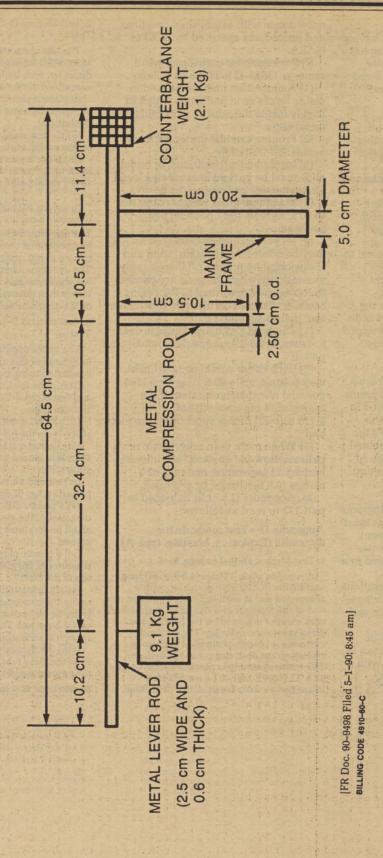
COMPRESSION APPARATUS FIGURE 1





Wednesday May 2, 1990

Part III

Department of Housing and Urban Development

Office of the Secretary

24 CFR Part 49 et al.

Temporary Disqualification From Financial Assistance of Aliens Granted Temporary/Permanent Resident Status; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Parts 49, 203, 207, 213, 221, 234, 237, 510, and 570

[Docket No. R-90-1477; FR-2600-F-01]

RIN Number 2501-AA77

Temporary Disqualification From Financial Assistance of Aliens Granted Temporary/Permanent Resident Status

AGENCY: Office of the Secretary, HUD. ACTION: Final rule.

SUMMARY: This rule implements a final rule published by the Immigration and Naturalization Service (INS) of the Department of Justice on July 12, 1989 (54 FR 29434). The INS rule amended 8 CFR part 245a to list a number of Federal programs, including a number of HUD programs, that are subject to a statutory restriction against the receipt of certain governmental benefits for a period of five years from the adjustment of an individual's immigration status to lawful resident status under a measure adopted by section 301 of the Immigration Reform and Control Act of 1986. This rule creates a new part 49 under the jurisdiction of the Office of the Secretary to state the restriction, since it applies to programs administered by more than one Assistant Secretary. Cross-references to that new part are then added to the various parts that govern the programs affected.

EFFECTIVE DATE: June 1, 1990.

FOR FURTHER INFORMATION CONTACT: For Block Grant Programs-Don Patch, Director, Office of Block Grant Assistance, (202) 755-6587; for the Urban Development Action Grants program-Roy Priest, Director, Office of Urban Development Action Grants, (202) 755-6290; for the Section 312 Rehabilitation Loan program-David Cohen, Director of Urban Rehabilitation, (202) 755-5685; for Multifamily Mortgage Insurance programs (223(e) and 221(d)(3) BMIR)-Donald A. Kaplan, Director, Office of Multifamily Housing Management, (202) 755-5730; and for Single Family Mortgage Insurance programs (223(e) and 237)-Stephen A. Martin, Director, Insured Single Family Housing, (202) 755-5210. (These are not toll-free telephone numbers.)

SUPPLEMENTARY INFORMATION:

I. Paperwork Reduction Act Statement

The Department has identified no information collection requirements in this rule that would require review by

the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980.

II. Background

Section 245A of the Immigration and Nationality Act, as adopted in 1986, permitted aliens who had been present illegally continuously since before January 1, 1982, to apply for legal resident status. Recognizing that many Federal benefit programs restrict participation to citizens and aliens who are lawful permanent residents of the United States, the statute also provided that these formerly illegal aliens would be prohibited from receiving Federal financial assistance furnished on the basis of financial need for a period of five years (section 245A(h) of the Immigration and Nationality Act, 8 U.S.C. 1101 note). The Attorney General, acting through the INS, was given authority by the statute to identify the programs to be covered, in consultation with the affected agencies.

The intent of the restriction, as stated in the preamble to the INS rule, was to minimize the financial burden of newly legalized aliens on U.S. taxpayers and to minimize the impact on citizens and lawful permanent residents of this increase in the number of persons eligible for these programs (54 FR 29435, July 2, 1989). The HUD programs listed by the INS as subject to this restriction do not require citizenship or lawful resident alien status for eligibility. (In fact, in many cases, the programs are intended to benefit broad classes of persons, and the individuals benefiting do so indirectly.) However, the INS determined that the programs satisfied its interpretation of the type of benefit to be covered by the statutory restriction. Thus, the anomaly results that illegal aliens may be eligible to receive these benefits, while alien residents who have been granted lawful resident status under section 245A of the INA are not

In discussions with the INS, HUD has been informed that an acceptable method of determining whether an applicant for a benefit is in the ineligible category of immigration status would be to request a certification of sttus at the time the benefit is to be provided. This position is reflected in the section on compliance, § 49.20.

The persons who are temporarily disqualified under section 245A are aliens who were granted lawful temporary resident status under that section, except for three categories of people: (1) Persons granted the status of lawful admission for permanent residence pursuant to section 249 of the INA (for certain admissions before July

1, 1924 or before January 1, 1972); (2) Cuban and Haitian entrants (as defined in paragraph (1) or (2) (A) of section 501(e) of Public Law 96–422, as in effect on April 1, 1983; and (3) persons who are at least 65 years of age or are blind or disabled.

