ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 355

[FRL-3574-2]

Reportable Quantity Adjustment—Radionuclides

AGENCY: U.S Environmental Protection Agency (EPA).

ACTION: Technical amendment.

SUMMARY: Sections 103(a) and 103(b) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, require that persons in charge of vessels or facilities from which a hazardous substance has been released within a 24-hour period in a quantity equal to or greater than its reportable quantity immediately notify the National Response Center of the release. As discussed elsewhere in today's **Federal Register**, the U.S. Environmental Protection Agency (EPA) has decided to exempt from CERCLA notification requirements the following four categories of releases of radionuclides: (1) Releases of radionuclides that occur naturally in soil from land holdings such as parks, golf courses, or other large tracts of land; (2) releases of radionuclides occurring naturally from the disturbance of land for purposes other than mining, such as for agricultural or construction activities; (3) releases of radionuclides from the dumping of coal and coal ash at utility and industrial facilities with coal-fired boilers; and (4) releases of radionuclides from coal and coal ash piles at utility and industrial facilities with coal-fired boilers. These releases also are exempt from the reporting requirements of section 304 of the Emergency Planning and Community Right to Know Act (EPCRA), also known as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). Under SARA Section 304(a)(3), releases of radionuclides must be reported to the community emergency coordinator for the Local Emergency Planning Committee (LEPC) and to the State Emergency Response Commission (SERC) of any State that is likely to be affected by the release, if the release occurs at a facility at which a hazardous chemical is produced, used, or stored, and if notification of the release is required under section 103(a) of CERCLA. Because of today's exemptions of certain radionuclide releases from CERCLA notification requirements, as described above, such exempted releases also are exempt from the reporting requirements of section 304 of SARA.

This Technical Amendment also adds language to 40 CFR 355.40(a)(2) that was inadvertently deleted in publishing the final rule adjusting Threshold Planning Quantities for Extremely Hazardous Substances (52 FR 13396; April 22, 1987). This amendment adds paragraph 355.40(a)(2)(iv) that provides that releases exempted from CERCLA section 103(a) reporting by CERCLA section 103(e) (which applies to the application, handling, or storage of a pesticide registered under the Federal Insecticide, Fungicide, and Rodenticide Act) also are exempt from reporting under SARA section 304. In addition, this Technical Amendment clarifies the language in paragraph (a)(2)(v). Section 355.40(a)(2)(v) exempts from section 304 reporting any occurrence not meeting the definition of release under section 101(22) of CERCLA. Such occurrences are also exempt from reporting under CERCLA Section 103(a).

EFFECTIVE DATE: July 24, 1989.

FOR FURTHER INFORMATION CONTACT: Ms. Pamela Harris, Project Officer, Response Standards and Criteria Branch, Emergency Response Division (WH-548B), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, or the RCRA/Superfund Hotline, 1-800/424-9346; in Washington DC metropolitan area, 1-202/382-3000.

Dated: May 11, 1989.

Jonathan Z. Cannon,

Acting Assistant Administrator.

For the reasons set forth above, Title 40 of the Code of Federal Regulations is amended as follows:

PART 355—EMERGENCY PLANNING AND NOTIFICATION

1. The authority citation for Part 355 is revised to read as follows:

Authority: 42 U.S.C. 11002 and 11048.

2. Section 355.40 is amended by adding paragraphs (a)(2)(v) and (a)(2)(vi), and by revising paragraph (a)(2)(iv) to read as follows ((a)(2) introductory text is republished):

§ 355.40 Emergency release notification.

(a) Applicability.

(1) * * *

(2) This section does not apply to:

* * *

(iv) Any release of a pesticide product exempt from CERCLA section 103(a) reporting under section 103(e) of CERCLA;

(v) Any release not meeting the definition of release under Section 101(22) of CERCLA, and therefore exempt from Section 103(a) reporting; and

(vi) Any radionuclide release which occurs (A) naturally in soil from land holdings such as parks, golf courses, or other large tracts of land; (B) naturally from the disturbance of land for purposes other than mining, such as for agricultural or construction activities; (C) from the dumping of coal and coal ash at utility and industrial facilities with coal-fired boilers; and (D) from coal and coal ash piles at utility and industrial facilities with coal-fired boilers.

* * * * *

[FR Doc. 89-12180 Filed 5-23-89; 8:45 am]

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federal register

Wednesday
May 24, 1989

Part III

Department of Transportation

Coast Guard

33 CFR Part 151

Implementation of the Shore Protection Act of 1988; Interim Rule with Request for Comments

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 151

[CGD 89-014]

RIN 2115-AD23

Implementation of the Shore Protection Act of 1988

AGENCY: Coast Guard, DOT.

ACTION: Interim rule with request for comments.

SUMMARY: The Coast Guard is publishing an interim rule to implement permitting the numbering requirements of the Shore Protection Act of 1988. The Coast Guard is issuing these requirements as an interim rule because the Shore Protection Act requires that permits be in place 240 days after the Act's enactment, which will occur on July 15, 1989. By issuing an interim rule, the Coast Guard and the public will be able to meet this mandated deadline.

DATES: *Effective Date:* 1. May 24, 1989.

2. The Coast Guard will accept comments on this interim rule until August 24, 1989.

ADDRESSES: Comments should be submitted to the Executive Secretary, Marine Safety Council (G-LRA-2/3600), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001 between the hours of 8:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be delivered to and will be available for copying at that address. The Categorical Exclusion from the requirements of the National Environmental Policy Act (NEPA) is available for inspection and copying at the same address.

Persons wishing to comment on the information collection requirements should submit their comments to: Office of Regulatory Policy, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: Lieutenant James H. McDowell, Office of Marine Safety, Security and Environmental Protection (G-MPS-3) (202) 267-0491, between 7:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: The public is invited to participate in this rulemaking by submitting written views, data or arguments. Comments should include the name and address of the person making them, identify this interim rule (CGD 89-014) and the specific section of the interim rule to which each comment applies, and give the reasons for the comment. If an acknowledgment of receipt is desired, a stamped, self-addressed postcard should be enclosed.

All comments received before the expiration date of the comment period will be considered before any action is taken on this interim rule. They will also be considered in preparing the notice of proposed rulemaking for the second regulatory project described below in the paragraphs under Regulatory Approach.

Drafting Information

The principal persons involved in drafting this rule are: Lieutenant James H. McDowell, Project Manager, and Stanley M. Colby, Project Counsel, Office of Chief Counsel.

Discussion of the Interim Rule

I. Background

On November 18, 1988, Congress enacted the Shore Protection Act (33 U.S.C. 2501 *et seq.*), hereafter referred to as the Act, to help prevent trash, medical debris and other unsightly and potential harmful materials from being deposited into the costal waters of the United States as as result of sloppy waste handling procedures. The Conference Report on the Ocean Dumping Ban Act (Report 100-1090) stated that landfills and attendant barging operations are a major source of floatable waste in harbor areas. The report concluded that this type of waste has fouled the beaches of this country over the last two summers, reducing the quality of coastal waters, endangering the health of humans, marine mammals, waterfowl and fish, and causing severe decline in coastal economies dependent upon tourism and recreational uses.

Section 4103(a)(1) of the Act requires owners or operators of waste sources, vessels transporting waste and waste reception facilities to take reasonable steps to minimize the amount of municipal or commercial waste deposited into coastal waters during vessel loading and unloading operations and during vessel transportation from a waste source to receiving facilities. The Act prohibits vessels from transportating municipal and commercial waste unless they have a permit and display a number of other prescribed marking 240 days after enactment, which will occur on July 15, 1989. The Act also outlines provisions for enforcing these requirements.

The Environmental Protection Agency (EPA) and the Department of Transportation (DOT) have been assigned responsibility for implementing the provisions of the Act. DOT is responsible for issuing permits, prescribing the number or marking which vessels must display, and enforcing regulations implementing the Act. On January 12, 1989, the Secretary of Transportation delegated these responsibilities to the Coast Guard.

II. Regulatory Approach

These interim regulations amend Part 151 of Title 33, Code of Federal Regulations. This part is concerned with shipboard requirements to prevent pollution. Existing regulation in this Part implement Annexes I, II and V of MARPOL 73/78. There are no new requirements in the regulations in this document which change Annexes I, II or V requirements. This interim rule reorganizes Part 151 into 2 Subparts. Subpart A will contain the existing regulations in Part 151. Existing Subparts A, B, C, and D will be reorganized as undesignated hearings under Subpart A. The new Subpart B will contain the regulations implementing the Act.

Due to the July 15, 1989 statutory implementation date, the Coast Guard has decided to issue two regulatory projects implementing the responsibilities delegated under the Act. The first regulatory project, which is this document, is being initiated in the public interest as expeditiously as possible, to meet this deadline and allow vessels to continue to operate without interrupting the flow of waste removal. It establishes the requirement for the owner or operator of each vessel, whose purpose is to transport municipal or commercial waste, to apply for a conditional permit and to display a vessel number. It details the procedure to apply for a conditional permit and requirements for displaying the vessel number. It establishes the procedures for issuing conditional permits and the conditions for denying issuance and withdrawing a conditional permit.

At a later date, procedures for applications and issuance of a regular permit will be proposed. These procedures will continue, modify or replace the procedures contained in this document. Regulations implementing the suspension and revocation provisions of the Act will also be proposed.

III. Vessels Effected By This Rule:

This rule applies to vessels whose purpose is to transport municipal or commercial waste in the coastal waters of the United States. The conference report on the Ocean Dumping Ban Act (Report 100-1090) states that the Act was intended "only to apply to vessels whose purpose is the transportation of municipal or commercial waste, not all

vessels. It was not intended to apply to vessels that may generate waste during their normal operations". There are many vessels which transport some quantities of municipal or commercial waste incidentally to the predominant business or purpose of the vessel, e.g., a ferry which transports a garbage truck loaded with municipal or commercial waste. In this example, the ferry is not required to apply for a permit, since the ferry's predominant business or purpose is not waste transportation. However, a vessel which regularly transports miscellaneous cargo but is hired to transport waste for a specific voyage would be required to hold a permit to transport waste for that voyage, since the predominant business or purpose of the vessel for that voyage in waste transportation.

IV. What Constitutes Municipal or Commercial Waste

Section 151.1006 defines the term "municipal or commercial waste", which is the same definition provided by section 4101(3) of the Act. This definition includes solid waste regulated under the Solid Waste Disposal Act [42 U.S.C. 6903) and transported for disposal on land, including municipal garbage, commercial refuse, medical wastes, and wood debris. However, in accordance with the Act, the term specifically excludes hazardous wastes identified and listed under the Solid Waste Disposal Act (42 U.S.C. 6921), waste generated by the vessel during normal operations, construction debris, sewage sludge as permitted by the EPA, and dredge spoil or fill materials subject to regulation under title I of the Marine Protection, Research and Sanctuaries Act of 1972 [33 U.S.C. 1401 *et seq.*), the Federal Water Pollution Control Act [33 U.S.C. 1251 *et seq.*), or the Rivers and Harbors Appropriation Act of 1899 [33 U.S.C. 401 *et seq.*).

V. Applying For a Permit

In order to receive a conditional permit to transport municipal or commercial waste, the owner or operator of a vessel must apply by letter to Commandant (G–MPS–1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, Attn: Shore Protection Act Desk. Applications must include the information required by § 151.1012, which is also required by section 4102(b) of the Act and an acknowledgment that the information provided on the application is true and correct. After reviewing the application for completeness, the Coast Guard will determine whether or not to issue the conditional permit. A vessel number and the termination date of the conditional permit will be added to the application. A copy of the application will be returned to the owner or operator to serve as the conditional permit for the vessel to transport municipal or commercial waste after July 15, 1989. This expeditious method of issuance is being implemented in the public interest to avoid the interruption of waste removal or any unnecessary accumulation of waste on vessels or shore structures.

Under the provisions of the Act, it will be unlawful to transport municipal or commercial waste after July 15, 1989 without a permit. To allow the continued transportation of municipal and commercial waste and to avoid the health hazards that would occur if waste accumulated, this interim rule provides for the issuance of conditional permits, which will be effective immediately. These conditional permits are subject to being withdrawn if further inquiry or consultation with Environmental Protection Agency (EPA) officials indicates the vessel would not qualify for a regular permit. As required by the Act, regular permits will not be effective until 30 days after they are issued.

Conditional permits will be valid for 18 months, unless a shorter period is specified on the permit. The Coast Guard may deny issuance of a conditional permit if the application for the conditional permit does not contain the required information or if the Coast Guard has reason to believe the information provided is not true or correct. The Coast Guard will notify the owner or operator in writing of the denial, the reason for the denial and the procedures for appealing this decision.

After issuing the conditional permit, the Coast Guard will consult with the regional director of the EPA, as required by 4102(d) of the Act, to determine whether or not the owner or operator of the vessel has a record or a pattern of serious violations of the Act, the Solid Waste Disposal Act (supra), the Marine Protection, Research and Sanctuaries Act of 1972 [33 U.S.C. 1401 *et seq.*), the Rivers and Harbors Appropriations Act of 1899 [33 U.S.C. 401 *et seq.*), or the Federal Water Pollution Control Act [33 U.S.C. 1251 *et seq.*).

A conditional permit may be withdrawn at any time after issuance if the Administrator of the EPA requests withdrawal because the Administrator has determined that the owner or operator of the vessel has a record or a pattern of serious violations of the statutes listed under section 4102(d) (1) through (5) of the Act and described above. The Coast Guard will notify the owner or operator in writing of the withdrawal, the reason for the withdrawal and the procedures for appealing this decision.

