC problem in perspective: NMSC is a disease which slowly develops and is almost always non-fatal. If diagnosed moderately early, it can be readily treated. It is usually the untreated very advanced cases that lead to the mortality that puts NMSC in the malignant category rather than in the benign tumor category.

Regarding the number of additional cases calculated to result from increased DUV using the R&N model, it should be emphasized that the fundamental idea for such estimates is that, all else being equal, an increase in DUV at the earth's surface will produce a proportional increase in effective uv which will essentially shorten the time for the appearance of a first case or a subsequent case in those who would contract it anyway. Shortening the time to the onset of skin cancer will lead to an increase in the absolute numbers of cases in the U.S. because there will be more people at risk at younger ages; some people who would have died from other causes before contracting a first or subsequent case of skin cancer may now contract it shortly before such death--with the caveat, again, that all other factors remain constant.

"All other factors remain constant" means that lifestyles will not change. In this regard, it is noteworthy that changes in lifestyle relating to exposure to solar radiation can ameliorate the increase in nonmelanoma skin cancer: To quote Urbach et al. (55) " . . . approximately 60% of the day's total erythemogenic radiation is received between the hours of 10 a.m. and 2 p.m. The relative effect of avoiding sunlight during noontime is significantly large. Even for an office worker, whose small exposure occurs primarily on weekends and vacations, the reduction is over 25% (for the day) by avoiding just the one hour from 12 noon to 1 p.m. By avoiding two noontime hours, all occupations can achieve reductions in UV exposure of the order of 35 to 50 percent. Thus, independent of location, by using a simple plan of avoiding sunlight during the noontime period, an individual can reduce exposure substantially without major changes in living habits."

Another potential ameliorating circumstance is the possibility that, through additional research, individuals who are highly susceptible to skin cancer induction may become identifiable. Identification of susceptible individuals (e.g., sensitive skin types) could allow application of preventive medicine, e.g., counseling to avoid solar radiation or to use solar uv-blocking agents.

3.3.4. Health Effects Summary

The following potential effects of increased DUV on human health are considered: skin cancer, eye damage, and skin aging. Increased incidence of skin cancer, i.e. basal and squamous cell carcinomas (nonmelanoma) and

malignant melanoma, is considered to be a likely consequence of increased DUV. Eye and skin damage are considered to be possible effects, but too little information is available to conclude that they represent a serious threat at this time. The available information on these diseases is summarized. The number of cases of nonmelanoma skin cancer/year that might be expected from various ozone reduction scenarios based on the NAS Committee report on halocarbons are projected. The projections amount to worst-case estimates. The large number of uncertainties in the models used for projection are emphasized. The models employed assume that increased DUV will decrease the time of onset of a diagnosable tumor in persons who would contract it anyway if they did not die first of other causes. Because there will be more persons at risk at somewhat earlier ages, the number of cases will increase. The model implies that the additional cases will occur in persons somewhat before their deaths from other causes. The time dependencies of the increased number of cases/year in the U.S. population projected to the year 2100 (based on the U.S. Census Bureau's Series II projection) are presented for a 7.5 percent ozone reduction, the central value estimate of the NAS report, and for 2 and 20 percent, the lower and upper limits. The ultimate ozone reduction in any case will not be reached until well into the 22nd century; the ultimate percentage increase in incidence will not be reached until approximately 75 years (the human lifespan) after that.

The ultimate increase in DUV from 7.5 percent ozone reduction is projected to be 17 percent; the ultimate increase in NMSC incidence is projected to be 68 percent in the 23rd century, if all other factors such as lifestyle and geographic distribution remain constant. Half of the increase will occur by about the year 2055. Comparable values for the 2 percent ozone reduction are 4.3 percent ultimate increase in DUV; 17 percent ultimate increase in nonmelanoma incidence in the 23rd century; half the ultimate increase also in the year 2055. For the 20 percent ozone reduction case, the values are 52 percent increase in DUV; 210 percent ultimate increase in incidence in the 23rd century; half the ultimate increase in about 2055. The incidence increases are based on the increase in DUV calculated using the DNA-damage action spectrum, so amount to worst-case estimates.

The time dependencies of the increases in the incidence of nonmelanoma are also projected for scenarios assuming a ban of chlorofluoromethane releases in either 1978 or 1980. For the 1978 ban, the maximum ozone reduction is projected to be 1.03 percent and the maximum increase in DUV is projected to be 2.19 percent in about 1990. The maximum increase in incidence would be 6.0 percent about the year 2035. For a ban in 1980, the comparable maximum values are 1.13 percent ozone reduction, 2.40 percent increase in DUV (both peaking in about 1990) and a 6.6 percent increase in incidence in about 2035. For bans in either year, the incidence will not decrease to normal until into the 22nd century because of the long time required for the excess chlorine to be removed from the

stratosphere. Averaged over the next century, the increase in nonmelanoma skin cancer resulting from a two-year delay in banning amounts to about 0.4 percent of the number of cases projected for the case where chlorofluoromethanes are banned in 1978.

For malignant melanoma, similar projections are not possible at this time because this disease does not appear to result from accumulated lifetime exposure as does nonmelanoma. Moreover, the age-response relationship for melanoma is biomodal suggesting two subpopulations with different sensitivities. Other evidence is discussed which indicates projections for this fairly rare disease would be premature at this time.

3.4. Impact of Chlorofluorocarbon Release on Climate and Resultant Effects of Climate Modification

3.4.1. Effects of Chlorofluoromethanes on Climate (Part of the U.S. paper presented at the March 1-9, 1977, UNEP Meeting on the Ozone Layer, drafted by Dr. Alden Bestul, National Oceanic and Atmospheric Administration)

Atmospheric release of chlorofluoromethanes can affect the earth's climate by two mechanisms. One mechanism is associated with stratospheric ozone diminution; the other is not.

Stratospheric ozone diminution allows more ultraviolet and visible radiation to reach the earth's surface, thus warming this surface and the lower atmosphere. However, as less ultraviolet radiation is absorbed by the reduced ozone content of the stratosphere, the associated heating of the stratosphere is reduced. Therefore, less thermal (infrared) radiation is emitted from the stratosphere toward the earth's surface. This effect tends to cool the earth's surface and the lower atmosphere. In addition to these two effects, ozone diminution would also alter the contribution by ozone to the atmospheric "greenhouse effect." Ozone absorbs infrared radiation in the 9-11 μm region which is emitted by the earth's surface toward space and hence causes a net reduction in the infrared radiation emitted to space by the earth-atmosphere system. The sign and magnitude of the alteration of this "greenhouse effect" due to ozone diminution would depend on the vertical distribution of ozone change, Currently available model calculations indicate that, if ozone is reduced at all altitudes within the stratosphere, the "greenhouse effect" due to ozone decreases would tend to cool the earth's surface and troposphere. The balance of the above warming and cooling effects in influencing tropospheric climate is sensitive to the distribution of ozone reduction in both altitude and latitude. The sensitivity of this analysis to the distribution of ozone reduction in altitude and latitude is emphasized by consideration of the $ClONO_2$ effect in which ozone

redistribution may play as large a role as ozone diminution. Attempts at quantitative analysis of the resultant net effect on tropospheric climate have not yet achieved sufficient resolution to determine the direction of the overall influence on climate.

Independent of ozone diminution, chlorofluoromethanes in the atmosphere can also affect climate simply by their accumulated presence. They absorb infrared (thermal) radiation in the 8-12 μm region which is emitted from the earth's surface toward space. Absorption in the 8-12 μm region of the infrared radiation spectra is of particular significance because much of the heat emitted from earth, under natural conditions, escapes through this infrared "window." The radiation absorbed by chlorofluoromethanes, instead of being lost to space, is thereby converted into heat which is retained in the earth's atmosphere, thus increasing the average temperature there. This mechanism creates a retention of additional heat which should, but is not yet certain to, produce a related warming of the earth's average temperature. Computations based on the 1973 release rates for chlorofluoromethanes indicate that in about a century this mechanism could raise the average temperature of the lower atmosphere to a steady state value about a half degree Celcius higher than at present.

The above mechanism is of the same type as the "greenhouse effect" by which increasing accumulations of carbon dioxide (CO_2) in the atmosphere may result in an increase of global average temperatures. Increasing CO_2 concentrations from combustion of fossil fuels are projected to produce a global average temperature increase around $0.5^{o}C$ by A.D. 2000. Even at that time the "greenhouse effect" from CO_2 would be greater than that from chlorofluromethanes, and would become even more so beyond that time (assuming current emissions of both CFMs and CO_2).

The above projections also indicate an increase of a few percent in precipitation as a result of the chlorofluoromethane and CO_2 "greenhouse effect" (approximately 1 percent for CFMs).

Global average changes of temperature and precipitation such as those mentioned above would probably be accompanied by much larger as yet undetermined changes of regional and local climate in various parts of the world.

Many uncertainties remain in the above predictions on the climatic effects resulting from chlorofluoromethane releases. The NAS report is careful to point out, however, that the uncertainty of effects should not be viewed as unlikelihood of effects.

3.4.2. Effects of Chlorofluoromethane-Induced Climatic Modification (Part of the U.S. paper presented at the March 1-9, 1977, UNEP Meeting on the Ozone Layer, drafted by Dr. Alden Bestul, National Oceanic and Atmospheric Administration)

Chlorofluoromethane releases have an impact on biological systems not only directly through the effects of the resultant increased intensity of DUV radiation at the earth's surface, but also indirectly through the effects of climate changes induced by chlorofluoromethane release.

These effects have been the subject of modeling studies of the sensitivity of crops to climate variables. Such studies examine the influence of an average climate warming without change of pattern or degree of fluctuation of various climate variables such as precipitation, minimum or maximum temperatures, and cloud cover. On this basis an average temperature increase of 0.5^{0}C can produce either an increase or a decrease up to about 5 percent in yields of different crops in a given region, or of a given crop in different regions. There is no suggestion that such increases and decreases would balance each other out. The possibility of yield decreases may be considered more threatening than the possibility of increases may be considered reassuring. Ignorance of the result to be expected in the specific cases of particular critical crops may prohibit the deliberate acceptance of the possibility of such climate changes.

It must be emphasized that changes in global average temperature and precipitation would be expected to be accompanied by much larger as yet undetermined changes of regional and local climate in various parts of the world. The impacts of climate changes in agriculture, etc., would be expected to depend much more on the regional and local changes than on the global average changes.

Local changes in temperature and precipitation on the order of those predicted would be great enough to eliminate existing production of commercial crops in selected marginal growing areas. However, it is less certain whether new production might be possible by development of new varieties or whether reduced production might be compensated by increased production in other areas. The only certainties that can be counted on are disruption of existing patterns with some areas losing and others gaining. Whether total agricultural production would increase or decrease from the predicted climatic changes remains an unknown.

3 4.3. Impacts of Other Fluorocarbons on Climate

3.4.3.1. Fully Halogenated Halofluorocarbons Other than Chlorofluoromethanes

a. Other Chlorofluorocarbons

These highly stable fluorocarbons would be expected to have infrared absorption properties similar to those of the chlorofluoromethanes. Since chlorofluorocarbons as a chemical group have long tropospheric lifetimes, similar potential impacts on stratospheric ozone (on a per chlorine atom basis), and possibly similar infrared radiation absorption properties, it is likely that all members of this group would pose similar risks of climatic change.

b. Fluorocarbons Containing Bromine or Iodine

Not enough information is available at this time regarding the potential contribution of bromo- and iodofluorocarbons to ozone destruction and the "greenhouse effect" to make any statement about their potential to cause climatic change.

c. Perfluorocarbons

To the extent that perfluorocarbons absorb in the 8-12 μm region of the infrared radiation spectra, they would prevent natural heat losses from earth into space. The magnitude and significance of this potential effect on climate are not yet known.

3.4.3.2. Fluorocarbons Not Fully Substituted with Halogen Atoms

a. Hydrochlorofluorocarbons

Regarding the potential for these compounds to impact on climate, DuPont (76) has reported in response to the FDA Call for Information (FEDERAL REGISTER of July 16, 1975, 40 FR 29914) that based on preliminary measurements, most hydrochlorofluorocarbons are weaker absorbers in the 8-12 μm region of the infrared spectra than chlorofluorocarbon-12. More important in the assessment of the climatic impacts associated with hydrochlorofluorocarbons is their shorter tropospheric lifetimes. DuPont estimates that the actual "greenhouse effect" for hydrochlorofluorocarbons is expected to be 10-500 times less than chlorofluorocarbon-12.

3.4.3.3. Compounds Other than Fluorocarbons

a. Chlorocarbons

Chlorocarbons (e.g., CCl_4, $CHCl_3$, CH_3Cl, CH_2Cl_2), like the chlorofluorocarbons, have been found to have strong infrared bands in the spectral region of 8 to 12 μm (83). The extent to which the chlorocarbons would contribute to the "greenhouse effect" would depend upon their tropospheric stabilities.

b. N_2O and CO_2

The release of both of these compounds may contribute to climatic alterations. Increases in stratospheric NO_x may cause indirect climatic effects as a result of the potential for these compounds to destroy and alter the distribution of stratospheric ozone. Additionally, nitrous oxide has an "infrared absorption band in the spectral region 7 to 14 μm and contributes to the atmospheric 'greenhouse effect'." (84). Emissions of carbon dioxide, although not likely to contribute to effects on stratospheric ozone, may cause climatic changes as a result of their infrared radiation absorption properties.

The major man-made sources of N_2O and CO_2 are not from their use as propellants. Significant amounts of nitrogen oxides may be entering the stratosphere through the increasing use of nitrogen fertilizers in food production and to a lesser extent from the emissions of high-flying aircraft. The combustion of fossil fuel is the major man-made source of CO_2 in the atmosphere. The potential climatic impacts from this activity have been briefly considered above (section 3.4.1).

3.5. Additional Research on Chlorofluoromethane Impacts on Stratospheric Ozone and Effects on Biological Systems (Nonhuman), Human Health, and Climate

3.5.1. NASA Upper Atmospheric Research Program

The National Aeronautics and Space Administration (NASA) is conducting an Upper Atmospheric Research Program. The NASA program has long- and short-term goals. The long-term goals are to produce a more significant understanding of the physics and chemistry of the upper atmosphere.

One of the short-term goals was to issue a report in September 1977, which would answer two questions:

(1) What is the prediction of the reduction of stratospheric ozone for a given chlorofluoromethane release scenario?

(2) What is the assessment of the validity of this prediction?

NASA met its September publication date for its final workshop and assessment reports which address the above questions to the best extent possible given today's scientific data base (77,78). These NASA reports have been briefly summarized in section 3.1.1.3. The purpose of the NASA Upper Atmospheric Research Program has been and is to obtain data which can increase the confidence in the prediction of ultimate ozone reduction; thus, it is the second question that continues to receive greater attention.

3.5.2. Biological and Climatic Effects Research Program

A multi-agency Biological and Climatic Effects Research Program (BACER) is investigating the direct and indirect effects of ozone depletion. The program will greatly expand the data base for more accurate estimates of known effects (e.g., skin cancer incidence rates and correlations). BACER will determine whether a number of suggested biological effects is of significance and to what degree.

The program should significantly improve estimates of the quantitative effects on key biological species (e.g., agricultural crops and aquatic organisms) and provide estimates of how near such species are to their limits of tolerance for increased uv radiation or other related environmental changes which could result from chlorofluorocarbon emissions. In addition, a number of basic investigations on cellular/molecular mechanisms are being conducted in order to understand the interactions of UV-B radiation with living matter.

There are long- and short-term objectives for BACER. The principal objective for the first phase of the program is to decrease uncertainties in existing scientific knowledge and investigate new potential problem areas.

The long-term BACER program has plans for conducting supporting studies with plants, animals, and other organisms, as well as studies at the molecular and cellular levels to understand uv damage and repair mechanisms and determine indicators of effects.

3.6. Direct Health Effects

In addition to the concern for stratospheric ozone depletion due to fluorocarbons, there has also been some concern regarding the direct health effects of these compounds. The fluorocarbon aerosol propellants have been responsible for numerous deaths when they were intentionally inhaled by individuals attempting to achieve an intoxicated state. The cause of death is probably cardiac arrhythmia, aggravated by elevated blood levels of epinephrine due to stress and/or an increase in blood carbon dioxide. The fluorocarbon anesthetic halothane has been associated with liver injury, headache, and mood alterations in patients, and with liver injury, spontaneous abortion, and congenital abnormalities in

chronically exposed operating room personnel. Studies have shown that inhaled fluorocarbons are rapidly absorbed into the blood and under conditions of continuous exposure they can enter certain tissues. When exposure is terminated, the fluorocarbons are eliminated through exhaled air with no indication that they accumulate in any tissue. Limited data indicate that some metabolism to carbon dioxide (less than 10 percent) may occur with chlorofluorocarbons-11 and -12. The metabolism of the fluorocarbon anesthetic halothane to compounds which bind covalently to cell lipid and protein has been demonstrated. The formation of bound metabolites has been associated with the liver toxicity of this and other compounds. Limited data indicate that inhaled chlorofluorocarbons-11 and -12 may also result in some cellular binding. More detailed studies on the formation of bound metabolites from the commercially important fluorocarbons are needed. Such studies are also indicated for the hydrogen-containing fluorocarbons which have been suggested as replacements for chlorofluorocarbons-11 and -12 since these are structurally similar to halothane.

In laboratory animals, the acute lethality of inhaled fluorocarbons is very low, with chlorofluorocarbon-11 and chlorofluorocarbon-113 being lethal at 5-25 percent of air and the other fluorocarbons being fatal only at concentrations of 40 percent to 80 percent or more. Chlorofluorocarbon-11 has been shown to elicit severe cardiac arrhythmias "in one of 12 dogs tested at 0.5 % and in five of 12 dogs at 1.0 %" when the exposures were followed by administration of a challenge injection of adrenalin (0.008 mg/kg) (85). Chlorofluorocarbons-11 and -113, the most toxic of the commercially significant fluorocarbons, produce cardiac arrhythmias, sensitize the heart to epinephrine-induced arrhythmias, and influence other cardiac parameters. Some studies have demonstrated that animals with diseased cardiac and respiratory systems are more sensitive to the acute cardiovascular and respiratory effects of the fluorocarbons than healthy animals. A possible increase in sensitivity to the fluorocarbons in humans with cardiac or respiratory illness may exist, but this is difficult to determine definitively on the basis of these animal studies.

Recent reports from industry indicate potential chronic toxicity problems with two of the hydrogen-containing fluorocarbons (F-22 and F-142b) which have been suggested as replacements for the chlorofluorocarbons. In a communication of November 18, 1976, DuPont indicates that fluorocarbon-22 has been found weakly mutagenic in 72-hour Ames tests (68). The Ames test, which measures the ability of a chemical to cause change or mutation in the genetic material of Salmonella bacteria, is used to identify chemicals to be tested in long-term exposure studies for possible carcinogenic effects. Ames tests conducted on F-142b also yielded positive

mutagenicity indications (69). In a March 1, 1977, letter from DuPont to its refrigerant customers, it is indicated that hydrochlorofluorocarbon-22 is weakly teratogenic in inhalation tests with rats. The letter states that "A very small, but statistically significant number of rats showed teratogenic effects at an exposure level of 500 ppm and above. Such effects are concerned with the production of malformed offspring in the uterus" (70). Long-term exposure of adult and developing animals will be needed to assess the chronic toxicity of these compounds.

For a more detailed discussion of direct health effects of fluorocarbons, the reader is referred to EPA's Environmental Hazard Assessment Report of August 1976 (71).

SECTION 4. REGULATORY ALTERNATIVES

The preceding sections of the impact statement present relevant background information and discuss in some detail the environmental impacts expected to result from continued release of fluorocarbons to the atmosphere. This section considers the various regulatory alternatives which may be employed to deal with this problem, leading to the selection of the preferred alternative. The section is divided into four parts:

- Factors to be considered,
- List of regulatory alternatives considered and selection of reasonable alternatives,
- Environmental impact of reasonable alternatives,
- Comparison of reasonable alternatives, selection of preferred alternative, and development of regulatory timetable.

4.1. Factors to be Considered

The development of regulatory options for reducing the magnitude of these impacts requires consideration of three principal factors: (1) fluorocarbon use to be regulated, e.g., aerosol propellant, solvent, refrigerant, etc., (2) type of fluorocarbon compounds to be regulated, e.g., chlorofluorocarbon, bromofluorocarbon, hydrochlorofluorocarbon, etc., and (3) regulatory timetable.

4.1.1. Fluorocarbon Use(s) to be Regulated

The selection of fluorocarbon use(s) to be regulated requires a determination of whether or not a particular fluorocarbon use is essential. The Commissioner of Food and Drugs has defined essentiality to mean that there are no technically feasible aerosol or non-aerosol alternatives to using a fluorocarbon in a product and that a product provides a substantial public benefit such as a therapeutic medical benefit (72). The product need not be indispensable to life, but the benefit must be important and consist of more than added convenience.

Public benefit is a broad concept that can encompass economic consequences, but an economic impact solely upon a manufacturer of a product would not ordinarily be sufficient to make a use essential, since most regulation involves at least some economic impact. A substantial economic impact on consumers or other users of a product could conceivably be an element to make a use essential, but only in conjunction with some other significant benefit provided by the product.

4.1.2. Fluorocarbon Types to be Regulated

The determination of which fluorocarbon compounds to regulate requires judgments regarding the environmental impact potential of and relative risk posed by a particular compound based upon a detailed analysis of available scientific information.

4.1.3. Regulatory Timetable

The development of a regulatory action schedule involves a balancing of the need to minimize environmental and health risks posed by fluorocarbon release with the need to allow a reasonable period to phase out regulated uses in order to minimize economic losses.

Based upon evaluation and integration of these factors, a list of possible regulatory alternatives was developed. From this list the reasonable alternatives were selected for detailed environmental impact assessment.

4.2. List of Regulatory Alternatives Considered and Selection of Reasonable Alternatives

Alternative 1. No Action

Alternative 2. Ban aerosol propellant uses of chlorofluorocarbons-11 and -12.

Alternative 3. Ban aerosol propellant uses of all chlorofluorocarbons, e.g., chlorofluorocarbons-11, -12, -13, -111, -112, -113, -114, and -115.

Alternative 4. Ban aerosol propellant uses of all fluorocarbons, e.g., chlorofluorocarbons, hydrofluorocarbons, fluorocarbons containing other halogens, etc.

Alternative 5. Ban all uses of chlorofluorocarbons, e.g., aerosol propellants, solvents, refrigerants, blowing agents, etc.

Alternative 6. Require label warning on aerosol products containing chlorofluorocarbon propellants.

The no action alternative was not considered to be a reasonable option for reducing the environmental impact of continued fluorocarbon release. It is, however, included with the reasonable alternatives selected below to provide a baseline for comparison. For the United States to take no

action, would mean that approximately 50 percent (page 15) of worldwide fluorocarbon emissions (43 percent of worldwide chlorofluorocarbon-11 and -12 emissions--table 4, page 12) would continue to be released with resultant environmental and health risks.

Alternatives 2, 3, and 4, which involve aerosol propellant uses of fluorocarbons were selected as reasonable alternatives. In 1973 aerosol propellant uses of fluorocarbons accounted for about 62 percent (table 8, page 19) of United States fluorocarbon release and roughly 30 percent (511 million lbs. ÷ 1730 million lbs. x 100, page 15, table 6 - page 17) on a worldwide basis. Furthermore, the Commissioner of Food and Drugs has determined that almost all aerosol propellant uses of fluorocarbons in FDA-regulated products are nonessential, since other means of product delivery exist and/or the products themselves serve only as a convenience providing no special benefit that would outweigh the risk (11).

Alternative number 5, which would control all chlorofluorocarbon uses, i.e. aerosol propellant, refrigerant, solvent, etc., was rejected for consideration as a reasonable alternative at this time. This judgment was made with the recognition that chlorofluorocarbons as a class pose the greatest risk of ozone depletion and that this alternative would regulate about 44 percent of worldwide fluorocarbon emissions (from table 8, page 19). Rejection of this alternative was based on the need for additional time to determine essential uses and to obtain information on the economic impact of regulation, availability of substitutes for fluorocarbons, and the environmental and health effects of substitutes. Detailed environmental impact consideration of all non-propellant uses of fluorocarbons will be deferred to a second phase. EPA, FDA, and CPSC are currently collecting information on nonpropellant uses of chlorofluorocarbons through a joint informal public meeting process. The first such public meeting was held on October 25-27, 1977; another is scheduled for February 21-23, 1978.

Alternative 6, which would require a warning statement on aerosol products using chlorofluorocarbons, was rejected as the sole regulatory approach because its effect on reducing chlorofluorocarbon use would be limited since any reduction in use would be due to consumer constraint and subsequent industry response. Furthermore, consumer constraint might not be long-lasting.

The FDA has, however, promulgated a warning statement requirement as an interim measure pending further regulatory action. The purposes of the warning statement include:

- Encourage consumer self-restraint and use of alternative products, thus possibly reducing the release of chlorofluorocarbons during the interim period;

- Discourage stockpiling;
- Single out those propellants posing the risk, thus averting the possibility that consumers will avoid other propellant systems not presenting an ozone depletion hazard;
- Encourage national uniformity in labeling requirements.

The FDA prepared and issued an environmental assessment (73) for the warning requirement at the time of the proposed rulemaking (11). The other regulatory agencies have also required labeling to indicate the presence of chlorofluorocarbons. The EPA has given notice that all pesticide products containing chlorofluorocarbons-11 and -12 as aerosol propellants must be labeled after April 15, 1977. The CPSC has issued a proposed rulemaking that would require a warning statement on consumer products containing chlorofluorocarbons identical to the one promulgated by FDA.

4.3. Environmental Impact of Reasonable Alternatives

The Agency has elected not to use the more recent U.S. chlorofluorocarbon emissions data (section 2.7) and the most recent NASA projection of ultimate ozone depletion of 10.8 to 16.5 percent (based on 1975 emissions data) to update the quantitative estimates made in section 4.3 of the amount of ozone reduction and increased DUV exposure for which the U.S. could be responsible. The quantitative estimates of potential impacts prevented by taking each regulatory option presented in section 4.3 are still based upon 1973 emissions data and the NAS projection of 7.5 percent ultimate ozone reduction. Therefore, these projections should be used only for comparative purposes to assess the relative potential impacts associated with each regulatory option.