In addition, individuals who are classified as Replenishment Agricultural Workers (RAWs) whose immigration status is adjusted to that of lawful admission for temporary or permanent residence under section 210A of the INA are disqualified under this rule, since section 210A(d)(6) states that the provisions of section 245A(h) apply to them. However, Special Agricultural Workers (SAWs) whose immigration status is adjusted to the status of lawful admission for temporary or permanent residence under section 210 of the INA are not affected by this rule.

A question has been raised about whether newly legalized aliens who are disqualified from participating in these programs are also disqualified from receiving Uniform Relocation Act benefits when they are required to move in connection with one of these programs. Since benefits are provided under that Act, in accordance 49 CFR part 24, not on the basis of financial need, but on the basis of displacement for a government program, HUD concludes that such aliens remain eligible for relocation benefits under the Act. (We also note that relocation benefits were not listed in the INS' rule that listed the programs affected by the disqualification.)

III. Programs Affected

The programs affected by this disqualification are the Community Development Block Grant program for small cities, for entitlement grants, and for States; the Urban Development Action Grants program; the section 312 Rehabilitation Loan program; mortgage insurance issued pursuant to section 237 (National Housing Act) for single family homes that are deemed to be special credit risks; mortgage insurance issued pursuant to section 223(e) (NHA) for housing in older, declining urban areas-both for single family and multifamily dwellings, and the section 221(d)(3) mortgage insurance program for below market interest rate projects.

However, the INS rule recognized that assisted activities in the Community Development Block Grant programs and the Urban Development Action Grant program are not limited to furnishing assistance on the basis of financial need. Therefore, these programs are covered only to the extent that a particular use of the grant funds is for

activities targeted to individuals in financial need. The disqualification applies where the use of these grant funds is targeted by restriction of benefits to persons with incomes below a certain level, or in a way that the assistance is intended to primarily benefit persons in financial need (except where the assisted activity serves the public at large, e.g., sewers, roads, sidewalks, and parks) and the benefits are provided to persons on the basis of applications.

The section 312 loan program and the various mortgage insurance programs covered by this rule are subject to these restrictions not necessarily because the income of the applicant is below a certain level but because the loan or loan guarantee is made to persons otherwise unable to obtain financing at reasonable rates, or is made in a way that will primarily benefit persons in financial need.

IV. Applicability

The Department has determined that the disqualification should apply to new applicants for benefits in the listed programs, and not to individuals already receiving benefits. In consultation with the INS, HUD has determined that the date from which the five year disqualification starts to run is the effective date of the adjustment of status. In most cases, the effective date is not the date it is granted but the date of application for lawful status under section 245A, since grants of temporary status are generally made retroactive by the INS to the date of application. Since the deadline for applying for such temporary resident status under the section 245A legalization program was May 4, 1988, the disqualification period may expire by May 4, 1993 for most individuals.

If a person has applied for legal resident status under section 245A by the time of application for HUD-funded assistance but no final action has been taken by the INS, the applicant will not be barred from participation under this rule.

V. Effective Date

The INS final rule stated that it was effective on the date of its publication—July 12, 1989. It also stated that compliance with its requirements could begin at a later date specified by administering agencies, but no later than October 1, 1989.

The Department was unable to publish a rule in time for it to be effective by October 1, 1989. Under section 7(o)(3) of the Department of Housing and Urban Development Act (35 U.S.C. 3535(o)(3)) as it was in effect

until December 15, 1989, HUD's rules could not become effective until 30 calendar days of continuous session of Congress following their publication. Under that statutory restriction, the HUD rule would have had to be published by July 31, 1989 in order to take effect by October 1, 1989. Since the INS final rule was not published until July 12, 1989, the Department did not have adequate time to develop its own final rule and process it for publication by July 31.

Since publication of the INS rule, the Department has been in contact with the INS about correcting its July rule with respect to two programs (the Rental Rehabilitation program and the Flexible Subsidy program), for which a correction document has been published by the INS (54 FR 49963, December 4, 1989). Neither program should have been included. The first was not actually included in the rule's list of covered programs but was described in the preamble as if it were. The second program was listed, although the INS had agreed with HUD's comment that it should not be.

The issue has arisen whether, in the case of a UDAG or CDBG grant, this rule's June 1, 1990, effective date applies to the time the Federal grant funds for the specific activity or project providing the benefit are obligated, or to the time that an ultimate beneficiary applies for and receives a benefit. The Department has concluded that Congress was concerned with the ultimate beneficiary's receipt of a benefit, and that the limitation on eligibility may be applied to a grant recipient after commitment of funds to a particular activity. This position is supported by the INS' suggestion in its rule that efficient administration of certain programs might require "a limited amount of 'grandfathering' " (54 FR 29437). This language implies that without such consideration for persons already receiving benefits, they too, could be deprived of benefits. Consequently, this rule provides that any applicant for a benefit who applies after the effective date of this rule is subject to the restrictions, regardless of the date the funds providing the benefit were obligated.

VI. Justification for Final Rule

Under the Department's regulations concerning rulemaking, 24 CFR part 10, rules are to be published for public comment before being issued for effect, unless the agency finds good cause to omit public participation. This good cause requirement is satisfied when prior public procedure is "impracticable,

unnecessary, or contrary to the public interest." 24 CFR 10.1.