Owners or operators of vessels which have been denied issuance of a conditional permit or have had a conditional permit withdrawn may request reconsideration by the issuing authority. Owners or operators who are not satisfied with a ruling after it has been reconsidered may appeal this decision to the Chief, Office of Marine Safety, Security and Environmental Protection, U.S. Coast Guard Headquarters, Washington, DC 20593–0001. Appeals must be in writing and contain complete supporting documentation and evidence which the appellant wishes to have considered.

VI. Displaying a Vessel Number

Vessels under the Act are required to display a number or other marking on the vessel as prescribed by the Secretary of Transportation. The purpose of this marking is to aid in identification. The number assigned to the vessel will be stated on the conditional permit as described above.

The vessel number must be displayed on the vessel so that it is readily visible from either side. The vessel number must be clearly legible, displayed against a contrasting background and in block figures that are at least 18 inches in height.

Regulatory Evaluation

There are approximately 400 vessels whose purpose is the transportation of municipal and commercial waste in coastal waters. As explained above, the owner or operator of each of these vessels will be required to apply by letter for a permit to transport municipal and commercial waste in coastal waters and to display a number on the vessel. Conditional permits issued under this rule are in effect for a period no longer than 18 months. At the end of this period, vessel owners or operators who intend to transport municipal or commercial waste will be required to reapply for a permit. The Coast Guard estimates the total cost to the public for completing the application and displaying the vessel number will amount to less than $15,000.00 Appeals, when utilized, are estimated to cost less than $2,000.00. The cost of this regulatory project is so low that no further regulatory evaluation is considered necessary.

The Coast Guard concludes that these regulations are non-major under Executive Order 12291 and nonsignificant under DOT regulatory

policies and procedures (44 FR 11034; February 26, 1979).

Regulatory Flexibility Act

The Coast Guard has considered the impact of these regulations on small entities. The Coast Guard has adopted the Small Business Administration's (SBA) definition of "small business" used when considering SBA loans to concerns engaging in transportation and wharehousing (13 CFR 121.10(f)) as a definition for small entities. A concern is considered small, under this definition, if its annual receipts do not exceed $1.5 million.

These regulations contain only minimal reporting requirements. Respondents are required to complete an application containing only the minimum information necessary for the Coast Guard to fulfill its obligation under the Act. They are also required to display a number on the vessel. The cost of complying with these requirements will be minimal. These costs are proportionally lower for small entities than for larger ones because a small entity will have fewer vessels and therefore will have fewer applications to complete and numbers to display. Since these costs are so low, the cost to any individual small entity will be negligible. Therefore, the Coast Guard certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule will add the new information reporting requirement that all vessels whose purpose is the transportation of municipal and commercial waste apply for a conditional permit. The information reporting requirements have been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB Control Number 2115–0579 has been assigned under the provisions of 5 CFR 1320.18.

Environmental Impact

The permit and numbering system, prescribed by the interim rule, are a part of a regulatory program intended to minimize the amount of municipal or commercial waste entering the coastal waters of the U.S. However, the proposed regulations are administrative in nature and do not prescribe any operational requirements which would have an impact on the environment. The interim rule has been thoroughly reviewed by the Coast Guard and has been determined to be categorically excluded from further environmental documentation as provided for in 10 CFR 51.22(c)(3). Therefore, neither an Environmental Assessment or Environmental Impact Statement has been prepared for this interim rule. The categorical exclusion determination is available in the docket for examination and copying as indicated under "**ADDRESSES**".

Federalism Assessment

This interim rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Information Number (RIN)

A regulatory information number has been assigned to this regulatory action and will be listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center (RISC) publishes the Unified Agenda in April and October of each year. The RIN number listed at the heading of this document can be used to follow the progress of this action in the Unified Agenda.

List of Subjects in 33 CFR Part 151

Oil pollution, Reporting and recordkeeping requirements, Water pollution control.

In consideration of the preceding, the Coast Guard amends Part 151 of Title 33, Code of Federal Regulations, as follows:

PART 151—[AMENDED]

1. By removing the authority citation for Part 151 and adding the authority citation for Subpart A to read as follows:

Authority: 33 U.S.C. 1321(j)(1)(C) and 1903(b); E.O. 11735, 3 CFR, 1971–1975 Comp., p. 793; 49 CFR 1.46.

2. By revising the title of Part 151 to read as follows:

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE AND MUNICIPAL OR COMMERCIAL WASTE

3. By removing all subpart designations but leaving the headings of those removed subparts and adding a new Subpart A above the undesignated "General" heading to read as follows:

Subpart A—Implementation of MARPOL 73/78

4. By adding a new Subpart B to read as follows:

Subpart B—Transportation of Municipal and Commercial Waste

Sec.

Subpart B—Transportation of Municipal and Commercial Waste

Authority: 33 U.S.C. 2602; 49 CFR 1.46.

§ 151.1000 Purpose.

The purpose of this subpart is to implement the permit provisions of the shore Protection Act of 1988, (33 U.S.C. 2601 *et seq.*).

§ 151.1003 Applicability.

(a) Except as provided by paragraph (b) of this section, this subpart applies to each vessel whose purpose is the transportation of municipal or commercial waste in coastal waters.

(b) This subpart does not apply to public vessels.

§ 151.1006 Definitions.

As used in this subpart—

"Coastal Waters" means—

(1) The territorial sea of the United States;

(2) The Great Lakes and their connecting waters;

(3) The marine and estuarine waters of the United States up to the head of tidal influence; and

(4) The Exclusive Economic Zone as established by Presidential Proclamation Number 5030, dated March 10, 1983.

Note: The Exclusive Economic Zone extends from the baseline of the territorial sea of the United States seaward 200 miles.

"Municpal and commercial waste" means solid waste as defined in section 1004 of the Solid Waste Disposal Act (42 U.S.C. 6903) except–

(1) Solid waste identified and listed under section 3001 of the Solid Waste Disposal Act (42 U.S.C. 6921);

(2) Waste generated by a vessel during normal operations;

(3) Debris solely from construction activities;

(4) Sewage sludge subject to regulation under title I of the Marine Protection, Research, and Sanctuaries Act of 1972 (33 U.S.C. 1401 *et seq.*); and

(5) Dredge or fill material subject to regulation under title I of the Marine Protection, Research and Sanctuaries Act of 1972 (33 U.S.C. 1401 *et seq.*), the Federal Water Pollution Control Act (33 U.S.C. 1251 *et seq.*), or the Rivers and Harbors Appropriation Act of 1899 (33 U.S.C. 401 *et seq.*).

"Public vessel" means a vessel that—

(1) Is owned, or demise chartered, and operated by the United States Government or a government of a foreign country; and

(2) Is not engaged in commercial service.

"Vessel" means every description of watercraft or other artifical contrivance used, or capable of being used, as a means of transportation on water.

§ 151.1009 Transportation of municipal or commercial waste.

A vessel may not transport municipal or commercial waste in coastal waters without—

(a) A conditional permit to transport municpal or commercial waste issued under this subpart; and

(b) Displaying a number in accordance with § 151.104.

§ 151.1012 Applying for a conditional permit.

(a) The owner or operator of each vessel to which this subpart applies shall apply by letter for a conditional permit required by § 151.1009. Applications must be submitted to Commandant (G–MPS–1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, Attn: Shore Protection Act Desk and include the following:

(1) The name, address, and telephone number of the vessel owner and operator.

(2) The vessel's name and official number, if any.

(3) The vessel's area of operation.

(4) The vessel's transport capacity.

(5) A history of the types of cargo transported by the vessel during the previous year, including identifying the type of municipal or commercial waste transported as—

(i) Municipal waste;

(ii) Commercial waste;

(iii) Medical waste; or

(iv) Waste of another character.

(6) The types of cargo to be transported by the vessel during the effective period of the conditional permit, including identifying the type of municipal or commercial waste as it is identified in paragraphs (a)(5)(i) through (iv) of this section.

(7) A statement of whether the application for a conditional permit is for a single voyage, a short term operation or a continuing operation. If the application is for a single voyage or a short term operation, the statement must include the duration of the voyage or operation.

(8) An acknowledgment that certifies as to the truthfulness and accuracy of the information provided.

(b) The owner or operator under paragraph (a) of this section shall provide any additional information the Coast Guard may require.

§ 151.1015 Issuing or denying the issuance of a conditional permit.

(a) After reviewing the application made under § 151.1012, the Coast Guard either—

(1) Issues the conditional permit for a vessel under this section; or

(2) Denies the issuance of the conditional permit to the vessel in accordance with paragraph (c) of this section. On denying the issuance of the permit, the Coast Guard notifies the applicant of the—

(i) Denial and the reason for the denial; and

(ii) Procedures under § 151.1021 for appealing the denial.

(b) Each conditional permit issued under this section is effective—

(1) On the date it is issued; and

(2) Until the expiration date stated on the conditional permit unless it is—

(i) Withdrawn under § 151.1018;

(ii) Terminated because—

(A) The vessel is sold; or

(B) This subpart no longer applies to the vessel.

(c) The Coast Guard may deny the issuance of a conditional permit if—

(i) The application does not contain the information required under § 151.1012; or

(ii) There is reason to believe that the information contained on the application is not true and correct.

§ 151.1018 Withdrawal of a conditional permit.

(a) The Coast Guard may withdraw a conditional permit if the Administrator of the EPA requests withdrawal because the Administrator has determined that the owner or operator of the vessel has a record or a pattern of serious violations of—

(1) Subtitle A of the Shore Protection Act of 1988 (33 U.S.C. 2601 *et seq.*);

(2) The Solid Waste Disposal Act (42 U.S.C. 6901 *et seq.*);

(3) The Marine Protection, Research, and Sanctuaries Act of 1972 (33 U.S.C. 1401 *et seq.*);

(4) The Rivers and Harbors Appropriations Act of 1899 (33 U.S.C. 1401 *et seq.*); or

(5) The Federal Water Pollution Control Act (33 U.S.C. 1251 *et seq.*).

(b) Upon reaching a determination to withdraw a conditional permit, the Coast Guard notifies the owner or operator of—

(1) The withdrawal and the reason for the withdrawal;

(2) The procedures for appealing the withdrawal.

(c) After receiving the notice under paragraph (b) of this section, the owner or operator shall ensure that—

(1) The vessel immediately ceases transporting municipal or commercial waste and the marking required by § 151.1024 is removed; and

(2) The conditional permit is returned to the Coast Guard within 5 days after receiving the notice.

§ 151.1021 Appeals.

(a) Any person directly affected by an action taken under this subpart may request reconsideration by the Coast Guard officer responsible for that action.

(b) The person affected who is not satisfied with a ruling after having it reconsidered under paragraph (a) of this section may—

(1) Appeal that ruling in writing within 30 days after the ruling to the Chief, Office of Marine Safety, Security and Environmental Protection, U.S. Coast Guard, Washington, DC 20593–0001; and

(2) Supply supporting documentation and evidence that the appellant wishes to have considered.

(c) After reviewing the appeal submitted under paragraph (b) of this section, the Chief, Office of Marine Safety, Security and Environmental Protection issues a ruling which is final agency action.

(d) If the delay in presenting a written appeal has an adverse impact on the operations of the appellent, the appeal under paragraph (b) of this section—

(1) May be presented orally; and

(2) Must be submitted in writing within five days after the oral presentation—

(i) With the basis for the appeal and a summary of the material presented orally; and

(ii) To the same Coast Guard official who heard the oral presentation.

§ 151.1024 Display of number.

(a) The owner or operator of each vessel under this subpart must ensure that the vessel number stated on the conditional permit issued under § 151.1015 is displayed so that it—

(1) Is clearly legible;

(2) Has a contrasting background;

(3) Is readily visible from either side of the vessel; and

(4) Is in block figures that are at least 18 inches in height.

(b) No person may tamper with or falsify a number required under this section.

J.D. Sipes,

Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Safety, Security and Environmental Protection.

April 28, 1989.

[FR Doc. 89–12396 Filed 5–23–89; 8:45 am]

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federal register

Wednesday
May 24, 1989

Part IV

Department of Education

34 CFR Part 755

National Program for Mathematics and Science Education; Notice of Proposed Rulemaking

DEPARTMENT OF EDUCATION

34 CFR Part 755

National Program for Mathematics and Science Education

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary issues a notice of proposed rulemaking for the National Program for Mathematics and Science Education. These amendments are needed to implement section 2012 of the Dwight D. Eisenhower Mathematics and Science Education Act, Title II, Part A of the Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988.

DATE: Comments must be received on or before June 23, 1989.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Daniel Schecter, Office of Educational Research and Improvement, Fund for the Improvement and Reform of Schools and Teaching, Mathematics and Science Program, U.S. Department of Education, 555 New Jersey Avenue NW., Room 522, Washington, DC 20208–5524.

A copy of any comments that concern information collection requirements should also be sent of the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Daniel Schecter, (202) 357–6496.

SUPPLEMENTARY INFORMATION: The National Program for Mathematics and Science Education supports projects of national significance in elementary and secondary schools in mathematics and science instruction designed to improve the skills of teachers and instruction in these areas and to increase the access of all students to such instruction.

The Secretary proposes to change the title of the program from the Secretary's Discretionary Program for Mathematics, Science, Computer Learning, and Critical Foreign Languages to the National Program for Mathematics and Science Education to reflect the revised statute.

Because projects in computer learning and critical foreign languages are no longer authorized by the program statute, the Secretary proposes to eliminate all references to these types of projects in the regulations.