Alternative 1 - No Action

This alternative is not considered to be a reasonable regulatory option, since it would have no impact in reducing the release of fluorocarbons; thus no effect on minimizing the potential environmental and health risks from such release. This statement is made with the recognition that an interim warning label requirement may have some short-term impact in reducing fluorocarbon emissions. The no action alternative is included as a baseline or point of departure for comparison with the reasonable regulatory approaches described below. The no action alternative would permit the continued release of about 50 percent of worldwide fluorocarbon emissions (43 percent of worldwide chlorofluorocarbons-11 and -12 emissions). Since chlorofluorocarbons-11 and -12 account for about 89 percent of worldwide fluorocarbon emissions (page 21, item b) and

because all predictive models of atmospheric and environmental impact have been generated using these compounds as their base, the discussion below considers only the impacts associated with the chlorofluoromethanes.

a. Impact on Stratospheric Ozone[1/]

The summary section of the preliminary NASA workshop report (14) states: "As noted in the NAS report, there is little doubt that ozone in the stratosphere will be destroyed by the release of chlorofluoromethanes into the troposphere. These compounds have been observed to accumulate in the troposphere at a rate consistent with the known release rate. They exist in the stratosphere at a concentration consistent with theory, and the concentration profile with altitude has been shown to decrease at a rate which corresponds to the combined impact of photolysis by ultraviolet radiation and transport. Laboratory measurements have shown that a photolysis product is the chlorine atom, and that this atom can enter into a catalytic cycle involving ozone and atomic oxygen to destroy ozone."

The NASA reports (14,77,78) and the NAS Panel report (8) attempt to estimate, with the use of 1-D models, the effects on total or column ozone resulting from continued releases of chlorofluoromethanes.

In this regard, the NAS concluded that "the ozone reduction and consequent DUV increase corresponding to a given CFM release is uncertain by a large factor. Continued release at the 1973 level, the usual example, is calculated to give an ultimate reduction in ozone of about 7 percent, where 'about 7 percent' is relatively certain to be between 2 percent and 20 percent."

The preliminary NASA workshop report summarizes as follows: "Using most of the available predictive 1-D models, the important reaction rates from a variety of competent sources, the best available information on eddy diffusion rates, and known solar flux values, we have concluded that the column ozone reduction will be between 5 and 9 percent for a continuing CFM injection rate of 750,000 metric tons per year. The time required to reach one half of this value will be 40 to 50 years. Insufficient data for all parameters preclude the calculation of an uncertainty on a statistical basis."

The uncertainties in these estimates are discussed in detail in both the NAS and NASA workshop reports. As the preliminary NASA workshop report explains: "The uncertainty in the prediction of the ozone column reduction using a 1-D model comes from several sources. Random errors which

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[1/] Also see section 3.1.1, pages 24-32.

arise from the experimental uncertainties in reaction rates, and from the choice of the transport coefficients can be reasonably well evaluated, but the systematic errors which arise from the simplifications that have been made in deriving the model are less subject to quantification."

A recent change in the rate constant for the NO + HO_2 reaction resulted in a factor of 2 increase in NASA's prediction of ultimate ozone reduction. As NASA states in their final workshop report, "where the new NO + HO_2 rate is used, all of the models (1-D temperature uncoupled) showed an increase in the calculated column-ozone depletion due to continued CFM release at 1975 rates of about a factor of 2 so that the range is from 10.8 to 16.5 percent," (77, p. 192). The NASA assessment report states that, "Using the NAS procedure, the overall uncertainty range is 4% to 30%." (78, p. 9).

In 1973, the U.S. was responsible for about 43 percent of the chlorofluorocarbons-11 and -12 emissions. Using the NAS projections of ultimate ozone depletion, U.S. chlorofluoromethane emissions alone could result in about a 3.2 percent decrease in ultimate column ozone (43 percent x 7.5). The uncertainties in this estimate are of a similar nature as those documented for the 7.5 percent ozone depletion estimate.

One dimensional models predict that maximum percentage reduction of ozone by chlorofluoromethanes would occur at about 40 km. This would allow more ultraviolet radiation to pass through this region to form extra ozone at about 20 km. As previously discussed, present models predict that this increase in ozone at 20 km will not completely counteract the decrease at the higher altitude. It is important to note that even without any effect of chlorofluoromethanes on column ozone, this redistribution in stratospheric ozone would remain as an impact resulting from chlorofluoromethane release.

b. Biological Impacts Resulting from Ozone Depletion and Increased DUV Radiation

As determined above, the U.S. contribution to ultimate ozone reduction resulting from chlorofluoromethane releases could be about 3.2 percent. The expected ultimate ozone reduction which could remain after a U.S. ban on chlorofluoromethane releases would be about 4.3 percent (7.5 percent-3.2 percent). Using the Rundel and Nachtwey model the expected ultimate increase in DUV associated with a 4.3 percent ozone reduction has been determined to be about 9.4 percent (table 16). Therefore, this U.S. action could prevent a DUV increase of about 7.6 percent (17 percent-9.4 percent). The 17 percent represents the DUV increase at a steady state ozone depletion of 7.5 percent.

Table 16. Worst-Case Estimates of Nonmelanoma Cancer Cases in the Next Century (1978-2078) for Different Regulatory Scenarios[1]

Regulatory Action	O_3 Decr. @ Equil. (%)[2]	DUV Incr. Equil. (%)[3]	Expected Background Cases/Century with No O_3 Decr. ($\times 10^6$)[4]	Expected Cases/Century with Given O_3 Decr. ($\times 10^6$)	Additional Cases/Century ($\times 10^6$)	Additional Cases/Century as % of Background	Cases/Century Avoided by Regulatory Action ($\times 10^6$)
No Ban	7.5	17	52.8	64.9	12.1	22.9[5]	0
Worldwide Ban, 1978	1.0 (peak in 1990)	2.2 (peak in 1990)	52.8	55.3	2.5	4.7	9.6[6]
U.S. Ban of All Uses, 1978 (57% of Releases Remain)	4.3	9.4	52.8	60.5	7.7	14.6	4.4
U.S. Ban of Aerosol Uses (69% of Releases Remain)							
1978	5.2	11.5	52.8	61.7	8.9	16.8	3.2
1980	5.2	11.5	52.8	61.8	9.0	17.0	3.1
Cost of Two Year Delay						0.15	0.078

[1]Prepared by Rundel and Nachtwey using R&N model.
[2]The ozone reduction scenarios are based upon the time-dependent ozone reductions projected by the NAS (1976) to result from continued release of CFMs at 1973 rates (baseline scenario). Banning effects were obtained by taking appropriate percentage reductions of the baseline scenario.
[3]The DUV, i.e. biologically effective UV-B (280-320 nm), was calculated using diurnally and seasonally averaged solar spectral irradiances at 40° N latitude (center of population of the U.S.) weighted by the DNA-damage action spectrum.
[4]10^6 = million
[5]Sample calculation: $12.1 \div 52.8 \times 100\% = 22.9\%$
[6]Sample calculation: $64.9 - 55.3 = 9.6$

(1) Human Health Effects[2/]

(a) Nonmelanoma

A considerable amount of evidence is available to support the concept that solar DUV plays a major role in the induction of nonmelanoma skin cancer.

Given a 7.5 percent equilibrium ozone reduction at 1973 chlorofluoromethane release rates, cases of nonmelanoma skin cancer can be calculated for various regulatory scenarios. Using the Rundel and Nachtwey model, the cumulative number of cases of nonmelanoma skin cancer which might occur in the white population of the U.S. over the next century for which the U.S. would be directly responsible as the result of taking no action to restrict chlorofluorocarbon releases is calculated to be about 4.4 million (table 16). This represents an average of about 44,000 cases per year.

(b) Melanoma

As pointed out earlier, (pages 65-67) there may be causes of malignant melanoma other than solar radiation, and the unknown fraction of melanoma incidence that is solar radiation-induced may not be related to accumulated dose as much as it may be related to lifestyle. Therefore, projections of melanoma cases and melanoma-related deaths cannot be made at this time. Suffice it to say that both cases and deaths could be higher with a no action alternative than would occur if U.S. chlorofluoromethane emissions were restricted.

(c) Other

In addition to the cases of nonmelanoma and melanoma skin cancer which would likely result from a no action alternative, the U.S. contribution to an increase in UV-B would promote sunburn, skin aging, and eye damage (page 68).

(2) Nonhuman Biological Effects[3/]

Those plants and animals living at their level of tolerance of DUV would be susceptible to any adverse effects associated with increased levels of DUV.

[2/] Also see section 3.3, pages 62-81.

[3/] See section 3.2, pages 36-62.

There is a potential for an increase in DUV to seriously affect natural plant ecosystems, especially those under stress from other unfavorable factors such as high temperature, low moisture, poor nutrient supply. The probability of occurrence of such potential effects cannot be assessed because the available data are insufficient.

The impact resulting from a 3.2 percent reduction in stratospheric ozone on agricultural plants would probably not be catastrophic but may cause subtle effects that result in decreased productivity and/or a decrease in the range a plant might be profitably grown. The effects may not be detectable against the effects produced by the changing climate and other factors. However, lack of detectability should not be equated with acceptability; an undetectable small percentage reduction in crop yield may have significant impact on the world's food supply in the 21st century.

The insufficiency of the available data precludes accurate assessment of the impact of increased DUV on domestic and wild animals. Given the shade-seeking behavior of most wild animals, and the protective hair, feathers, and pigmented skin, about the only potentially vulnerable site for DUV damage is the eye. High doses of monochromatic DUV can cause photokeratitis and even higher doses can cause cataracts. Whether the increased DUV doses which would result from a no action alternative would cause such effects is unknown. An accumulation of DUV damage to eyes, if it occurs, may shorten the lifetimes of individual animals which are thus removed from competition with younger survivors.

Ozone reduction leading to increased DUV may affect aquatic ecosystems by inhibition of photosynthesis of phytoplankton, by killing phytoplankton and zooplankton, by killing eggs and larvae of finfish and shellfish or causing abnormal development.

Despite our paucity of knowledge on the nonhuman biological impacts resulting from increased DUV exposures, the available data do indicate a potential for detrimental effects that must be considered.

c. Impact on Climate[4/]

The introduction of chlorofluoromethanes into the atmosphere creates a risk of significant alteration in the global climate. Climatic change could result directly from the absorption of infrared radiation by the chlorofluoromethanes or indirectly from the potential change in the total thickness and distribution of the stratospheric ozone layer.

4/ See section 3.4, pages 81-85.

The direct climatic effects result from the fact that chlorofluoromethanes absorb and emit radiation in the infrared "window" region of the electromagnetic spectrum. The normal composition of the Earth's atmosphere is such that infrared radiation is emitted through the "window." The net effect of increased chlorofluoromethanes would be a partial closing of the window and a trapping of the thermal (infrared) radiation emitted from the Earth's surface leading to an associated warming of the lower atmosphere.

It has been estimated that the ultimate climatic effects resulting from the infrared absorption properties of chlorofluoromethanes might be an increase of about 0.5°C in mean global surface temperature and a 1 percent change in average global precipitation. These average temperature and precipitation changes would be associated with much larger regional and local changes in many parts of the world. However, it is presently impossible to identify with any confidence specific temperature and precipitation changes for any particular global regions.

Local changes in temperature and precipitation on the order of those predicted would be great enough to eliminate existing production of commercial crops in selected marginal growing areas. However, it is less certain whether new production might be possible by development of new varieties or whether reduced production might be compensated by increased production in other areas.

Indirect climatic effects could result from the possible destruction and redistribution of stratospheric ozone owing to photolytic decomposition of chlorofluoromethanes that migrate to the stratosphere. A redistribution, even without a net decrease in stratospheric ozone, would likely cause changes in stratospheric temperature gradients which, in turn, could be expected to result in climatic changes of an unknown nature and magnitude.

The only certainties that can be counted on are disruption of existing patterns with some areas losing and others gaining. Whether total agricultural production would increase or decrease from the predicted climatic changes remains an unknown.

Since the U.S. is responsible for about 43 percent of 1973 chlorofluoromethane releases, no action by the U.S. might permit a similar percentage of the above climatic impacts to occur.

Alternative 2 - Ban Aerosol Propellant Uses of Chlorofluorocarbons-11 and -12

a. Description of Alternative

This option would phase out the aerosol propellant uses of chlorofluorocarbons-11 and -12. These two chlorofluorocarbons account for roughly

95 percent of the total U.S. fluorocarbon propellant emissions (from table 8, page 19; table 9, page 20). The types of aerosol products covered by this alternative are shown in table 9 and include personal products, household products, and others, such as insecticides, and industrial and veterinary products. Approximately 31 percent of worldwide chlorofluorocarbon-11 and -12 emissions (page 21, items b and g) or roughly 28 percent of worldwide fluorocarbon emissions (page 21, items a and g) would be controlled as a direct result of this action.

b. Environmental Impact

(1) Beneficial Environmental Impacts

(a) Impact on Stratospheric Ozone

Control of 31 percent of worldwide chlorofluorocarbon-11 and -12 emissions would reduce the predicted steady state ozone depletion level by 2.3 percent from 7.5 to 5.2 (table 16).

(b) Biological Impacts Resulting from Ozone Depletion and Increased DUV Radiation

The expected ultimate ozone reduction which could remain after a U.S. ban on releases of chlorofluoromethanes used as propellants would be about 5.2 percent (7.5 percent - 2.3 percent). Using the Rundel and Nachtwey model, the expected ultimate increase in DUV associated with 5.2 percent ozone reduction has been determined to be about 11.5 percent (table 16). Therefore, this U.S. action would prevent a DUV increase of about 5.5 percent (17 percent - 11.5 percent). The 17 percent represents the DUV increase at steady state ozone depletion of 7.5 percent.

- Human Health Effects

- Nonmelanoma Skin Cancer

The Rundel and Nachtwey model can be used to make predictions related to the incidence of nonmelanoma skin cancer which might be prevented by a U.S. ban on propellant uses of chlorofluorocarbons-11 and -12. As shown in table 16, such a ban in 1978 might prevent about 3.2 million cases of nonmelanoma skin cancer in the U.S. over the next century (an average of 32,000 cases per year).

- Melanoma

As indicated for Alternative 1, projections of melanoma cases and melanoma-related deaths cannot be made at this time. However, it is reasonably certain that both cases and deaths would be reduced as a result of a 31 percent decrease in worldwide chlorofluoromethane emissions.

- Nonhuman Biological and Climatic Effects

This alternative is expected to prevent exposure to increased DUV radiation and is, therefore, expected to have a beneficial impact on certain species of animals and plants, natural and man-made ecosystems, including agricultural crops and farm animals. This option would also reduce the potential for possible climatic changes and resultant biological impacts. The precise nature and magnitude of such beneficial impacts is not known; however, this option is expected to substantially mitigate the effects that would occur under the no action alternative.

c. Replacement Propellants and Associated Hazard

In considering the extent to which the beneficial impacts discussed above will occur, it is necessary to assess the potential impact of substitute propellant systems on stratospheric ozone and their potential for absorbing and emitting infrared radiation.

At the present time it is not possible to know all of the potential replacement systems with certainty nor the extent to which the likely potential substitutes will replace aerosol products containing chlorofluorocarbons-11 and -12. Furthermore, precise information regarding the environmental effects of known substitute systems is not available. Potential candidates for substitution include: fluorocarbons other than chlorofluorocarbons-11 and -12, e.g., other chlorofluorocarbons, bromochlorofluorocarbons, hydrochlorofluorocarbons, etc.; compressed gas, e.g., nitrous oxide, carbon dioxide, etc.; soluble liquefied hydrocarbon gases, e.g., propane, butane, isobutane, etc.; and combinations of the above. The potential impacts on stratospheric ozone and climate of these potential replacements are discussed in section 3.1.2, pages 33-36, and section 3.4, pages 81-85.

In the following discussion, the individual compounds within these classes are evaluated in terms of their suitability as aerosol propellants based on consideration of boiling point and vapor pressure. The Midwest Research Institute reported that to function as an aerosol propellant, a material should have to have a boiling point between -43^{o} and $41^{o}C$ and have a vapor pressure in the range of 25 to 95 psia at $21^{o}C$ (13).

Chlorofluorocarbons-114, -114a, and -115 are the only chlorofluorocarbons other than the chlorofluoromethanes that appear to have the necessary physical properties to make them suitable as aerosol propellants. Chlorofluorocarbon-113 has a boiling point and vapor pressure outside the the desirable range for aerosol propellant use, though its use as a vapor pressure depressant in aerosol propellant systems is possible. The boiling point of chlorofluorocarbon-113a ($45.7^{o}C$) is similar to chlorofluorocarbon-113, but chlorofluorocarbon-113a freezes at $14^{o}C$, compared

to -35°C for chlorofluorocarbon-113. Utilization of chlorofluorocarbon-113a as an aerosol propellant, or as a vapor pressure depressant in aerosol propellant systems is unlikely. Chlorofluorocarbons-111 and -112a are solids at room temperature and, therefore, unsuitable for use as aerosol propellants. The boiling point (92.8°C) and low vapor pressure of chlorofluorocarbon-112 would also preclude its use as a propellant.

Though presently not being used as aerosol propellants, the boiling points of bromochlorofluorocarbon-12B1 (-4°C) and of bromofluorocarbon-12B2 (24.5°C) are within the acceptable range for propellant use. The boiling point of bromofluorocarbon-13B1 (-57.8°C) is beyond the acceptable range for propellant use. Information regarding the suitability of iodofluorocarbons as aerosol propellants is not available.

The perfluorocarbons, F-14 and F-116, have low boiling points and high vapor pressures and are, therefore, beyond the acceptable range for use as aerosol propellants.

The hydrochlorofluorocarbons, particularly F-22 and F-142b, have been given serious consideration by industry as possible replacements for chlorofluorocarbons-11 and -12. The potential for replacement of chlorofluorocarbons-11 and -12 by hydrochlorofluorocarbons-22 and -142b is uncertain due to the recent toxicological findings described in section 3.6. DuPont, a leading producer of these compounds, has planned long-term inhalation studies and indicated that these products may not be available for use in personal products until "approximately January 1, 1980" (74).

Propellant systems that utilize compressed gas such as nitrous oxide (N_2O) and carbon dioxide (CO_2) were not until recently expected to be major replacements for the largest uses of FDA-regulated chlorofluorocarbons in hair sprays and antiperspirants. This was because of the coarse spray pattern and because the solvent produces a wet, cold spray that is unpleasant to the skin. However, one major manufacturer of hair sprays is now using CO_2 propellants for products shipped to Oregon which now has a ban on the aerosol use of chlorofluorocarbons.

The soluble hydrocarbon gases (propane, butane, etc.) are currently in wide use as propellants for many classes of aerosol products. However, until recently these propellants had only limited use in personal products due to concern about flammability. Hydrocarbon propellants such as isobutane and propane blends in combination with methylene chloride appear to result in acceptable flammability levels. Thus, the potential exists for replacement of chlorofluorocarbons-11 and -12 uses in personal products with this propellant system. The hydrocarbon propellants such as butane and propane have not been implicated either as a threat to the ozone shield or a potential cause of climate changes. Methylene chloride is a chlorocarbon containing hydrogen atoms; thus, this compound is more

reactive in the troposphere thereby decreasing the threat to stratospheric ozone. There is, however, some uncertainty regarding the future potential of methylene chloride because of possible direct toxicity effects to the user of an aerosol product. The long-term toxicological properties of methylene chloride are presently being investigated both in government-sponsored studies and those supported by private industry. Methylene chloride is closely related in chemical structure to chloroform, which has recently been shown to be carcinogenic. The FDA has invited the submission of information in a notice published in the FEDERAL REGISTER of April 29, 1977, (42 FR 21843) about the health risks to the immediate user of all halocarbons.

To the extent that hydrocarbons replace chlorofluorocarbons as propellants, the potential for thermal injury to the worker involved in the manufacture, processing, and distribution of hydrocarbons and hydrocarbon-propelled products will increase. To the extent that compounds which are more reactive in biological systems than are chlorofluorocarbons, e.g. methylene chloride and certain hydrochlorofluorocarbons, are used in propellant formulations, the potential for direct toxicity to workers will increase. Both hazards may be kept to a minimum by the introduction of properly designed ventilation systems in the work place.

Table 17, which summarizes the above considerations, clearly reflects the importance of carefully evaluating the potential environmental impacts of possible replacement propellants in assessing the potential for realization of beneficial effects of banning chlorofluorocarbons-11 and -12. The table shows, based upon current knowledge, that other chlorofluorocarbons, e.g., -114 and -115, would pose the greatest potential risk to stratospheric ozone and to climate should they be substituted for chlorofluorocarbons-11 and -12.

(d) Direct Health Impact

The Consumer Product Safety Commission estimates from the National Electronic Injury Surveillance System that there were approximately 5,700 aerosol product-related injuries treated in hospital emergency rooms in calendar year 1975. These injuries have been grouped into four major categories. They are: incidents involving spraying of the contents of the container onto the victim's body; injuries resulting from inhalation or ingestion of the container contents; mechanical injuries involving the physical properties of the container (e.g., sharp edges, hard exterior); and thermal injuries resulting from vapor ignition or explosion of the container.

Spraying injuries constitute about 66 percent of aerosol-related injuries; approximately 12 percent involves ingestion or inhalation of

Table 17. Comparison of the Relative Risks of Potential Replacement Propellants with Respect to Chlorofluorocarbons-11 and -12 on a Per Molecule Basis

Potential Replacement Propellant	Risk of Ozone Depletion[1]	Contribution to Greenhouse Effect[2]
Chlorofluorocarbons (114, 115)	S	PS
Bromochlorofluorocarbons (12B1, 12B2)	PS	PS
Hydrochlorofluorocarbons (F-22, 142b)	L	L
Hydrochlorocarbons (methylene chloride)	L	U
CO_2	LIA	L
N_2O	PS	U
Hydrocarbons (pentane, butane, etc.)	LIA	LIA

S - Risk similar to chlorofluorocarbons-11 and -12

PS - Possibly similar; additional study needed

L - Lower risk

LIA - Little, if any, risk

U - Unknown

[1] Refer to pages 33-36 for discussion.

[2] Refer to pages 81-85 for discussion.

the container contents. Mechanical and thermal incidents account for 10 percent and 3 percent of the injuries, respectively. About 8 percent of the injuries could not be assigned to any category because the injury diagnosis was not specified. Table 18 summarizes these findings.

Only those aerosol container-related injuries classified as thermal and ingestion/inhalation involve the aerosol propellant (spraying injuries primarily relate to the non-propellant contents of the container). Although recognizing that the majority of aerosol product-related injuries does not involve the aerosol propellant, this alternative may nevertheless result in a reduction in aerosol product-related injuries to the extent that aerosol products are replaced by non-propellant packaging. The magnitude of this impact, should it occur, cannot be predicted since the extent of replacement is not known.

The most severe of all aerosol-related hazards results from intentional inhalation. In 1975, the Consumer Product Safety Commission received 89 aerosol container-related death certificates. Intentional inhalation was the apparent cause of death in almost all of these cases. The "high" produced by intentional inhalation is an effect of the chlorofluorocarbon propellant. The phaseout of chlorofluorocarbons-11 and -12 and replacement by non-propellant packaging or by less toxic, non-hallucinogenic propellants would effectively address this hazard.

(e) Energy and Natural Resources

To the extent that aerosol packaging is replaced by non-propellant packaging, there will be a net energy savings. One study which compared the energy requirements of liquid cooking oil with aerosol cooking oil found that the former used about ten times less energy to produce 1 ounce of cooking oil than the latter (1,440 BTU's/ounce versus 10,103 BTU's/ounce) (75). The energy consumption associated with the existing use of chlorofluorocarbons in FDA-regulated aerosol packages and the energy requirements of potential substitutes are not known. It is therefore not possible to estimate the magnitude of energy savings that might result from the proposed action. In FDA's Notice of Intent to phase out chlorofluorocarbons, published in the FEDERAL REGISTER of November 26, 1976, the Commissioner invited comments on the differences between the energy requirements of the substitutes and the energy consumption associated with the existing uses of chlorofluorocarbons. The only comment received regarding energy consumption characterized aerosols as energy saving. The comment did not, however, provide any data or information to support this assertion.

(f) Solid Waste

To the extent that aerosol packaging is replaced by non-aerosol systems, there will be a net reduction in the volume of solid waste. This is based on the assumption that fewer non-aerosol packages than aerosol packages will be required to dispense an equal volume of active ingredients. The magnitude of this impact cannot be predicted, since the extent to which such replacement will occur is not known.

Table 18. Frequency and Rate of Hospitalization of Aerosol Product-Related Injuries by Gross Hazard Pattern (January 1, 1975 - December 31, 1975)

Gross Hazard Pattern	Frequency of ERT[1/]	Percent of Total	Hospitalization/ 100 Injuries
Spraying	3,750	66%	2.8
Ingestion/ Inhalation	700	12%	8.0
Mechanical	600	10%	11.4
Thermal	160	3%	15.0
Not Specified	470	8%	0.0
Total	5,660	100%	4.4

[1/] ERT - Emergency Room Treatment

Source: Bureau of Epidemiology, U.S. Consumer Product Safety Commission.

(2) Adverse Environmental Impacts Resulting from Ban on Chlorofluorocarbons-11 and -12

(a) Direct Effects

There are no anticipated direct adverse environmental effects, since this alternative will reduce environmental exposure to non-naturally occurring chemicals that may harm the public health and environment by depleting stratospheric ozone and by contributing to the "greenhouse effect."

(b) Indirect Effects

- The Consumer Product Safety Commission reports that during 1975, 160 aerosol product-related thermal injuries were treated in hospital emergency rooms (table 18). For thermal injuries the important feature of the aerosol propellant is its flammability. To the extent that hydrocarbon propellants replace chlorofluorocarbons-11 and -12 these injuries would probably increase.