In this case, the INS has made a determination of the HUD programs affected by the statute by a rulemaking process that provided for public participation. This rule merely codifies the statutory restriction in the Department's own rules consistent with the requirements of the INS rule and gives guidance on how to apply the restriction. Therefore, the Department has determined that solicitation of public comment on the content of the HUD rule is unnecessary and would improperly delay further the implementation of the statutory restriction enacted in 1986.

VII. Findings and Certifications

Environment. A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC 20410.

Executive Order 12291, Regulatory Planning Process. This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 issued by the President on February 17, 1981, and therefore no regulatory impact analysis is necessary. Excluding this new class of lawful resident aliens from participation in the programs identified will not have an annual effect on the economy of \$100 million or more. Furthermore, it will not cause a major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, nor have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreignbased enterprises in domestic or export markets.

Regulatory Flexibility Act. Under the Regulatory Flexibility Act (5 U.S.C. 601), the Undersigned hereby certifies that this rule, as distinguished from the statute that mandates the disqualification, will not have a significant economic impact on a substantial number of small entities. The rule merely recites the disqualification required by the statute and suggests a self-certification approach to determining who is disqualified that will

minimize the impact on administrators of the programs affected.

Executive Order 12612, Federalism. The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, has determined that this rule, as distinguished from the statute that mandates the disqualification, will not have federalism implications and, thus, is not subject to review under the Order. The rule affects only the use of Federal funds in the hands of State of local government or a private project owner participating in a Federal program. It does not disturb the relationship between State or local governments and the Federal government.

Executive Order 12606, the Family.
The General Counsel, as the Designated Official under Executive Order 12606, has determined that this rule, as distinguished from the statute that mandates the disqualification, does not have potential significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the Order.

Regulatory Agenda. This rule was listed as sequence number 1131 under the Office of the Secretary in the Department's semiannual agenda of regulations published on April 23, 1990 (55 FR 16226, 16237), under Executive Order 12291 and the Regulatory Flexibility Act.

Catalog. The Catalog of Federal Domestic Assistance Program numbers for this rule are 14.123, 14.136, 14.140, 14.218, 14.219, 14.220, 14.221, and 14.228.

Information Collection Requirements.

There are no information collection requirements contained in this rule.

List of Subjects

24 CFR Part 49

Aliens, Grant programs—housing and community development, Loan programs—housing and community development, Mortgage insurance.

24 CFR Part 203

Home improvement, Loan programs housing and community development, Mortgage insurance, Solar energy.

24 CFR Part 207

Mortgage insurance, Rental housing, Mobile home parks.

24 CFR Part 213

Mortgage insurance, cooperatives.

24 CFR Part 221

Condominiums, Low and moderate income housing, Mortgage insurance, Displaced families, Single family housing, Projects, Cooperatives.

24 CFR Port 234

Condominiums, Mortgage insurance, Homeownership, Projects, Units.

24 CFR Part 237

Low and moderate income housing, Mortgage insurance.

24 CFR Part 510

Loan programs—housing and community development, Housing, Relocation assistance, Home improvement, Rehabilitation, Urban renewal.

24 CFR Part 570

Community development block grants, Grant programs—housing and community development, Loan programs: housing and community development, Low and moderate income housing, New communities, Pockets of poverty, Small cities.

Accordingly, Title 24 of the Code of Federal Regulations is amended as

follows:

 A new part 49 is added, to read as follows:

PART 49—INELIGIBILITY OF CERTAIN PERSONS BASED ON ALIEN STATUS

Sec.

49.1 Purpose and applicability.

49.5 Programs affected.

49.10 Category of resident aliens affected.

49.15 Period of disqualification.

49.20 Compliance.

49.25 Distinction from other eligibility restrictions based on alien status.

Authority: Sec. 245A(h), Immigration and Nationality Act (8 U.S.C. 1101 note); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

§ 49.1 Purpose and applicability.

(a) Purpose. The purpose of this rule is to decrease the cost to United States taxpayers of the legalization of certain newly legalized aliens by denying them eligibility to certain Federal financial assistance. The Immigration and Naturalization Service has determined that certain of HUD's programs fit its definition of Federal financial assistance that is to be covered: assistance is provided to eligible individuals, or to private suppliers of goods or services to individuals, and the assistance is targeted to individuals in financial need. The determination of financial need is made either on an individual basis or on the basis of intention to primarily benefit persons in financial need. In the case of a loan or loan guarantee program, the inability to obtain financing from alternative sources or at a prevailing or reasonable interest rate is sufficient to determine that the program provides assistance based on financial need. See 8 CFR 245a.5.

(b) Applicability. This disqualification applies to new applicants for benefits in the affected programs, and not to individuals already receiving benefits in the programs. If an applicant for benefits has already applied for legal resident status under section 245A of the Immigration and Nationality Act but no final action has been taken by the INS on the application for such status, the applicant will not be barred from participation in programs affected by this part (see § 49.5).

§ 49.5 Programs affected.

There are three principal types of programs affected by this disqualification. They are grouped as follows:

(a) Single family mortgage insurance programs. The programs affected are the

following:

(1) Mortgage insurance issued pursuant to section 223(e) of the National Housing Act for housing in older, declining urban areas (see 24 CFR 203.43a, as well as § 213.45a for cooperatives and § 234.68 for condominiums); and

(2) Mortgage insurance issued pursuant to section 237 of the National Housing Act for mortgages that are deemed to be special credit risks (see 24

CFR 237.5].