The Secretary proposed to add to § 755.12 several priorities established by the Act. These priorities are for projects to train and retrain teachers in methods of scientific inquiry, and to build upon and add to projects that are already developed and disseminated.

The Secretary proposes to amend the definition of magnet school programs for gifted and talented children currently in the regulations at § 755.13(a)(1) to include a school or education center that offers a special curriculum to which students are not automatically assigned but may seek to attend on a voluntary basis because of the special curriculum.

As required by the Act, the Secretary proposes to amend the priority for projects serving historically underrepresented and underserved populations in the fields of mathematics and science at § 744.13(a)(2) of the current regulations and § 755.12(a)(1) of these proposed regulations to include specifically gifted and telented children from these populations.

The Secretary proposes to amend the definition of historically underserved and underrepresented populations to include economically disadvantaged persons in order to be consistent with the language in the statute for the Mathematics and Science Education Program (State grants).

The Secretary proposes to amend the selection criteria concerning the plan of operation and the quality of key personnel to include specific references to the selection of project participants and personnel without regard to race, color, national origin, gender, age, handicapping condition.

In order to emphasize more clearly the impact, outcomes and transferability of project results, the Secretary proposes to modify and synthesize language pertaining to the national significance criterion.

The Department published proposed regulations implementing the amended Part E of the General Education Provision Act on December 2, 1988 at 53 FR 48866, and those regulations, when final, will apply to this program.

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities.

The small entities that would be affected by these proposed regulations are small LEAs and small private non-profit organizations receiving Federal funds under this program. However, the regulations would not have a significant economic impact on the small LEAs and organizations affected because the regulations would not impose excessive regulatory burdens or require unnecessary Federal supervision. The regulations would impose minimal requirements to ensure the proper expenditure of program funds.

Paperwork Reduction Act of 1980

Sections 755.20 and 755.32 contain information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these sections to the Office of Management and Budget for its review. (44 U.S.C. 3504(h))

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503; Attention: James D. Houser.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 522, 555 New Jersey Avenue NW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 755

Historically underserved and underrepresented populations, Gifted and talented studends, Grant programs—Education, Instruction, Mathematics, Reporting and recordkeeping requirements, Science.

Dated: March 8, 1989.

Lauro F. Cavazos,

Secretary of Education.

(Catalog of Federal Domestic Assistance number 84.168, Mathematics and Science)

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by revising Part 755 to read as follows:

PART 755—NATIONAL PROGRAM FOR MATHEMATICS AND SCIENCE EDUCATION

Subpart A—General

Sec.

Subpart B—What Types of Projects Does the Secretary Assist Under This Program?

Subpart C—How Does One Apply for a Grant?

Subpart D—How Does the Secretary Make a Grant?

Authority: 20 U.S.C. 2992, unless otherwise noted.

Subpart A—General

§ 755.1 What is the National Program for Mathematics and Science Education?

The National Program for Mathematics and Science Education assists projects of national significance in elementary and secondary school mathematics and science instruction designed to improve the skills of teachers and instruction in these areas and to increase the access of all students to that instruction.

(Authority: 20 U.S.C. 2992)

§ 755.2 What parties are eligible for a grant under this program?

The Secretary may award grants to State educational agencies, local educational agencies, institutions of higher education, and public and private nonprofit organizations, including museums, libraries, educational television producers, distributors, and stations, and professional science, mathematics, and engineering societies and associations.

(Authority: 20 U.S.C. 2992)

§ 755.3 What regulations apply to this program?

The following regulations apply to grants made under this program:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations), Part 75 (Direct Grant Programs), Part 77 (Definitions That Apply to Department Regulations), Part 79 (Intergovernmental Review of Department of Education Programs and Activities), Part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), and Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)); and

(b) The regulations in this Part 755.

(Authority: 20 U.S.C. 2992)

§ 755.4 What definitions apply to this program?

(a) *Definitions in the Act.* The following terms used in this part are defined in section 2013 of the Act:

Institution of higher education
State agency for higher education

(b) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Applicant
Application
Award
Budget
Department
Elementary school
EDGAR
Facilities
Fiscal year
Grant
Local educational agency
Nonprofit
Private
Project
Public
Secondary school
Secretary
State
State educational agency

(c) *Additional definitions.* The following terms are used in this part:

"Act" means the Dwight D. Eisenhower Mathematics and Science Education Act, Title II, Part A of the Elementary and Secondary Education Act of 1965, as amended.

"Gifted and talented student" means a student, identified by various measures, who demonstrates actual or potential high performance capability, particularly in the fields of mathematics and science.

"Historically underserved and underrepresented populations" includes females, minorities, handicapped persons, persons of limited-English proficiency, economically disadvantaged persons, and migrants.

"Magnet school" means a school or education center that offers a special curriculum and to which students are not automatically assigned but may seek to attend on a voluntary basis because of the special curriculum, including but not limited to a school or education center capable of attracting substantial numbers of students of different racial backgrounds.

"Unsolicited application" means an application, not specifically invited by the Secretary, that supports one or more of the activities listed in § 755.11.

(Authority: 20 U.S.C. 2992, 2993)

Subpart B—What Types of Projects Does the Secretary Assist Under This Program?

§ 755.11 What types of projects does the Secretary assist?

(a) The Secretary funds applications proposing projects of national significance in mathematics and science instruction.

(b) Projects of national significance in mathematics and science instruction include those designed to—

(1) Improve teacher recruitment and retention in the fields of mathematics and science;

(2) Improve teacher qualifications and skills in the fields of mathematics and science; and

(3) Improve curricula in mathematics and science, including the use of new technologies.

(c) The Secretary does not provide operating revenue to meet local needs to any applicant under this program.

(Authority: 20 U.S.C. 2992)

§ 755.12 How does the Secretary establish priorities for this program?

(a) The Secretary may establish the following priorities:

(1) Establishing or improving magnet schools.

(2) Providing special services to historically underserved and underrepresented populations, especially gifted and talented children from these populations.

(3) Building upon and adding to a project that is already developed and disseminated.

(4) Training and retraining teachers in methods of scientific inquiry.

(5) Providing materials that aid the education of students.

(b) In addition to the priorities established in paragraph (a) of this section, each year the Secretary may select as a priority one or more of the types of projects listed in § 755.11.

(c) The Secretary may limit any priority to mathematics or science, particular educational levels, or any combination of these subject areas and educational levels.

(Authority: 20 U.S.C. 2992)

Subpart C—How Does One Apply for a Grant?

§ 755.20 What assurances must an applicant make?

(a) An applicant that is a State (including a State educational agency or a State agency for higher education) or a local educational agency shall comply with the provisions of section 2010 of the Act governing the equitable participation of private school children and teachers in the purposes and benefits of the Act.

(b) An applicant described in paragraph (a) of this section shall include an assurance in its application that, in accordance with section 2010 of the Act, it will provide for consultation with appropriate private school representatives and for the equitable participation of children and teachers in private elementary or secondary schools if the applicant proposes to use grant funds to provide benefits to children and teachers in public elementary or secondary schools, including the provision of services, materials, equipment, and inservice or teacher training and retraining.

Note: EDGAR establishes requirements for participation of private school children. See 34 CFR 75.650.

(Authority: 20 U.S.C. 2992)

Subpart D—How Does the Secretary Make a Grant?

§ 755.30 How does the Secretary evaluate applications?

(a) For each competition, the Secretary evaluates an application submitted under this program on the basis of the applicable selection criteria in § 755.32.

(b) The Secretary awards up to 100 points, including a reserved 10 points to be distributed in accordance with paragraph (d) of this section, based on the applicable criteria in § 755.32.

(c) Subject to paragraph (d) of this section, the maximum possible points for each criterion in § 755.32 is indicated in parentheses.

(d) For each competition, as announced through a notice published in the **Federal Register**, the Secretary distributes the reserved 10 points among the applicable criteria listed in § 755.32.

(Authority: 20 U.S.C. 2992)

§ 755.31 How does the Secretary evaluate unsolicited applications?

(a)(1) At any time during a fiscal year, the Secretary may accept and consider for funding an unsolicited application for a project that does not meet a priority established in accordance with § 755.12 if the project—

(i) Furthers the purposes and objectives of the program as described in § 755.1; and

(ii) Satisfies all other requirements for funding under this program.

(2) In a fiscal year in which the Secretary does not establish absolute priorities, the Secretary does not consider unsolicited applications for funding.

(b) Notwithstanding the provisions of 34 CFR 75.100, the Secretary may fund an unsolicited application without publishing an application notice in the **Federal Register**.

(c) The Secretary may select unsolicited applications for funding in accordance with the procedures contained in § 755.30(a)–(c).

(d) The Secretary reviews and evaluates an unsolicited application on the basis of the selection criteria in § 755.32.

(e) The Secretary assigns the reserved 10 points under § 755.30(b) to the selection criterion at § 755.32(f) (National significance) so that the maximum number of possible points for this criterion is 30.

(Authority: 20 U.S.C. 2992)

§ 755.32 What are the selection criteria?

The Secretary uses the following criteria in evaluating each application:

(a) *Plan of operation.* (15 Points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) The quality of the design of the project;

(2) The extent to which the plan of management is effective and ensures proper and efficient administration of the project;

(3) The quality of the applicant's plans to use its resources and personnel to achieve each objective; and

(4) For an applicant who makes an assurance under § 755.20 as to the equitable participation of children and teachers in private elementary or secondary schools, how the applicant will ensure that equitable participation.

(b) *Quality of key personnel.* (5 Points)

(1) The Secretary reviews each application to determine the quality of key personnel the applicant plans to use on the project, including—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (b)(1) (i) and (ii) of this section will commit to the project; and

(iv) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age or handicapping condition.

(2) To determine personnel qualifications under paragraphs (b)(1) (i) and (ii) of this section, the Secretary considers—

(i) Experience and training in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the quality of the project.

(c) *Budget and cost-effectiveness.* (5 Points) The Secretary reviews each application to determine the extent to which—

(1) The budget is adequate to support the project; and

(2) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation plan.* (10 Points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent

to which the applicant's methods of evaluation—

(1) Are appropriate to the project; and

(2) Are objective; and

(3) Document and quantify the project's effectiveness in achieving its stated goals.

Cross-reference. See 34 CFR 75.590 Evaluation by the grantee.

(e) *Improvement of the quality of teaching and instruction in mathematics and science.* (25 Points) The Secretary reviews each application to determine the extent to which the project will contribute to the improvement of teaching and instruction in mathematics and science, including—

(1) The objectives of the project; and

(2) The manner in which the objectives of the project further the purposes of improving the quality of teaching and instruction in mathematics and science.

(f) *National significance.* (20 Points) The Secretary reviews each application to determine the national significance of the project, including—

(1) The magnitude of the need for the proposed project;

(2) The likely impact of the proposed project; and

(3) The potential transferability of the proposed project to other settings with the likelihood of accomplishing similar results.

(g) *Applicant's commitment and capacity.* (10 Points) The Secretary considers the extent of the applicant's commitment to the project, its capacity to continue the project, and the likelihood that it will build upon the project when Federal assistance ends.

(Authority: 20 U.S.C. 2992)

§ 755.33 What special considerations may the Secretary use in selecting an application for funding?

(a) After evaluating applications according to the criteria contained in § 755.32, the Secretary may determine whether the most highly rated applications are broadly and equitably distributed throughout the Nation for each competition or under this program.

(b) The Secretary may select other applications for funding if doing so would improve—

(1) The geographical distribution of projects funded under a particular competition or under this program; or

(2) The diversity of activities or projects funded under a particular competition or under this program.

(c) The Secretary may decline to fund a project that is eligible for funding by the Secretary under a different, specific Department of Education competition or program.

(d) The Secretary does not fund a project that receives Federal funds from other programs authorized under the Act.

(Authority: 20 U.S.C. 2992)

§ 755.34 Are there restrictions on the use of funds for equipment under this program?

Of the funds made available through a grant under this program, the Secretary may restrict the amount of funds used under this part to purchase equipment.

(Authority: 20 U.S.C. 2992)

[FR Doc. 89-12446 Filed 5-23-89; 8:45 am]

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federal register

Wednesday
May 24, 1989

Part V

Environmental Protection Agency

Preliminary Determination To Cancel Certain Daminozide Product Registrations; Availability of Technical Support Document and Draft Notice of Intent To Cancel; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/40A; FRL-3575-4]

Preliminary Determination To Cancel Certain Daminozide Product Registrations; Availability of Technical Support Document and Draft Notice of Intent To Cancel

AGENCY: Environmental Protection Agency (EPA, Agency).

ACTION: Notice of Preliminary Determination.

SUMMARY: This Notice sets forth EPA's preliminary determination regarding the registrations of pesticide products containing daminozide based on the Agency's assessment of the risks and benefits associated with the use of daminozide as a growth regulator. This Notice announces the Agency's preliminary determination to cancel all registrations of daminozide products that are used on food and to retain the daminozide non-food uses on ornamentals and bedding plants. In addition, this Notice announces the availability of the Daminozide Special Review Technical Support Document, which sets forth the bases for this action, and the Draft Notice of Intent to Cancel.

DATE: Written comments must be received on or before August 22, 1989.

ADDRESS: Submit three copies of written comments, bearing the document control number "OPP-30000/40A"

By mail to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

In person bring comments to: Room 246, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this Notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked CBI may be publicly disclosed by EPA without prior notice to the submitter. The daminozide public docket, which contains all non-CBI written comments and the correspondence index, will be available for public inspection and copying in Rm. 246 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

By mail: Mark T. Boodée, Special Review Branch, Special Review and Reregistration Division (H7508C), Office of Pesticide Programs, 401 M Street SW., Washington, DC 20460.