- Replacement of chlorofluorocarbons-11 and -12, which have a very low acute toxicity (section 3.6, pages 86-88), with new propellants presents the potential for direct effects such as acute and chronic toxicity to the user of aerosol products. For new products subject to premarket approval by FDA, the Agency would evaluate these risks prior to approval for use in a propellant system. The manufacturer would have to substantiate the safety of a product with respect to such a hazard before using it in cosmetics (21 CFR 740.10).

- Chlorofluorocarbons-11 and -12 may be replaced by compounds posing less risk to the stratosphere because they are more reactive to the lower atmosphere. Intermediate products formed from the breakdown of such compounds might, if generated in sufficient concentrations, cause health and environmental problems. The Commissioner of Food and Drugs requested information on intermediate products formed from the breakdown of halocarbons with current and projected use in FDA-regulated products (10). Specifically requested was information on potential for intermediates to be formed, their tropospheric residence times, concentrations in respirable air, and toxicity. The only information received related to the breakdown of hydrochlorofluorocarbons (76). The expected decomposition products would include hydrogen chloride, hydrogen fluoride, and carbonyl halides. According to the above source, carbonyl halides, although toxic in concentrated form, would not be expected to pose any hazard to health in the concentrations which would result should global aerosol chlorofluorocarbon release be converted on an equal weight basis to hydrochlorofluorocarbons.

Alternative 3 - Ban Aerosol Propellant Uses of All Chlorofluorocarbons

This option would ban in addition to chlorofluorocarbons-11 and -12 (covered by Alternative 2), the use of all other chlorofluorocarbons as aerosol propellants, e.g., -114 and -115. Approximately 30 percent (table 9, page 20 and page 21, items a, e, and f) of worldwide fluorocarbon emissions and virtually all of the U.S. fluorocarbon aerosol propellant emissions would be controlled as a result of this action. This represents an increase of 2 percent over worldwide fluorocarbon emissions controlled by Alternative 2 (page 98). This increase is from the regulation of chlorofluorocarbon-114, which is used almost exclusively as a propellant in personal aerosol products.

The short-term environmental impact of this alternative is not expected to be substantially different from Alternative 2. However, some non-measurable beneficial impacts would probably accrue since the percent of worldwide fluorocarbon emissions controlled would be increased from 28 percent to 30 percent. The primary beneficial impact of this action, compared to number 2, is to prevent replacement of the chlorofluoromethanes with other chlorofluorocarbons which pose a similar environmental risk.

The potential adverse environmental impacts are expected to be the same as recorded for Alternative 2 (page 106).

Alternative 4 - Ban Aerosol Propellant Uses of All Fluorocarbons

This alternative is identical to Alternative 3 except that in addition to the chlorofluorocarbons, all other fluorocarbons would be restricted. This would include for example, the perfluorocarbons, fluorocarbons containing halogens other than chlorine and fluorine, i.e. bromine, iodine, and the hydrochlorofluorocarbons. These other fluorocarbons have not been used as aerosol propellants; therefore, this alternative would not, in the short term, have any greater impact on worldwide emissions than Alternative 3. The primary beneficial impact of this action would, however, be to prevent substitution and use of other fluorocarbon compounds which pose some, largely unknown, risk to the environment in terms of ozone depletion and/or their contribution to the "greenhouse effect."

4.4. Comparison of Reasonable Alternatives, Selection of Preferred Alternative

In making his decision regarding the appropriate course of action, the Commissioner had to choose first between "no action" and "some" regulation of fluorocarbon release. The no action alternative, as previously indicated, was not considered to be a reasonable approach to the problem. This course of action could be selected only if there was a determination

that fluorocarbon use and release did not pose an unreasonable risk to health and the environment. The Commissioner has concluded from the available evidence, as reviewed in section 1, pages 1-6, that continued use and release of these compounds do pose a substantial environmental risk.

Alternative 2, regulation of chlorofluorocarbons-11 and -12, would control roughly 95 percent of current U.S. fluorocarbon propellant emissions (28 percent of worldwide fluorocarbon emissions). This alternative would have a substantial beneficial impact in the short term; however, long-term benefits might not accrue since chlorofluorocarbons-11 and -12 could be replaced by other suitable chlorofluorocarbon propellants posing similar environmental risks and by other fluorocarbons posing lesser potential for impact.

Regulation of all chlorofluorocarbons, as provided by Alternative 3, would control almost 100 percent of current U.S. aerosol emissions (chlorofluorocarbons-11 and -12--95 percent; chlorofluorocarbon-114--5 percent). This represents about 30 percent of worldwide fluorocarbon release. Also it would prevent the use of chlorofluorocarbons not currently used in large amounts as aerosol propellants (e.g., chlorofluorocarbons-114, -115) but which are suitable replacements for chlorofluorocarbons-11 and -12. Based on available scientific information, these other chlorofluorocarbons pose a risk similar to chlorofluorocarbons-11 and -12.

Alternative 4, which would ban aerosol propellant use of all fluorocarbons, is identical to Alternative 3 in terms of current fluorocarbon emissions controlled, i.e. about 30 percent of worldwide emissions. This option differs, however, in that it would mitigate potential environmental impact by preventing the use of any fluorocarbon as a replacement for the currently used propellants--chlorofluorocarbons-11, -12, and -114. Although this is the most thorough solution, the Commissioner has determined that it is premature at this point to resolve whether or not fluorocarbons other than chlorofluorocarbons pose unacceptable risks. The available data, albeit limited, suggest that the risk from hydrochlorofluorocarbons is considerably less than the risk from chlorofluorocarbons. Should brominated fluorocarbons reach the stratosphere, it has been shown that bromine atoms would be at least as efficient as chlorine in its ability to act as a catalyst in the destruction of ozone. Unfortunately, there are very little data regarding the stability of these compounds in the troposphere, thus the potential for these compounds to reach the stratosphere is unknown. The FDA will continue to monitor scientific developments regarding the risks posed by these compounds and will reassess the need to consider this option should an increased use of fluorocarbons other than the chlorofluorocarbons as aerosol propellants occur.

Based on the foregoing considerations, Alternative 3, i.e. ban on aerosol propellant uses of all chlorofluorocarbons, was selected as the preferred course of action. The global impact of this option is to control 30 percent of worldwide fluorocarbon emissions (62 percent of U.S. fluorocarbon emissions and virtually all U.S. aerosol propellant uses of fluorocarbons). This alternative compared to regulation of only -11 and -12 (Alternative 2), would mitigate potential long-term environmental effects by preventing substitution of the chlorofluoromethanes by other chlorofluorocarbons (-113, -114, -115) which have similar environmental risk.

4.5 Selection of Regulatory Timetable

The development of the regulatory timetable involves a balancing of the need to minimize environmental and health risks posed by chlorofluorocarbon release with the need to allow a reasonable period to phase out regulated uses in order to minimize economic losses.

Regarding environmental impact considerations, the regulatory agencies examined the effects that might be prevented by a U.S. ban on propellant uses of chlorofluorocarbons in 1978 versus 1980. The only effects that can be quantified are data relating to the incidence of nonmelanoma skin cancer generated by the Rundel and Nachtwey model previously described (table 16).

Table 16 shows the potential effects on the U.S. incidence of nonmelanoma skin cancer in white populations resulting from continued chlorofluoromethane releases at 69 percent of 1973 worldwide release rates starting in 1978 (corresponds to a ban of 31 percent of worldwide chlorofluoromethanes in 1978 such as that which would occur with a U.S. ban on propellant uses of chlorofluoromethanes in 1978). This table also shows the potential effects on the U.S. incidence of nonmelanoma skin cancer should the same reduction in chlorofluoromethane releases not occur until 1980.

The cumulative numbers of cases of nonmelanoma skin cancer expected to be prevented in white populations in the U.S. over the next century as a result of a ban on U.S. propellant uses of chlorofluoromethanes in 1978 and 1980 can be calculated in a manner similar to that described in the nonmelanoma section of the no action alternative (page 96). Such a ban might prevent about 3.2 million cases of nonmelanoma skin cancer in the U.S. over the next century if it were to occur in 1978 and about 3.1 million cases if it were to occur in 1980. The estimated increase in the number of additional cases of nonmelanoma skin cancer in the U.S. over the next century resulting from a two-year delay in eliminating U.S. chlorofluorocarbon propellant emissions is 78,000; the average number of cases/year over the next century is 780. The peak increase in numbers of

cases would be about 1,140 which would occur in the year 2040. These would not be detectible increases in the numbers of nonchlorofluoromethane-related nonmelanoma skin cancers which will occur each year.

The other biological and climatic effects cannot be quantified; whatever impacts might be prevented by a U.S. ban on the propellant uses of chlorofluoromethanes in 1980, these same impacts would be reduced even sooner and to a greater extent if the ban were to occur in 1978.

For a detailed discussion of the economic impacts associated with the regulation of chlorofluorocarbon aerosol propellants the reader is referred to the study entitled, The Economic Impact of Potential Regulation of Chlorofluorocarbon Propellant Aerosols (April 1977) that was performed by International Research and Technology Corporation and Policy Models Incorporated under contract to the Environmental Protection Agency (EPA). The FDA helped direct and finance this study through an inter-agency agreement with EPA.

The study collected data and assessed the phasing out of chlorofluorocarbons for three different time periods; 6 months, 18 months, and 30 months. These phaseout periods are the time which would be allowed for firms to cease manufacturing chlorofluorocarbons for use in aerosols. Data generated from this study along with the concurrent review of the environmental impacts associated with a phaseout occurring in 1978 versus 1980, led to the formulation of the FDA regulatory timetable: Foods, drugs, devices, or cosmetics manufactured or packaged after December 15, 1978, and finished products initially introduced into interstate commerce after April 15, 1979, would be prohibited. The reader is also referred to the FDA Inflation Impact Statement for specific discussion of the inflation impact of FDA's regulatory action described below. Both documents are available in the Office of the Hearing Clerk.

4.6. Consideration of International Restrictions on Chlorofluorocarbon Emissions

As previously stated throughout section 4 of this document, the elimination of all releases of chlorofluoromethanes in the U.S. would reduce worldwide emissions by about 43 percent. A U.S. ban of chlorofluoromethanes used as propellants would reduce worldwide emissions by about 31 percent. Indeed, in order to reduce the total threat of chlorofluorocarbon emissions to health and the environment, action at the international level is required.

Recognition of the possibility of damage to the ozone layer from human activities has been widespread in the international community for some time. In relation to the specific threat posed by chlorofluorocarbons, the publication and wide distribution of the National Academy of Sciences reports (7,8) stimulated considerable international interest. As in the

U.S., there are differences of opinion within and among countries concerning the urgency of the threat and the need to take early remedial action. However, it was explicitly recognized in the final report of the March 1977 international scientific meeting on the ozone layer, sponsored by the UN Environmental Program that "CFM emissions are a matter of concern." The consensus of an April 1977 meeting of policy level officials on the regulation of chlorofluorocarbons attended by 13 of the world's leading producers and users of chlorofluorocarbons was also that the issue of ozone depletion is a serious one which requires close attention. Several countries in fact stated that they had initiated or were considering taking actions which would follow the broad lines of the U.S. and Canadian approach to controlling emissions. Several others stated that they would be making decisions during 1978. All concurred that if additional scientific evidence currently being gathered continues to point in the same direction, broad international control of chlorofluorocarbon emissions would probably be called for in the foreseeable future. It is also worth noting that many countries are able to institute and implement action such as control of chlorofluorocarbon emissions much more rapidly than the U.S., with its lengthy regulatory process. They thus stated that they did not feel the urgency of initiating action on the same time scale as the U.S.

SECTION 5. DESCRIPTION OF PROPOSED ACTION

5.1. Action by the Food and Drug Administration

The FDA is proposing to prohibit the use of certain fluorocarbons, these being the fully halogenated chlorofluoroalkanes (chlorofluorocarbons), as propellants in self-pressurized (aerosolized) containers in any product subject to the Federal Food, Drug, and Cosmetic Act (FFD&C). The products to which the regulation applies are human foods, food additives, human drugs, including biological products, animal food, animal drugs, cosmetics, and medical devices. Products manufactured or packaged after December 15, 1978, and finished products initially introduced into interstate commerce after April 15, 1979, would have to comply with this regulation.

The proposed FDA action will control approximately 25 percent of worldwide fluorocarbon release. The proposed prohibition would not apply to the following uses specified as essential in the rule:

- metered dose steroid human drugs for nasal inhalation
- metered dose steroid human drugs for oral inhalation
- metered dose adrenergic bronchodilator human drugs for oral inhalation
- contraceptive vaginal foams for human use
- metered dose ergotamine tartrate for oral inhalation.

Also not covered by the proposed ban are FDA-regulated non-propellant uses of chlorofluorocarbons, e.g.:

- pressurized cylinders of chlorofluorocarbons and ethylene oxide used for sterilization purposes
- cylinders used simply to transport chlorofluorocarbons for industrial uses, as in the case of liquid food freezants and foam-blowing agents used in the fabrication of food packaging containers
- chlorofluorocarbons used as a stabilizer in food toppings and spreads.

The control of chlorofluorocarbon emissions from non-propellant sources is currently under consideration by FDA, EPA, and CPSC (see p. 91). The FDA-regulated essential propellant and non-propellant uses described

above are estimated to account for about 1 percent of worldwide fluorocarbon release and less than 5 percent of all FDA-regulated fluorocarbons.

5.2 Action by the Environmental Protection Agency

The phaseout proposed by the EPA essentially parallels and complements the FDA proposal described above.

The FDA proposed prohibition applies to uses of chlorofluorocarbons in self-pressurized containers subject to the FFD&C Act. The EPA action is being proposed under the Toxic Substances Control Act which excludes from its coverage any food, food additive, drug, cosmetic or device when manufactured, processed or distributed for use as these articles. EPA and FDA have coordinated their proposals to avoid unnecessary duplication, prevent gaps in coverage, and promote efficient enforcement of the pertinent laws. The EPA's proposed regulation applies to the manufacture of chlorofluorocarbons for use as an aerosol propellant other than for uses in FDA-regulated products, and essential uses specified in the EPA phaseout regulation. At present, according to EPA, all fully halogenated chlorofluoroalkane propellants are manufactured in an identical manner regardless of potential end use. At the manufacturing stage, the ultimate intended use is undetermined or not clearly established. Since FDA will have prohibited nonessential propellant uses in the products FDA regulates, it is reasonable to believe that chlorofluorocarbons would not be manufactured for these uses.

5.3 Action by Consumer Product Safety Commission

CPSC, in November 1976, made a preliminary finding that products using fully halogenated chlorofluoroalkanes present an unreasonable risk of injury to consumers from the destruction of ozone in the stratosphere, and that no feasible consumer product safety standard would adequately protect the public. The Commission directed its staff to prepare a draft FEDERAL REGISTER notice under section 8 of the Consumer Product Safety Act proposing to declare such aerosol products as hazardous products. CPSC subsequently has agreed to terminate its proceedings to the extent that timely EPA action makes CPSC regulation unnecessary.

SECTION 6. SUMMARY OF ENVIRONMENTAL IMPACT OF PROPOSED ACTION

6.1. Beneficial Impacts (Impact b provides the major basis for issuing the proposed rule; the remaining potential impacts listed have been taken into account in assessing regulatory action.)

a. reduce currently predicted steady state ozone depletion levels and resultant increase in DUV (damaging ultraviolet radiation) reaching the earth;

b. reduce the peak number of new cases of nonmelanoma and probably melanoma skin cancer that would be expected to occur at currently predicted ozone depletion levels;

c. reduce potential for other health effects of increased exposure to DUV radiation, e.g., premature skin aging, increased incidence of sunburn, eye damage;

d. reduce potential for adverse nonhuman biological impacts and possible climatic changes;

e. reduce the hazard of intentional inhalation to the extent that chlorofluorocarbon propellants will be replaced by non-propellant packaging or by less toxic, non-hallucinogenic propellants;

f. possibly reduce other aerosol product-related-injuries--explosion, cuts, etc.--to the extent that aerosol products using chlorofluorocarbon propellants are replaced by non-propellant packaging;

g. reduce energy consumption and solid waste volume to the extent that chlorofluorocarbon-containing self-pressurized products are replaced by non-propellant packaging.

6.2. Potential Adverse Environmental Impacts

a. To the extent that hydrocarbon propellants replace chlorofluorocarbons, there would probably be an increased risk of aerosol product-related thermal injuries.

b. Replacement of chlorofluorocarbons with new propellants presents the potential for direct effects such as acute and chronic toxicity to the user of aerosol products if manufacturers fail to fulfill their responsibilities to substantiate the safety of the product.

c. Replacement of chlorofluorocarbons by more reactive propellants may result in the formation of intermediate products in the lower atmosphere which, if generated in sufficient concentrations, could cause health and environmental impacts.

6.3. Discussion of Probable Adverse Environmental Impacts Which Cannot Be Avoided

There are no anticipated adverse environmental impacts that cannot be avoided should the proposed action be implemented. This statement is made with the recognition that there is some uncertainty regarding the environmental effects of potential replacement propellants, both in terms of impact on stratospheric ozone and climate and also from the standpoint of direct health effects to the user. The FDA will carefully monitor all studies relating to the environmental and health effects of substitute products and replacement propellant systems.

For new products subject to premarket approval by FDA, the Agency would evaluate these risks prior to approval for use in a propellant system. The manufacturer would have to substantiate the safety of a product with respect to such a hazard before use in cosmetics.

6.4. Description of the Relationship Between the Local Short-Term Use of the Environment with Respect to the Proposed Action and the Maintenance of Long-Term Productivity

Since the intent of the proposed action is to reduce environmental exposure to substances that may harm health and the environment, the proposed action will not pose a long-term risk, but will minimize such risk.

6.5. Description of Any Irreversible or Irretrievable Commitment of Resources Which Would Be Involved in the Proposed Action Should It Be Implemented

There will not be an irreversible or irretrievable commitment of resources should the proposed action be implemented. In fact, an energy savings is predicted to the extent that aerosol packaging is replaced by non-propellant packaging.

6.6. Objections to the Proposed Action Raised by Interested Persons

All objections to the proposed action are addressed fully in the preamble to the final rule that requires warning statements on foods, drugs, animal food, animal drugs, cosmetics, and medical devices in self-pressurized containers that contain chlorofluorocarbon propellants (42 FR 22018).

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APPENDIX A

1. abiotic: Not living; basic inorganic and organic compounds such as water, carbon dioxide, oxygen, calcium, nitrogen and phosphorus salts, amino and humic acids; ant. biotic.

2. aerosol propellant: A liquefied or compressed gas in a container where the purpose of the liquefied or compressed gas is to expel from the container a liquid or solid material(s) different from the aerosol propellant.

3. aliphatic: Belonging to a class of carbon compounds, especially the saturated or unsaturated compounds in which the carbon atoms are joined in open chains.

4. apical dominance: In plants, the inhibition of lateral bud growth by terminal buds.

5. basal cell carcinoma: An epithelial tumor that seldom metastasizes but has potentialities for local invasion and destruction.

6. biomass: Living weight, the total mass or amount of living organisms in a particular area or volume.

7. biosphere: 'All of the earth's living organisms, interacting with the physical environment as a whole so as to maintain a steady state system intermediate in the flow of energy between the high energy input of the sun and the thermal sink of space; syn. ecosphere.

8. biotic: Of life, or caused by living organisms, a biotic community is any assemblage of populations living in a prescribed area or physical habitat; ant. abiotic.

9. calcareous: Of, like, or containing calcium carbonate, calcium, or lime.

10. catalyst: A substance which alters the velocity of a chemical reaction but undergoes no permanent chemical change itself.

11. cataract: An opacity of the crystalline lens of the eye.

12. chitin: A tough, horny polysaccharide secreted by the epidermis and forming the main bulk of the outer covering of insects and crustaceans.

13. chlorofluorocarbon: Chemical compound consisting of chlorine, fluorine, and carbon.

14. chlorophyll: The green pigment found in the chloroplasts of plant cells involved in the photosynthetic process.

15. clones: Genetically identical individuals derived asexually from a single individual, as by cuttings, bulbs, division in plants.

16. cuticle: A waxy layer over the outer surface of the epidermis of terrestrial plants which protects primarily against water loss.

17. deoxyribonucleic acid (DNA): An essential component of all living matter and a basic material in chromosomes of the cell nucleus; it contains the genetic code and transmits the hereditary pattern.

18. diurnal: Happening each day; daily.

19. DUV: Biologically active ultraviolet radiation. Consists of ultraviolet radiation in the wavelength range of 290-320 nm weighted according to its relative effectiveness on DNA. Ultraviolet radiation below 290 nm does not reach the ground and ultraviolet radiation above 320 nm does not affect DNA seriously.

20. erythema solare: A morbid redness of the skin of many varieties, due to congestion of the capillaries, as a result of sunburn.

21. erythema: A name applied to redness of the skin produced by congestion of the capillaries, which may result from a variety of causes, the etiology or specific type of lesion often being indicated by a modifying term.

22. etiology: The study or theory of the factors that cause disease and the method of their introduction to the host.

23. euphotic zone: The uppermost portion of a body of water, into which light enters to a degree sufficient for photosynthesis and the consequent growth of plants.

24. fluorocarbons:

    general--Compounds consisting of at least fluorine and carbon, but additionally could contain hydrogen, chlorine, bromine, and/or iodine.

    specific--Compounds consisting only of fluorine and carbon. (A compound consisting of fluorine, carbon, and hydrogen would be referred to as a hydrofluorocarbon.)

25. free radical: An atom or group of atoms possessing an odd (unpaired) electron.

26. fully halogenated chlorofluoroalkanes: Chlorofluorocarbons in which all carbon-carbon bonds are single bonds.

27. halocarbons: Compounds consisting of halogen(s) and carbon, or halogen(s), carbon, and hydrogen.

28. halogen: Any of the five very active, nonmetallic chemical elements fluorine, chlorine, bromine, iodine, and astatine.

29. infrared radiation: Denotes thermal radiation and consists of light rays (specifically, electromagnetic radiation) which have lower energy and longer wavelengths (770-1200 nm) than visible light rays.

30. insolate: To expose to the sun's rays.

31. internodes: The portion of a plant stem between two successive nodes, nodes being the places on the stem where leaves, flowers, and branches originate.

32. irradiance: The amount of light or other radiant energy striking a given area of a surface.

33. keratitis: Inflammation of the cornea.

34. malignant melanoma: A malignant (tending to become progressively worse and result in death) tumor, usually developing from a nevus (mole) and consisting of black masses of cells with a marked tendency to metastasis; syn. melanocarcinoma, melanoepithelioma, melanosarcoma.

35. melanin: The dark amorphous pigment of the skin, hair, various tumors, and other animal tissues.

36. melanocyte: The cell responsible for the synthesis of melanin; constitutes 5-25 percent of human epidermal cells.

37. microcosm: Syn. microecosystem; laboratory or field-sized model ecosystems with discrete boundaries, either derived directly from nature or synthesized by adding organisms from cultures; these miniature biospheres are manipulated by ecologists in order to understand ecological principles operating in natural ecosystems, e.g., freshwater lakes, grasslands, etc.

38. nastic: Of, relating to, or constituting a movement of a plant part caused by disproportionate growth or increase in cellular pressure.

39. ozone: A molecule consisting of three oxygen atoms, i.e., O_3. (An oxygen molecule is O_2). By absorbing ultraviolet radiation, mainly of wavelengths between 200 and 320 nanometers (nm), the ozone layer in the stratosphere acts as a protective shield preventing much of the sun's harmful ultraviolet radiation from reaching the earth's surface.

40. photodynamic: Of or pertaining to the energy of light.

41. photokeratitis: See keratitis.

42. photolysis: Chemical decomposition by the action of radiant energy.

43. photosensitization: The development of abnormally heightened reactivity of the skin to sunlight.

44. photosynthate: Products of photosynthesis, including plant sugars used for respiration.

45. photosynthesis: Production of organic substances, chiefly sugars, from carbon dioxide and water occurring in green plant cells supplied with enough light to allow chlorophyll to aid in the transformation of radiant energy into a chemical form.

46. pterygium: Wing-like triangular fold of membrane extending from the conjunctiva to the cornea of the eye, being immovably united with the cornea at its apex, sclera throughout its middle portion, and conjunctiva at its base.

47. ribonucleic acid (RNA): An essential component of all living matter present in the cytoplasm of all cells and composed of long chains of phosphate and sugar ribose along with several bases; one form of RNA is the carrier of genetic information from the nuclear DNA and is important in the synthesis of proteins in the cell.

48. self-pressurized container: An aerosol product, i.e., any product which depends on the power of a liquefied or a compressed gas to expel the contents, liquid or solid, from the container.

49. siliceous: Of, like, or containing silica, as the shells of certain microscopic algae called diatoms.

50. squamous cell carcinoma: A malignant new growth made up of squamous epithelium cells tending to infiltrate the surrounding tissues and give rise to metastases.

51. stamen: A pollen-bearing organ in a flower made up of a slender stalk (filament) and a pollen sac (anther).

52. stratosphere: The atmosphere above the troposphere, which extends up to about 30 miles above the earth's surface. Unlike the troposphere, the stratosphere is relatively cloudless and remarkably quiescent (the upper atmosphere).

53. tropopause: The transition zone between the troposphere and stratosphere at which the drop in temperature with increasing height ceases.

54. troposphere: The part of the atmosphere which extends up to about 5 miles above the earth's surface at the poles and 10 miles at the equator (the lower atmosphere).

55. ultraviolet radiation (uv): Light rays (specifically, electromagnetic radiation) which have higher energy and shorter wavelengths (below 390 nm) than visible light rays.

56. xeroderma pigmentosum: A rare and frequently fatal pigmentary and atrophic disease in which the skin and eyes are extremely sensitive to light.

57. zenith: The point in the sky directly overhead.