(b) Multifamily mortgage insurance programs. The programs affected are the following:

(1) Mortgage insurance issued pursuant to section 223(e) of the National Housing Act for housing in older, declining urban areas (see 24 CFR 207.31a); and

(2) The mortgage insurance program for below market interest rate projects, administered pursuant to section 221(d)(5)—but often referred to as the section 221(d)(3) BMIR program (see 24 CFR 221.537).

(c) Community Planning and Development Programs. (1) The section 312 Rehabilitation Loan program (for single family and multifamily dwellings), administered under part 510 of this title

is covered, in its entirety.

(2) The following programs are affected only to the extent that benefits provided under a particular activity are furnished to eligible individuals or are furnished to private suppliers of goods or services to such individuals and the benefits are targeted to individuals in financial need. An activity is so targeted if benefits are restricted to persons with incomes below a certain level or is provided in a way intended to primarily benefit persons in financial need, where the benefits are provided to persons on the basis of an application:

(i) The Community Development Block Grant program for small cities, administered under subpart F of part 570 of this title.

(ii) The Community Development Block Grant program for entitlement grants, administered under subpart D of

part 570 of this title.

(iii) The Community Development Block Grant program for States, administered under subpart I of part 570 of this title.

(iv) The Urban Development Action Grants program, administered under subpart G of part 570 of this title.

§ 49.10 Category of resident aliens affected.

(a) General. The category of aliens affected by this part is any alien who has obtained the status of an alien lawfully admitted for temporary residence pursuant to section 245A or section 210A of the Immigration and Nationality Act. Section 245A provides for adjustment of status of certain aliens who have resided in the United States as unlawful residents since before January 1, 1982. Section 210A provides for determinations of agricultural labor shortages and admission of additional Special Agricultural Workers (Replenishment Agricultural Workers, or RAWs).

(b) Exceptions. There are three classes of resident aliens who are excepted from the coverage of this part:

(1) An alien granted the status of an alien lawfully admitted for permanent residence pursuant to section 249 of the Immigration and Nationality Act, as evidenced by a record of admission for permanent residence for certain aliens who entered the United States before July 1, 1924 or before January 1, 1972;

(2) A Cuban or Haitian entrant, as defined in paragraph (1) or (2)(a) of section 501(e) of Public Law 96-422 as it

was in effect on April 1, 1983; and
(3) An alien who is aged, blind, or
disabled, i.e., at least 65 years of age,
blind, or having a physical or mental
impairment that is expected to last at
least twelve months and that prevents
the individual from engaging in any
substantial gainful activity.

§ 49.15 Period of disqualification.

(a) Individuals who fall into the category of resident aliens described in § 49.10(a) are disqualified for a period of five years from the date such status is obtained, for being admitted to participation in receiving benefits from the programs enumerated in § 49.5.

(b) The disqualification period starts to run on the date lawful status is obtained, including any retroactive effect given by the INS to the date of

application. Since the deadline for applying for such temporary resident status under the section 245A legalization program was May 4, 1988, the disqualification period may expire by May 4, 1993 for many individuals.

§ 49.20 Compliance.

Providers of benefits will be regarded as in compliance with this section if they obtain certifications from applicants that they are not in the status of restricted resident aliens.

§ 49.25 Distinction from other eligibility restrictions based on alien status.

The disqualification imposed by this part derives from section 245A of the Immigration and Nationality Act (8 U.S.C. 1101 note). It does not affect any of the applicants or participants in assisted housing programs that are subject to the restrictions imposed by the section 214 of the Housing and Community Development Act of 1980 (42 U.S.C. 1436 note). Participation in the programs covered by that statute is specifically permitted for the category of newly legalized aliens prohibited from participation under this part. (See 24 CFR parts 200, 812 and 912, for the principal rules implementing that statute.)

PART 203—MUTUAL MORTGAGE INSURANCE AND REHABILITATION LOANS

2. The authority citation for part 203 continues to read as follows:

Authority: Secs. 203, 211, National Housing Act (12 U.S.C. 1709, 1715b); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)). In addition, subpart C is also issued under sec. 230, National Housing Act (12 U.S.C. 1715u).

3. In § 203.43a, a new paragraph (d) is added, to read as follows:

§ 203.43a Eligibility of mortgages covering housing in certain neighborhoods.

(d) For restrictions against approving mortgage insurance for a certain category of newly legalized alien, see 24 CFR part 49.

PART 207—MULTIFAMILY HOUSING MORTGAGE INSURANCE

4. The authority citation for part 207 continues to read as follows:

Authority: Secs. 207, 211, National Housing Act (12 U.S.C. 1713, 1715b); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)). Sections 207.258 and 207.258b are also issued under section 203(e), Housing and Community Development Amendments of 1978 (12 U.S.C. 1701z–11(e)).

5. In §207.31a, a new paragraph (d) is added, to read as follows:

§ 207.31a Eligibility of mortgages covering housing in certain neighborhoods.

(d) For occupancy restrictions that apply to a certain category of newly legalized alien with respect to a project which has a mortgage determined to be eligible for insurance under this section, see 24 CFR part 49.

PART 213—COOPERATIVE HOUSING MORTGAGE INSURANCE

6. The authority citation for part 213 continues to read as follows:

Authority: Secs. 211, 213, National Housing Act (12 U.S.C. 1715b, 1715e); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

7. In § 213.45a, a new paragraph (d) is added, to read as follows:

§ 213.45a Eligibility of mortgages covering housing in certain neighborhoods.