Office location and telephone number: Room 1006, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 557-7402.

Copies of the Daminozide Technical Support Document and Draft Notice of Intent to Cancel are available from the contact person at the address given above.

SUPPLEMENTARY INFORMATION: This Notice is organized into seven units. Unit I is the Introduction and provides background information related to daminozide and the initiation of the Special Review of all daminozide products. The availability of the Technical Support Document and the draft Notice of Intent to cancel are also discussed. Unit II summarizes the legal background for pesticide regulation and discusses the Special Review process. Unit III provides information regarding dietary and non-dietary exposure to daminozide and UDMH and associated risks, as well as the benefits assessment. Unit IV summarizes the regulatory options considered by the Agency and the regulatory decision proposed. This Notice concludes with Units V, VI, VII and VIII summarizing procedural matters regarding review by the Secretary of the Department of Agriculture and the Scientific Advisory Panel, the References used, the opportunity for public comment, and the availability of the public docket, respectively.

I. Introduction

Daminozide is the active ingredient of Alar®, Kylar®, and B-nine®, formulated products manufactured by Uniroyal Chemical Company, Inc. Daminozide is manufactured by reacting succinic acid with 1,1-(unsymmetrical) dimethylhydrazine (UDMH) to make succinic acid dimethyl hydrazine (SADH) "The Pesticide Manual," 1979). Although daminozide is the parent compound and active ingredient in the products, UDMH is also present as a degradate and metabolite of daminozide. It is a contaminant in both technical and formulated products, and daminozide degradation into UDMH increases as a function of time or increasing temperature. For example, the formulation of UDMH from daminozide residues is known to occur following the boiling and/or cooking of apples. Metabolism data have shown that daminozide hydrolyzes to UDMH in the mammalian body.

Daminozide is a plant growth regulator used in controlling vegetative and reproductive growth of orchard crops such as apples, cherries, nectarines, peaches, and pears and other crops such as peanuts, grapes and tomatoes. On apples, daminozide's major use, it affects flower bud initiation, fruit set and maturity, preharvest fruit drop and the market quality of fruit at harvest and during storage. Daminozide can hasten and concentrate ripening on peaches, sweet and tart cherries, and nectarines. On grapes, it can increase fruit set. Daminozide can also retard stem elongation on tomato transplants. On peanuts, daminozide can produce shorter, more erect peanut vines and can increase yields. The use of daminozide on ornamental plants can produce shorter, more compact growth on chrysanthemums, azaleas, hyrangeas, and bedding plants.

Daminozide was first registered in 1963 by the Uniroyal Chemical Co., Inc., for use on potted chrysanthemums. In 1968, daminozide was first registered for use on crops (apples) and was later registered for use on several other raw agricultural commodities.

A variety of tolerances, which are the maximum permissible residue levels allowed on raw agricultural commodities or as secondary residues such as those found in meat, milk, and eggs, have been established for daminozide in a variety of crops. In instances where pesticides concentrate during processing, food and feed additive regulations have been established. Tolerances for daminozide in or on raw agricultural commodities, processed foods and animal feeds are listed in 40 CFR 180.246, 185.1550 and 186.1550. There are no separate tolerances established for residues of UDMH.

In the early 1980's, the Agency decided to review daminozide through its Registration Standard process and identify outstanding data gaps. This process was completed in 1984 and a Registration Standard was issued in June of that year. Prior to the completion of the Registration Standard, in August 1983, the Agency issued a Data Call-In (DCI) Notice under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requiring registrants to generate certain metabolism and feeding studies data. In the Registration Standard, the Agency expressed its cancer risk concern about daminozide and UDMH and through the

accompanying DCI required additional data not asked for in the August 1983 Data Call-In Notice.

On July 18, 1984, EPA issued a Notice of Special Review of daminozide products (49 FR 29186) and a Position Document 1 (PD 1), which sets forth the scientific rationale for the Agency's action. This action was based on the Agency finding that registrations of pesticide products containing daminozide met the risk criterion relating to oncogenicity in 40 CFR 162.11(a)(3)(ii)(A) (now 40 CFR 154.7(a)(2)(i)). That section provided that a Special Review shall be conducted if the use of a pesticide "induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure * * *." The PD 1 cited four chronic oncogenicity studies that had been conducted during the 1970's, two studies with daminozide and two studies with UDMH, that suggested a potential basis for concern (Toth, 1973; Toth 1977a; Toth, 1977b; NCI, 1978), each of which had certain deficiencies that limited the usefulness of the studies for cancer risk assessment. The Agency decided to proceed with a cancellation action, despite the limitations in the cancer data base because it believed that all four relevant studies, plus a 1984 inhalation study conducted by the U.S. Air Force (Haun, 1984), were sufficient when considered together to warrant such actions. In addition to causing oncogenic effects in laboratory animals, UDMH also appeared to be mutagenic in both the presence and absence of metabolic activity (Rogers and Back, 1981). The Agency has since received additional data which show a negative UDMH mutagenic response in four assays.

Because of the level of concern about dietary exposure, particularly to young children, the Agency developed a combined draft Preliminary and Final Determination (draft PD 2/3/4) and Draft Cancellation Notice, in September 1985. The Draft PD 2/3/4 and Cancellation Notice were submitted to the Scientific Advisory Panel (SAP) and the United States Department of Agriculture (USDA) as required by FIFRA. The SAP was established by Congress to provide scientific review of pesticide actions taken by the Agency. The SAP believed that the data from these studies were insufficient to support a quantitative risk asssessment for either daminozide or UDMH because of various limitations in methodology and documentation. Although EPA is not bound by SAP's opinion, the Panel's view is an integral part of Agency decisions. Based in large part on the SAP's review, EPA concluded that it should not proceed with the cancellation action at that time, but instead should take steps to minimize exposure to daminozide and UDMH and require Uniroyal to begin a wide range of testing that would enable EPA to base its cancer risk assessment on more complete and sound scientific data. In addition to requiring data, several measures were taken which were intended to reduce exposure. These included:

(1) The application rates for use on apples was reduced from 8 lbs/acre to 4 lbs/acre for Spring treatment and 3 lbs/acre for later treatment.

(2) A use advisory cautioning against the use of daminozide on apples meant for processing was to be included with each product labelled for use on apples.

(3) The use on daminozide on grapes was limited to those not used for raisins.

The Agency also lowered the tolerance for residues of daminozide on apples from 30 parts per million (ppm) to 20 ppm (51 FR 12889); the Agency set an expiration date of July 31, 1987, for the reduced apple tolerance since it believed that some of the required residue data would be completed by then and a further evaluation of the tolerance could be undertaken.

The new data required in 1986 under section 3(c)(2)(B) of FIFRA included a 2-year drinking water oncogenicity study of UDMH using mice and rats. (A 2-year feeding study of daminozide using mice and rats had already been started as a result of the DCI issued with the Registration Standard.) Uniroyal was required to perform interim sacrifices at 8 and 12 months in the mouse UDMH study and at 12 months in the rat UDMH study, with the possibility that regulatory action could be taken on the basis of these interim data, rather than waiting until the studies were finished. In addition to oncogenicity studies, the Agency also required extensive other data submissions including mutagenicity data, plant and animal metabolism studies, livestock feeding data, crop field trials, degradation in food data, storage stability information, market basket surveys, and the development of more sensitive analytical methods.

The majority of the required data have been received and reviewed. Based on this information, EPA has made a preliminary determination to propose cancellation of registrations of all products containing daminozide for use on food and to retain non-food uses as currently registered. EPA's position and a summary of the rationale underlying that position are set forth in this Notice. The basis for the Agency's action is explained more fully in the Daminozide Special Review Technical Support Document. Copies of the Technical Support Document are available upon request from the contact person listed under "**FOR FURTHER INFORMATION CONTACT:**" above. The Technical Support Document also contains references, background information, and other information pertinent to the Special Review of products containing daminozide.

In addition, copies of a draft Notice of Intent to Cancel daminozide products are also available from the contact person listed above. Preparation of the draft Notice of Intent to Cancel is required by 40 CFR 154.31(b)(1). The draft Notice is being forwarded to the SAP and the Secretary of Agriculture to permit their review of the Agency's proposed action. The draft Notice of Intent to Cancel, along with the Daminozide Technical Support Document and other notices and analyses prepared pursuant to 40 CFR 154.31, will be sent to the sole registrant of pesticide products containing daminozide.

The draft Notice of Intent to Cancel is not now legally effective, but is intended only to provide a basis for comment by the SAP, U.S. Department of Agriculture, the registrant, and the public. The draft Notice provides that continued distribution or sale of daminozide products registered for food uses will not be allowed after cancellation. Also, EPA will not allow the continued use of such existing stocks of cancelled products. The draft Notice also discusses procedures for requesting a cancellation or denial hearing after issuance of a final notice of intent to cancel. Comments on the draft Notice of Intent to Cancel, this Notice, and the Technical Support Document must be filed within 90 days of the issuance of this Notice.

II. Legal Background

A. The Statute

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under FIFRA as amended (7 U.S.C. 136 et seq.). Before a product can be registered it must be shown that it can be used without "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)), that is, without causing "any reasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide" (FIFRA section 2(bb)).

The burden of proving that a pesticide meets this standard for registration is, at all times, on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets this standard for registration, then the Administrator may cancel this registration under section 6 of FIFRA.

B. The Special Review Process

The Special Review process, formerly called the Rebuttable Presumption Against Registration (RPAR), is a mechanism by which the Agency collects information on the risks and benefits associated with the uses of pesticides to determine whether any use causes unreasonable adverse effects to human health or the environment. The Special Review process is currently governed by 40 CFR Part 154.

Through the Special Review process, the Agency:

(1) Announces and describes the Agency's risk concerns regarding pesticidal use based on certain risk criteria.

(2) Establishes a public docket.

(3) Proposes a regulatory decision.

(4) Solicits comments from the public on the proposed decision and issues concerning the Special Review.

(5) Responds to significant comments from the Secretary of Agriculture and the SAP.

(6) Makes a final regulatory decision based on a balancing of risks and benefits associated with a pesticide's use.

Issuance of this Notice means that the Agency has assessed the potential risks and benefits associated with the food and non-food uses of pesticide products containing daminozide and that the Agency has preliminarily determined that the risks from daminozide outweigh the benefits of its continued use on food commodities. Further, the Agency has preliminarily determined that the benefits of use of daminozide on non-food commodities outweigh the risks of use.

III. Summary of Risk and Benefit Determinations

A. Risk Concerns

Based on information available to date, the Agency has determined that the adverse effect of primary concern from daminozide/UDMH exposure is cancer. An in-depth discussion of the historical data base supporting this conclusion can be found in the Daminozide Technical Support Document. Since issuing the Draft PD 2¾ in 1985, which detailed the then-existing data base regarding the potential for daminozide and UDMH to cause cancer, the Agency has received additional studies and information to support the conclusion that daminozide and UDMH are carcinogenic.

1. Recently received oncogenicity information. EPA evaluated the tumor responses seen in the completed daminozide studies, in which mice (CD–1) fed levels of 0, 300, 3,000, 6,000 and 10,000 ppm for 2 years and rats (Fischer 344) were fed levels of 0, 100, 500, 5,000, and 10,000 ppm for 2 years (Uniroyal, 1988a; and Uniroyal, 1988b, respectively). Review of the daminozide mouse study indicates that there is a statistically significant increase in hemangiosarcomas, and combined hemangiomas/hemangiosarcomas (benign and malignant blood vessel tumors, respectively) with increasing dose in males and females (by the Cochran Armitage test—a statistical recognition of a positive increase in tumors with increasing dose) but not by pairwise comparison (Fisher Exact test—statistical comparison of the control and treated animals). In addition, combined benign and malignant alveolar/bronchiolar tumors showed a dose-related trend in male mice as well as a significant pairwise difference between the 6,000 ppm dose and the controls in males and females. The rate studies did not show a statistically significant increase in tumors of any kind. Although not used for risk calculation, a complete discussion of the daminozide tumor response in the mouse study has been presented in the Daminozide Technical Support Document.

Uniroyal is currently conducting 2-year UDMH drinking water oncogenicity studies in the rat (Fischer 344) and mouse (CD–1). The Agency required that Uniroyal submit interim sacrifice reports from the mouse and rat studies in order to better characterize the formation of tumors and serve as a basis for regulatory action if the data warrant.

In one study (Uniroyal, 1988c), groups of Fischer 344 rats (70 sex/dose) are being administered UDMH in drinking water at 0, 1, 50, and 100 ppm for 2 years. The 1-year interim sacrifice (20 animals per sex/dose) data has been submitted and reviewed by the Agency. Although there was a dose-related increase in the incidence of corneal opacity in all treated female groups, there was no significant difference in the incidence of tumors in any dose group when compared to controls.

The CD–1 mouse is currently being tested for oncogenic effects in two separate studies at several dosage levels. In the first mouse study (Uniroyal, 1988d), UDMH was administered in water using low doses of 0, 1, 5, and 10 ppm UDMH in males and 0, 1, 5, and 20 ppm in females. The test used 90 animals per sex per dose. Fifty animals per sex per dose were dosed for 2 years. Twenty animals each were sacrificed at 8 months and 12 months from the initiation of the study. Although at 8 months some toxicity was observed in the liver, no apparent increase in tumors was seen. The liver toxicity noted was in the form of brown pigment and hypertrophy of the liver in males at the highest dose. The 12-month report did not show a significant increase in tumor formation when comparing treated animals to controls. The terminal sacrifice of this study occurred in January 1989 and the final report of this study is due in September 1989.