APPENDIX B

RUNDEL AND NACHTWEY MODEL FOR ULTRAVIOLET RADIATION AND NON-MELANOMA SKIN CANCER

A variety of models for quantifying the relationship between ultraviolet radiation and non-melanoma skin cancer (NMSC) have been published. All of these models rely on the latitudinal gradient of NMSC incidence obtained in one or several epidemiological studies. In most of the earlier epidemiological studies under-reporting of cases was a serious problem: NMSC, being a relatively benign form of cancer, is frequently treated on an out-patient basis in the offices of general practitioners and general surgeons as well as those of dermatologists. The best available epidemiological data are those obtained in a Supplemental Study to the Third National Cancer Survey (10). They too show a latitudinal gradient and gradient with sunburning UV dose (Figure 1). However, the scatter of points is such that it is difficult to accurately quantitate the dose-response.

A new approach is needed to quantify more accurately the relationship between ultraviolet radiation and skin cancer incidence. Our new approach to this problem employs the TNCS data on the skin cancer incidence as a function of age to derive a dose-response model, and then uses this model to predict the effects of increased biologically harmful ultraviolet radiation (BHUV, see Note (3)) resulting from ozone reduction. By

this means an amplification factor is calculated separately for each geographic region for which skin cancer incidence data are available. Utilization of the latitudinal variation of incidence is thus completely avoided.

A condensation of a preliminary draft of a paper describing the new model follows: (some references have been omitted from the condensed version but not from the reference list).

Dose-Response Considerations

For obvious reasons, there have been no controlled studies on humans to establish the relationship of a UV dose to skin cancer response. However, Blum (8) performed a number of such studies using mice, and found that when mice are irradiated with a constant daily dose of ultraviolet radiation, the cumulative fraction of mice with tumors, as a function of time since commencement of irradiation, can be well-represented by a cumulative normal distribution for which the independent variable is the logarithm of time; this is commonly referred to as a lognormal distribution. Mathematically, if t is the time since commencement of irradiation, then the number N(t) of mice developing tumors in the time interval between t and t + dt is given by

$$N_{(t)} = \frac{N_o}{\sigma \sqrt{2\pi}} \exp\left[-\tfrac{1}{2}\left(\frac{\ln t - \ln t_m}{\sigma}\right)^2\right] d(\ln t) \qquad (1)$$

where N_o is the total number of mice in the experiment, and $\ln t_m$ and σ are the mean and standard deviation parameters characterizing the distribution. The values of the distribution parameters differ for different dose rates, daily doses, intervals between doses, or different strains of mice, but the functional form is observed to be consistent with the lognormal distribution (Figure 2).

Because it is reasonable to assume that, on the cellular level, the same biological processes are responsible for skin cancer induction in both mice and humans, the first attempt at establishing a human dose-response model should be to examine whether the available data on human skin cancer are also consistent with a lognormal distribution of incidence as a function of accumulated exposure time, which we assume to be proportional to age. A priori, a lognormal distribution of incidence might reasonably be expected. A lognormal distribution results from multiplicative or proportionate interactions in a series of small steps leading to some given end point (12). Much evidence indicates that, in experimental animals, the induction of a diagnosable skin tumor by various agents involves multiple steps of initiation, promotion, conversion, and propagation through the stages from a

normal cell, through an initiated cell (altered), through a dormant tumor cell or focus of cells, to a growing tumor (13). Considering UV-induced tumors, other variables may be involved all along the way: e.g., pigmentation, enzyme repair mechanisms, immunological responses, sloughing of initiated cells, etc. Interactions of such multiple steps and factors could generate a lognormal distribution of skin cancer incidence as a function of age even in an ethnically homogeneous population receiving exactly the same dose at the same dose rate under identical conditions of life style. In a large heterogeneous population exposed to different doses at different dose rates under different conditions of life style, one can assume that there are many subpopulations consisting of essentially comparable individuals. In each subpopulation, the skin cancer incidence can be expected to follow a lognormal distribution with a given mean onset time to appearance of a tumor and a given variance. It is a property of lognormal distributions that the sum of many overlapping lognormally distributed subpopulations, i.e. the total heterogeneous population, will also be lognormally distributed with a variance equal to the sum of the variances of the subpopulations and mean onset time to appearance of a tumor reflecting the average of the mean onset times of the subpopulations. Thus, even though a host of factors are involved in skin cancer induction by solar UV, the end result may still very likely be represented by a lognormal distribution of incidence as a function of age.

The best data available at present on human skin cancer incidence comes from the previously mentioned Supplement to the Third National Cancer Survey (10). For this study, data were obtained by a careful canvassing of dermatologists, radiotherapists, pathologists, and other physicians, seeing and treating skin cancer during the six-month period from September 1, 1971, to February 29, 1972. The data were converted to age-specific incidence rates (cases/year for particular age classes) for white males and for white females, for each of the four regions surveyed. It is important to note, however, that the TNCS data are not directly comparable to the data using mice. In the experiments with mice, an animal developing a tumor is removed from the experiment, so that the distribution function refers only to first cases of skin cancer. The TNCS data include all patients observed in the six-month period, with no distinction made as to whether or not a given case was the first for that individual. However, with one additional assumption, the TNCS data can be converted to data on first cases: We assume that skin cancer cases are independent events--i.e., the probability of skin cancer in an individual does not depend on whether or not he has had it before. The validity of this assumption may be questioned because individuals developing one carcinoma apparently tend to develop others within a few years (14). This problem is partially circumvented by using the TNCS data on patients, not cases,

and thus counting patients with multiple cases as only one. Our model, however, does not take into account the possibility that genetic susceptibility could lead to subsequent cases occurring with a higher probability than that expected for the population as a whole. Because adequate epidemiological data on first cases are not at present available, we have no choice but to proceed with the assumption of independence. We hope that the model we suggest may contribute to an improved design for future epidemiological surveys; in such future studies attempts to determine first case incidences should be made.

Dose-Response Model

If P_a is the probability per unit time of contracting skin cancer (both first and subsequent cases) at age a, then the probability, Q_a, per unit time, of not contracting skin cancer at age a is

$$Q_a = 1 - P_a \tag{2}$$

The probability of never having contracted skin cancer before age a is the product of the probabilities of not having contracted it at any previous age

$$Q_{0\to\underline{a}} = \prod_{i=1}^{\underline{a}-1} \qquad Q_i = \prod_{i=1}^{\underline{a}-1} (1 - P_i) \tag{3}$$

The probability $P'_{\underline{a}}$ of contracting skin cancer for the first time at age $\underline{a}$ is given by

$$P'_{\underline{a}} = P_{\underline{a}}\, Q_{0\to\underline{a}} = P_{\underline{a}} \prod_{i=1}^{\underline{a}-1} (1 - P_i) \tag{4}$$

Data obtained from the TNCS, broken down into five year age groups are shown in Table 1 (15). These data expressed as age-specific incidences (Table 1B) can be converted to probabilities of contracting skin cancer per person per year, that is, experimental values for $P_{\underline{a}}$. We assume that the incidence for each age group represents the mid-point age of that group and that the 85+ age group effectively represents the 85-90 group. We can then calculate probabilities for the first case incidence using Eq. 4. For example, $P'_{42.5}$ represents probability (per person per year) of first contracting skin cancer at the midpoint of the 40-45 age group, and is given by

$$P'_{42.5} = P_{42.5}\,(1 - P_{42.5})^{2.5}\,(1 - P_{37.5})^{5}\,(1 - P_{32.5})^{5}\,(1 - P_{27.5})^{5}\,(1 - P_{22.5})^{5} \qquad (5)$$

(The 5th power of the probability of not contracting skin cancer at a given age, $(1-P_{\underline{a}})^5$, represents the probability of not contracting skin cancer during the entire 5-year age period.)

The TNCS data for each region and sex, transformed to first-case incidences, were fitted to a lognormal distribution using a non-linear least-squares fitting method developed by Marquardt (16) as adapted for computer by Bevington (17). Results are shown in Figures 3a and 3b, and in Table 2. The complete distributions are not shown because few people live beyond about 90. However, the model implies that if a person lived long enough he would surely contract a case of skin cancer. The t_m values in Table 2 indicate the age by which 50% of the surviving population will have contracted at least one case of skin cancer. Figure 4 shows the cumulative fitted probabilities as a function of age; these curves show the probability of contracting a first case of skin cancer by a given age in a given area. For example in Dallas-Fort Worth, 30% of the 70-year old males would be expected

to have contracted a first case of skin cancer at sometime in their lives. Appropriate epidemiological studies (for example, surveys of nursing home populations) could verify this aspect of our model.

It is important at this point to discuss the possible uncertainties in the data, and the goodness of fit of these data to the postulated log-normal distribution. A lower bound to the uncertainty in the data can be obtained from the square root of the actual number of individuals reflected by each data point (see Table 1A). These uncertainties in values of P_a can then be used to calculate, by standard error-propagation techniques (17), the uncertainties in P'_a. There may also be systematic errors present in the data, due to incomplete canvassing, seasonal variations in seeking treatment, the transformation of the data to first case incidences, etc. We assume that these uncertainties can be included approximately by postulating an additional 10% uncertainty in P'_a, which is added in a root mean square manner to the statistical uncertainty.

We have used the X^2 goodness of fit test (17) to evaluate the extent to which the data support the assumption of a lognormal distribution. This test measures the ratio of the actual squared deviations of the data from the fitted function to the squared deviations expected on the basis of experimental uncertainties. For the entire data set, the reduced X^2 (X^2 divided by the number of degrees of freedom, 96 in this case) is

1.13, indicating a 20% confidence in the goodness of fit. Considering the very approximate epidemiological uncertainties, we feel that this result yields fairly strong confirmation that first incidences of human skin cancer can be well-represented by the lognormal distribution.

Having established the best-fitted lognormal distribution of first case incidence $P'_{\underline{a}}$ vs age, we may now employ it to calculate expected values for all cases $P_{\underline{a}}$ by the recursive relations

$$P_1 = P'_1$$

$$P_2 = P'_2/(1-P_1)$$

$$P_3 = P'_3/(1-P_1)\ (1-P_2)$$

.

.

.

$$P_{\underline{a}} = P'_{\underline{a}}/\prod_{i=1}^{\underline{a}-1}(1-P_{\underline{a}}) \qquad (6)$$

Then the total expected incidence I for a given locality, expressed in units of patients per 100,000 population per year, is obtained by multiplying the age-specific incidences for all cases P_a by the fraction W_a of the population in that age group (18) and summing over all ages,

$$I = 10^5 \sum P_a W_a \qquad (7)$$

The incidences calculated in this manner are shown in Table 3.

Effects of Increased BHUV

We now assume that the law of reciprocity is valid for human skin cancer induction. The law of reciprocity states that the photochemical effect of a given total radiation dose is independent of the dose rate, i.e., the effect is determined by the product of dose rate times exposure time. Blum (8), in his studies with mice, observed that the reciprocity law was valid over a fairly wide range of dose rates, failing only at the lowest dose rate used. There is no comparable evidence for reciprocity in human skin cancer, although the apparent suitability of the lognormal distribution in fitting human first case incidence suggests that the reciprocity law may be at least approximately valid. If there is a reciprocity failure in human skin cancer incidence like that observed by Blum at very low dose rates, then our model will underestimate the effect of an increased BHUV dose rate, and in this sense our model provides a lower limit on these effects.

Assuming that reciprocity holds, we may model the effect of an increased BHUV dose rate by taking the effective age of an individual to be his chronological age increased by the same proportional amount that his accumulated BHUV dose is increased. For example, consider an individual who is exactly 70 years old when the BHUV dose rate is suddenly increased by 10%. After one year, his chronological age is 71, but his effective skin cancer age is 71.1. His probability of contracting skin cancer is given by the value of $P_{\underline{a}}$ appropriate to his effective age, rather than his chronological age. Thus the net effect of an increased BHUV dose rate is to cause skin cancer to appear at an earlier age than would be the case without such a perturbation. Because the population per unit age range decreases sharply with increasing age above about age 55, and most skin cancer occurs in this age range, a shift of the incidence to earlier ages will manifest itself as an increased number of cases.

For the general case of an arbitrary time-dependent increase in BHUV dose rate, a complicated time-dependent calculation must be carried out to obtain the increase in skin cancer incidence that will appear at any given subsequent time. However, there is a special case for which a simple result can be obtained, and this case provides a basis for

estimating approximately the net long-term effect of more complicated cases. The special case occurs when the BHUV radiation flux suddenly increases by some fraction f, and then remains constant at that new level. After a sufficient time (the human life span), everyone in the population will have an accumulated lifetime dose which is increased by the same fraction f. Thus, at equilibrium, a 1% increase in BHUV would, on average, cause skin cancer to appear about 4 months earlier in those individuals destined to contract it early in life (e.g. at age 33) and about 9 months earlier in those destined to contract it later in life (e.g. at age 75). The new equilibrium skin cancer incidence is calculated from Eq. 7, with $P_{\underline{a}}$ being replaced by $P_{\underline{a}'}$, where the effective age $\underline{a}' = a(1+f)$. We refer to this special case as a constant perturbation. For $f \ll 1$, this case is characterized by a constant amplification factor A given by

$$A = \frac{1}{f} \frac{\sum_{\underline{a}} (P_{\underline{a}'} - P_{\underline{a}}) W_{\underline{a}}}{\sum_{\underline{a}} P_{\underline{a}} W_{\underline{a}}} \qquad (8)$$

Equation (9) omitted

The amplification factors calculated in the above manner for the four regions of the TNCS are presented in Table 3. We have verified that the amplification factors as defined are indeed constant for constant perturbations up to 5%.

It should be noted that these amplification factors are defined in a different way from that of McDonald (7). McDonald used as an amplication factor the ratio of fractional increase in skin cancer incidence to fractional decrease in ozone,

$$A = \frac{\Delta I/I}{\Delta O_3/O_3} \tag{10}$$

This can be rewritten as

$$A \equiv \frac{\Delta I/I}{\Delta D/D} \cdot \frac{\Delta D/D}{\Delta O_3/O_3} \tag{11}$$

Thus McDonald's amplification factor, expressing the increase in skin cancer incidence per unit ozone decrease, is the product of two terms, one the increase in BHUV radiation per unit ozone decrease (radiation amplification factor), and the other the increase in skin cancer incidence per unit BHUV increase (biological amplification factor). The

biological amplification factor is the one calculated here. The radiation amplification factor has been calculated separately (19), and is approximately 2, so the amplification factors presented in this paper should be doubled to be directly comparable with McDonald's.

Sun-Seeking/Ethnicity Factors

Within the framework of the present model, in the absence of hereditary (ethnicity) or lifestyle factors the median age t_m of the age-incidence distribution for a given region should be inversely proportional to the mean yearly dose rate, i.e. their products should be a constant. Any departure from this proportionality should be an indication of differences in ethnicity/lifestyle. A region with a small value of this product (relative to other regions) indicates that the population of that region is either "sun-seeking" or more genetically prone to skin cancer. We can thus derive a relative "sun-seeking/ethnicity index" by taking the inverse of the product of dose rate times median age t_m. In Table 4 we present values for this index, normalized to one for the Iowa region. Results are quite consistent for males and females, and indicate sun-seeking or genetic susceptibility in the Minneapolis-St. Paul region and sun-avoidance or genetic resistance in San Francisco-Oakland, relative to the other two regions. We might speculate that the higher than expected value (based on latitude) for Minneapolis-St. Paul may be attributable to

the large Scandinavian population and to sun-seeking behavior in the summer months that follow the frequently cloudy months of winter and early spring (greater than 60% average sky cover (20)). In addition, the UV albedo of snow is high, so that the effective winter BHUV dose rate may be higher than that measured by an upward-looking dosimeter. Similarly the low index for San Francisco-Oakland, indicating sun avoidance or genetic resistance, may be partially attributable to the large Italian and Latin populations and partially attributable to the cool summers in the San Francisco-, San Mateo-, and Marin-County portions of the SMSA. Cool summers obviously encourage greater clothing cover and less swimming activity.

Increase in Skin Cancer in the U.S. from an Increase in BHUV

In order to estimate the effect of an increase in BHUV radiation flux on the United States as a whole, we must assume that the distribution parameters derived from a particular region are characteristic of the entire latitude band containing that region. Then the four regions may be averaged, each one with a weight proportional to the 1970 population living in that latitude band (see Table 3 for weights) (21). The results of this averaging procedure are presented in Table 5. Actually, there is no evidence that heredity/lifestyle factors remain constant for a given latitude band, as we assume. However, amplification factors for the

four regions all lie within approximately ±15% of the mean, so that the average U.S. values we report are not very sensitive to the assumption of constancy within a latitude band, or to the details of the averaging process. It should be emphasized that the calculated numbers of new cases are based on 1970 population figures; increases in population will naturally increase these values proportionally.

We should re-emphasize that all the above calculations refer specifically to non-melanoma types of skin cancer, which are generally not fatal. Epidemiological data (10) on the more fatal form of skin cancer, melanoma, show that the incidence is about 2.7% of that for non-melanoma, and the mortality rate is 40% of the incidence. We wish to caution the reader against attempting to scale the present calculations to predict melanoma deaths resulting from an increase in the UV-B radiation flux. The predictions of the present model are sensitive to the details of the age-distribution of incidence, and existing data clearly indicate that the age distributions of melanoma and non-melanoma incidence are quite different (5). In fact, the age distribution of melanoma tends to show a double-peaked structure, which cannot be modelled by a simple lognormal distribution. The prediction of melanoma deaths resulting from a perturbation thus requires development of a new dose-response model specifically for melanoma. Work is presently under way to develop such a model.

CONCLUSIONS

We have developed a dose-response model for non-melanoma skin cancer incidence in Caucasians which is biologically reasonable and which is consistent with available epidemiological data. The model postulates that the probability of first incidence of skin cancer is distributed lognormally as a function of total accumulated lifetime doses of BHUV, and that, for any given location, the accumulated lifetime BHUV dose of an individual is proportional to his age. The effect on skin cancer incidence of an increase in BHUV (due to a reduction of stratospheric ozone) can then be calculated directly from the extent to which each individual's lifetime accumulated dose is thereby increased. The result of such a perturbation, on average, would be to cause skin cancer to appear at an earlier age. Since skin cancer is predominantly a disease of the elderly, this shift to younger ages has the effect, when integrated over the entire population, of increasing the overall total number of cases of skin cancer. It should be noted, however, that many of these additional cases will occur in elderly people shortly before their deaths from other causes.

For the United States as a whole, we estimate that a 1% permanent decrease in the average stratospheric ozone thickness, which produces about a 2% increase in BHUV, would lead ultimately to an increase of

8% in skin cancer incidence. We assume, of course, in this estimate that lifestyle, genetic susceptibility, and the geographical distribution of population remain unchanged. This increase in cases would occur gradually over the course of human lifespan (approximately 75 years).

Within the framework of the postulated dose-response model, the uncertainty in the above results is estimated to be approximately $\pm$25%. However, there are also uncertainties in the model postulates that cannot at present be quantitatively evaluated: (a) the degree to which BHUV is the predominant cause of skin cancer, (b) the degree to which the lifetime BHUV dose is accumulated at dose rates where reciprocity might fail, and (c) the influence of genetic susceptibility on subsequent cases. Therefore, the overall prediction uncertainty may be substantially greater than $\pm$25%. This uncertainty can be significantly reduced in the future by carefully designed epidemiological surveys and experimental studies.

References and Notes

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21. For calculational purposes, we assume the Dallas-Ft. Worth region to represent the sates AL, AZ, AR, 2/3 CA, FL, GA, HI, LA, MS, NM, SC, TX: San Francisco to represent 1/3 CA, CO, DE, DC, KS, KY, MD, MO, NV, NC, OK, TN, VA, WV; Iowa to represent CT, IL, IN, IA, MA, MI, NB, NH, NJ, NY, OH, PA, RI, VT, WI, WY; and Minneapolis-St. Paul the rest. Weights (from the 1970 U.S. Census) are then as shown in Table 3.

TABLE 1

A. NUMBER NONMELANOMA SKIN CANCER CASES AMONG WHITES NEWLY DIAGNOSED IN SURVEY PERIOD, SEPT. 1, 1971-FEB. 28, 1972

Age	Dallas-Ft. Worth		Iowa		Minneapolis-St. Paul		San Francisco-Oakland	
Group	Male	Female	Male	Female	Male	Female	Male	Female
<5	0	0	0	0	0	0	0	0
5-9	0	0	0	0	0	0	0	0
10-14	0	0	0	0	0	0	0	0
15-19	0	1	0	0	0	0	0	1
20-24	2	3	1	1	2	1	8	3
25-29	14	10	4	9	4	9	18	7
30-34	28	28	9	5	7	7	17	19
35-39	61	54	26	8	16	8	27	22
40-44	118	65	42	21	34	22	80	44
45-49	155	109	60	33	46	32	112	94
50-54	254	112	95	52	49	39	163	103
55-59	253	122	126	50	77	53	193	135
60-64	303	137	152	72	73	49	217	120
65-69	248	151	174	82	88	55	223	101
70-74	232	159	196	126	77	75	168	102
75-79	154	129	157	113	93	82	143	125
80-84	107	97	121	113	72	51	86	84
85+	47	65	74	74	32	40	50	65

(Annual rates were based on one-half year's complete experience)

TABLE 1

B. ANNUAL AGE-SPECIFIC INCIDENCE RATES (per 100,000 population) FOR NONMELANOMA SKIN CANCER AMONG WHITES IN FOUR AREAS OF THE UNITED STATES

Age	Dallas Ft. Worth		Iowa		Minneapolis-St. Paul		San Francisco Oakland	
Group	Male	Female	Male	Female	Male	Female	Male	Female
<5	-	-	-	-	-	-	-	-
5-9	-	-	-	-	-	-	-	-
10-14	-	-	-	-	-	-	-	-
15-19	-	2.2	-	-	-	-	-	1.9
20-24	5.0	6.3	2.1	1.8	5.7	2.2	14.0	5.0
25-29	34.5	24.5	9.8	21.6	11.6	25.7	34.9	13.7
30-34	84.7	86.4	25.2	13.6	26.2	26.3	41.6	48.9
35-39	202.3	178.7	76.4	22.2	67.3	33.8	72.9	62.4
40-44	393.9	213.3	111.2	54.2	141.8	89.9	203.8	109.7
45-49	531.7	357.4	157.2	82.4	197.0	133.4	264.8	211.5
50-54	1,031.3	444.7	258.9	133.5	242.6	176.8	431.6	258.0
55-59	1,245.3	543.8	372.9	139.5	449.3	276.7	584.5	375.9
60-64	1,852.5	718.4	508.3	217.6	521.4	289.4	804.6	390.3
65-69	2,167.1	959.0	722.7	279.7	847.3	378.2	1,146.5	402.4
70-74	2,903.4	1,301.0	992.9	479.1	926.5	585.0	1,168.8	479.9
75-79	3,025.8	1,436.9	1,069.3	535.2	1,526.7	832.9	1,465.5	779.3
80-84	3,848.9	1,755.3	1,369.6	807.0	2,108.6	815.6	1,539.2	811.7
85+	2,797.6	1,724.5	1,370.7	719.3	1,568.2	960.6	1,384.4	877.3

Source: J. Scotto, Personal Communication

TABLE 2

Lognormal Distribution Parameters

Region	Sex	t_m* (years)	σ (ln-years)	Reduced X^2
Dallas-Ft. Worth	Male	83.3	.340	0.99
	Female	105.8	.431	0.92
Iowa	Male	113.5	.393	0.82
	Female	142.3	.434	1.63
Minneapolis-St. Paul	Male	110.5	.389	1.35
	Female	133.9	.449	1.05
San Francisco-Oakland	Male	104.0	.394	1.52
	Female	134.7	.490	0.79

Overall X^2 = 1.13

df = 96

*Antilog of mean ln t_m.

TABLE 3

Calculated Incidence and Amplification Factors

Region	Sex	Incidence*	A^+	Weight°
Dallas-Ft. Worth	Male	472	3.7	.120
	Female	280	3.4	.124
Iowa	Male	161	4.3	.231
	Female	91	4.4	.245
Minneapolis-St. Paul	Male	177	4.2	.037
	Female	126	4.0	.038
San Francisco-Oakland	Male	230	3.9	.101
	Female	147	3.5	.105

*Per 100,000 Caucasian population standardized to the population of the United States for 1970.

+Ratio of increased skin cancer incidence to increased biologically harmful ultraviolet radiation for constant perturbation.

°Based on population distribution from 1970 U.S. census (18).

TABLE 4

Calculated Lifestyle/Ethnicity Factors

	Dose Rate*	Sun-Seeking/Ethnicity Index	
	($x10^{-6}$)	M	F
Dallas-Ft. Worth	1.61	1.06	1.04
San Francisco-Oakland	1.51	0.90	0.87
Iowa	1.25	1.00**	1.00**
Minneapolis-St. Paul	1.07	1.20	1.24

*Annual BHUV, i.e. counts from Robertson-Berger Sunburning Ultraviolet Meters (reference 10).

**Normalization

TABLE 5

Calculated Incidence and Amplification Factors

Region	Sex	Incidence*	A+	Weight°
Dallas-Ft. Worth	Male	472	3.7	.120
	Female	280	3.4	.124
Iowa	Male	161	4.3	.231
	Female	91	4.4	.245
Minneapolis-St. Paul	Male	177	4.2	.037
	Female	126	4.0	.038
San Francisco-Oakland	Male	230	3.9	.101
	Female	147	3.5	.105

*Per 100,000 Caucasian population standardized to the population of the United States for 1970.

+Ratio of increased skin cancer incidence to increased biologically harmful ultraviolet radiation for constant perturbation.

°Based on population distribution from 1970 U.S. census (18).

TABLE 6

Calculated Lifestyle/Ethnicity Factors

	Dose Rate*	Sur-Seeking/Ethnicity Index	
	($x10^{-6}$)	M	F
Dallas-Ft. Worth	1.61	1.06	1.04
San Francisco-Oakland	1.51	0.90	0.87
Iowa	1.25	1.00**	1.00**
Minneapolis-St. Paul	1.07	1.20	1.24

*Annual BHUV, i.e. counts from Robertson-Berger Sunburning Ultraviolet Meters (reference 10).