(d) For restrictions against approving mortgage insurance for a certain category of newly legalized alien, and for occupancy restrictions that apply to the same category of resident alien with respect to a project which has a mortgage determined to be eligible for insurance under this section, see 24 CFR part 49.

PART 221—LOW COST AND MODERATE INCOME MORTGAGE INSURANCE

8. The authority citation for part 221 continues to read as follows:

Authority: Secs. 211, 221, National Housing Act (12 U.S.C. 1715b, 17151); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)); section 544(a)(3) is also issued under sec. 201(a), National Housing Act (12 U.S.C. 1707(a)).

9. In § 221.537, a new paragraph (f) is added, to read as follows:

§ 221.537 Additional occupancy requirements; preferred purchasers or tenants.

(f) Restriction with respect to resident aliens. For restrictions against admission of certain newly legalized aliens, see 24 CFR part 49.

PART 234—CONDOMINIUM OWNERSHIP MORTGAGE INSURANCE

10. The authority citation for part 234 continues to read as follows:

Authority: Secs. 211, 234, National Housing Act (12 U.S.C. 1715b, 1715y); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)). Section *

234.520(a)(2)(ii) is also issued under sec. 201(a), National Housing Act (12 U.S.C. 1707(a)).

11. In § 234.68, a new paragraph (d) is added, to read as follows:

§ 234.68 Eligibility of mortgages covering housing in certain neighborhoods.

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(d) For restrictions against approving mortgage insurance for a certain category of newly legalized alien, see 24 CFR part 49.

PART 237—SPECIAL MORTGAGE INSURANCE FOR LOW AND MODERATE INCOME FAMILIES

12. The authority citation for part 237 continues to read as follows:

Authority: Secs. 203, 211, 237, National Housing Act (12 U.S.C. 1709, 1715b, 1715z-2); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

13. In § 237.5, a sentence is added at the end, to read as follows:

§ 237.5 Cross-reference.

* * * For restrictions against approving mortgage insurance for a certain category of newly legalized alien, see 24 CFR part 49.

PART 510—SECTION 312 REHABILITATION LOAN PROGRAM

14. The authority citation for part 510 continues to read as follows:

Authority: Sec. 312, United States Housing Act of 1964 (42 U.S.C. 1452b); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)). Section 510.106 is also issued under the authority of sec. 165, Housing and Community Development Act of 1987 (42 U.S.C. 3543).

15. A new § 510.51 is added, to read as follows:

§ 510.51 Eligibility restrictions for certain resident aliens.

Certain newly legalized aliens, as described in 24 CFR part 49, are not eligible to apply for a rehabilitation loan under this part. Similarly, that category of resident aliens is not eligible to occupy units in a multifamily building rehabilitated with assistance under this part applied for after the effective date of 24 CFR part 49, so long as the loan is outstanding.

PART 570—COMMUNITY DEVELOPMENT BLOCK GRANTS

16. The authority citation for part 570 is amended to read as follows:

Authority: Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301– 5320); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

17. In § 570.496, a new paragraph (h) is added, to read as follows:

§ 570.496 Program requirements.

(h) Eligibility restrictions for certain resident aliens. The restrictions described in § 570.613 are applicable to the State's Program under this subpart.

18. A new § 570.613 is added, to read as follows:

§ 570.613 Eligibility restrictions for certain resident aliens.

(a) Restriction. Certain newly legalized aliens, as described in 24 CFR part 49, are not eligible to apply for benefits under covered activities funded by the programs listed in paragraph (e) of this section. "Benefits" under this section means financial assistance, public services, jobs and access to new or rehabilitated housing and other facilities made available under covered activities funded by programs listed in paragraph (e) of this section. "Benefits" do not include relocation services and payments to which displacees are entitled by law.

(b) Covered activities. "Covered activities" under this section means activities meeting the requirements of § 570.208(a) that either:

(1) Have income eligibility requirements limiting the benefits exclusively to low and moderate income

persons; or

(2) Are targeted geographically or otherwise to primarily benefit low and moderate income persons (excluding activities serving the public at large, such as sewers, roads, sidewalks, and parks), and that provide benefits to persons on the basis of an application.

(c) Limitation on coverage. The restrictions under this section apply only to applicants for new benefits not being received by covered resident aliens as of the effective date of this

section.

(d) Compliance. Compliance can be accomplished by obtaining certification as provided in 24 CFR 49.20.

(e) Programs affected. (1) The Community Development Block Grant program for small cities, administered under subpart F of part 570 of this title until closeout of the recipient's grant.

(2) The Community Development Block Grant program for entitlement grants, administered under subpart D of

part 570 of this title.

(3) The Community Development Block Grant program for States, administered under subpart I of part 570 of this title until closeout of the unit of general local government's grant by the State.

(4) The Urban Development Action Grants program, administered under subpart G of part 570 of this title until closeout of the recipient's grant.

Dated: April 16, 1990.

Jack Kemp. Secretary.