On March 19, 1987, EPA required Uniroyal to perform an additional oncogenicity study in mice. This action was taken because the Agency did not believe the maximum tolerated dose (MTD) would be achieved in the CD–1 mouse oncogenicity study with high doses of only 10 to 20 ppm. Uniroyal believed that the results of a 13-week subchronic study (Cranmer, M. and Frith, C., 1987) supported the 20 ppm MTD for mice and that elevating the dose would threaten the lives of the animals and the validity of the study. (Uniroyal's opinion was based on: (1) Microscopic examination of liver, spleen and bone marrow which they believe suggested significant cellular alterations, (2) evaluation of hematological effects from which they suggested significant changes had occurred to critical blood elements resulting in life-threatening anemia, and (3) changes in alkaline phosphatase levels which they considered to be significant and which they correlated with histopathological changes in the liver.) The Agency considered this interpretation of the 13-week data but was not satisfied that the changes noted in the report were biologically meaningful. The Agency was of the opinion that the effects were not life-threatening in nature. EPA believed that higher doses were necessary and required the additional carcinogenicity study at 0, 40, and 80 ppm dose levels.

The second study in the CD–1 mouse is currently underway (Uniroyal, 1988e). Groups of 90 animals/sex/dose are being administered UDMH at 0, 40, and 80 ppm. As with the low dose study, 20 animals/sex/dose were sacrificed at 8 and 12 months. The 8-month interim sacrifice report noted hematological effects (dose-related increases in erythrocyte count, hematocrit and

hemoglobin levels when compared to controls) in high dose males, accentuation of liver lobulation in both dosage groups of males, liver cell hypertrophy, single cell necrosis and bile pigment accumulation in liver of treated males as well as increased bile pigment accumulation in the females. Increases in benign lung tumors (alveolar/bronchiolar adenomas) in both sexes were reported at 80 ppm.

The 12-month interim sacrifice report showed the same toxicity effects as reported in the 8-month sacrifice (liver lobulation, single cell necrosis, etc., in the males). In addition to these effects, there was an increased incidence of vascular tumors of the liver in male and female mice and an increased incidence of alveolar/bronchiolar tumors in the lungs of the male and female mice.

As discussed later in this section, the cancer risk assessment and the basis for Agency regulatory action is the tumor response seen at the 80 ppm UDMH dose level in mice at 1 year. The blood vessel tumors seen in this study are the same type of tumors seen in the earlier UDMH and daminozide studies (Toth, 1977a; Toth, 1977b; Toth, 1973; Haun, 1984). The terminal sacrifice for this study is scheduled for mid-May 1989 and the final report is due to EPA in January 1990. The incidence of vascular liver tumors is noted in the following Table 1.

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Table 1-INTERIM SACRIFICE RESULTS, UDMH (CD-1) MOUSE STUDY
INCIDENCE OF BLOOD VESSEL TUMOR RATES[1,2]

Tumor Type	DOSAGE LEVELS (ppm) AND INCIDENCE OF BLOOD VESSEL TUMORS		
	0	40	80
Males			
Hemangiomas	0/45(0)[3]	1/45(2)	2/53(4)
Hemangiosarcomas	0/45(0)**	0/45(0)	9/53(18)**
COMBINED INCIDENCE	0/45(0)**	1/45(2)	11/53(22)**
Females			
Hemangiomas	0/43(0)	1/47(2)	2/51(4)
Hemangiosarcomas	0/43(0)**	0/47(0)	6/51(12)*
COMBINED INCIDENCE	0/43(0)**	1/47(2)	8/51(16)**

NOTE: Significance of trend denoted at control. Significance of pairwise comparison with control denoted at dose level. For quantitative risk assessment, these tumor proportions may be amended very slightly due to differences in necropsy interpretation. However, these differences do not affect the estimate of upper bound risk.
* denotes $p<0.05$
** denotes $p<0.01$

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[1] Source: September 9, 1988 EPA memorandum from W.B. Greear based on data from Uniroyal, 1988e.

[2] rate= number of tumor bearing animals/number of animals examined.

[3] the number in parentheses indicates the percentage incidence.

The incidence of lung tumors is presented in Table 2.

Table 2-INTERIM SACRIFICE RESULTS, UDMH (CD-1) MOUSE STUDY
INCIDENCE OF ALVEOLAR/BRONCHIOLAR TUMOR RATES[4,5]

Tumor Type	DOSAGE LEVELS (ppm) AND INCIDENCE OF BLOOD VESSEL TUMORS		
	0	40	80
Males			
Adenomas	6/45(13)[6]**	11/45(24)	22/53(41)**
Adenocarcinomas	0/45(0)	0/45(0)	1/53(2)
COMBINED INCIDENCE	6/45(13)**	11/45(24)	23/53(43)**
Females			
Adenomas	4/44(9)**	13/47(30)*	19/51(37)**
Adenocarcinomas	0/44(0)	1/47(2)	0/51(0)
COMBINED INCIDENCE	4/44(9)**	14/47(32)*	19/51(16)**

NOTE: Significance of trend denoted at control. Significance of pairwise comparison with control denoted at dose level. For quantitative risk assessment, these tumor proportions may be amended very slightly due to differences in necropsy interpretation. However, these differences do not affect the estimate of upper bound risk.
* denotes $p<0.05$
** denotes $p<0.01$

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[4] Source: September 9, 1988 EPA memorandum from W.B. Greear based on data from Uniroyal, 1988e.

[5] rate = number of tumor bearing animals/number of animals examined.

[6] the number in parentheses indicates the percentage incidence.

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The Agency estimated an interim cancer potency factor for use in risk calculation based on the data from the "high dose" UDMH mouse study. (Cancer potency is a quantitative measure or estimate of the relationship between exposure to increasing doses of the chemical substance in question and the increased severity (e.g., number of tumors) of the carcinogenic effect.) The Agency used the linearized multi-stage model to extrapolate from effects seen at high doses to predict tumor response at low doses. The actual calculation of the Q^*_1 for UDMH is described in greater detail in the Daminozide Technical Support Document.

The Agency believes that data from the 1-year interim sacrifice of the "high dose" UDMH mouse study are appropriate to use for estimating oncogenic potency for the following reasons: (1) Hemangiosarcomas are uncommon malignant tumors and have a low background rate in the strain of mouse used; (2) hemangiosarcomas are the same type of tumors seen in the earlier UDMH and daminozide studies; and (3) since malignant blood vessel tumors have already been noted at the 40 ppm dose level at the one year interim sacrifice, it is very likely that a dose-response relationship will be observed for the occurrence of hemangiomas/hemangiosarcomas by the termination of the UDMH mouse study after two years. The daminozide mouse study was not used for potency estimation since no statistically significant increase in tumors by pairwise comparison was noted in the study. In addition, because at this stage the lung tumors have not yet been shown to be outside the normally high incidence of lung tumors in CD–1 mice, for purposes of this document these tumors were not included in the interim potency estimation used in the Preliminary Determination.

Based on the incidence of the vascular tumors at 80 ppm UDMH after 1 year of treatment, the Agency calculated an interim cancer potency factor of 0.88 $(milligrams/kilogram/day)^{-1}$ $((mg/kg/day)^{-1})$ using the Crump Global 86 model. In addition, an interim Q^*_1 of 2.9 $(mg/kg/day)^{-1}$ was calculated on the incidence of lung tumors seen in this same study. As noted above, for purposes of this document, the Q^*_1 calculated on the basis of the increased incidence of blood vessel tumors alone was used in the risk estimates.

Considered with the results of the earlier oncogenicity studies on daminozide and UDMH, which showed the same tumor types as the newer Uniroyal studies, the Agency has classified both daminozide and UDMH as Group B_2 chemicals, probably human carcinogens.

2. *Metabolism data.* The Agency has recently received and reviewed the results from a metabolism study in miniature swine (Uniroyal, 1987d). This study utilized Charles River miniature swine which were administered approximately 5 mg/kg (approximately 100 ppm) daminozide orally. Daminozide was found in almost all tissues, at levels up to 73 ppb, with the liver and kidney containing the highest levels. Analysis of urine indicates that both UDMH and dimethyl nitrosamine (NDMA) were excreted in the urine. From the urine analysis data, the Agency estimates that approximately 1 ppm average (or 1 percent) of daminozide was metabloized to UDMH. NDMA levels ranged from 0.01 to 0.69 ppm. However, the Agency believes that most of the UDMH and NDMA were excreted in the feces in the first 24 hours. Because fecal data were not analyzed for the 0–24 hour portion of the study, analysis of urine and feces is considered incomplete. This study is described in greater detail in the Daminozide Technical Support Document.

3. *Mutagenicity information.* The Agency evaluated information concerning the potential of daminozide and UDMH to cause mutagenic effects, or damage to the genetic material of cells. The results of several mutagenicity assays on daminozide tend to indicate that daminozide *per se* is not mutagenic. These studies are discussed in greater detail in the Daminozide Technical Support Document.

Conflicting results for mutagenicity have been reported in several studies for UDMH, however. Uniroyal (Uniroyal, 1988g) has recently submitted reports of several mutagenicity studies which were negative for mutagenic activity. Based solely on these studies, UDMH does not appear to be mutagenic.

However, open literature reports of several studies with positive results for UDMH provide a basis for a mutagenicity concern. These studies are discussed in greater detail in the Technical Support Document.

4. *Exposure.* A chemical's cancer potency is one of two components of cancer risk assessment. The other component is exposure. The Agency calculated dietary exposure to daminozide and UDMH for the general population, nursing infants, non-nursing infants, and children aged 1 to 5 years, and non-dietary exposure for mixers, loaders, and/or applicators exposed dermally to daminozide and UDMH.

a. *Dietary exposure.* Dietary exposure consists of two parts. First, the residue value, or the amount of daminozide and UDMH found or estimated on raw and processed food, was estimated. Second, residue values were considered in relation to food consumption patterns of differing age groups to determine exposure.

1. *Residue Estimates.* Daminozide and UDMH residues were determined from (1) market basket survey data, (2) data from controlled field trials conducted in 1986 and 1987, and (3) estimates of residues in meat, eggs, and meat by-products based on livestock feeding studies. The studies from which these data were obtained were submitted by Uniroyal in response to the 1986 Data Call-In Notice. The studies are described in greater detail in the Daminozide Technical Support Document.

The residue estimates used to calculate human dietary exposure have been tabulated in Tables 3 and 4 for both raw and processed foods. The following Table 3 shows the estimates of UDMH levels in raw and processed foods.

TABLE 3.—ESTIMATES OF UDMH LEVELS IN RAW AND PRODUCED FOODS

Commodity	Percent of crop treated	Average, ppb UDMH*
Apples	NA	2.6
Apple sauce (—baby)	NA	33.3
Appled sauce (—adult)	NA	14.0
Apple juice (—baby)	NA	44.0
Apple juice (—adult)	NA	23.9
Dried raw apples	NA	**20.8
Dried cooked apples	NA	**352.0
Cherries, sweet and sour	30	18.6
Cherry filling (and juice)	NA	108.1
Grapes	NA	0
Grape juice	NA	1.5
Grape preserves	NA	1.5
Nectarines	3	25.0
Peaches	3	21.3
Peaches, canned	NA	*21.3
Peanuts	NA	24.9
Peanut butter	NA	24.9
Peanut oil	NA	24.9
Pears	3	11.9
Pears, canned	NA	11.9
Beef meat	NA	2.0
Beef kidney	NA	2.0
Beef fat	NA	2.0
Beef milk	NA	2.0
Poultry meat	NA	0.5
Poultry eggs	NA	0.5
Tomatoes, whole	10	1.6
Tomato juice	10	**2.4
Tomato puree	10	**5.3
Tomato paste	10	**8.6
Catsup	10	**4.0

*For commodity items beef, beef byproducts, milk, poultry, and eggs, the residue values were extrapolated from feeding studies.

** Residue levels of dried apples include a concentration factor of 8. For processed tomato products, the average residue of 1.6 ppb was multiplied by the following concentration factors to derive the value used in estimating exposure: 1.5 for tomato

juice, 3.3 for tomato puree, 5.4 for tomato paste, and 2.5 for catsup.

The following Table 4 shows the estimates of daminozide levels in raw and processed foods.

TABLE 4.—ESTIMATES OF DAMINOZIDE LEVELS IN RAW AND PROCESSED FOODS

Commodity	Percent of crop treated	Average ppm Daminozide*
Apples	NA	1.00
Apple sauce (-baby)	NA	0.50
Apple sauce (-adult)	NA	0.40
Apple juice (-baby)	NA	0.50
Apple juice (-adult)	NA	0.40
Dried raw apples	NA	**8.00
Dried cooked apples	NA	**4.00
Cherries, sweet and sour	30	23.7
Cherry filling (and juice)	NA	1.5
Grapes	NA	0
Grape juice	NA	0.02
Grape preserves	NA	0.02
Nectarines	3	14.5
Peaches	3	11.3
Peaches, canned	NA	11.3
Peanuts	NA	0.80
Peanut butter	NA	0.80
Peanut oil	NA	0.80
Pears	3	8.8
Pears, canned	NA	8.8
Beef meat	NA	0.01
Beef kidney	NA	0.2
Beef fat	NA	0.01
Beef milk	NA	0.01
Poultry meat	NA	0.001
Poultry eggs	NA	0.002
Tomatoes, whole	10	0.20
Tomato juice	10	**0.30
Tomato puree	10	**0.66
Tomato paste	10	**1.10
Catsup	10	**0.50

*For commodity items beef, beef byproducts, milk, poultry, and eggs, the residue values were extrapolated from feeding studies.