**Normalization

TABLE 7

United States Averages*

Current incidence (per 100,000 population)	200
Total current cases (per year)+	360,000
Amplification factor (constant perturbation)	4.0
Total "new cases" for a 1% increased in BHUV at equilibrium (per year)+	15,000

*Calculated from results in Table 2, weighted by U.S. population distribution. (See Note 21.)

+Based on 1970 U.S. Caucasian population; increases in population will, of course, increase these values proportionately.

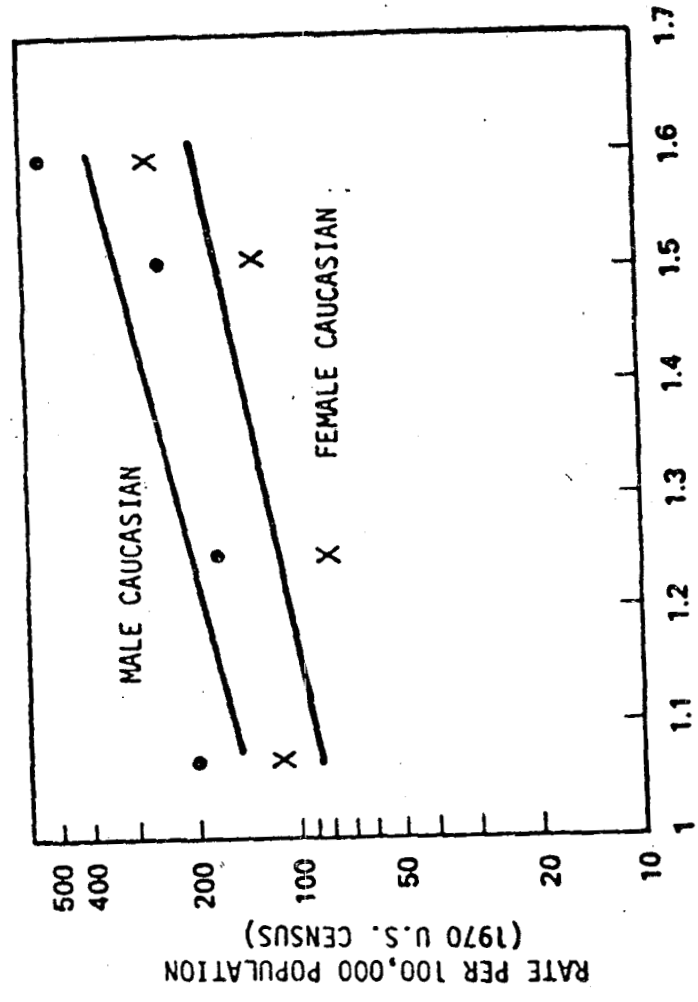

Figure 1.-Annual age-adjusted incidence rates for non-melanoma skin cancer for four TNCS areas

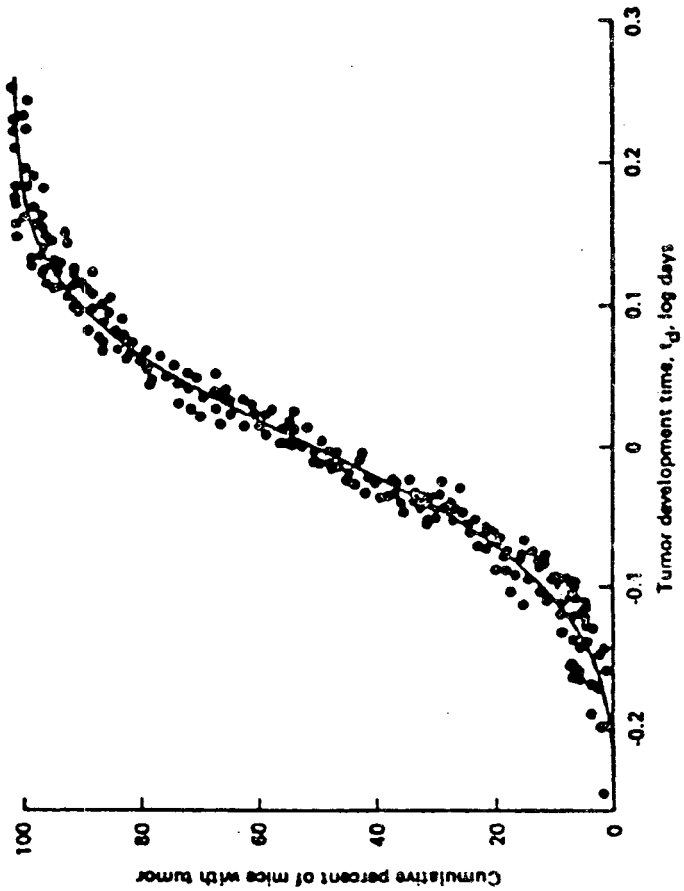

Figure 2.-Tumor development time in a population of genetically homogeneous male mice

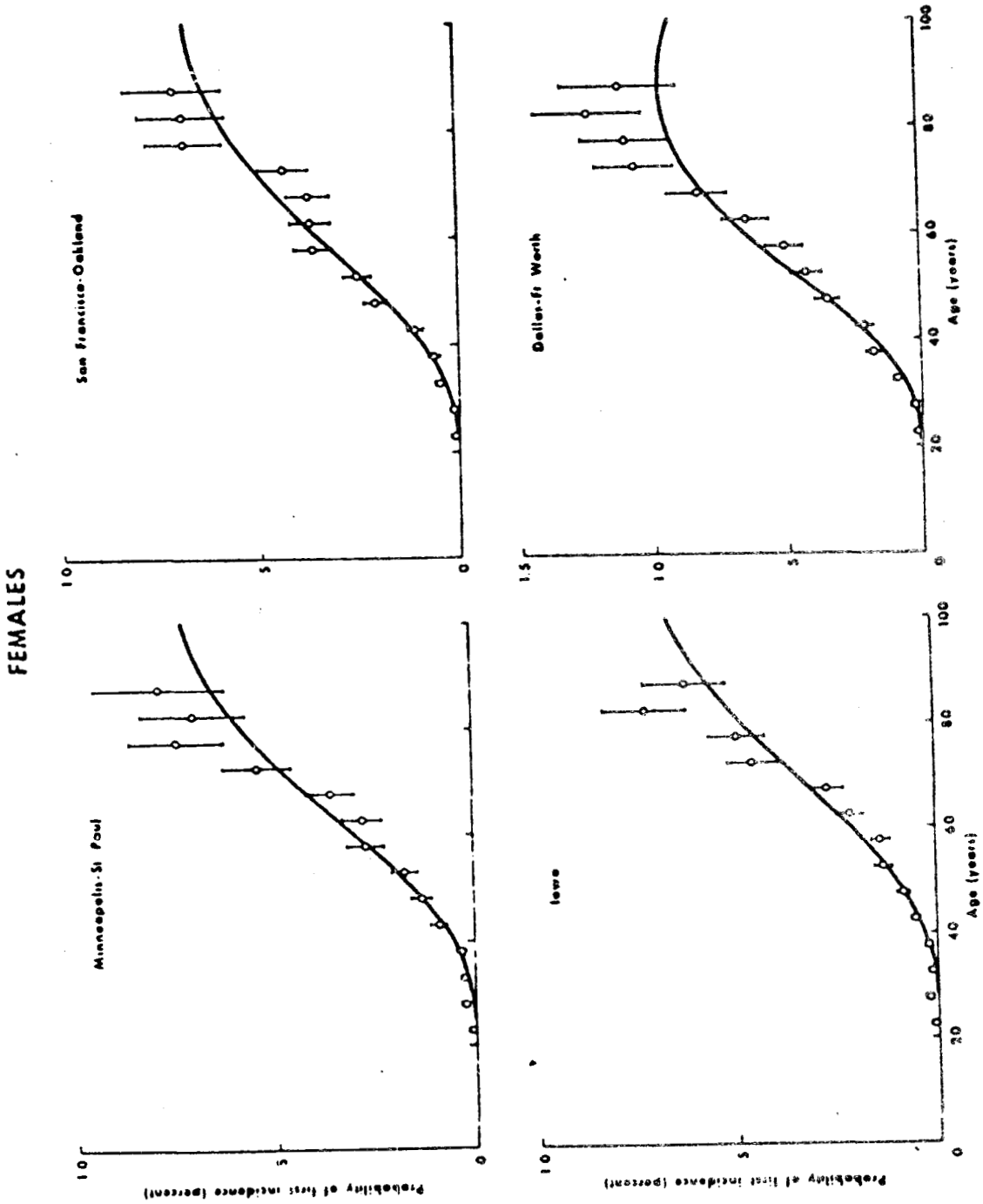

Figure 3a.-Probability of first skin cancer incidence vs age

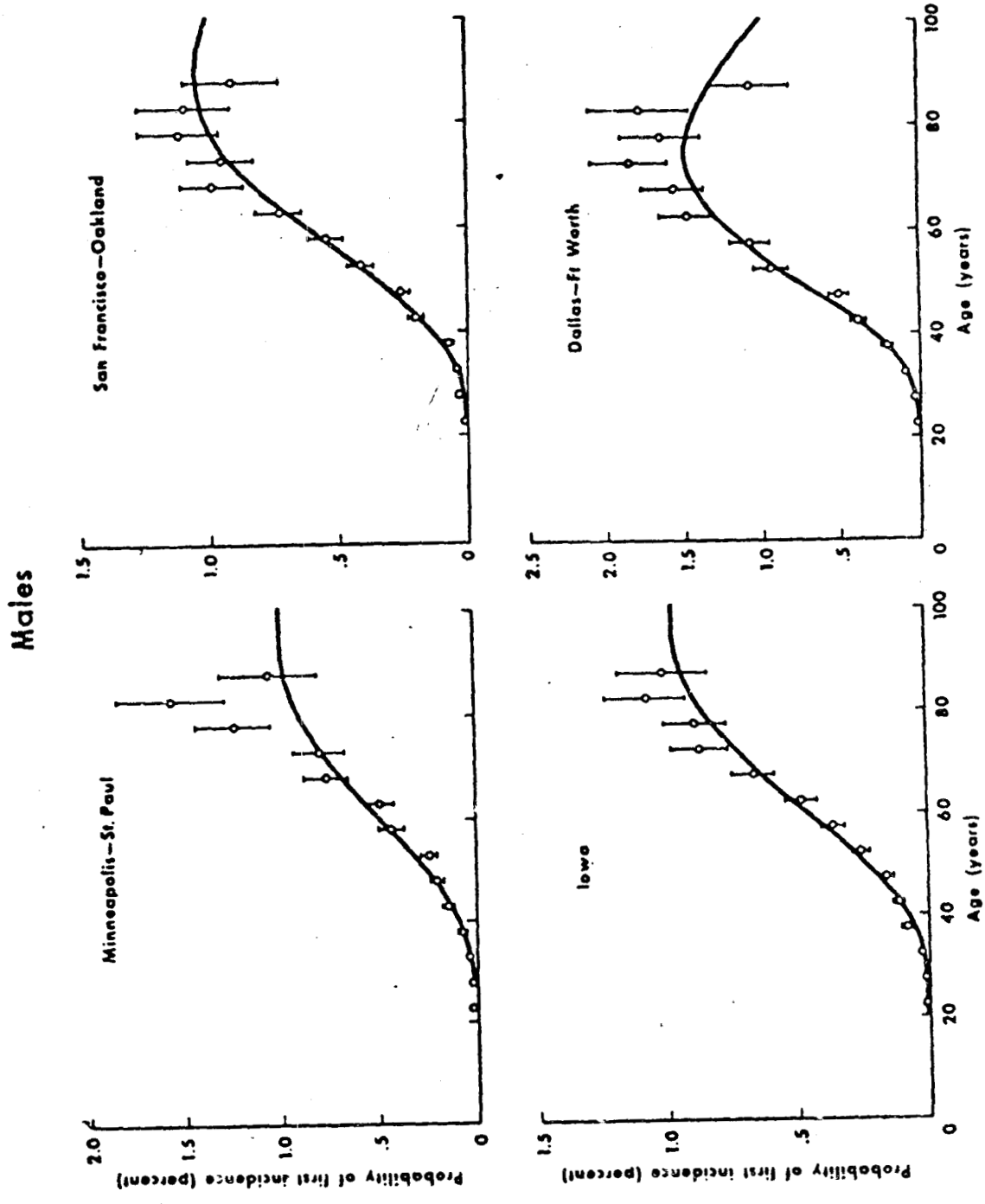

Figure 3b.-Probability of first skin cancer incidence vs age

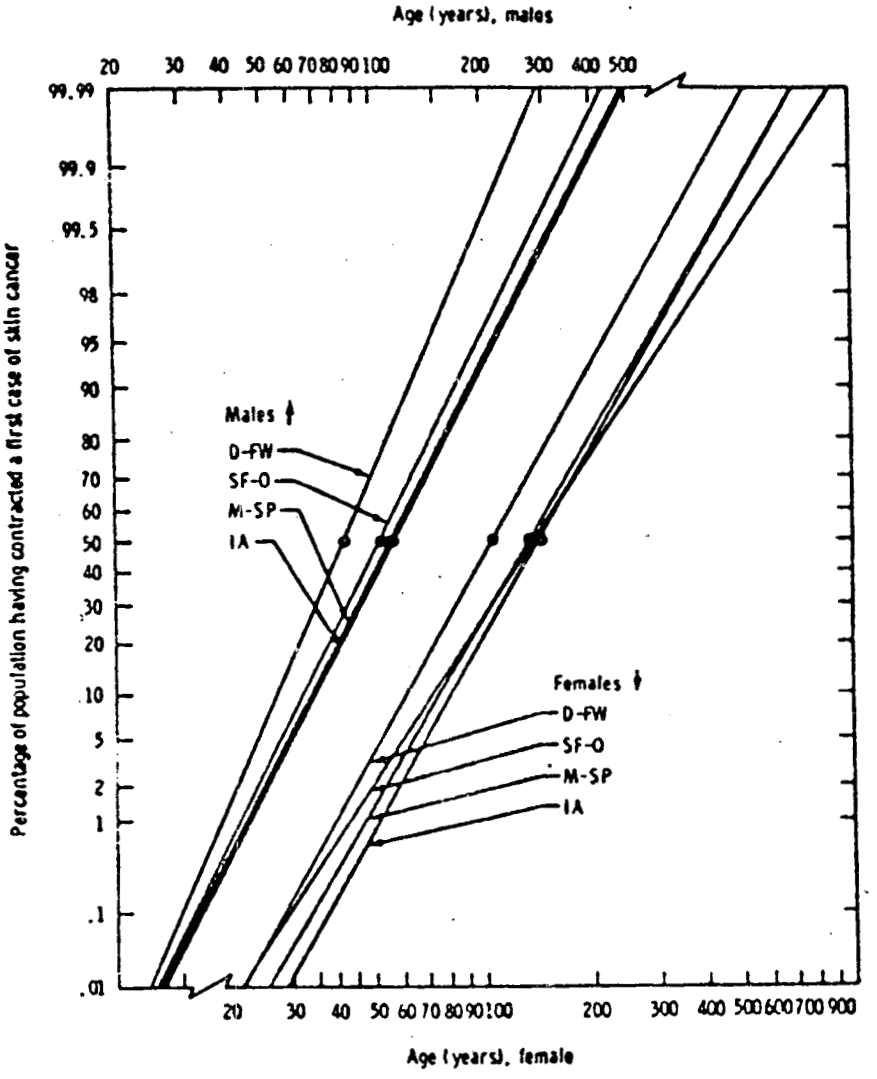

Figure 4.-Percentage of population having contacted first case of skin cancer as a function of sex and location

NASA-JSC

APPENDIX C

Response to Comments

Comment

Response to Comment

Docket #
C0102

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

E. KENNETH AYCOCK, M.D., M.P.H., COMMISSIONER
J. MARION SIMS BUILDING — 2600 BULL STREET
COLUMBIA, SOUTH CAROLINA 29201

June 16, 1977

Hearing Clerk
U.S. Food & Drug Administration
5600 Fishers Lane, Room 4-65
Rockville, MD 20857

Dear Sir:

This office has reviewed the Draft Environmental Impact Statement for Fluorocarbons: Environmental & Health Implications, and we have no comments at this time. We appreciate the opportunity to comment on this statement and if we can be of any assistance please contact us.

Sincerely,

John E. Jenkins, P.E.
Deputy Commissioner
Environmental Quality Control

JEJ:JME:bg

cc: James G. Zack, Jr.
C. Barry Shedrow

C-1

Comment

Docket #
C0105

UNIVERSITY OF CALIFORNIA, IRVINE

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DEPARTMENT OF CHEMISTRY — IRVINE, CALIFORNIA 92664

July 2, 1977

Office of the Hearing Clerk, Room 4-65
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

Comments on DRAFT ENVIRONMENTAL IMPACT STATEMENT, FLUOROCARBONS: ENVIRONMENTAL AND HEALTH IMPLICATIONS

I have several technical scientific statements to make on particular aspects of this Environmental Impact Statement.

(1) Page 31, Paragraph 2. The Murcray analysis for chlorine nitrate has been satisfactorily resolved, and chlorine nitrate is not present in the stratosphere in the amounts which would be predicted from the NASA working group calculations of January, 1977. The observation is still only an upper limit, and is using the more conservative (i.e. predicts more chlorine nitrate and less ozone depletion) absorption coefficients for chlorine nitrate. A preprint of this paper is enclosed as Appendix 1, and the article has appeared in the June issue of Geophysical Research Letters, illustrating the upper limit on stratospheric chlorine nitrate.

(2) Page 31, Paragraph 3. The NAS calculations did include the diurnal effect in a crude way, using a rate constant for formation of chlorine nitrate only half as large as expected, on the assumption that 24 hours at half the rate (the model calculation) is roughly equivalent to 12 hours at the full rate (roughly the real diurnal effect). However, the January, 1977, NASA working group calculations used actual diurnal calculations and also included multiple-scattering (the reflection of visible and UV-A radiation). The multiple scattering calculation reduced the overall dependence on chlorine nitrate because it made chlorine nitrate less important overall. However, since the multiple-scattering correction also reduced the importance of NO_2 in the calculations, the 7% figure of NAS did not rise very much in the NASA work-shop calculation. Since that workshop in January, two reasonably important changes have occurred. First, the formation rate for Chlorine nitrate is now usually assumed to have a pressure dependence, which will tend to reduce its importance in the stratosphere. Second, the rate constant for the reaction of HO_2 + NO has been directly measured for the first time, and has proven to be very much faster than previously estimated from indirect measurements. Although the effect of this rate constant on ozone depletion calculations have been mentioned in the press release from NOAA (Appendix 2),

Response to Comment

(1) Page 31, Paragraph 2 - has been revised to include the more recent information provided in this comment. C-2

(2) Page 31, Paragraph 3 - The pertinent information provided in this comment has been included in the text on pages 30 and 31.

UNIVERSITY OF CALIFORNIA, IRVINE

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DEPARTMENT OF CHEMISTRY IRVINE, CALIFORNIA 92664

the effect is now believed to be considerably larger than the 35% described in the press release. Whereas the general consensus in the January, 1977, NASA workshop was a steady-state depletion of 5% to 9%, the current (July, 1977) calculations appear to be falling in the 13-16% range for ozone depletion at steady-state with 1973 production rates. I am enclosing a graph of the June 28 calculations of Chang at the Lawrence Livermore Laboratory, and I have been informed by telephone that Crutzen and Cicerone at NOAA and Michigan are also obtaining ozone depletion estimates in this range. The Chang value of 14.6% is roughly a factor of two higher than his January results, and was calculated with the NASA chlorine nitrate rates(i.e. if he were to substitute the newer, pressure-dependent rates, this number would probably be increased somewhat.) The Chang graph is labeled Appendix 3.

(3) Page 33, Paragraph 3. We have measured the ultraviolet absorption characteristics of several brominated compounds, and find that $CBrF_3$ (F-13B1), $CBrClF_2$ (F-12B1) and $CBrF_2CBrF_2$ (F-114B2) will not photodissociate in the troposphere. Neither have identifications been made for any other tropospheric sinks for these molecules which would alter their lifetimes appreciably. Accordingly, we have estimated lifetimes for stratospheric removal and have found about 50 years for the lifetime of F-13B1 and about 30 years for the other two. All of our present information therefore indicates that the perhalo bromoalkanes are generally comparable in stratospheric hazard to FC-11, FC-12 and the other perhalo chloroalkanes. These experimental results are being described in a paper to be presented at the American Chemical Society meeting in Chicago in late August, 1977. A copy of the abstract for that meeting is furnished as Appendix 4. A preprint of a longer paper will be furnished when available.

From a regulatory point-of-view I would assume that the perhalo bromo compounds would be treated similarly to FC-11 and FC-12. Since they are unlikely to be considered as candidates for general aerosol propellant use because of their cost, their inclusion in or exclusion from the aerosol propellant regulation would probably have negligible impact either way.

Most iodocarbon compounds absorb in the ultraviolet for wavelengths longer than 3000A, and are therefore subject to tropospheric photodissociation. In these cases, then, the stratospheric hazard is slight. We have not tested enough iodo compounds to be certain that there are no exceptions to this observation.

(4) Page 34, Paragraph 3. Our own laboratory experiments with atmospheric samples have shown that it is very difficult to avoid large "blanks" with methylchloroform, CH_3CCl_3. We thus urge caution in drawing conclusions now about

(3) Page 33, Paragraphs 3 & 4 - have been modified to reflect the information contained in this document.

(4) Page 34, Paragraph 4 - has been added to reflect this comment.

C-3

UNIVERSITY OF CALIFORNIA, IRVINE

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DEPARTMENT OF CHEMISTRY — IRVINE, CALIFORNIA 92664

the lifetimes of hydrochlorofluorocarbons in the atmosphere from apparent observations of methylchloroform concentrations in the atmosphere. Our experiments were described in the American Chemical Society meeting in New Orleans, in March, 1977, but no written material is available which will describe these conclusions in more detail than the sentences above.

(5) Page 83, Paragraph 3. The enclosed report presented in the DuPont publication INNOVATION describes lethality to one beagle at a concentration of 0.5% (out of 24) and lethality to 3 of 12 at a concentration of 1%. These data seem inconsistent with the 5-25% lethality range given in this paragraph. The difference is presumably the synergistic effect of the adrenalin injections, given to simulate stressful conditions.

(6) The following minor comments:
(a) Page 7, first paragraph under 2.2. Some fluorocarbons (e.g. CH_3CF_3) are rather polar and do dissolve in water.
(b) Page 25. Paragraph 4, Line 5. The contribution of natural chlorine such as CH3Cl is subject to the uncertainties of total chlorine from such sources, and to the ozone-depletion capability of the chlorine. The uncertainties in the latter are the same whether from natural or artificial sources, and a calculation of 1 percent would, by analogy with the 2% lower limit, 7% central, 20% upper limit of the NAS report, be 0.3% to 3%. The contribution of natural ClO_x is thuse somewhat more uncertain than this statement suggests, although its actual magnitude has only slight relevance to the question of artificial ClO_x will depress the stratospheric ozone concentrations below normal levels.
(c) Page 34, Paragraph 1, Line 8. Is the first breakdown product meant to be HCl or is this meant as an abbreviation for hydrocarbons?
(d) Page 35, Paragraph 3.1.2.3. In my copy this paragraph stops abruptly in mid-sentence.

Sincerely yours,

F. S. Rowland

Professor of Chemistry

(5) Page 83, Paragraph 3 - has been modified to reflect this comment.

(6a) Page 7, Paragraph 1 under 2.2 - has been modified to reflect this comment.

(b) Page 25, Paragraph 4 - has been modified to reflect the uncertainty in the contribution of natural ClO_x to the estimated ozone destruction rate.

(c) Page 34, Paragraph 1, Line 8 - was a typographical error. "HC" has been changed to "HCl."

(d) Page 35, Paragraph 3.1.2.3 has been completed.

Comment

Docket #
C00107

NATIONAL CENTER FOR ATMOSPHERIC RESEARCH
P. O. Box 3000 • Boulder, Colorado 80303
Telephone: (303) 494-5151 • TWX: 910-940-3245 • Telex: 45 694

7 July 1977

Dr. David S. Klauder
Environmental Impact Staff
Department of Health, Education and Welfare
Food and Drug Administration
Rockville, MD 20852

Dear Dr. Klauder:

I have given below my comments on Section 3.4 of your report "Draft environmental impact statement fluorocarbons: Environmental and Health Implications."

(1) Section 3.4.1: The discussions (in second paragraph) concerning the climatic effects of ozone dimunition have neglected to mention the important effect arising from the infrared bands of ozone. The following paragraph discusses this effect and I have indicated in a copy of p. 78 of your report, the appropriate place where this discussion can be included.

> Insert 1--In addition to these two effects, ozone dimunition would also alter the contribution by ozone to the atmospheric "greenhouse effect." Ozone absorbs infrared radiation in the 9-11 μm region which is emitted by the earth's surface toward space and hence causes a net reduction in the infrared radiation emitted to space by the earth-atmosphere system. The sign and magnitude of the alteration of this greenhouse effect due to ozone dimunition would depend on the vertical distribution of ozone change. Currently available model calculations indicate that, if ozone is reduced at all altitudes within the stratosphere, the greenhouse effect due to ozone decreases which would tend to cool the earth's surface and troposphere. (Appendix A)

(2) Section 3.4.3.3.a: Contrary to the statement made here, the greenhouse effect of chlorocarbons have been evaluated and I am enclosing a reprint of the paper which discusses these effects.

(3) Section 3.4.3.3.b: N_2O has strong infrared bands and their potential effects on the earth's surface temperature have been evaluated (Wang, et al., Science, 194, 655-660, 1976).

Response to Comment

(1) Section 3.4.1: The paragraph provided by this comment has been inserted as indicated in section 3.4.1.

(2) Section 3.4.3.3.a: has been revised to indicate that the infrared absorption properties of certain chlorocarbons are known.

(3) Section 3.4.3.3.b: has been supplemented to indicate the potential effects of N_2O on climate.

On the whole, I found the discussions in Section 3.4 quite adequate for the purposes of your report. I will be glad to answer any further questions you may have on this topic.