[FR Doc. 90-9774 Filed 5-1-90; 8:45 am] BILLING CODE 4210-32-M



Wednesday May 2, 1990

Part IV

Environmental Protection Agency

Hazardous Waste Management System:
Identification and Listing of Hazardous
Waste and CERCLA Hazardous
Substance Designation and Reportable
Quantity Adjustment—1,1Dimethylhydrazine Production Wastes;
Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 271, and 302

[SWH-FRL-3719-6]

RIN 2050-AC91

Hazardous Waste Management
System: Identification and Listing of
Hazardous Waste and CERCLA
Hazardous Substance Designation and
Reportable Quantity Adjustment—1,1Dimethylhydrazine Production Wastes

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) today is amending the regulations for hazardous waste management under the Resource Conservation and Recovery Act (RCRA) by listing as hazardous four wastes generated during the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazides. The effect of this regulation is that these wastes will be subject to regulation under 40 CFR parts 262–266, and parts 270, 271, and 124.

In addition, the Agency also is making final amendments to regulations promulgated under the Comprehensive Environmental Response,
Compensation, and Liability Act (CERCLA) in 40 CFR part 302 that are related to today's hazardous waste listings. In particular, EPA is making final the designation as CERCLA hazardous substances all of the wastes made final in today's rule and the final reportable quantities that would be applicable to those wastes.

EFFECTIVE DATE: This regulation becomes effective on November 2, 1990. ADDRESSES: The official record for this rulemaking is identified as Docket Number F-90-DMHF-FFFFF and is located in the EPA RCRA Docket, Room 2427, 401 M Street SW., Washington, DC 20460. The public must make an appointment to review docket materials by calling (202) 475-9327. Copies of the non-CBI version of the listing background document, the Health and Environmental Effects Profiles (HEEPs), and not readily available references are available for viewing and copying only in the OSW docket. Copies of materials relevant to the CERCLA portions of this rulemaking are also located in Room 2427, U.S. EPA, 401 M Street SW., Washington, DC 20460. Both dockets are available for inspection from 9:00 a.m. to 4:00 p.m. Monday through Friday, excluding Federal holidays. The public

may copy a maximum of 100 pages from

the docket at no charge; additional copies are available at \$0.15 per page.

FOR FURTHER INFORMATION CONTACT:
The RCRA/Superfund Hotline at (800)
424–9346 or at (202) 382–3000. For
technical information on the RCRA
hazardous waste listings, contact Dr.
Cate Jenkins, Office of Solid Waste
(OS–332), U.S. Environmental Protection
Agency, 401 M Street SW., Washington,
DC 20460, (202) 382–4786. For technical
information on the CERCLA final rule,
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SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

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I. Legal Authority

These regulations are being promulgated under the authority of sections 2002(a) and 3001 (b) and (e)(2) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a) and 6921 (b) and (e)(2) (commonly referred to as RCRA), and section 102(a) of the comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9602(a).

II. Background

Pursuant to section 3001 of subtitle C of the Resource Conservation and Recovery Act (RCRA), EPA today promulgates final rules listing four wastes generated during the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazides. The following discussion provides a brief overview of regulatory actions affecting the wastes being finalized today.

On December 20, 1984, EPA proposed to amend the regulations for hazardous

waste management under RCRA by listing as hazardous four wastes generated during the production of 1,1dimethylhydrazine (see 49 FR 49556). These wastes are: (1) Column bottoms from product separation (EPA Hazardous Waste No. K107), (2) condensed column overheads from product separation and condensed reactor vent gases (EPA Hazardous Waste No. K108), (3) spent filter cartridges from product purification (EPA Hazardous Waste No. K109), and (4) condensed column overheads from intermediate separation (EPA Hazardous Waste No. K110).

The basis for this action was a determination by the Agency that these wastes contained significant concentrations of 1,1-dimethylhydrazine (UDMH). UDMH is carcinogenic, mutagenic, and teratogenic. UDMH is typically present in each waste at significant levels. In addition, UDMH is mobile and persistent, and can reach environmental receptors in harmful concentrations if these wastes are mismanaged. (See the preamble to the proposed listing for those wastes (49 FR 49556) and the Listing Background Document, available from the ADDRESSES section, for more information on the hazards of these wastes.)

On August 17, 1989, the Agency made available for public comment additional data which supports the conclusion that UDMH should be considered a potential human carcinogen (54 FR 33942). The Agency requested comments on the use of this new data as part of the basis for listing wastes generated from the manufacture of UDMH. The comments received on the December 20, 1984 proposal to list the four wastes and on the use of this new data are responded to in this Federal Register notice. These comments do not refute the Agency's conclusion that UDMH is carcinogenic,

mutagenic and teratogenic.

In addition, in a document published elsewhere in today's Federal Register, EPA is proposing to list as hazardous two additional wastes generated during the production of UDMH from carboxylic acid hydrazides. These wastes are: (1) Flush water from the catalyst removal system, and (2) spent catalyst and filter media. As a result of comments received from a manufacturer of UDMH in response to the proposed listing of four wastes generated during the manufacture of UDMH (December 20, 1984, 49 FR 49556), the Agency received data that supports a preliminary determination that these two additional wastes also should be listed as hazardous.

On November 8, 1984, the Hazardous and Solid Waste Amendments of 1984 (HSWA) were enacted. These amendments had far reaching ramifications for EPA's hazardous waste regulatory program. Section 3001(e)(2), which was one of the many provisions added by HSWA, directed EPA to make a decision on whether or not to list certain specified wastes, including wastes from the manufacture of UDMH, as hazardous. Today's rule fulfills this mandate, in part, by promulgating the final listing for four UDMH production wastes. EPA also plans to decide, within the next several years, whether to list as hazardous wastes generated during a different UDMH manufacturing process, namely that used by the Olin corporation. After EPA has (1) made that final decision, and (2) taken final action on today's proposal to list as hazardous two additional wastes generated during the manufacture of UDMH from carboxylic acid hydrazides, the Agency will have fulfilled its mandate under section 3001(e) of RCRA.