**Residue levels of dried apples include a concentration factor of 8. For processed tomato products, the average residue of 0.20 ppm was multiplied by the following concentration factors to derive the value used in estimating exposure: 1.5 for tomato juice, 3.3 for tomato puree, 5.4 for tomato paste, and 2.5 for catsup.

ii. *Consumption.* The Agency used the residue values in treated commodities, discussed in the previous section, and food consumption estimates to calculate dietary exposure. The model for calculating dietary exposure is called the Tolerance Assessment System (TAS). Using TAS, the Agency determined exposure profiles for several different age groups, including the U.S. population as a whole, nursing infants, non-nursing infants, and children aged 1 to 6 years old.

The food consumption data files used to calculate dietary exposure were derived from a nationwide survey of individual food consumption patterns of 30,770 people, conducted by the U.S. Department of Agriculture (USDA) in 1977–1978 (White, et al., 1983). This survey, TAS, and the assumptions considered when assessing dietary exposure are described in greater detail in the Daminozide Technical Support Document.

Average daily consumption values from the USDA survey were multiplied by residue information for each commodity. Residue information from crop field trials was adjusted by percent of crop treated estimates. Residue data from the market basket survey were not adjusted for percent of crop treated. Multiplication of average daily consumption values and residue information results in the daily anticipated residue contribution (ARC) for each food-form and for the pesticide as a whole. The ARC represents the Agency's dietary exposure estimate.

The following Table 5 shows the average daily consumption, UDMH residue, and exposure values for each commodity containing residues of UDMH. The exposure estimate is for the general population and includes various sub-group exposures.

TABLE 5.—ESTIMATES OF UDMH DIETARY EXPOSURE FOR THE U.S. POPULATION *

Commodity	Average daily consumption (g food/kg bwt/day)	Residue levels (in ppb)	Exposure (μg/kg/day)
Apples, fresh	0.3074	2.6	0.000799
Apples, cooked: Fresh and juice	.2004	44.0	.008818
Dried raw apples	.0001	20.8	**.000002
Dried cooked apples	.0001	352.0	**.000035
Apple juice, raw	.1709	33.3	.005691
Cherries, raw fresh and raw juice	.0105	5.6	.000059
Cherries, cooked: Fresh and juice	.0251	108.1	.002713
Eggs	.5803	0.5	.000290
Grapes	.0438	0	.000000
Grape juice	.0901	1.5	.000135
Wine and sherry	.0842	1.5	.000126
Nectarines	.0130	0.8	.000010
Peaches	.2154	0.6	.000129
Peanuts, raw, cooked, and oil	.0748	24.9	.001863
Pears	.1225	0.4	.000049
Meat	2.2318	2.0	.004464
Milk	1.3705	2.0	.021068
Tomatoes, whole	.4920	1.6	.000787
Tomato juice	.0551	2.4	**.000132
Tomato puree	.1702	5.3	**.000902
Tomato paste	.0395	8.6	**.000340
Catsup	.0420	4.0	**.000168
Total			.000047 or 4.7×10^{5} mg/kg/day

* For commodity items meat, milk, and eggs, the residue values were extrapolated from feeding studies data. All beef, beef byproducts and poultry were combined under "meat" in this table.

** Residue levels for dried apples includes a concentration factor of 8. For processed tomato products, average residue of 1.6 was multiplied by the following concentration factors: 1.5 for tomato juice, 3.3 for tomato puree, 5.4 for tomato paste, and 2.5 for catsup.

The following Table 6 shows the average daily consumption for each commodity containing residues of daminozide.

TABLE 6.—ESTIMATES OF DAMINOZIDE DIETARY EXPOSURE FOR THE U.S. POPULATION *

Commodity	Average daily consumption (g food/kg bwt/day)	Residue levels (in ppm)	Exposure (mg/kg/day)
Apples, fresh	0.3074	1.00	0.000307
Apples, cooked: Fresh and juice	.2004	0.50	.001000
Dried raw apples	.0001	8.00	**.000001
Dried cooked apples	.0001	4.00	**.0000004
Apple juice, raw	.1709	0.50	.000085
Cherries, raw fresh and raw juice	.0105	7.11	.000075
Cherries, cooked: Fresh and juice	.0251	1.50	.000038
Eggs	.5803	0.002	.000001
Grapes	.0438	0.02	.000001
Grape juice	.0901	0.02	.000002
Wine and sherry	.0842	0.02	.000002
Nectarines	.0130	0.45	.000006
Peaches	.2154	0.34	.000073
Peanuts, raw, cooked, and oil	.0748	0.80	.000060
Pears	.1225	0.26	.000032
Meat	2.2318	0.20	.000446
Milk	1.3705	0.01	.000014
Tomatoes, whole	.4920	0.20	.000098
Tomato juice	.0551	0.30	**.000017
Tomato puree	.1702	0.66	**.000112
Tomato paste	.0395	1.10	**.000043
Catsup	.0420	0.50	**.000021
Total			.000951 or 9.5×10^{-4} ***mg/kg/day

* For commodity items meat, milk, and eggs, the residue values were extrapolated from feeding studies data.
** Residue levels for dried apples includes a concentration factor of 8. For processed tomato products, average residue of 0.2 ppm was multiplied by the following concentration factors: 1.5 for tomato juice, 3.3 for tomato puree, 5.4 for tomato paste, and 2.5 for catsup.
*** 1 percent of total daminozide exposure (0.95×10^{-5}) used in risk estimates for UDMH contribution from metabolic conversion of daminozide to UDMH.

Table 7 shows the average daily dietary exposure to UDMH for the overall U.S. population and selected age groups.

TABLE 7.—TAS ESTIMATES OF AVERAGE DAILY EXPOSURE TO UDMH FOR SELECTED AGE SUBSETS

Subset (age)	Exposure (mg/kg/day)
Overall U.S. population	0.000047
Nursing infants (<1 year old)	0.000229
Non-nursing infants (<1 year old)	0.000410
Children (1–6 years old)	0.000138
Children (7–12 years old)	0.000071
Males (13–19 years old)	0.000042
Females (13–19 years, not pregnant or nursing)	0.000034
Females (13+ years, pregnant)	0.000027
Females (13+ years, nursing)	0.000037
Females (20+ years, not pregnant or nursing)	0.000023
Males (20+ years old)	0.000025

The UDMH exposure values are slightly lower than the values presented in the apple tolerance extension document published on February 10, 1989 (54 FR 6392). The lower exposure results from an adjustment in the TAS.

Table 8 shows the average daily dietary exposure to daminozide for the overall U.S. population and selected age groups.

TABLE 8.—TAS ESTIMATES OF AVERAGE DAILY EXPOSURE TO DAMINOZIDE SELECTED AGE SUBSETS

Subset (age)	Exposure (mg/kg/day)
Overall U.S. population	0.000951
Nursing infants (<1 year old)	0.003396
Non-nursing infants (<1 year old)	0.005427
Children (1–6 years old)	0.002786
Children (7–12 years old)	0.001514
Males (13–19 years old)	0.000730
Females (13–19 years, not pregnant or nursing)	0.000662
Females (13+ years, pregnant)	0.000692
Females (13+ years, nursing)	0.000824
Females (20+ years, not pregnant or nursing)	0.000575
Males (20+ years old)	0.000523

b. *Non-dietary Exposure.* The exposure component of non-dietary risk was calculated for daminozide and UDMH for the use of daminozide in greenhouses. This estimation was used to calculate carcinogenic risk for workers believes the Agency that greenhouse workers are likely to receive the highest exposures of any workers.

The Agency received a daminozide greenhouse worker exposure study in response to the 1986 DCI Notice. However, this study was found to be deficient for several reasons which are further explained in the Daminozide Technical Support Document. To calculate non-dietary exposure for workers who mix, load and/or apply daminozide, EPA used a recently reviewed study on exposure of greenhouse workers to acephate (Sumagic PGR) to assess non-dietary exposure. The Agency believes it appropriate to use acceptable surrogate data instead of relying on the uncertain results of a more limited study when more suitable exposure data are not available for an exposure assessment.

The surrogate study (Merricks, 1987) was based on the dermal exposure to nine workers as they filled the spray tank with pesticide, diluted the spray, and then sprayed the plants by hand in a 20' by 100' greenhouse to run-off. Dermal exposure was monitored using cellulose patch dosimeters placed on the shoulders, chest, back, head, forearms, upper arms, thighs, and shins. Further description of this study has been provided in the Technical Support Document. From this study, dermal exposure per pound active ingredient for mixer/loaders was calculated to be 87

mg/lb a.i. and 74 mg/lb a.i. for applicators. The geometric mean (unit exposure) of these data sets was calculated to be 58 mg/lb a.i. and 59 mg/lb a.i., respectively.

Daminozide exposure and risk to mixers, loaders and applicators was calculated for typical application scenarios. The Agency used several assumptions in its exposure calculations which are described in the Technical Support Document. The following calculation was used to estimate mixer/loader and applicator exposure for UDMH:

Average Daily UDMH Exposure (mg/kg/day) = Application Rate × 1A treated/application × 2 applications/year × Unit Exposure × 1.00 UDMH absorbed × 0.00005 UDMH in daminozide × 1/70 kg × 365 days/year

where the Application Rate is 5.1 lb a.i./A for chrysanthemums and 0.61 lb a.i./A for tomato transplants, and the Unit Exposure is 58 mg/lb a.i. for mixer/loaders and 59 mg/lb a.i. for applicators. Dermal exposure estimates for mixer/loaders and applicators calculated using this equation is summarized in the following Table 9:

TABLE 9.—AVERAGE DAILY DERMAL EXPOSURE TO UDMH

Worker	Greenhouse tomatoes (mg/kg/day)	Greenhouse chrysanthemums (mg/kg/day)
Mixer/loader	1×10^{-3}	1×10^{-5}
Applicator	1×10^{-3}	1×10^{-6}
Mixer/loader applicator	2×10^{-3}	2×10^{-5}

5. *Risk calculation.* Although the previous section presented exposure values to both the parent compound, daminozide, and the metabolite, UDMH, cancer risk was calculated using the UDMH interim cancer potency factor. As noted previously, the Agency has not received the final results of the Uniroyal UDMH carcinogenicity studies in mice and rats. Although the same types of tumors were observed in the daminozide mouse study (hemangiomas/hemangiosarcomas), only biological trends were observed. Therefore, no cancer potency factor was calculated from the daminozide study. The Agency has identified UDMH as the primary chemical of oncogenic concern at this time.

a. *Dietary risks.* The 95 percent upper bound lifetime increased cancer risk for the general population was obtained by taking the interim UDMH Q^*_1 (cancer potency factor) from the Dose-Response Assessment (0.88 per mg/kg/day^{-1}) and multiplying it by the exposure estimate found in Table 5. Lifetime risk for non-nursing infants, the highest exposure group, was obtained by taking the exposure value in Table 7 and multiplying it by the cancer potency factor. This value was then divided by 70 average lifetime years.

When calculating risk from exposure to UDMH, EPA separately calculated metabolic conversion from daminozide to UDMH. Based on the incomplete results of the miniature swine metabolism study described earlier in this Notice and in the Technical Support Document, the Agency estimated that approximately 1 percent of ingested daminozide is converted into UDMH in the gut. Any conversion from daminozide to UDMH in apple, peanut and cherry products due to processing is assumed to be included in the residue estimates from the market basket survey. The additional UDMH exposure/risk from metabolism is noted at the end of the following Table 10.

TABLE 10.—ESTIMATES OF UDMH DIETARY RISK FOR THE U.S. POPULATION

(interim Q^*_1 + 0.88 mg/kg/day)

Commodity	Dietary exposure (μg/kg/day)	Dietary risk*
Milk	0.021068	1.8×10^{-5}
Apples	0.015331	1.4×10^{-5}
Red meat	0.004464	3.9×10^{-6}
Cherries	0.002772	2.4×10^{-6}
Peanuts	0.001863	1.6×10^{-6}
Eggs	0.000290	2.5×10^{-7}
Grapes	0.000261	2.3×10^{-7}
Poultry	0.000252	2.2×10^{-7}
Tomatoes	0.000234–0.00234	2.1×10^{-7}–2.1×10^{-6}
Peaches	0.000129	1.1×10^{-7}
Pears	0.000049	4.3×10^{-8}
Nectarines	0.000010	8.8×10^{-9}
Totals	0.046715	4.1×10^{-5}
	+ [0.009500 metabolic UDMH from daminozide]	$0.84\times2.^{-5}$
		4.9×10^{-5}

Oncogenic risk for the general population from exposure to UDMH is based on lifetime (70 years) dietary exposure. Risk estimates posed by exposure to UDMH residues for individuals in different age subgroups are also lifetime risks in that a tumor response can occur anytime the person's lifetime, but the level of exposure (and calculated risk) changes as a person grows older and enters different age subgroups. Exposure estimates for infants and children are higher than those of adults because consumption patterns very and because infants consume more food (particularly certain fruit) per unit body weight than adults. Infants and children have greater relative UDMH exposure than do adults and, therefore, may incur a substantial portion of lifetime risk during these exposure periods. Estimates of potential lifetime carcinogenic risk posed by 1 year exposure to UDMH residues for the general population and selected age subgroups is shown in the following Table 11.