Sincerely yours,

V. Ramanathan

V. Ramanathan
Climate Project

cc: Office of the Hearing Clerk
Room A-65, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

(Appendix A on file in the Hearing Clerk's Office.

is projected to be 2.19 percent in about 1990. The maximum increase in incidence would be 6.0 percent about the year 2035. For a ban in 1980, the comparable maximum values are 1.13 percent ozone reduction, 2.40 percent increase in DUV (both peaking in about 1990) and a 6.6 percent increase in incidence in about 2035. For bans in either year, the incidence will not decrease to normal until into the 22nd century because of the long time required for the excess chlorine to be removed from the stratosphere. Averaged over the next century, the increase in nonmelanoma skin cancer resulting from a two-year delay in banning amounts to about 0.4 percent of the number of cases projected for the case where chlorofluoromethanes are banned in 1978.

For malignant melanoma, similar projections are not possible at this time because this disease does not appear to result from accumulated lifetime exposure as does nonmelanoma. Moreover, the age-response relationship for melanoma is biomodal suggesting two subpopulations with different sensitivities. Other evidence is discussed which indicates projections for this fairly rare disease would be premature at this time.

3.4. Impact of Chlorofluorocarbon Release on Climate and Resultant Effects of Climate Modification

3.4.1. Effects of Chlorofluoromethanes on Climate

Atmospheric release of chlorofluoromethanes can affect the earth's climate by two mechanisms. One mechanism is associated with stratospheric ozone diminution; the other is not.

Stratospheric ozone diminution allows more ultraviolet radiation to reach the earth's surface, thus warming this surface and the lower atmosphere. However, as less ultraviolet radiation is absorbed by the reduced ozone content of the stratosphere, the associated heating of the stratosphere is reduced. Therefore, less thermal (infrared) radiation is emitted from the stratosphere toward the earth's surface. This effect tends to INSERT-1 cool the earth's surface and the lower atmosphere. The balance of the above warming and cooling effects in influencing tropospheric climate is sensitive to the distribution of ozone reduction in both altitude and latitude. The sensitivity of this analysis to the distribution of ozone reduction in altitude and latitude is emphasized by consideration of the $ClONO_2$ effect in which ozone redistribution may play as large a role as ozone diminution. Attempts at quantitative analysis of the resultant net effect on tropospheric climate have not yet achieved sufficient resolution to determine the direction of the overall influence on climate.

Independent of ozone diminution, chlorofluoromethanes in the atmosphere can also affect climate simply by their accumulated presence. They absorb infrared (thermal) radiation in the 8-12 μm region which is emitted from the earth's surface toward space. Absorption in the 8-12 μ region of the infrared radiation spectra is of particular significance

Comment

Response to Comment

Docket #
C0108

E. I. DU PONT DE NEMOURS & COMPANY
WILMINGTON, DELAWARE 19898

ORGANIC CHEMICALS DEPARTMENT

July 11, 1977

Ms. Jennie Peterson
Hearing Clerk (HFC-20)
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Peterson:

Attached are comments of the Du Pont Company concerning the Food and Drug Administration's (Docket No. 76-N-0460) proposed phase-out of chlorofluorocarbon propellants (21 CFR Parts 2, 189, 310, 500, 510, 700, 801).

We appreciate this opportunity to comment on the agency's proposed rules. The Freon® Products Division would be pleased to consider any questions the FDA may have concerning the attached submission.

Sincerely,

P. M. Alexander, Director
Freon® Products Division

PMA/jmp
Attach.

C-8

Consistent with our above views, we request the agencies obtain an update of the NAS scientific assessment by June 1, 1978, and that regulations to phase out chlorofluorocarbon propellants not be finalized until thirty days after receipt of this vital update. This approach, already recommended to the NAS Panel on Atmospheric Chemistry (Appendix A), provides for the completion of near-term stratospheric and laboratory research programs, consideration of the impact of then current scientific findings on the proposed regulations, and would still permit promulgation of any appropriate regulations of propellant uses without extending the proposed EPA and FDA timetable.

In addition to the above proposal, we offer more specific comments on the proposed rules covering the following general categories:

- **Technical Data Base**
- **Legal Authority of the EPA Under Toxic Substances Control Act**
- **Inflation Impact Analysis**

EPA/FDA ENVIRONMENTAL IMPACT STATEMENTS

The FDA and EPA Environmental Impact Statements[1,2] summarize what is known about the predicted environmental consequences of continued chlorofluorocarbon usage. The documents also present many opinions and conclusions based on previous reports (IMOS[3], NAS[4,5], and NASA[6]). However, an important conclusion of all previous reports, not embraced by the impact statements, was that completion of a research program to reduce the uncertainties in ozone depletion calculations is necessary before the effects of continued chlorofluorocarbon release can be adequately assessed.

Major research programs have been launched by government and industry to improve the basis for ozone depletion calculations and to provide reasonable tests of atmospheric models. The most significant objectives are:

1. **Improvement in thermal and photochemical rate data in several key areas, especially hydroperoxy radical (HO_2) reactions.**

2. **Simultaneous stratospheric measurements of hydroxyl (OH), chlorine oxide (ClO), hydrogen chloride (HCl) and total chlorine.**

Using the available data, the NAS attempted to assess the potential effects resulting from continued chlorofluorocarbon releases on stratospheric ozone and their secondary effects on human health, non-human organisms, and climate (7,8). Using the available data, NASA attempted to update the NAS assessment of the potential effects resulting from continued chlorofluorocarbon releases on stratospheric ozone (77,78). These assessments of potential effects were made with full recognition of the uncertainties.

The FDA environmental impact statement (EIS) is also an attempt to assess the potential effects resulting from continued chlorofluorocarbon releases drawing upon the above reports and other related data. Likewise, in this assessment, the attempt was made to discuss or reference discussions of the current uncertainties. Furthermore, section 3.5 of the EIS specifically discusses the nature of ongoing research programs designed to reduce existing uncertainties. Therefore, the Agency is not in agreement with this comment.

Comment

PENNWALT
CORPORATION

900 FIRST AVENUE, P. O. BOX C, KING OF PRUSSIA, PENNSYLVANIA 19406 · (215) 265-3200

July 11, 1977

Hearing Clerk (HFC-20)
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

Reference: Docket No. 76N-0460*

The Four Bases For the Proposed Regulations

In our opinion the FDA plans to prohibit the nonessential use of chlorofluorocarbons as propellants in self-pressurized containers in products subject to the FFD&C Act are premature. The conclusion of the Commissioner of Food and Drugs "that the available information indicated an unreasonable risk of long-term biological and climatic impacts and delay to improve estimates was not warranted in view of the risks and the negligible benefit from nonessential uses that primarily serve as conveniences" is not based on a dispassionate assessment of the information but is colored by the "nonessentiality" of the uses in question. The bases for issuing the proposed rule are said to be provided by the following four impacts:**

1. reduce currently predicted steady state ozone depletion levels and resultant increase in DUV (damaging ultraviolet radiation) reaching the Earth

2. reduce the peak number of new cases of nonmelanoma and probably melanoma skin cancer that would be expected to occur at currently predicted ozone depletion levels

3. reduce potential for other health effects of increased exposure to DUV radiation, e.g., premature skin aging, increased incidence of sunburn, eye damage

4. reduce potential for nonhuman biological impacts and possible climatic changes.

Discussion of Basis 1

Basis 1 can be eliminated immediately as reason for precipitate action. Basis 1 is not in itself a reason for action--the effect of the DUV has to be established as in fact damaging

*Federal Register, Vol. 42, No. 93, Friday, May 13, 1977, pages 24536-42.

**Reference 1, page iii. For scientific references see pages 14-15.

C-10

Response to Comment

Discussion of Basis 1: These comments do not contradict the FDA position. The summary sheet, p. iii, has been modified to more accurately reflect the FDA position.

before it becomes a reason and then it is merely a preamble to the true basis for action.

Discussion of Basis 3

Basis 3 is not an urgent concern--in the words of the FDA Draft Environmental Impact Statement

> "Eye and skin damage are considered to be possible effects, but too little information is available to conclude that they represent a serious threat at this time." (Ref. 1a)

It is also noted in the FDA Impact Statement that

> "Of the above listed conditions, sunburn and photokeratitis are temporary, reversible conditions, which although uncomfortable, are not serious; therefore, they will not be considered further." (Ref. 1b)

Discussion of Basis 4

Basis 4 is concerned in part with a number of effects postulated to result if the amount of UV-B reaching the Earth's surface increases. The nonhuman biological impacts are discussed under the headings

(a) Biosphere in General,

(b) Agricultural Plants,

(c) Natural Plant Communities,

(d) Terrestrial Animals, Domestic and Wild, and

(e) Aquatic Organisms and Ecosystems.

These are the classifications used in the supporting document by Nachtwey and Rundel (Ref. 2); however, the material presented in the FDA Impact Statement has been rewritten to furnish as much support to the FDA position as possible.

Biosphere

The last paragraph of the summary on the biosphere (Ref. 2a) has been rewritten (Ref. 1c) so as to change its sense significantly. The two versions are reproduced in Appendix A. It seems clear that the Nachtwey and Rundel assessment is that this effect is not a basis for urgent action.

Discussion of Basis 3: These comments do not contradict the FDA position. The summary sheet, p. iii, has been modified to more accurately reflect the FDA position.

Discussion of Basis 4, above Biosphere: Because the original supporting document by Nachtwey and Rundel was too long to be included in its entirety in the EIS, some editing was necessary. Most of the editing involved the removal of redundancies and lengthy descriptive detail. In all cases, the attempt was made not to distort the meaning of the original document but to maintain a balanced account of the problem as presented in the original Nachtwey and Rundel version.

The first condensation of the original support document was made by the Environmental Protection Agency. This version was further edited by FDA personnel working directly with Dr. Nachtwey in order to ensure that the shortened version was not a distortion of the original document. At the EPA hearing of August 1-3, 1977, on the regulation of nonessential uses of chlorofluorocarbon propellants, Dr. Nachtwey stated that "There may be some slight differences in emphasis, but I think I can subscribe to this condensation and edited version and support it."

Biosphere: See response to Appendix A.

Agricultural Plants, Terrestrial Animals, and Aquatic Organisms

Similarly the summaries on agricultural plants (Ref. 2b vs. Ref. 1d), terrestrial animals (Ref. 2c vs. Ref. 1e), and aquatic organisms (Ref. 2d vs. Ref. 1f) have been recast to make the effects in question appear to be established as stronger bases for action than the Nachtwey and Rundel assessment indicates. Appendixes B, C, and D reproduce the two versions of each of these summaries.

Natural Plant Communities

The essentially identical summaries on natural plant communities (Ref. 2e and Ref. 1g) indicate that available data are insufficient for assessment of potential effects. Clearly the effect of increased UV-B on all five categories of nonhuman biological impacts is purely speculative at this time, and facts are badly needed before any one of them can be considered sufficiently important to warrant immediate regulation.

Climatic Changes

Basis 4 is also concerned with possible climatic changes. Two mechanisms are discussed: (a) stratospheric ozone diminution and (b) the greenhouse effect due to accumulation of chlorofluorocarbons in the atmosphere. The former can be dismissed as a reason for urgent action because in the words of the FDA Draft Environmental Impact Statement

> "Attempts at quantitative analysis of the resultant net effect on tropospheric climate have not yet achieved sufficient resolution to determine the direction of the overall influence on climate." (Ref. 1h)

Insofar as the greenhouse effect is concerned the NAS committee has clearly stated that it is not a matter of immediate concern. It says

> "The direct climate effect, which seems most likely to be serious, is immediate (is not delayed for the CFMs to reach the stratosphere) and shows no overshoot (the effects of curbed release show more rapidly). It is probably not a concern at present levels of CFM accumulation. Thus, delay in decision is even more reasonable, as far as direct climate effects go, than for the effects of ozone reduction." (Ref. 3a)

Agricultural Plants, Terrestrial Animals and Aquatic Organisms: See responses to Appendixes B, C, and D.

Natural Plant Communities: The present regulatory action is not being taken to protect natural plant communities from the threat of increased UV-B exposure. However, since some data indicate that plant communities may be affected by increased UV-B, it is FDA's position that further research to determine the nature and magnitude of these effects should be done in the laboratory rather than in the natural environment.

Climatic Changes: This comment has been responded to in the preamble to the final regulation to ban nonessential uses of chlorofluorocarbon propellants, comment No. 9, subsection (b)(2).

It should be added that there is no chain reaction involved in this effect, so that if it is important it is a one-to-one effect. It should also be noted that Ramanathan (Ref. 4) does not consider his calculations other than quite preliminary because he comments

> "The results discussed here are based upon one-dimensional models of the atmosphere that neglect several potentially important feedback mechanisms between surface temperature, cloud cover, ice cover, and circulation. The list of variables is by no means exhaustive. Due to the present lack of quantitative climatological data, it is not clear whether the inclusion of all of these feedback mechanisms will have an amplifying or an ameliorating effect on the situation as currently visualized. Accordingly, it is suggested that the present results be considered as merely indicative of the potential effects of fluorocarbons on the global surface temperature."

Neither possible mechanism for climate modification is of such a nature that it makes a two or three year delay in regulation while more knowledge is accumulated intolerable.

Discussion of Basis 2

There thus remains only one item, namely the threat of increase in skin cancer, as the basis for the FDA action, and the decision to regulate now rather than waiting for more definitive results depends on how the skin cancer risks entailed in waiting two or three years are evaluated. The NAS committee has put on record its view:

> "Selective regulation of CFM uses and releases is almost certain to be necessary at some time and to some degree of completeness. Neither the needed timing nor the needed severity can be reasonably specified today. Costs of delay in decision are small, not more than a fraction of a per cent change in ozone depletion for a couple of years' delay. Measurement programs now under way promise to reduce our uncertainties quite considerably in the near future." (Ref. 3b)

> "As soon as the inadequacies in the bases of present calculations are significantly reduced, for which no more than 2 years need be allowed, and provided that ultimate ozone reductions of more than a few per cent then remain a major possibility, we recommend undertaking selective regulation of the uses

C-13

Discussion of Basis 2: FDA's evaluation of the risks entailed in waiting two or three years can be found in section II of the preamble to the final regulation to ban nonessential uses of chlorofluorocarbon propellants.

Discussions on the nature of nonmelanoma skin cancer are provided in the FDA EIS under sections 3.3.1 and 3.3.3. The specific discussion from the Nachtwey and Rundel original document on nonmelanoma and melanoma which are quoted on pages 7 and 8 of this submission are also in the FDA EIS, sections 3.3.3 and 3.3.4.

and release of CFMs on the basis of ozone reduction." (Ref. 3c)

"In view of the present inadequacies in the bases of our calculations, in view of the reduction in these inadequacies promised by ongoing measurement programs, and in view of the small changes in ozone reductions following from a year or two delay, we wish to recommend against decision to regulate at this time." (Ref. 3d)

The first quotation gives the NAS committee conclusions in their entirety. It is interesting to note that the FDA Impact Statement in describing these conclusions (Ref. 1i) makes no reference to the second sentence--"Neither the needed timing nor the needed severity can be reasonably specified today."--although it paraphrases all the rest of the sentences in the conclusion.

The British Government also does not consider that the risks involved are sufficient for immediate action Its position is

"At this early stage in the debate the available information points to the conclusion that although possible health effects due to increased UV exposure cannot be ignored, the magnitude of the increased exposure is uncertain and its significance is still more uncertain. More information is needed if rational decisions are to be taken. The USA in particular already has an extensive programme of research; other countries have more modest and selective programmes. The UK is concentrating its efforts on atmospheric chemistry and large-scale mathematical modelling; both being areas where existing expertise can make a valuable contribution. The Manufacturing Chemists Association, an international body based in the USA, which represents worldwide all aspects of the CFC industry, is also independently mounting a major programme of research. In two or three years time the results obtained will help narrow the uncertainties in those areas where future decisions and actions are needed. The possibility of ozone depletion is a global issue and regulatory action, if necessary, would need to be taken on an international basis in order to be effective." (Ref. 5a)

The British comments on skin cancer follow:

"Cancer of the skin, which is a relatively common form of cancer, constitutes a more complex problem. The most common skin cancers are only locally invasive and respond readily to treatment. Some types tend to occur on exposed areas of the body eg face, neck, arms, legs, etc. They occur most frequently among people with outdoor occupations and there is a higher incidence among fair-skinned peoples and for people living in the low latitudes where UV radiation is more intense. Even so, skin cancers only appear as a result of dosage over a considerable period which may be 20 years or more. From experimental and research data, some association has been established between the incidence of locally invasive skin cancers and exposure to sunlight, and animal experiments have confirmed that the UV component of sunlight is responsible [Blum 1956]. However, UV radiation is only one cause of skin cancer and a minor one in the UK [Hunter 1975].

"Skin cancer with general dissemination is much rarer and can occur on unexposed as well as exposed parts of the body. For this reason, although again it occurs more frequently at lower latitudes and in fair-skinned people, it is difficult to establish a causal relationship with UV exposure.

"Even so, although sufficient medical evidence now exists on the relationship of UV radiation and skin cancer for this to be considered the most important health effect likely to arise from the depletion of the ozone layer, it does not allow a prediction to be made with any confidence of the increased number of skin cancers for a given increase in UV radiation, especially when this could well fall within the natural variation of UV levels. For example, there are considerable discrepancies between American and Australian estimates of the UV exposure required to double the incidence of skin cancer [Emmett 1973]. A further indication of the uncertainties involved is provided by the IMOS report which quotes a range of 7 to 1 in its prediction of the increased number of cases of locally invasive skin cancer resulting from a 1% reduction in the equilibrium level of the stratospheric ozone layer [IMOS 1975]. These predictions relate solely to the incidence of locally invasive skin cancer which is normally amenable to treatment and not to mortality rates. The IMOS report specifically excludes from its calculations the type of tumour associated with high mortality

although these would be a more serious problem. Similar calculations have not been attempted for the UK situation because of the tenuous assumptions on which these would be based. Nevertheless, such estimates might well be lower than those claimed for the US due to the more northerly mean latitude of the UK and the lower mean temperature which results in less exposure of the skin to solar radiation at these latitudes although these factors could be offset by the higher proportion of people of Celtic origin in the UK than in other countries (see Appendix E).

"In conclusion, therefore, although the limited epidemiological data available suggests that UV does play some part in the incidence of skin cancer (especially locally-invasive forms), there are so many other factors which appear to be also involved eg race, social habits, environment, pollution levels, cloud cover, length of time and exposure regime etc. that it is difficult to establish a direct quantitative relationship between decrease in the ozone column and the incidence of skin cancer." (Ref. 5b)

The discussion of NMSC* by Nachtwey and Rundel does not suggest that the problem is critical:

"Despite the uncertainties expressed above, even if the projected numbers are incorrect by a factor of say 2, the use of the very large base number for the current incidence of NMSC leads to large number of additional cases resulting from increased UV-B (BE). Because such numbers are sensationally large and because we are dealing with a type of cancer, a term that has frightening connotations to many or most Americans, it is important to put the NMSC problem in perspective: NMSC is a disease which slowly develops and is almost always non-fatal. If diagnosed moderately early, it can be readily treated. It is usually the untreated very advanced cases that lead to the mortality that puts NMSC in the malignant category rather than in the benign tumor category." (Ref. 2f)

"Averaged over the next century the increase in NMSC resulting from a 2-year delay in banning amounts to about 0.4% of the number of cases projected for no ozone reduction at all or for the case where CFMs are banned in 1978." (Ref. 2g)

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*Nonmelanoma Skin Cancer

Nachtwey and Rundel do not consider it desirable to consider malignant melanoma at this time.

> "For malignant melanoma, similar projections are not possible at this time because this disease does not appear to result from accumulated lifetime exposure as does non-melanoma. Moreover, the age-response relationship for melanoma is bimodal suggesting two subpopulations with different sensitivities. Other evidence is discussed which indicates projections for this fairly rare disease would be premature at this time." (Ref. 2h)

It is our belief that the decision to regulate at this time is a reaction to the word cancer without adequate consideration of what cancer means in this situation. We believe that there is wide support for the position that regulation should be delayed among those who have carefully considered the problem. Perhaps the British Government report has summarized the situation the best.

> "There is a corresponding increase in ultraviolet radiation with a reduction in ozone and there is little doubt that UV and locally-invasive skin cancers are in some way associated; but there are also many other causes [Urbach 1966]. It would be too simplistic, therefore, to take present statistics of skin cancers and assume that these will increase proportionally with increases in UV exposure. In fact, most people in the UK are probably completely unaware of what an increase of 16% (see para. 21) in UV radiation means in terms of weighing up the possible risk factors. To put the matter in perspective, this would be equivalent to the increase in exposure incurred by a person moving from Northern England to the south coast of England--an increased risk that most people would accept without further thought even if they were aware of it. Obviously the risk to a single individual is not great but one cannot disguise the fact that if the background of UV rises, then both UV exposure and the risk to the general population increases." (Ref. 5c)

Model Predictions of the Effects of CFM Release on Ozone

Because the quantitative effect of chlorofluorocarbons on stratospheric ozone has only been predicted, it is germane to consider the validity of the prediction methods used. The British Government report has summarized the situation in the following manner.

Model Predictions of the Effects of CFM Release on Ozone: The response to the question of uncertainties in current model predictions of ultimate ozone depletion resulting from continued chlorofluorocarbon emissions is provided in the preamble to the final regulation to ban non-essential uses of chlorofluorocarbon propellants, comment No. 9(a).

"In essence there are two main aspects of modelling--chemical and meteorological. Most modellers to date have concentrated on including the most important chemical variables and their models have been of the relatively unsophisticated one-dimensional type (Appendix C). As Table 6 Appendix C shows, there is broad agreement between the predictions of the various modellers of the possible effect of CFCs on the ozone layer. This does not necessarily mean that they are completely accurate, but probably reflects the similarity of the assumptions made in the different models. However, it is apparent that of all the ozone reducing mechanisms, those involving CFCs are potentially the most substantial so far considered.

"There is some agreement that current models predict an ozone depletion of about 8% at equilibrium in more than 100 years time if 1973 rates of release are continued; but these models do not have the capacity to portray accurately the complex meteorological systems within the atmosphere. Moreover, the rates of interchange between the troposphere and stratosphere and of movement within the stratosphere are inadequately known. There are some views [Scorer 1976] that the stratosphere is influenced more by tropospheric events than thought hitherto; and that even large-scale dynamical models are inadequate to make meaningful predictions. If the rate of exchange between the stratosphere and the troposphere is greater than usually assumed from diffusion theories then the lifetimes of CFCs in the stratosphere could be materially shorter than those at present predicted." (Ref. 5d)

Work in Britain toward more complete mathematical predictions is being undertaken using 2-D models that also take account of atmospheric transport mechanisms. It is expected that a more comprehensive assessment of the problem will be provided within three years.

Recent work in the USA has emphasized the shortcomings of currently used modeling procedures. Three different models were used for the calculation of profiles for species for which stratospheric measurements are available, and rather similar agreement was obtained for all three although two models are considered highly improbable. It was concluded that for observational data to be used to discriminate among models the concentration distributions must be known within a factor of two at the very least (Ref. 6a). The same group at the Lawrence Livermore Laboratory has found that temperature feedback has a 5-10% restoring effect on the ozone column for small ozone reductions (Ref. 6b).

An analysis of the application of 1-D modeling to the distribution of carbon monoxide in the atmosphere has prompted Newell to point out that one-dimensional mixing-length models ignore the fact that atmospheric mean motions bring about a sinking motion in middle latitudes, so air actually passes from stratosphere to troposphere (Ref. 7). He consequently questions whether the premises of such models are sound enough to warrant placing trust in their conclusions.

In a report distributed within the last few weeks, the Institute for Defense Analysis has compared a number of modeling efforts directed toward the effect of SSTs on stratospheric ozone. Their conclusions include the following comments:

"In general, uncertainties are larger than indicated previously and include, in some cases, questions of sign as well as magnitude.* These uncertainties must be reduced in order to improve confidence in forecast of future fleet effects relative to HAPP or possible other guidelines. Continuing revisions in estimates of effects are to be expected as work progresses." (Ref. 8a)

"Ozone chemistry is more complex and uncertainties regarding effects of NO_x injections are larger than previously recognized. Current chemistry, however, leads to smaller than previous estimates of reductions in the ozone column from NO_x additions at SST cruise altitudes, and to enhancement or near-zero effects, rather than reductions, in the ozone column, from NO_x addition at altitudes typical of subsonics."* (Ref. 8b)

"The Crutzen model results are considered to be preliminary by Dr. Crutzen in view of uncertainties in both the chemistry and dynamics and in recognition of the need for further model development. The great difference between these results and prior results should, however, be noted, as should the fact that the model shows enhancement rather than reduction (as in the other models) in the ozone column for NO_x injection below about 14 km. These results indicate that subsonics enhance but supersonics reduce ozone; furthermore, effects of SSTs are generally smaller than found in the earlier models. Where ozone enhancements occurred, the ozone increase came about due to increased ozone concentrations near flight altitude. Effects at low latitudes were smaller than at midlatitudes in the Northern Hemisphere and slight depletions in the Southern.

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*Underlining added.

"A full explanation of the differences between the Crutzen 2-D model and prior results cannot be offered. It should not be concluded that the reduced effects are due only to inclusions of the methane oxidation reactions and the use of a lower OH + HO_2 reaction rate." (Ref. 8c)

Among the problem areas identified are the following:

"As stratospheric NO_x, chlorine, and water content all affect calculated ozone changes due to NO_x additions, results of new measurements or new projections (as policy decisions are made) should be incorporated into the models. The present large uncertainty in the N_2O budget raises questions about the understanding of all odd nitrogen budgets and needs resolution." (Ref. 8d)

"Ozone models need additional work, using 1-D, 2-D, and eventually 3-D models; present uncertainties seem to be unacceptably large:" (Ref. 8e)

Other comments include:

"With inclusion of these various cycles, the problem becomes exceedingly difficult. It would appear, for example, that in order to establish the relative importance of the various cycles, data on trace species, such as H_2O, NO_x, ClO_x, etc., must be obtained in a detail to match that of the existing ozone data, and highly accurate reaction rate, photolysis, and radiation (scattered and direct) data must be available. Interactions between these different cycles (HNO_3, ClONO, $ClONO_2$, HCl, HOCl, etc.) would all need to be included." (Ref. 8f)

"As noted earlier, in developing 1-D models of the natural atmosphere, tracer profiles of various trace species are given, such as ozone, nitrogen oxides, HNO_3, etc., and compared to available measurements, which usually show wide variations and are not claimed to be global averages. One important tracer, however, namely water vapor, on which a great amount of (not very reliable) data exist, is normally excluded; water vapor is normally put into these models as a fixed or known species rather than as a computed quantity. A simple reason is that, with normally assigned tropopause temperatures, far too much water vapor would be present in the stratosphere if saturation at the tropopause is assumed.