III. Summary of the Final Regulation

This regulation designates as RCRA hazardous wastes the following wastes generated during the manufacture of UDMH from carboxylic acid hydrazides:

 K107—Column bottoms from product separation from the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazines

 K108—Condensed column overheads from product separation and condensed reactor vent gases from the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazines

 K109—Spent filter cartridges from product purification from the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazines

 K119—Condensed column overheads from intermediate separation from the production of 1,1dimethylhydrazine (UDMH) from carboxylic acid hydrazines.

The hazardous constituent of concern in these wastes is UDMH. UDMH is carcinogenic, mutagenic, and teratogenic. UDMH is typically present in each waste at significant levels (i.e., these wastes contain up to 50 percent UDMH). In addition, UDMH is mobile and persistent, and can reach environmental receptors in harmful concentrations if these wastes are mismanaged.

In addition to its toxicity, the flash point of the condensed column overheads from product separation and condensed vent gases from the reactors (EPA Waste No. K108) has been measured to be between 11 to 14 °C (52 to 55 °F), which makes this waste ignitable according to the criteria in 40 CFR 261.21(a)(1). Also, the pH of the column bottoms from product separation (EPA Waste No. K107) has been measured to be between 13 and 14, which makes this waste corrosive according to the criteria in 40 CFR 261.22(a)(1).

EPA has evaluated these wastes against the criteria for listing hazardous wastes (40 CFR 261.11(a)), and has determined that they typically contain high concentrations of the constituent of concern (UDMH), that this toxicant is mobile and persistent in the environment, and that the toxicant in the wastes is regulated by other EPA regulations, as well as by regulations of other government agencies. In addition, one of the wastes is corrosive, and another is ignitable, and thus these wastes are also being listed as hazardous based on these characteristics. The Agency, therefore, believes that these wastes are capable of posing a substantial present or potential threat to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed, and thus are hazardous wastes. (Additional information on the hazards and the toxic constituents of these wastes may be found in the listing background document and the Health and Environmental Effects Profiles, available as described in the "ADDRESSES" section.)

The Agency received comments on the proposed listings from the generator of the wastes (Uniroyal Corporation) as well as another manufacturer of UDMH that uses a different process not subject to these listings. Uniroyal also submitted comments on the new data on UDMH made available on August 17, 1989. We have evaluated these comments carefully, and have modified the supporting documentation accordingly. This notice makes final the regulations proposed on December 20, 1984, and provides EPA's response to the comments received.

The manufacturer of UDMH from carboxylic acid hydrazides, Uniroyal Corporation, also supplied the Agency with information on the generation of two additional wastes from the manufacture of UDMH as part of their comments—namely (1) flush water from the catalyst removal system, and (2) spent catalyst and filter media. As a result, the Agency is proposing to add these two wastes to the list of hazardous wastes in 40 CFR 261.32 in a document published elsewhere in today's Federal Register.

IV. Response to Comments

EPA received comments on several aspects of the proposed regulations (and on the use of the data made available for public comment on August 17, 1989) from the generator of these wastes, Uniroyal Corporation; the Agency also received comments on the proposed regulations from another manufacturer of UDMH that uses a different process not subject to these listings, Olin Corporation. The Agency has evaluated these comments carefully, and has modified the supporting documentation to this regulation accordingly, as well as proposing new hazardous waste listings based on these comments. This section presents the comments received, as well as the Agency's response.

A. Concentration Level Criteria for Listing Waste as Hazardous

One commenter requested that the Agency's listing of UDMH include a "delisting threshold" so that industry would have criteria for determining whether a waste containing UDMH (or any other toxicant) is considered hazardous, and could use this as a basis for a petition pursuant to 40 CFR 260.22 to exclude a particular UDMH manufacturing waste from the list of hazardous waste, the "delisting" process.

When evaluating delisting petitions, the Agency considers a number of factors, including the presence of any additional toxicants other than those for which the waste was listed and the behavior of the toxicants in the environment. See 40 CFR 260.22(a). Therefore, the delisting process is more complex than a simple evaluation of the concentration of the toxicant(s) for which the relevant waste was listed. The Agency has described its general approach to evaluating delisting petitions in the Federal Register. See 50 FR 48886, November 27, 1985. In that notice and in many subsequent proposed and final delisting determinations, the Agency described its evaluation process in detail and explained how it uses information provided by the petitioner (e.g., see 54 FR 14101, April 7, 1989). For the reasons described in those notices and above, the Agency is not including a concentration level of UDMH in the wastes below which the wastes would not be considered hazardous.

B. Assessment of Risk for UDMH in the Wastes

Uniroyal challenged the Agency's evaluation of the carcinogenicity of UDMH for several reasons. In response to the December 20, 1984 proposed

UDMH listings (49 FR 49556), Uniroyal contended that a study by Toth,1 which was used by EPA to conclude that UDMH should be considered a probable human carcinogen (a B2 carcinogen using EPA's weight-of-evidence classification system), was so flawed as to be invalid for any risk assessment. Uniroyal also challenged the validity of EPA's conclusions on the carcinogenicity of UDMH based on the interim results of new studies currently being conducted by Uniroyal. These new studies were conducted by Uniroyal pursuant to requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (U.S.C. part 136 et. seq.), and were proposed to be used as a partial basis for the UDMH listing regulations under RCRA on August 17, 1989 (54 FR 22942).