TABLE 11.—ESTIMATES OF RISKS TO SELECTED AGE SUBJECTS FROM ONE YEAR EXPOSURE TO UDMH

Subset (age and other)	Dietary exposure (mg/kg/day)	1-year exposure lifetime risk
Nursing infants (<1 year old)	0.000229	2.9×10^{-6}
Non-nursing infants (<1 year old)	0.000410	5.2×10^{-6}
Children (1–6 years old)	0.000138	1.7×10^{-6}
Average 1-year risk for all age groups	0.000047	4.9×10^{-7}

The dietary exposure values used for risk calculation, except for tomatoes, are found in Table 5. The exposure estimates for tomatoes used to calculate risk are 10 times the value reported in Table 5. The Agency made this exposure adjustment to reflect exposure situations where the consumer grows and cans his own tomatoes, puree and/or juice. The exposure value in Table 5 reflects a 10 percent-of-crop treated assumption. That value was derived from usage estimates which show that 50 percent of the tomato transplants intended for the home grower market are treated and no tomato transplants used for commercially grown tomatoes are treated. The home garden market accounts for approximately 20 percent of the tomatoes consumed nationally (50 percent×20 percent=ten percent of crop treated). This approach to calculating risk spreads total dietary risk over the entire population and does not account for those situations where people grow their own markets and can tomato products. For this reason, a range of risks from consuming tomatoes was calculated based on 10 percent-of-crop-treated and 100 percent of crop treated. Table 10 lists the dietary risk estimates from individual food commodities.

b. *Non-dietary risks.* The non-dietary exposure estimates discussed above in Unit III.A.4.b. are used as a basis for estimating non-dietary carcinogenic risk. The Agency assumed that the cancer potency factor for the dermal route of exposure is equivalent to that for the dietary route (0.88 (mg/kg/day)$^{-1}$ and that the length of lifetime exposure is 35 years worked/70 years lived. To calculate non-dietary carcinogenic risk from exposure to UDHM, the Agency used the following equation:

UDMH risk=UDMH exposure×35/70×W*Q_1

where the Q_1 is (0.88 (mg/kg/day)$^{-1}$). Based on this calculation, the carcinogenic risks from worker exposure to UDMH is tabulated in the following Table 12:

TABLE 12.—QUANTITATIVE ASSESSMENT OF RISKS FROM EXPOSURE TO UDMH TO WORKERS APPLYING DAMINOZIDE

(Interim Q^*_1=0.88 (mg/kg/day)$^{-1}$)

Worker	Greenhouse tomatoes, risk	Greenhouse chrysanthemums, risk
Mixer/loader	6×10^{-8}	5×10^{-7}
Applicator	6×10^{-8}	5×10^{-7}
Mixer/loader-applicator	1×10^{-7}	1×10^{-6}

Uncertainties in both the dietary and non-dietary risk assessments that could underestimate or overestimate risk are described in the Daminozide Technical Support Document.

B. Benefits

The Agency's benefit analysis examined in-depth the following use sites: (1) the food commodities apples, peanuts, cherries, grapes, peaches/nectarines, pears and tomatoes, and (2) ornamentals and bedding plants. In the Daminozide Technical Support Document, the Agency reviewed the biological effects associated with the use of daminozide on these crops, methods of application, agricultural practices, and chemical and nonchemical alternatives and estimated the impacts of cancellation of daminozide's registration upon growers, consumers and society as a whole. The Technical Support Document provides an in-depth discussion of the benefits associated with each use of daminozide which are summarized in Tables 13–15.

TABLE 13.—SUMMARY OF DAMINOZIDE BENEFITS

Use (site/site category)	Extent of usage		Key effects	Economic Impacts—Grower Annual Income Impacts (millions)			Significance
	A.I./year (1000 lbs.) (% of total)	Percent of 1988 site treated		Users	Non-users	Total	
Apples:							
Red Delicious		14	Improve storage, fruit color	−$4.28	+$7.73	+$3.45	(1)
Golden Delicious		13	Improve storage	−.55	+1.93	+1.38	(1)
McIntosh		18	Stop drop, improve fruit color	−5.68	+.98	−4.70	(1)
Stayman		17	Prevent	−1.82	+.29	−1.53	(1)
All Apples		10		−14.56	+16.11	+1.55	(1)

[1] Insignificant users impacts offset by non-users windfall gains. McIntosh/Stayman growers most adversely impacted (30% reduction in total revenue/treated acre); some growers may go out of business or must replant with other varieties.

TABLE 13.—SUMMARY OF DAMINOZIDE BENEFITS—Continued

Use (site/site category)	Extent of Use		Key effects	Economic Impacts	Significance
	A.I./year (1000 lbs.) (% of total)	Percent of 1988 site treated			
Apples				Market:	
				Fresh—Reduced quantity of 160.6 million lb. (−3.4%); price increases from $.156 to $.161/lb.	Moderate; impacts to diminish over time.
				Processed—Increased quantity of 47.7 million lb. (+1.3%); price decreases from $.051 to $.050/lb.	
				Consumer:	
				Fresh—Price increases from $.6274 to $.6401/lb. (+4.9%). Total expenditures decrease $109.5 million (−3.7%) for 160.6 million fewer pounds.	Moderate.
				Processed—Price decreases from $.3254 to $.318/lb. (−2.3%). Total expenditures increase $8.4 million (+.7%) for 47.7 million more pounds.	Insignificant.
				Total—Total apple expenditures decrease $101.1 million/year (−2.4%) for 270.9 million fewer pounds.	
				Microeconomic: Increased importations of fresh apples in the summer from Southern Hemisphere countries may augment seasonal supply shortfall.	Minor.
				Welfare/Efficiency: Net social cost estimates current usage (10%) of apples treated $18 to 81 million 1985 usage (24%) of apples treated: $44 to 198 million.	Minor.
Grapes	1985: 45.1 to 51.3	1985: 42–47%	Increase set and yield	Users:	
	1988: Negligible	1988: Negligible		1985: $2.4 million annual income loss	Minor
				1988: Negligible	Negligible.
				Consumers:	
				1985: 1 to 5% price increase for 2 to 5% reduction in quantity.	Minor
				1988: Negligible	Negligible.
Cherries	1985:	1985:	Enhanced color; uniform ripening increased yield; less bruising; easier pit removal.	Users:	
	Tart: 48—112.8	Tart: 57–72%		1985:	
	Sweet: 0.2—1.2	Sweet: <2%		Tart: $2.2 million net income loss/year	Minor.
	1988:	1988:		Sweet: Negligible	
	Tart: Negligible	Tart: Negligible		1988: Sweet and tart: Negligible	Negligible.
	Sweet: Negligible	Sweet: Negligible			
				Consumers: Sweet and Tart: Negligible for 1985 and 1988.	Negligible.
Ornamentals	1985 and 1988: 30 to 40.	1985 and 1988: 90% for mums to 50% of bedding plants.	Produces compact plants with greener foliage.	Users: 1985: Costs increase $0.7 to $4.7 for 1985 and 1988.	Minor.
				Consumers: 1985: Lower quality plants, higher prices for 1985 and 1988.	Minor.
Tomato Trans	1985 and 1988: 1.4	1985 and 1988: 50% of sales for home gardeners.	Shorter plants, more easily shipped.	Users: Losses of crop quality with lower grade prices and income for 1985 and 1988.	Minor.
				Consumers: Lower quality plants, higher prices for 1985 and 1988.	Minor.
Peaches & Nectarines.	1985 and 1988: 6.5 to 18.	1985 and 1988: <5%	Increased color and hastened maturity.	Users: $1.5–$5.5 million loss of income for 1985 and 1988.	Minor.
				Consumers: Negligible for 1985 and 1988	Negligible.
Pears	1985 and 1988: Negligible.	1985: and 1988: 1–3%.	Reduces premature ripening of Bartlett pears.	Users:	
				1985: <$500,000 income loss	Minor.
				1988 Negligible	
				Consumers: Negligible for 1985 and 1988	Negligible.
Peanuts	1985: 175—225; 1988: 42.5.	1985: 11–12%; 1988: 3%.	Shorter, more erect vines; assists harvesting.	Users:	
				1985: About $2.0 million; <1% of total grower income.	Minor.
				1988: $260,000 income loss	Negligible.
				Consumers: Negligible for 1985 and 1988	Negligible.

[a] Usage for several minor use sites (ornamentals, tomato transplants and peaches/nectarines) appeared stable between 1985 and 1988. For apples, the economic impact estimates were based on a currently representative usage level for daminozide.

[b] Usage for mid-season/summer treatments only; usage by variety for early bearing and pruning reduction is unknown.

TABLE 14.—ANNUAL DAMINOZIDE USAGE BY SITE: 1985 AND CURRENT MARKET

Site	1,000 lbs. A.I./Year		Percent of site treated	
	1985	Current market	1985	Current market
Apples	327.4–423.6	136–177	24	10.
Grapes	45.1–51.3	(1)	42–47	(1).
Cherries				
Tart	48.0–112.8	(1)	57–72	(1).
Sweet	.2–1.2	(1)	<2	(1).
Ornamentals	30–40	30–40	50 bedding plants, 90 mums	50 bedding plants, 90 mums.
Tomato Transplants	1.4	1.4	50 home/garden	50 home/garden.
Peaches/Nectarines	6.5–18	6.5–18	<5	<5.
Pears	(1)	None	1–3	None.
Peanuts	175–225	42.5	11–12	<3.
Total	633.6–873.3	216.4–278.9		

[1]Negligible.

TABLE 15.—USE LEVELS AND EFFECTS OF DAMINOZIDE CANCELLATION—BY APPLE VARIETY

	Percent fresh crop treated		Increased dropped/ cracked as percent of treated fresh [3]	Reduction in storage life[3] (months)
	Current usage [1]	1985 usage[2]		
Red Delicious	16	39	5	3.3
Gold Delicious	18	43	1	3.3
McIntosh	23	55	35	2.
Jonathan	8	19	3	1.
Stayman	24	56	35	2.

[1] Current assumed total usage distributed among varieties in same proportions as 1985 usage.
[2] From expert opinion gathered from 1984/85 telephone survey (EPA, 1985).
[3] From expert opinion gathered from 1984/85 telephone survey (EPA, 1985); supported by scientific literature and SAP hearing testimony.

The Agency has reviewed the available information and has concluded that, with the exception of use on ornamentals and bedding plants, the impacts of cancellation would be insignificant to minor on both growers and consumers. In assessing benefits, the Agency considered usage information from 1985, which might reflect the higher end of the use-spectrum, and from 1988 when use was significantly lower.

One benefits consideration, not readily quantifiable but recognized, is the nature of the benefit resulting from daminozide use. Unlike pesticides used to protect the existence of the crop, many of the biological benefits of daminozide use are related to the appearance of the crops.

There are no alternatives to daminozide that alone will accomplish all of the growth regulator benefits attributed to daminozide. For the principal apple varieties that have historically had the highest percent of crop treated with daminozide, there are no alternatives for the key biological effects of use (i.e., Red Delicious—reduce watercore, improve storage and fruit color; Golden Delicious—improve storage; McIntosh—delay premature ripening, prevent fruit drop, improve fruit color and increase storage life; Stayman—prevent splitting).

The impact of cancellation of registrations for use on apples at 1988 usage levels is estimated to be insignificant to the apple industry in the aggregate; the overall effect on all growers is estimated to be an increase of $1.5 million annually in income. Growers of certain varieties, particularly Eastern McIntosh and Stayman, may be most adversely affected. Growers of these two varieties which use daminozide are estimated to have annual income losses of $5.68 and $1.82 million, respectively, and may have a greater than 30 percent reduction in total revenues per treated acre; some growers may not be able to stay in business or may need to replant to other apple varieties or crops over time. Non-users of daminozide may experience a significant gain in income from higher market apple prices.

A cancellation of daminozide is expected to reduce the supply of fresh apples by 160 million lbs (annual U.S. production is 8 billion lbs) and apples available for processing may increase by 47.7 million lbs. These changes are estimated to result in a corresponding 3 percent price increase and a 2 percent price decrease for fresh and processed apple products, respectively.

The net social cost (total society cost) based on 10 percent of the crop treated is estimated to range from $18 to $81 million as compared to $44 to $198 million for 1985 usage levels. (The 10 percent estimate is higher than the earlier 1989 estimate, discussed in conjunction with the apple tolerance extension **Federal Register** Notice (54 FR 6392; February 10, 1989), which were 4 to 8 percent. The increase in the usage estimates is from additional and more in-depth use information gathered in February and March 1989.) The Agency expects the net social cost will be closer to the lower end of the presented ranges because of the large transfer payments expected between the farm and retail markets.

For the remaining food crops (grapes, sweet and tart cherries, pears, peaches, nectarines, and peanuts), grower level economic impacts of a cancellation based on 1988 usage estimates are estimated to be negligible except for peach/nectarine growers who could suffer a minor $1.5 to $5.5 million loss of income. Based on 1985 usage estimates, annual grower level impacts may be minor for all crops except sweet cherries, which are estimated to be negligible. Annual income losses for these crops were estimated as: grapes—$2.4 million; peaches/nectarines—$1.5 to $5.5 million; pears—<$500,000; and peanuts—$2.0 million.

Economic impacts of a daminozide cancellation upon consumers for non-apple food crops at 1988 usage levels is estimated to be negligible. Based on

1985 usage levels, consumer impacts are estimated to be negligible for sweet and tart cherries, peaches/nectarines, pears, and peanuts. However, grape consumers may experience a 1 to 5 percent price increase and a 2 to 4 percent reduction in the marketed qualtity, which is minor.