(The 45° N July standard atmosphere tropopause is at -57.5° C at 177.8 mb, for which saturation water vapor partial pressure would be 53 ppm.) The behavior of water vapor is not well understood, although measured data (which vary widely) can be reproduced empirically in reasonable fashion in 2-D models." (Ref. 8g)

"With regard to the results from the 3-D tracer studies, COMESA concluded that: 'Consideration of these results casts considerable doubts on the value of current 1-D models except for the purpose of first estimates and emphasizes the need for a more sophisticated treatment of the dynamics.' In discussion, COMESA also questions the concept of 2-D models." (Ref. 8h)

"Demonstration that a given model reasonably reproduces certain observed characteristics of the natural atmosphere, e.g., the distribution of ozone or other trace species, is never proof that the model will correctly predict the effect of some hypothesized perturbation.* It is thus always of interest to compare the observed behavior of the atmosphere following some known perturbation, such as NO_x introduced by a nuclear weapons test, to the model predictions." (Ref. 8i)

There thus is ample reason for caution in accepting the results of 1-D modeling as a basis for precipitate action. Certainly the history of the study of the effect of SSTs on ozone would suggest that one should not consider the current modeling results on the effect of chlorofluorocarbons on ozone as other than very preliminary in nature. There is considerable activity in this area, however, in recognizing and surmounting the problems, so it can be anticipated that within the next two or three years more credible predictions will be forthcoming.

Direct Measurement of Abnormal Ozone Changes

There is currently also much interest in trend analysis of ozone data. Recent work indicates that it may be possible to detect changes in ozone concentration due to man's activities in a much shorter time than previously believed (Ref. 9). A meeting of people qualified to evaluate this possibility is being held later this month under NASA sponsorship. Positive findings would mean that modeling predictions of ozone changes can be directly tested within two or three years, the most satisfying way to resolve the question.

*Underlining added.

Direct Measurement of Abnormal Ozone Changes: The limitations to directly monitoring ozone perturbations are discussed in the preamble to the final regulation to ban nonessential uses of chlorofluorocarbon propellants, comment 10.

The FDA Draft Environmental Impact Statement has apparently been written as an adversary document. Nevertheless, it is not proper to rewrite material in such a way that the original meaning is distorted. In addition to the explicit information given in Appendixes A-D on differences between References 1 and 2, pages on which a number of further differences occur are listed in Appendix E as a matter of record.

Sincerely yours,

B Peter Block

B. Peter Block
Senior Research Scientist

BPB:mrm

Attachments: References
Appendixes A-E

References

1. Draft Environmental Impact Statement, Fluorocarbons: Environmental and Health Implications, Food and Drug Administration, May, 1977.

   a. p. 77
   b. p. 61
   c. p. 44
   d. p. 51
   e. pp. 55-6
   f. p. 60
   g. p. 53
   h. p. 78
   i. p. 3

2. Biological (Non-Human) and Human Effects of Increased UV-B, D. S. Nachtwey and R. D. Rundel, report on file with FDA.

   a. p. 5-26
   b. pp. 5-53 and 5-54
   c. p. 5-68
   d. pp. 5-86 and 5-87
   e. p. 5-59
   f. pp. 18-19, chpt. 6
   g. pp. 24-5, chpt. 6
   h. p. 25, chpt. 6

3. Halocarbons: Environmental Effects of Chlorofluorocarbon Release, Committee on Impacts of Stratospheric Change, Assembly of Mathematical and Physical Sciences, National Research Council, 1976.

   a. p. 13
   b. p. 7
   c. p. 7
   d. p. 8

4. Atmospheric Fluorocarbons: Possible Effects of a Large Increase on the Global Climate, V. Ramanathan, Environ. Conserv., 3 (2), 90 (1976).

5. Chlorofluorocarbons and Their Effect on Stratospheric Ozone, Department of the Environment, Central Unit on Environmental Pollution, Pollution Paper No. 5, 1976.

   a. p. 13
   b. pp. 8-9
   c. p. 12
   d. pp. 11-12

References (Cont.)

6. Lawrence Livermore Laboratory, First Annual Report to the High Altitude Pollution Program, F. M. Luther, June, 1976.

    a. p. 9
    b. p. 34

7. One-Dimensional Models: A Critical Comment, and Their Application to Carbon Monoxide, R. E. Newell, J. Geophys. Res., 82 (9), 1449-50 (1977).

8. Aircraft Emissions: Potential Effects on Ozone and Climate, A Review and Progress Report, R. C. Oliver with E. Bauer, H. Hidalgo, K. A. Gardner, and W. Wasylkiwskyj, March, 1977.

    a. p. S-3
    b. p. S-4
    c. pp. S-10 and S-12
    d. p. S-17
    e. p. S-18
    f. p. 3-8
    g. p. 3-23
    h. p. 3-37
    i. p. 3-85

9. Analyzing Worldwide Total Ozone for Trends, W. J. Hill, P. H. Sheldon, and J. J. Tiede, Geophys. Res. Lett., 4 (1), 21-4 (1977).

Appendix A

Biosphere

Nachtwey and Rundel Report, page 5-26

The potential for detrimental community structure shifts is discussed. At present it is not possible to project quantitatively or qualitatively the occurrence or characteristics of any community structure shift, [detrimental or benign. We can be somewhat reassured by the fact that the diversity of organisms in most natural ecosystem currently allows usually benign community structure shifts to occur frequently and repeatedly in nature in response to the varying pervasive chemical and physical factors. The influence of increased UV-B(BE) on such shifts may be small when compared to these more pervasive factors.]

FDA Draft Environmental Impact Statement, page 44

The potential for detrimental community structure shifts does exist. At present it is not possible to project quantitatively or qualitatively the occurrence of characteristics of any community structure shift.

Notes:

Differences in wording between N & R Report and FDA Statement have been underlined.

Material in N & R Report but not in FDA Statement has been enclosed in brackets.

Biosphere: The changes and deletions in the Nachtwey and Rundel report cited in Appendix A were made to eliminate a redundancy. A similar discussion on the ability of organisms and natural ecosystems to respond to stress is given on page 43 of the draft EIS.

Appendix B

Agricultural Plants

Nachtwey and Rundel Report, pages 5-53, 54

5.2.5 Summary - Agricultural Plants

[This section summarizes the CIAP studies, upon which were based the conclusions of the NAS Report on Halocarbons, and a few post-CIAP studies.] The available data are inadequate for a quantitative estimate of the potential impact of increased UV-B(BE), but they suggest that a 17% increase as might result from an equilibrium level 7.5% ozone reduction will not have a catastrophic effect on agricultural plants, but may have subtle effects that reduce productivity, decrease the range a plant might be profitably grown, and/or increase the cost of production. Because of the great normal variation in crop yields resulting from the vicissitudes of weather and improved agricultural practices, an effect of increased UV-B(BE) may not be detectable. However, lack of detectability should not be equated with acceptability; an undetectable small percentage reduction in crop yield may have significant impact on the world's food supply in the 21st century.

FDA Draft Environmental Impact Statement, page 91

3.2.2.5. Summary - Agricultural Plants

The available data are inadequate for a quantitative estimate of the potential impact of increased DUV, but they suggest that a 17 percent increase (section 3.2) as might result from an equilibrium level of 7.5 percent ozone reduction is unlikely to have a catastrophic effect on agricultural plants, but could have subtle effects that reduce productivity and/or decrease the range a plant might be profitably grown, and/or increase the cost of production. Because of the great normal variation in crop yields resulting from the vicissitudes of weather and improved agricultural practices, an effect of increased DUV may not be detectable. However, lack of detectability should not be equated with acceptability, and undetectable small percentage reduction in crop yield may have significant impact on the world's food supply in the 21st century.

Notes:

Differences in wording between N & R Report and FDA Statement have been underlined.

Material in N & R Report but not in FDA Statement has been enclosed in brackets.

Agricultural Plants: The deletion of the first sentence of the Nachtwey and Rundel report does not eliminate any substantive information. The changes in the underlined wording went unnoticed by FDA personnel. However, neither the Agency nor Dr. Nachtwey feels that the intent of the original document has been distorted by the modifications made.

Appendix C

Animals

Nachtwey and Rundel Report, page 5-68

5.4.5 SUMMARY - ANIMALS

The insufficiency of the available data preclude accurate assessment of the impact of increased UV-B(BE) on domestic and wild animals, [but in general a serious impact seems unlikely.] Given the shade-seeking behavior of most wild animals, and the protective hair, feathers, and pigmented skin, about the only potentially vulnerable site for UV-B(BE) damage is the eye. High doses of monochromatic UV-B can cause photokeratitis and even higher doses can cause cataracts. Whether increased UV-B(BE) doses in nature will cause such effects is unknown. An accumulation of UV-B(BE) damage to eyes, if it occurs, may shorten the lifetimes of individual animals, which are thus removed from competition with younger survivors.

[The most likely potential impact involves cancer eye in those cattle that lack pigment around the eyes. A speculative projection suggests that a 17% increase in UV-B(BE) may increase the number of cattle with parts condemned from 0.34% up to 0.40% of the total slaughtered each year in the U.S. However, cancer eye may reduce the useful life of breeding cattle that contract it. An estimate of the increase in the number so affected is not available.]

FDA Draft Environmental Impact Statement, pages 35-6

3.2.4.4. Summary - Animals

The insufficiency of the available data precludes accurate assessment of the impact of increased DUV on domestic and wild animals. Given the shade-seeking behavior of most wild animals, and the protective hair, feathers, and pigmented skin, about the only potentially vulnerable site for DUV damage is the eye. High doses of monochromatic UV-B can cause photokeratitis and even higher doses can cause cataracts. Whether increased DUV doses in nature will cause such effects is unknown. An accumulation of DUV damage to eyes, if it occurs, may shorten the lifetimes of individual animals, which are thus removed from competition with younger survivors.

Note:

Material in N & R Report but not in FDA Statement has been enclosed in brackets.

Animals: The first deletion is a redundancy since this point is made throughout section 3.2.4. The second deletion was made to eliminate unnecessary detail. This deletion certainly does not make the document more supportive of the FDA position.

Appendix D

Aquatic Organisms and Ecosystems

Nachtwey and Rundel Report, pages 5-86, 87

5.5.5 SUMMARY—AQUATIC ORGANISMS AND ECOSYSTEMS

Studies to date have demonstrated that small aquatic organisms are the most sensitive to the lethal effects of UV-B(BE) of any organisms tested; current levels of solar UV-B(BE) at the surface can kill 50-90% of a population with a few hours exposure. Yet these organisms can thrive in nature. Therefore, in addition to demonstrated basic tolerance mechanisms (screening pigment, DNA-damage repair mechanisms, etc.) the attenuation of UV-B(BE) by natural waters must play a major role. There are few measurements of the penetration of UV-B into natural waters [and none in the short wavelength range around 295-305 nm.] This lack of information precludes quantitative projections of the effects of ozone reduction/[increased UV-B(BE)] [other than an estimate of the size of the zone of potential impact (see Section 5.1.3)] and speculative assessments on the maximum reductions possible if only the top meter or two is subjected to increased UV-B(BE).]

Despite [the inability to project effects], the available data indicate a potential for detrimental effects. [By the same token, the available data suggest the possibility of negative feedback effects that might ameliorate increased killing by UV-B(BE). Such feedback effects might lead to no change in productivity, but subtle changes in community structure cannot be ruled out.]

[It must be concluded that the question, Will increased UV-B(BE) overwhelm the coping mechanisms of aquatic organisms and ecosystems?, is still an open one.]

FDA Draft Environmental Impact Statement, page 60

3.3.3.3. Summary - Aquatic Organisms and Ecosystems

Studies to date have demonstrated that small aquatic organisms are the most sensitive to the lethal effects of DUV of any organisms tested; current levels of solar DUV at the surface can kill 50-90 percent of a population with a few hours exposure. Yet these organisms can thrive in nature. Therefore, in addition to demonstrated basic tolerance mechanisms (screening pigment, DNA-damage repair mechanisms, etc.) the attenuation of DUV by natural waters must play a major role. There are few measurements of the penetration of UV-B into natural waters. This lack of information precludes quantitative projections of the effects of ozone reduction/increased DUV.

Despite our paucity of knowledge, the available data (do) indicate a potential for detrimental effects (that must be considered before we consciously accept reductions in stratospheric ozone and increased UV-B radiation exposures on the surface waters of the earth.)

Notes:

Differences in wording between N & R Report and FDA Statement have been underlined.

Material in N & R Report but not in FDA Statement has been enclosed in brackets.

Material in FDA statement but not in N & R Report has been enclosed in parentheses.

Aquatic Organisms and Ecosystems: The deletions in the first paragraph were made to eliminate unnecessary detail. The indicated deletions and changes went unnoticed by FDA personnel in paragraphs two and three of the Nachtwey and Rundel report. The Agency agrees that these alterations distort the meaning of the original document and the original language has been restored in the final EIS.

Appendix E

Pages in Nachtwey and Rundel Report (Ref. 2)	Pages in FDA Statement (Ref. 1)
5-10*, 5-11*, 5-19*, 5-22+*	42
5-24+*	43
5-49*	49
5-58+	53
5-70*	56
5-82*	59
5-83*	59
Chpt. 6, 3-4+*	62
Chpt. 6, 6*	64
Chpt. 6, 9+	67
Chpt. 6, 13-14+*	68
Chpt. 6, 16+	74
Chpt. 6, 17*	75
Chpt. 6, 17-18*	75
Chpt. 6, 25*	78

*material omitted
+wording changed

The modifications in the original Nachtwey and Rundel document noted in this appendix were largely made to reduce detail and to eliminate redundancies. Where material was omitted it was usually to eliminate lengthy descriptive and often complex detail. Most of the wording changes noted in this appendix came about as a result of the condensation of paragraphs into sentences. In all cases, the attempt was made not to alter the meaning of the material being edited.

The Agency agrees that the wording changes noted on page 62 of the draft EIS do not seem appropriate and the original wording has been restored in the final EIS, i.e. in paragraph 4, "fortunately" has been replaced by "very" and "roughly" has been added after "(58)."

Comment

Response to Comment

Docket #
C00113

STATE OF NEW MEXICO
HEALTH and SOCIAL SERVICES department

Planning & Regulations Development Office
P. O. Box 2348, SANTA FE, NEW MEXICO

July 5, 1977

Hearing Clerk
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

TO WHOM IT MAY CONCERN:

We have reviewed the Draft Environmental Impact Statement, fluorocarbons: Environmental and Health Implications.

While we share your concern about fluorocarbon and chlorofluorocarbon -11 and -12 emissions, we do not have the facilities to properly document any comment, and we thank you for the opportunity to review.

Yours truly,

Charles A. Marquez

Charles A. Marquez
Environmental Planner

CAM:dg

C-30

Comment

Docket #
C00126

United States Department of the Interior

OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20240

ER 77/499

JUL 15 1977

Ms. Jennie Peterson
Hearing Clerk
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Peterson:

Thank you for transmitting copies of the Food and Drug Administration's draft environmental statement on Fluorocarbons: Environmental and Health Implications, dated May 1977.

We have no major comments but have noted two sections in which it would be desirable to provide additional information to clarify the text. On page 80, section 3.4.2, it is noted that local changes in temperature and precipitation resulting from increasing abundance of fluorocarbons in the atmosphere are predicted to be great enough to eliminate existing production of commercial crops in some marginal growing areas. Potential secondary effects of these changes on streamflow, reservoir storage, and increased soil erosion should be considered.

On page 99, table 18, it is noted that there were 160 thermal injuries in 1975, a number of which required hospitalization. Since the fluorocarbons are normally considered non-flammable, these thermal injuries require further explanation as to cause in the final statement.

We hope these comments will be helpful to you.

Sincerely,

Larry E. Meierotto
Deputy Assistant SECRETARY

Response to Comment

Page 80, section 3.4.2 - In response to this comment it must be emphasized that the direction and magnitude of possible climatic effects resulting from chlorofluorocarbon releases are largely unknown. Some reasonable hypotheses exist and these are discussed in section 3.4 of the EIS. The Agency has determined that it would be unwise at this time to discuss potential secondary effects when the primary effects on climate resulting from chlorofluorocarbon releases are so little understood.

Page 99, table 18 - lists the frequency of all aerosol-product related injuries for 1975. It is likely that most of the 160 thermal injuries resulted from missuse of hydrocarbon-propelled, not fluorocarbon-propelled, aerosol products.

Comment

Response to Comment

Docket #
C00136

FEDERAL COMMUNICATIONS COMMISSION
WASHINGTON, D.C. 20554

July 20, 1977

IN REPLY REFER TO:

Mr. Charles Custard
Office of Environmental Affairs
Department of Health, Education,
and Welfare
Office of the Secretary
Washington, D.C. 20201

Dear Mr. Custard:

In response to your letter of July 15, 1977 on the Draft Environmental Impact Statement on Flurocarbons: Environmental and Health Implications, the Federal Communications Commission, having no expertise in this area, offers no comment.

Sincerely,

Raymond E. Spence
Chief Engineer

Comment

Response to Comment

Docket #
C00137

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 23 1977

Mr. Charles Custard
Director
Office of Environmental Affairs
Office of the Secretary
Department of Health, Education,
and Welfare
Washington, D. C. 202001

Dear Mr. Custard:

This is in response to your letter dated July 15, 1977 inviting our comments on the Draft Environmental Impact Statement entitled *Fluorocarbons*: Environmental and Health Implications, May 1977.

We have reviewed the statement and have determined that the proposed action has neither radiological health and safety impacts nor will it adversely affect any activities subject to regulation by the Nuclear Regulatory Commission. Accordingly, we have no comments or suggestions to offer.

Thank you for providing us with the opportunity to review this draft environmental impact statement.

Sincerely,

Voss A. Moore

Voss A. Moore, Assistant Director
for Environmental Projects
Division of Site Safety
and Environmental Analysis

cc: Council on Environmental
Quality (5)

Comment

Response to Comment

Docket #
C0138

DEPARTMENT OF STATE
Washington, D.C. 20520

BUREAU OF OCEANS AND INTERNATIONAL
ENVIRONMENTAL AND SCIENTIFIC AFFAIRS

July 20, 1977

Hearing Clerk
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

This letter contains our comments on the Draft Environmental Impact Statement, prepared by the FDA in relation to the proposed regulation of non-essential uses of chlorofluorocarbons.

First, I would like to state that we found the material very clearly presented and very comprehensive, yet concise. It strikes us, in brief, as a good EIS.

Our only comments relate to the international ramifications of the issue of ozone depletion and the role of chlorofluorocarbons. The EIS makes clear in many places (e.g., page 87) that fluorocarbon emissions in the U.S. account for only a fraction of the emissions in the world. While making a good case for regulation in this country in order to s gnificantly reduce the total threat to the ozone and impact on the environment, the EIS only implicitly calls attention to the need for eventual broad international action analogous to that in the U.S. if the threat and impact are ultimately truly to be minimized. More explicit reference in appropriate places to this need would seem desirable. In this regard, it would perhaps also be useful to include in the consideration of alternatives a "sub-alternative," or overlay to all the action alternatives, along lines such as: In cooperation with the State Department, press for international action to limit fluorocarbon emissions in other countries similar to steps undertaken in the U.S.

Lastly, apropos this general point, it might be useful if, in preparing the final EIS, you could include reference to the important international meeting on the regulation of fluorocarbons which was held in Washington April 26-28.

A new section 4.6 has been drafted to highlight the international scope of the chlorofluorocarbon emissions problem and to describe recent activities at the international level.

The results of that meeting, including the agreed follow-up activities (exchange of information, a second meeting, etc.) are directly relevant to the need to work toward action in other countries directed at controlling emissions of fluorocarbons on a worldwide basis.

Sincerely,

Donald R. King
Director
Office of Environmental Affairs

Comment

Docket #
C00139

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
WASHINGTON, D.C. 20410

AUG 29 1977

OFFICE OF THE ASSISTANT SECRETARY
FOR COMMUNITY PLANNING AND DEVELOPMENT

IN REPLY REFER TO:
CSP

Mr. Charles Custard
Director, Office of Environmental Affairs
Department of Health, Education and Welfare
Washington, D.C. 20201

Re: Draft Environmental Impact Statement for Fluorocarbons, Environmental and Health Implications

Dear Mr. Custard:

We have reviewed the draft Environmental Impact Statement, dated May 1977, on Fluorocarbons and are submitting the following comments and questions.

1. Appendix B discusses four individual urban communities in terms of health effects upon their populations. If there is a potential for urban areas to be affected by varying rates of occurrence of skin cancer as a result of the ozone depletion as projected in the Environmental Impact Statement (EIS), then various metropolitan areas (such as Minneapolis-St. Paul) with the potential to experience the greatest amount of environmental impact should be identified in the final EIS. It is also recommended that a copy of the final EIS be forwarded to the metropolitan planning agencies concerned (see attachment).

2. The "zone of potential impact, in miles", should be clarified and made more applicable to various communities and populations of living organisms by providing an example.

Response to Comment

1. Since background levels of DUV are higher in the southern latitudes of the United States than in the northern latitudes, the calculated incidence rate for nonmelanoma skin cancer (Appendix B, table 1B) is highest for the southern sites and lowest for the northern sites (note that the data in this table are also age-adjusted).

   All areas of the world, including the United States, would receive increased levels of DUV radiation if total stratospheric ozone is reduced. Approximate increases in DUV resulting from a 7.5 percent ultimate ozone reduction were calculated for various latitudes (page 38 of the draft EIS). As indicated, the calculated latitudinal differences of increases in DUV within the United States are small (15.8 percent in the south up to 17.7 percent in the north). The risk of contracting nonmelanoma skin cancer as a result of a given DUV exposure depends upon such factors as age (Appendix B, table 3) and lifestyle (Appendix B, table 4). When all factors are considered, it is true that there is a slightly greater calculated percent increase in the risk of contracting nonmelanoma skin cancer in northern latitudes than in southern latitudes of the United States, even though the absolute number of cases would be greater in the south. However, due to the current limits of our understanding of DUV-induced skin cancer, the calculated regional differences in incidence rates should not be over emphasized. FDA's present approach is to treat this as a national and global problem rather than to dwell on the small latitudinal differences which may occur.

2

It is difficult for the reader to apply the concept of a reduction in the living environment unless he has a basis of reference to assist him. The final EIS could provide a more precise description of the environmental and health consequences involved by showing a contour map of the projected incidence of skin cancer in the United States under conditions of increased damaging ultra-violet wavelength radation, DUV, as compared to the incidence of skin cancer that would be expected under conditions of zero ozone depletion. Thus, the example could provide a practical descriptive analogy to potential impact zones within the United States affecting the spatial arrangement of people, flora and fauna as well as urban settlements and retirement communities.

3. A short review of the specific technical uncertainties yet to be resolved would be helpful. This could be given in outline format and included in the foreword of the final EIS or as a separate appendix. A possible format is given as follows.

   A. Scientific Uncertainties about the Physical Environment
      (1) An adequate data record of ozone measurements to verify model predictions
      (2)
      (3)

   B. Scientific Uncertainties about Health Effects
      (1)
      (2)

   C. Scientific Uncertainties about Climatic Trends

   D. Scientific Uncertainties concerning Adverse Effects on plants and animals

2. Contour maps illustrating the differences between projections of the incidence of skin cancer with and without a given ozone depletion could be a useful addition to the EIS. It would involve a complicated set of calculations which would take a considerable amount of time to develop. For this reason, such maps have not been appended to the final EIS.

3. "A short review of the specific technical uncertainties yet to be resolved" sounds like a good idea but is likely to be misleading. An accurate discussion of scientific uncertainties apart from the discussion of the known facts as represented by published scientific data would be an extremely difficult task and one which the Agency decided not to attempt. Section 3 of the EIS in its entirety is to be viewed as the Agency's attempt at a short discussion of the available scientific data relating to the potential problems resulting from fluorocarbon releases and the uncertainties associated with this data base. Particular emphasis in this section has been placed on the uncertainties accompanying the potential health, non-human biological, and climatic effects. The Agency's best effort at a review of the present scientific data and uncertainties relating to the predictions of stratospheric ozone depletion are provided in comment No. 9 of the preamble to the Agency's final regulation to phase out nonessential uses of chlorofluorocarbon propellants for which this EIS was written.

4. The recommended course of action, alternative No. 3, would only control 30 percent of the world wide fluorocarbon emissions. Are there any mitigation measures, new monitoring efforts (with respect to epidemiology or climate), or changes in community and individual life styles that will be required as a consequence of the remaining 70 percent of the world emissions? If these implications are foreseen, they should be discussed as an unresolved segment of the overall fluorocarbon problem. Also, if only 62 percent of the United States emissions will be controlled by alternative No. 3, the recommended course of action in the EIS, what activities comprise the remaining 38 percent of our nation's emissions.

5. In section 5, Description of the Proposed Action, where the responsibilities of various federal agencies are contained, are there any responsibilities or compliance actions that should be implemented by (a) producers and large scale industrial users of fluorocarbons, (b) the general public?

6. In reviewing the list of alternative courses of action to resolve the fluorocarbon problem, has any consideration been given to chemical modifications of the existing fluorocarbon substances which would reduce the magnitude of the ozone depletion by making the present fluorocarbons degradable in the troposphere?

We hope this review will assist you in preparation of the final Environmental Impact Statement. If we can be of further assistance or if you should have any questions you may contact Mr. Mike McGee of the Environmental Planning Division at (202) 755-6201.

Sincerely,

for Richard H. Broun
Director
Office of Environmental Quality

Attachment

4. Indeed the risks associated with chlorofluorocarbon emissions are global in nature. The action being taken by the United States government will reduce the risk of injury to all by about 30 percent leaving about 70 percent of the risk due to aerosol emissions of chlorofluorocarbons in other countries and non-aerosol emissions from all countries. A description of the recent activities at the international level to deal with the risks associated with emissions of chlorofluorocarbons on a global scale is provided in a new section 4.6.

   The major non-propellant sources of chlorofluorocarbons by end use in this country are given in Table 8 of the EIS.

5. Industry and the general public are encouraged to take and have taken voluntary action to reduce the use of chlorofluorocarbon propellants.

6. It is because the chlorofluorocarbon molecule is so stable that the current threat to stratospheric ozone exists. Chlorofluorocarbons have been shown to degrade only in UV light at wavelengths present in the stratosphere and at extremely high temperatures. The reactivity of the molecule is increased, and therefore, the threat to stratospheric ozone is decreased, by substituting hydrogen atoms for halogen atoms. However, those hydrochlorofluorocarbons which have properties suitable for propellant use have also been found to be mutagenic in a bacterial bioassay test (the Ames test). Therefore DuPont is not planning to market these compounds until further toxicity studies are completed (p. 96 of the draft EIS).

ATTACHMENT 1

Listing of Metropolitan Planning Agencies to Receive Copy of Final EIS on Fluorocarbons, Environmental and Health Implications

1. Executive Director
   Metropolitan Council
   Metro Square Building
   7th and Roberts Streets
   St. Paul, Minnesota 55101

2. Executive Director
   Association of Bay Area Governments
   Hotel Claremont
   Berkeley, California 94705

3. Executive Director
   Office of Planning and Programming
   State Capitol
   Des Moines, Iowa 50319

4. Executive Director
   North Central Texas Council
   of Governments
   P.O. Drawer COG
   Arlington, Texas 76011

Comment

Response to Comment

Docket #
C00141

ACTION
WASHINGTON, D.C. 20525

OFFICE OF THE DIRECTOR

August 1, 1977

Dr. Buzz Hoffman
U.S. Department of Health,
Education, and Welfare
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Hoffman:

We have reviewed the draft Environmental Impact Statement on Fluorocarbons: Environmental and Health Implications, and have no changes to suggest.

While this Agency possesses no expertise as to the probability or the consequences of ozone depletion from the use of fluorocarbons, we believe the actions proposed to be taken by the Food and Drug Administration, the Environmental Protection Agency, and the Consumer Product Safety Commission are in the public interest.

Sincerely,

Sam Brown

Comment

Response to Comment

Docket #
C00143

CENTRAL INTELLIGENCE AGENCY
WASHINGTON, D.C. 20505

22 AUG 1977

Dr. Buzz Hoffman
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Hoffman:

Thank you for the opportunity to comment on the draft Environmental Impact Statement on Fluorocarbons: Environmental and Health Implications.

The quality of the human environment is certainly the concern of every American citizen, therefore, we support fully the efforts of the Department of Health, Education, and Welfare to improve it for the benefit of all. However, we do not have specific comments with respect to the instant case.

Thank you for your consideration in referring the draft statement to this Agency.

Sincerely,

James H. McDonald
Director of Logistics

Comment

Response to Comment

Docket #
C00144

NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE
WASHINGTON, D. C. 20418

September 7, 1977

Dr. Buzz Hoffman
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Hoffman:

The following statement was developed from comments submitted by the Committee on Impacts of Stratospheric Change and its Panel on Atmospheric Chemistry in response to the draft environmental impact statement--"Fluorocarbons: Environmental and Health Implications." We hope they may still be of some use.

Sincerely yours,

John S. Coleman

John S. Coleman
Executive Officer

Enclosure

COMMENTS ON THE FDA DRAFT ENVIRONMENTAL STATEMENT OF MAY 1977

Committee on Impacts of Stratospheric Change

1. Overall, the statement seems well informed and reasonably balanced.

2. A certain number of detailed points deserve attention. We list those we have identified in page order:

Page 28. As the NAS report is quoted it may be misleading. The second paragraph ends, "This range does not allow for possible inadequacies in the bases of the calculation." In the NAS report this statement is followed by a sentence giving examples of possible inadequacies. This might be added in a footnote to clarify the meaning of the quoted statement.

Page 30, last paragraph. It is stated that the differing results of the NAS and NASA models are the result of the differing number of reactions included. In fact, the models differ significantly more than this and the uncertainty assessment techniques are also different. It might give a more accurate picture to delete the sentence beginning, "These uncertainty factors... and to state, as one member of our committee has suggested, "The differences of uncertainty range are within the expected variations among 1-D models of the stratosphere. For all practical purposes they are in excellent agreement, even though they are derived from two very different and independent analyses."

Page 31, first paragraph. The last sentence states that 1-D models are used "because the effects of CFMS on ozone is primarily through chemical reactions." The effects are primarily chemical and thus 1-D models can be accurate, but the reason that they are depended upon almost exclusively is the lack of chemically adequate 2-D or 3-D models. If available they would surely be used.

Page 31, second paragraph, first sentence. The details of the chemical kinetics are not as clearcut as the statement implies. We recommend that the agency assure itself that it has the latest available information when it releases its statement in final form.

Page 28 - The sentence in the NAS report giving examples of possible inadequacies has been included.

Page 30 - The suggested changes have been made.

Page 31, first paragraph - This paragraph has been modified to reflect the intent of this comment.

Page 31, second paragraph - This paragraph has been revised to reflect the recommended reaction rates for the formation of chlorine nitrate made by NASA in its final workshop report.

Page 31, second paragraph, second half. Murcray has recently published his data in the J. G. R. letters and it is consistent with the NAS report's $ClONO_2$ profile.

Page 31, third paragraph. This is factually incorrect, the NAS calculations do include the diurnal effects on $ClONO_2$.

Page 34, third paragraph. One well informed member of the Panel feels the measurements and associated analysis will be strongly challenged in the literature.

Page 35, para. 1, lines 6 to 9. This last is at best misleading. Only uncoverted CCl_4 has the possibility of affecting the ozone layer as such. Suggest a sentence such as: "Most carbon tetrachloride is converted into other compounds before use or release. The manufacture of chlorofluoromethanes takes up 95% of carbon tetrachloride production. Thus only a few % of present reported carbon tetrachloride production can directly participate in or contribute to ozone reduction. The total amount (not the %) of this direct participation would not be likely to be altered by changes in chlorofluorocarbon use and production."

Page 49, para. 4, line 13. ..."or it may be, accidently more." (See comment to page 50).

Page 50, para. 2. This discussion seems either inadequate or inappropriate. The "zone of potential impact" is the zone between an unperturbed boundary and a perturbed boundary. Neither of these boundaries is either smooth, or in one piece. It is possible, essentially because of ecogeographic accidents in which unusually large areas fall in a particular range of stresses due to all other effects than DUV, that the area affected by a given DUV increase would be greater than that corresponding to the calculated zone of impact. If this did occur, it would, so far as we can now understand, be an "accidental" matter and its occurence in one longitude belt, or for one species of plant, would not increase the chance that it would occur for another.

Page 31, second paragraph, second half - The latest information on Murcray's analyses of chlorine nitrate has been included.

Page 31, third paragraph - This paragraph has been modified to reflect the comment.

Page 34, third paragraph - An additional paragraph has been included to indicate the uncertainties associated with this indirect method for estimating tropospheric lifetimes for compounds which react with hydroxyl radical.

Page 35, paragraph 1, lines 6-9 - The suggested language in this comment has been included.

Page 49, paragraph 4 and page 50, paragraph 2 - Additional explanatory phrases have been provided in the designated paragraphs in an attempt to clarify the apparent confusion over the concept of "zone of potential impact."

Page 50, para. 4, line 6. Replace "increases" at end of line by "decreases" or "changes".

Page 59, para. 4, line 4. Replace "basic" by "laboratory" and, in line 5, "low" by "high" (otherwise subject to misinterpretation).

Page 62, para. 4, line 3. Insert "accompanied by it" after "deaths" in view of the discussion in the next paragraph.

Page 78, para. 4, line 1. Insert "and visible" after "ultraviolet."

Page 79, para. 1, line 5. We know of no certainty that the net effect, after all feedbacks are allowed for will be a warming. Suggest replacing "an unequivocal warming" by "a retention of additional heat which should, but is not yet certain to, produce a related warming."

Page 87, para. 2. In view of the recent decrease in US production, it is not clear that 1973 is an appropriate base for such calculations.

Page 87, para. 6, line 6. The word "self-enduring" is not self-explanatory. Recommend some change.

Page 90, para. 3, end. Add "The increase in the number of deaths would be very much smaller than this, so small as not to be calculable."

Page 90, para. 4. Even though the numbers are admittedly quite fluid, it seems to us important to make at least an order of magnitude estimate of the number of deaths from melanoma (This would of course require substantial changes earlier to support such an assessment.)

Page 50, paragraph 4, line 6 - "Increases" has been replaced by "changes."

Page 59, paragraph 4, line 4 - "Basic" has been replaced by "laboratory-obtained," and "low" has been replaced by "high."

Page 62, paragraph 4, line 3 - "Accompanied by nonmelanoma skin cancer" has been inserted after "deaths."

Page 78, paragraph 4, line 1 - "And visible" has been inserted after "ultraviolet."

Page 79, paragraph 1, line 5 - The suggested language has been added in place of "an unequivocal warming."

Page 87, paragraph 2 - The fact that the calculations are based on 1973 data is indicated and a new subsection 2.7 titled "Chlorofluorocarbons Produced for Aerosol Propellant Uses in 1977" has been added in section 2. Former subsections 2.7 and 2.8 are now 2.8 and 2.9 respectively.

Page 87, paragraph 6, line 6 - This sentence has been rewritten for clarification.

Page 90, paragraph 3, end - As explained in subsection 3.3.1, it is extremely rare for anyone to die "of" nonmelanoma skin cancer. Although it is possible, under conditions of gross neglect, for deaths to result "from" nonmelanoma skin cancer, the Agency has decided not to state that deaths would result from chlorofluorocarbon-related nonmelanoma skin cancers.

Page 90, paragraph 4 - Also discussed in subsection 3.3.1 are the uncertainties relating to the etiology of malignant melanoma. The NAS projections of increases in melanoma deaths resulting from a 7 percent ultimate ozone depletion are given in subsection 3.3.2.3.

Although much of the available data strongly suggest that solar radiation exposure is a causative factor of malignant melanoma, other evidence indicates that there are other causative factors as well. Because the data are inadequate for specifying what fraction of malignant melanoma cases is associated with solar radiation, the Agency has decided only to conclude that both melanoma cases and deaths could be higher in the absence of restrictions on chlorofluorocarbon emissions.

Comment

Docket #
C00146

U.S. DEPARTMENT OF LABOR
EMPLOYMENT AND TRAINING ADMINISTRATION
WASHINGTON, D.C. 20211

9 SEP 1977

Dr. Buzz Hoffman
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Hoffman:

The Department of Labor has reviewed the Food and Drug Administration's (FDA) recent draft environmental impact statement on fluorocarbons and wishes to express support for the proposed action to prohibit the nonessential use of chloroflurocarbons as propellants in self-pressurized containers.

We commend the thoroughness with which public health and environmental issues have been addressed in this document. However, while it is understood that FDA's primary concern is for the protection of public health, it is felt that the proposed action raises issues, especially those associated with the direct health effects of fluorocarbons, which bear on the Department of Labor's charge (through the Occupational Safety and Health Administration) to protect the health of American workers.

We agree with FDA's assumption that a phase-out of chlorofluorocarbons in aerosol propellant uses would result in a reduction of related injuries to th public to the extent that aerosol products are replaced by non-propellant packaging. However, it is felt that the potential impacts which may accrue to workers as a result of the substitution of the chlorofluorocarbons with other possibly more hazardous or toxic agents was not adequately addressed in FDA's environmental impact statement.

It has been stated that chlorofluorocarbons 11 and 12 were chosen for use as propellants due to their chemical stability and relatively low toxicity. Many of the chemicals suggested as substitutes for the chlorofluorocarbons, such as the hydrogen-containing fluorocarbons

Response to Comment

Descriptions of the potential hazards of alternative propellants are provided in several sections under the discussion of Alternative 2, pages 94-101 in the draft EIS. For clarification purposes, the major discussion of these potential hazards has been included in a new section "c. Replacement Propellants and Associated Hazards" under the discussion of Alternative 2. A paragraph has been added to this new section which more directly describes the potential hazards to the worker of a conversion to nonchlorofluorocarbon propellants.

(F22 and F142b), however, show indications of chronic toxicity problems. It seems obvious that an increase in the production and use of these more hazardous chemicals may result in increased health hazards for workers as well as for consumers. For this reason, we recommend that FDA investigate the impact that substitution of other fluorocarbons or chemicals for chlorofluorocarbons 11 and 12 will have on the health of those involved in the production and industrial use of aerosol propellants.

Sincerely,

WILLIAM B. HEWITT
Administrator
Policy, Evaluation and Research

Comment

Docket #
C00147

UNITED STATES
ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION
WASHINGTON, D.C. 20545

SEP 22 1977

Dr. Buzz Hoffman
Department of Health, Education,
and Welfare
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Hoffman:

This is in response to Mr. Custard's transmittal dated July 15, 1977, in which he invited the Energy Research and Development Administration (ERDA) to review and comment on the Department of Health, Education, and Welfare's Draft Environmental Impact Statement, Fluorocarbons: Environmental and Health Implications.

We have reviewed the statement and are concerned over the availability of a continued supply of chlorofluorocarbons for uranium enrichment operations. We would hope that there will still be incentive for manufacturers to continue producing Freon 114 for which about 90% of the market will be eliminated by this action. The non-availability of this product could be far reaching if a resulting shortage of enriched uranium develops. Replacement of chlorofluorocarbon refrigeration and other systems at ERDA facilities will cost many millions of dollars. While there are substitute materials for many of the ERDA applications, reuse of these substitutes will return the fire and health hazard problems that were significantly decreased when the use of freons was selected over the initial materials.

The above impact evaluation is not meant to imply that the Food and Drug Administration's proposed action to prohibit the non-essential use of chlorofluorocarbons as propellants in self-pressurized containers in products subject to the Federal Food, Drug, and Cosmetic Act should not take place.

Additionally, there is another possible concern related to ERDA programs in that the shortage of trifluroethanol may affect future development work with the Rankin engine. You may wish to consider addressing the potential impacts of the aforementioned concerns in the final statement.

Staff feels that the technical discussion relevant to biological and human health effects is adequate. However, there are so many uncertainties that extrapolations regarding effects on human health, biological and environmental effects must be considered extremely tenuous. Any new and relevant data complete with literature references

Response to Comment

Paragraph 2, first part - with respect to the continued production of chlorofluorocarbon 114 (F-114) after the action to prohibit its use as a nonessential propellant becomes effective, FDA can only suggest that ERDA contact the manufacturers of F-114 directly. FDA is aware of other uses for F-114, (e.g., anesthetic, refrigerant, blowing agent), which will not be affected by the regulation of chlorofluorocarbon propellants. Therefore, it is likely that there will still be a market, albeit small, for the manufacture of F-114.

Paragraph 2, second part - The present regulatory action does not cover the use of chlorofluorocarbons as refrigerants.

Paragraph 4 - Trifluoroethanol is not a chlorofluorocarbon and would not present a threat to stratospheric ozone.

Paragraph 5 - The Environmental Impact Staff at FDA will gladly assist anyone who has difficulty obtaining any of the reference material cited in the EIS.

should be included. Staff feels that statements should be updated and firmed up; for instance, the listing on page 62 of unpublished studies should not be considered reference material in the environmental statement. If these studies are to be quoted, they should be published and literature references given so others may review them.

Thank you for the opportunity to review and comment on the draft statement.

Sincerely,

W. H. Pennington, Director
Office of NEPA Coordination

cc: Council on Environmental
Quality (5)
C. Custard, HEW

Comment

Docket #
C00151

NASA

National Aeronautics and
Space Administration

Washington, D C
20546

In reply refer to: ADA-1

October 17, 1977

Dr. Buzz Hoffmann
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Hoffman:

NASA has reviewed the Draft Environmental Impact Statement, "Fluorocarbons: Environmental and Health Implications," and our comments are contained within the following paragraphs.

Impact on Stratospheric Ozone (Section 3.1)

The evaluation of the impact of fluorocarbons upon stratospheric ozone is based, in part, upon work carried out under NASA auspices and coordinated with FDA. We therefore have no comments on this section except to note that the preliminary assessment report (reference 14 of the draft environmental impact statement) has recently been revised. The revised report* is based on additional meetings of working groups held in June and July 1977. Thus, the report represents knowledge as of about June 1977.

The major change from the preliminary report is in the rate of the reaction

$$HO_2 + NO \longrightarrow OH + NO_2$$

*Hudson, R.D., ed., August 1977. Chlorofluoromethanes and the Stratosphere, NASA Reference Publication 1010, National Aeronautics and Space Administration, Goddard Space Flight Center, Greenbelt, Maryland

Response to Comment

Impact on Stratospheric Ozone: Section 3.1.1.3 of the final EIS has been updated to reflect the more recent information contained within this comment.

which is now evaluated to be considerably faster than previously believed. The net effect upon the steady state ozone depletion resulting from releases of chlorofluoromethanes (CFM's) is calculated to be about a factor of two; that is, for the given 1975 release profile of CFM's, the percentage ozone depletion is now estimated to be about twice as great as the earlier estimates. These new estimates, which have been discussed with FDA personnel, should be incorporated into the material beginning on page 30 and in following sections, as required.

Human Health Effects of Increased UV-B (Section 3.3)

NASA has no Federal jurisdiction in the assessment of the effects of ultraviolet radiation (UV-B) upon humans. We have, however, developed relevant expertise in the course of assessing the effects of NASA activities that might result in increase in the amount of such radiation reaching the earth's surface. It is our understanding that the relationship between UV-B exposure and the incidence of skin cancer is sufficiently uncertain that numerical estimates of increases in skin cancer cases are correspondingly uncertain and their use may be misleading. If numerical estimates are employed at all, the appropriate assumptions, limitations, and caveats should be clearly stated. We recommend that the paragraphs provided in the enclosure be incorporated as an introduction to Section 3.3.2.2. We also suggest that the use of estimates of increased number of cases having up to seven significant figures (e.g., Tables 11-15) be avoided.

In addition, we would appreciate your incorporating in the statement the following additional specific corrections:

1. The specific acknowledgements contained within the next to last paragraph of the Foreword (page ii) should be deleted. If any acknowledgement is appropriate at all, it might better be to those members and associates of the Interagency Chlorofluorocarbon Workgroup who contributed importantly to the environmental impact statement.

Human Health Effects of Increased UV-B: The suggested introductory language for section 3.3.2.2 has been added to the final EIS.

The statement "Reporting the results to six significant figures should not be construed as indicating such a degree of accuracy." in section 3.3.2.2 of the draft EIS has been placed in the legends of tables 11-15.

1. The acknowledgements of individuals in the Foreword have been deleted. References to individuals who have contributed to sections of the FDA EIS are made at the beginning of the specific section to which the contribution was made.

2. On page 36, Section 3.2, the first paragraph should be changed to read "...condensed, edited and modified version of a more detailed unpublished report..."

3. On page 61, Section 3.3, the first paragraph should be changed to read "...condensed, edited and modified version of a more detailed unpublished report..."

4. On the first line of page 67, after the word "latitude," the following sentence should be added: Most projections to date have relied on the latitudinal gradient of skin cancer incidence found in the Supplemental Study to the Third National Cancer Survey (TNCS), which was conducted for purposes other than predicting the incidence of non-melanoma skin cancer.

5. The second full paragraph on page 68 should be modified to indicate that the degree to which results from animal studies can be extrapolated to man is uncertain.

6. On page 74, the first paragraph of Section 3.3.2.3 should be modified to indicate that the relationship between melanoma skin cancer and ultraviolet radiation is uncertain and should be discussed only qualitatively.

We appreciate the opportunity to comment.

Sincerely,

Nathaniel B. Cohen

Nathaniel B. Cohen, Director
Office of Policy Analysis

Enclosure

2, 3, and 4. The suggested language has been incorporated in the final EIS.

5. A sentence has been added in the paragraph noted to reflect the uncertainty associated with the extrapolation of animal studies to man.

6. A sentence to indicate that the extent of the relationship between melanoma skin cancer and ultraviolet radiation is uncertain and should only be discussed qualitatively has been added at the beginning of section 3.3.2.3.

ENCLOSURE

3.3.2.2. Projections of Increased Nonmelanoma Skin Cancer Resulting from Increased DUV

There is no question in the research community among those most knowledgeable that there is a relationship between nonmelanoma skin cancer and ultraviolet radiation. However, because there are many variables and uncertainties concerning this relationship, any attempts at quantification must, of necessity, use certain assumptions. These uncertainties, assumptions, and ameliorating circumstances are discussed in Section 3.3.3.

Nonetheless, recognizing the uncertainties extant, the inadequacies of the data available, and the assumptions that must be made at this time, in a following subsection we attempt to quantify and project the incidence of nonmelanoma skin cancer that might obtain in the future following ozone reduction. Such a quantitative estimate of impact, even if uncertain by a factor of 2-4, is useful in order to assess whether the impact is potentially important or trivial.

APPENDIX D

Additional Changes in EIS by FDA Staff to (A) Update Information Presented or (B) Further Clarify an Intended Meaning

Former Page	Present Page	Correction
6, para. 3 and 4	6, para. 3 and 4	The most recent information on state and non-U.S. regulatory actions on chlorofluorocarbon propellants has been included.
27, para. 2, line 5	27, para. 2, line 5	Replaced "thus" with "to date"
30-32	30-32	Discussion of the final NASA workshop and assessment reports added.
46, footnote 2	46, footnote 2	Replaced "of" in last line with "at."
52 last para., line 1	53. last para., line 1	Deleted the word "catastrophic."
61, last para., line 1	63, para. 2 line 1	Replaced "forms" with "types."
64, line 3	65, para. 4, line 8	Deleted "of" after "Because."
64, line 5	65, para. 4, last line	Added "in the absence of any ozone reduction" after "5 years."
65, end of page	67, para. 3,4	A section titled "Photosensitivity" has been added to the final EIS to describe additional health impacts which could result from increased DUV exposure.
76, para. 2, line 2	78, last para. line 2	Replaced "two" with "2-4" after "say" (to be consistent with NASA comment).
82, section 3.5.1	85, section 3.5.1	Section 3.5.1 has been revised to indicate the completion of the NASA reports on "Chlorofluoromethanes and Stratospheric Ozone."

82, section 3.5.2, para. 2	86, section 3.5.2, para. 2	For clarification purposes, "which could result from chlorofluorocarbon emissions" has been added at the end of the first sentence in this paragraph and "are being conducted" has been inserted after "molecular mechanisms" in the second sentence.
82, section 3.5.2, para. 3	86, section 3.5.2, para. 3	The phrase "by December 1977" after "the program is" has been deleted.
87, end of second full para.	91, end of end of second full para.	Two sentences were added in place of the last sentence in this paragraph to describe ongoing activities by the regulatory agencies relating to non-propellant uses of chlorofluorocarbons.
88, section 4.3	92, section 4.3	An introductory paragraph was added under this section to explain the fact that new quantitative estimates of potential impacts prevented by each regulatory option based on more recent data have not been generated for the final EIS.
88, Alternative 1 - No Action, line 6	92, Alternative 1 - No Action, line 6	"Emissions" was added at the end of the second sentence.
89	93, 94	Revisions and additions were made on these pages to include relevant citations from and reference to the final NASA workshop and assessment reports.
89, last para., first line	94, para. 3, first line	The phrase "percentage reduction of" has been inserted after "maximum."
90, first para., line 2	94, last para., line 2	"is" has been replaced by "could be."

90, first para., lines 3 and 8	94, last para., lines 3 and 8	"would" has been replaced by "could."
92, para. 1, line 1	96, last para., line 1	"in" has been replaced by "at."
94, para. 3, line 1	99, para. 2, line 1	"would" has been replaced by "could."
95, para. 2, line 1	100, para. 1, line 1	"will" has been replaced by "is"
104, para. 2, lines 1 and 6	109, para. 4, lines 1 and 7	"potential" has been inserted before "effects"
104, para. 3, line 8	109, last para., line 8	"actual difference" has been replaced by "estimated increase"
104, para. 3, line 10	109, last para., line 10	"in eliminating U.S. chlorofluorocarbon propellant emissions" has been inserted after "two-year delay"
104, para. 3, line 11	109, last para., last line	"difference" has been replaced by "increase"
106, para. 2, • 5	112, para. 2, • 5	"cytology fixatives" has been deleted and "metered dose ergotamine tartrate for oral inhalation" has been added. (See section V of preamble to final regulation for explanations.)
106, last para., first line	112, last para., first line	"The control of chlorofluorocarbon emissions from non-propellant sources is currently under consideration by FDA, EPA, and CPSC (see p. 91)." was substituted for the first line in draft.
107, section 5.2, para. 2, line 9	113, section, 5.2, para. 2, line 9	"for" has been inserted after "other than"

107, section 5.2, para. 2, line 10 and last line	113, section 5.2, para. 2, line 10	The first "essential" in line 9 and the last sentence in the paragraph have been deleted (see section III of preamble to final regulation for explanation).
107, section 5.3, line 7	113, section 5.3, line 7	"banned" has been replaced by "as"
109, section 6.6, line 1	115, section 6.6, line 1	"preamble to the" has been inserted after "addressed fully"
B-8, para. 2	B-11, para. 2	Misspelling of "independent" in line 3 has been corrected.
B-12, line 15	B-15, last 2 lines	"High value" has been replaced by "higher than expected value (based on latitude)."
B-23-25	B-27-29	Tables 3, 4, and 5 have been changed to 5, 6, and 7.