Tomato growers may suffer income losses from reduced crop quality. Consumers may experience higher prices and lower quality plants based on 1985 and 1988 usage data.

If the use of daminozide on ornamentals and bedding plants were cancelled, both users and consumers could be significantly affected. Based on 1985 and 1988 usage data (90 percent of chrysanthemums and 50 percent of bedding plants are treated), users might suffer cost increases from $700,000 to $4.7 million. Accordingly, consumers could expect to pay higher prices for lower quality plants.

IV. Regulatory Options

The Agency has concluded that, when daminozide is used as currently registered, the combined dietary risk from all daminozide treated food crops outweighs the benefits based on either 1988 or 1985 usage levels. Therefore, the purpose of evaluating regulatory options is to determine if there are modifications in the terms and conditions of use that would result in benefits outweighing risks for some or all uses. The specific regulatory options considered and the resultant reduction in exposure and risk are discussed in this unit.

A. Apples

1. Reducing Application Rate and Increasing Pre-Harvest Intervals.

Reducing application rates can, in general, be a practical action for reducing exposure. The use rate on apples was reduced in 1986 as an interim exposure reduction measure and further reductions would adversely affect the efficacy of daminozide. Since daminozide is a systemic growth regulator and is incorporated into the flesh of the fruit, EPA believes that increasing the pre-harvest interval would not generate a significant reduction in the level of daminozide and UDMH residues present in the fruit.

2. Reducing UDMH Exposure From Applies, Apple Sauce and Juice, and Apple Pomace Used in Animal Feed.

With apples accounting for the majority of daminozide's use, any meaningful dietary exposure reduction would have to come from lower UDMH residues in raw apples, apple products, and apple pomace used as cattle feed. Thirty-three percent of UDMH exposure comes from residues found in fresh apples (2 percent) and apple products (31 percent). The Agency estimates that cancer risks based on dietary exposure to apple products alone would be sufficient to warrant consideration of regulatory action. Theoretical residues in milk (42 percent) and meat (9 percent) account for 51 percent of UDMH's estimated dietary exposure used in calculating risk. Although no actual market basket residues have been found in milk, meat, poultry or eggs, residues are possible because data from feeding studies show that daminozide and UDMH residues do transfer from apple pomace as well as from other daminozide treated foods that are fed to cattle such as grape pomace, and peanut byproducts.

Two possible modifications to apple use were evaluated. Prohibiting use on apples used in processing would theoretically eliminate UDMH residues in apple sauce and juice and residues in animal and cattle feed from apple pomace by almost 90 percent (assuming other animal feeds, such as peanut by-products, were also eliminated). This restriction would lower dietary risk to almost 10^{-6}, but the Agency still believes that the risks outweigh benefits. Limiting use to certain varieties could also further reduce exposure. In particular, the Agency looked at limiting use to McIntosh and Stayman apples intended for the fresh market. Both varieties are widely marketed as fresh apples and the Agency estimates that growers of these varieties would suffer the biggest economic losses from the cancellation of daminozide. The McIntosh and Stayman varieties account for approximately 15 percent of total apple treatments. A rough estimate of the UDMH dietary contribution from fresh McIntosh and Stayman apples is 0.3 percent of the total apple/apple product contribution (2 percent UDMH from all fresh apples $\times$15 percent of fresh apples that are McIntosh and Stayman). The total risk contribution from McIntosh and Stayman fresh apples is approximately 4×10^{-8} (1.35×10^{-5} risk from all fresh apples and apple products $\times$0.3 percent, the percentage of exposure from these two varieties).

While such a reduction in risk would appear to warrant reconsideration of the risk/benefit assessment, as a practical matter, the Agency does not believe it can reasonably ensure that use will be confined to these varieties, or to apples that are not processed. Many users grow more than one variety and virtually all growers hope to be able to sell as much of their harvest as possible in the fresh market where prices are significantly higher. Rejected apples, often treated, are then sold for processing. Daminozide products have a caution included on the label since 1986 warning growers not to treat apples intended for processing. However, the high number of positive samples for apple sauce and juice as seen in recent surveys, such as those conducted by Consumers Union ("Consumer Reports", May 1988) show that treated apples are being used in processed apple products. [Consumers Union reported in the May, 1989, issue that 23 out of 31 (71 percent) adult apple juice samples contained daminozide residues above the 0.02 ppm detection limit of the analytical method and an overall average residue of 0.11 ppm.] As a note, however, the high number of positve samples in the Consumers Union report may be in part a result of the sampling area, New York City, where McIntosh and Stayman apples are more likely to be incorporated into processed apple products. Carryover in trees sprayed in previous years may also account for some of the positive samples.

Thus, although there are very restrictive use limitations that could theoretically result in significantly reduced risks, the Agency does not believe that for daminozide use on apples, a practical, enforceable way of ensuring adherence to these limited use restrictions can be achieved.

B. Peanuts and Cherries

Because apples account for such a large percentage of daminozide's use, cancellation of daminozide use on peanuts and/or cherries alone, the two food commodities with the highest exposure contribution after apples (not including theoretical residues in meat and milk), would have little effect on total dietary risk. Risk would be reduced from 4.1×10^{-5} to 3.7×10^{-5}. Benefits are estimated to be minor for peanuts ($2.0 million in net income loss to growers; <1 percent of total peanut farm income) and minor to negligible for cherries (sweet cherries, negligible; tart cherries, $2.2 million in net income loss) based on 1985 data. Based on 1988 usage, grower and consumer losses are estimated to be negligible. Even if apples were cancelled, the remaining risk from peanuts (1.6×10^{-6}) and cherries (2.4×10^{-6}) both exceed the estimated benefits and cancellation is being proposed.

C. Grapes, Pear, Peaches/Nectarines, and Tomatoes

Cancellation of daminozide on any or all of these crops would not appreciably affect total dietary risk or aggregate

benefits related to daminozide use. Individual dietary risk from exposure for these crops is presented below:

Commodity	Dietary risk
Tomatoes	9.3×10^{-7}-9.3×10^{-6}
Grapes	2.3×10^{-7}
Peaches	1.1×10^{-7}
Pears	4.3×10^{-8}
Nectarines	8.8×10^{-9}

Total dietary risk from exposure to these crops is approximately 1×10^{-6} (using the low end of the tomato risk range). These risks are based on 1988 percent of crop treated and therefore reflect the lower end of the risk range. If usage returned to 1985 levels, the risks from dietary exposure would increase but it would still be likely that most individual crop risks would be below 10^{-6}.

Impacts on growers and consumers of sweet and tart cherries, peaches, pears, nectarines, peanuts and grapes would be minor or negligible based on 1985 or 1988 usage. There may even be various intangible benefits to the grower from renewed consumer confidence supported by the fact that daminozide and UDMH residues would no longer be present in the marketplace. Although the dietary risk from exposure to peanuts, grapes, pears, and peaches/nectarines is small, the Agency has concluded that these risks outweigh the negligible to minor benefits and cancellation is being proposed.

Although an estimated 50 percent of tomato transplants grown for home garden use are reportedly treated with daminozide, quantitative economic impacts could not be calculated because of a lack of specific data. Loss of daminozide on tomato transplants would result in "lower quality" plants and higher prices to the consumer with a loss of crop quality and subsequent income to the grower based on either 1985 or 1988 usage data. In balancing the risks and benefits of daminozide use on tomatoes, the Agency was particularly concerned about home gardeners whose source of fresh tomatoes and tomato products may be totally from treated plants. The 20 percent of tomatoes grown by home gardeners likely represents the highest percentage of home grown versus commercially grown crop of the major food commodities. The Agency believes a significant portion of the population, particularly in warmer geographic regions where tomatoes can be easily grown, may be experiencing risks closer to the upper end of the risk range. Further, the risk range for tomatoes was based on "average" consumption patterns. It is possible that people who can tomato products are likely to eat more tomato products than those who do not. The Agency has therefore concluded that the risks of 9×10^{-7} to 9×10^{-6} (1988 or 1985 usage estimates) outweigh the benefits and is proposing cancellation of use on tomato transplants.

The Agency recognizes that, in some instances where significant benefits have been demonstrated or assumed, it has considered risks of the magnitude estimated for these minor uses sufficiently negligible to forego regulatory action (see, e.g., "Delaney Paradox", 53 FR 41104, October 19, 1988). However, the Agency's current assessment of the benefits related to these minor uses indicates that they are so insignificant as to be trivial. Accordingly, given some level of risk and almost no benefit, the risk/benefit balance shifts in favor of cancellation. The Agency acknowledges that more data on the economic impacts of daminozide use on tomatoes are needed and is requesting information during the public comment period.

D. Ornamentals and Bedding Plants

With regard to the use of daminozide on ornamentals and bedding plants, the Agency estimated the greatest individual lifetime cancer risks posed by non-dietary exposure to UDMH from use on greenhouse ornamentals to be 1×10^{-6}. In addition, the Agency believes that annual grower and consumer losses (as high as $4.7 million in an industry with an annual wholesale value of $78.5 to $104.5 million) would be substantial if the greenhouse uses of daminozide on ornamentals were cancelled. Therefore, the Agency believes that the benefits of continued use outweigh the carcinogenic risks for non-dietary use of daminozide on ornamentals and bedding plants and is proposing to continue the registration of these uses.

E. Conclusions and Proposed Regulatory Actions

The Agency has concluded that all food uses of daminozide should be cancelled because the resultant risk from dietary exposure to daminozide and/or its metabolite, UDMH, outweigh the benefits of continued use of each food commodity.

EPA has also determined that the benefits outweigh the risks for the non-food uses of daminozide and that all registrations for use on ornamentals and other uses on non-food bedding plants should be retained without modifications in the label.

In a related action, the Agency will also propose in the near future to revoke the daminozide tolerances for all raw agricultural commodities as well as the daminozide food and feed additive regulations for processed commodities.

F. Existing Stocks

Pursuant to FIFRA section 6(a)(1), "the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is cancelled [pursuant to section 6 of FIFRA] to such extent, under such conditions, and for such uses as he may specify, if he determines that such sale or use is not inconsistent with the purposes of [FIFRA] and will not have unreasonable adverse effects on the environment." For purposes of this action, EPA defines the term "existing stocks" as any quantity of daminozide products subject to this Notice that:

(1) is the United States,

(2) was formulated, packaged, and labelled for use on the date of publication in the Federal Register of this Notice, and

(3) is being held for shipment or release or was shipped and released into commerce prior to the date on which the registration of the product is cancelled pursuant to this Notice.

The Agency has determined that no further shipment, distribution, sale or use of existing stocks of daminozide products labelled for cancelled uses will be permitted after the effective date of cancellation. In addition to daminozide products in channels of trade, this existing stocks prohibition is applicable to daminozide products in the hands of end users. The Agency made this determination based on several factors. First, daminozide is a systemic pesticide that remains in plants for a considerable time after application and may result in residues in subsequent harvests. In addition, much of daminozide use is on crops for processed foods that can remain in the market system for long periods of time. In both of these instances, allowing use of existing stocks would effectively extend potential exposure well beyond the final use season—an option that the Agency believes will result in unreasonable adverse effects on human health. Finally, because of the extensive regulatory history leading to the cancellation of daminozide, users will have ample time to prepare themselves for this eventuality by exploring alternative options, including discontinuance of daminozide use.

Accordingly, after May 24, 1989, no person who is a registrant or producer of a product subject to this Notice may release for shipment existing stocks of any product whose registration is cancelled or denied by this action or no

persons may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver existing stocks of products whose registration is cancelled by this action. EPA has found this disposition of existing stocks to be consistent with the purposes of FIFRA.

V. Procedural Matters

As required by FIFRA sections 6(b) and 25(d), and 40 CFR 154.31(b), EPA has transmitted copies of a draft Notice of Intent to Cancel consistent with this Notice, together with support documents, to the Secretary of Agriculture and the Scientific Advisory Panel for comment. EPA will publish any comments received from the Secretary or the Panel, and EPA's responses, in the Notice of Final Determination.

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(23) USEPA. (1988) EPA Memorandum from Greear, W. to Boodee, M. regarding the UDMH 2-year mouse oncogenicity study at high doses (0, 40 and 80 ppm).

(24) USEPA. (1989) 54 FR 6392, "Pesticide Tolerance for Daminozide", February 10, 1989.

(25) White et al. (1983) Interim Report #1: The Construction of a Raw Agricultural Commodity Consumption Data Base, Research Triangle Institute, Research Triangle Park, NC.

VII. Public Comment Opportunity

The Agency is providing a 90-day period for the public to comment on this Notice and on the Daminozide Technical Support Document. Comments must be submitted by August 22, 1989. All comments and information should be submitted in triplicate to the address given in this Notice under ADDRESS. The comments and information should bear the identifying notation OPP–30000/40A.

All comments, information, and analyses which come to the attention of EPA may serve as a basis for final determination of regulatory action during the Special Review.

VIII. Public Docket

The Agency has established a public docket (OPP–30000/40A) for the daminozide Special Review. This public docket will include (1) this Notice; (2) the Technical Support Document; (3) any other notices pertinent to the daminozide Special Review; (4) non-CBI documents and copies of written comments or other materials submitted to the Agency in response to this Notice, and any other documents regarding daminozide submitted at any time during the Special Review process by any person outside the government; (5) a transcript of all public meetings held by the Agency for the purpose of gathering information on daminozide; (6) memoranda describing each meeting on daminozide held during the Special Review process between Agency personnel and any person outside government; and (7) a current index of materials in the public docket.

Dated: May 12, 1989.

John A. Moore,

Acting Deputy Administrator.

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