The response to challenges by Uniroyal on the use of either the earlier Toth study or the new interim results of the studies conducted by Uniroyal are provided below.

1. Use of the Toth Study to Establish Carcinogenic Risk of UDMH

Uniroyal stated that EPA based its risk assessment of the carcinogenicity of UDMH solely on a study by Toth.2 Uniroyal contended that this study deviated from scientifically valid protocols, thus invalidating the use of the study for establishing the carcinogenic risk of UDMH to humans.

The specific areas where Uniroyal claimed that the Toth study was not in conformance with EPA Guidelines for oncogenicity studies,3 and the Agency's specific responses to these comments are given below. In general, however, while noting that there are certain deficiencies in the methodological conduct of the Toth study, the Agency's Human Health Assessment Group (HHAG) (formerly the Carcinogen Assessment Group (CAG)) made a final determination in 1988 that the Toth study may be used as the basis for a carcinogenicity determination for UDMH.4 This determination was made

after evaluating the results of an audit performed on the Toth study by the Agency in 1985.5 The CAG noted that although the study had certain deficiencies, the increases in the tumor incidence was striking and that the evidence from the Toth study was more than adequate to classify UDMH as a carcinogen in animal test systems, and as a B2 category carcinogen (a probable human carcinogen) using EPA's weightof-evidence system.

The Agency notes that even if the Toth study were as flawed as Uniroyal alleges, subsequent results of new studies also confirm the Agency's determination that UDMH is carcinogenic. These studies, conducted by Uniroyal as part of the requirements of the Registration Process under FIFRA. were noticed for public comment on August 17, 1989 for their potential use to

support these UDMH listing regulations under RCRA (54 FR 33942). The results of this new interim study are also discussed in this Response to Comments section.

a. Uniroyal asserted that one deficiency in the Toth study was that there were no concurrent controls (animals maintained under the same test conditions, but not administered UDMH. which provide a reference point for comparison of any statistical increase in tumors) for any particular animals. The control group that Dr. Toth described in his publication actually lived over a different time span than those animals which were administered UDMH, and thus could not be assured to have lived under the exact same laboratory conditions as the animals which were administered UDMH.

Response: As a result of an audit of the Toth study performed by the Agency,6 data was located to establish the existence of as well as records for concurrent controls that were maintained by Dr. Toth's laboratory during the UDMH bioassay. These concurrent controls were found to have essentially the same tumor incidence as in the non-concurrent control group reported upon by Dr. Toth in his original publication of his study. Thus, the Agency does not believe there are problems in utilizing the Toth study because of Uniroyal's allegations

concerning lack of concurrent control animals.

b. Uniroyal stated that only one dose level of UDMH was tested, and this dose level exceeded the Maximum Tolerated Dose (MTD). The MTD is an administered level of substance that significantly shortens the life span of test animals, due to toxicological effects of the test substance (such as suppression of the immune system, endocrine disturbances, and organ damage). Thus, an exceedance of the MTD could interfere with any assessment of the carcinogenic effects of an administered substance. Uniroyal contended that any observed carcinogenicity findings in the Toth study were therefore likely to have been caused by metabolic overload and/or cytotoxicity (exceedance of the MTD). and not due to a genuine carcinogenic response to UDMH. Uniroyal pointed out that after 15 months, there were only 26 percent survivors among the treated mice instead of the allegedly required 50 percent. The company also stated that there were no survivors at the end of 18 months, although it alleged that the Guidelines require a survival rate of 25 percent, thus allegedly providing further evidence that the dose was in excess of the MTD.

Response: First, according to the EPA Guidelines for Carcinogenic Risk Assessment, only one dose is required to determine qualitatively the carcinogenicity of an agent if the results are positive and if the MTD has not been exceeded.7 Even if the MTD has been exceeded, the study is not necessarily invalidated, but instead must be evaluated closely to determine if concomitant pathology and/or metabolic overload have influenced results.8 Second, contrary to Uniroyal's suggestion, there is nothing in the Guidelines for Carcinogenic Risk Assessment,9 the uniform procedures

¹ Toth, B. (1973) 1.1-Dimethylhydrazine (Unsymmetrical) Carcinogenesis in Mice. Light Microscopic and Ultrastructural Studies on Neoplastic Blood Vessels. J. Natl. Cancer Inst.,

² Toth, B. (1973). ibid.

^a Pesticide Assessment Guidelines. Subdivision F. 1982

⁴ U.S.EPA, CAG (June, 1988) Evaluation of the Potential Carcinogenicity of 1.1-Dimethylhydrazine (57-14-7), in Support of Reportable Quantity Adjustments Pursuant to CERCLA section 102 (OHEA-C-073-95, June 1988, Final); W. Pepelko through Wm. Farland, Director, CAG, to E. Claussen, Director, Characterization and Assessment Division, OSW (January 9, 1987) Evidence for Carcinogenicity of 1.1-

Dimethylhydrazine (DMZ). (Both documents are in the docket for this final rule, available as indicated in the ADDRESSES section.)

⁶ U.S. EPA, OPP (April 22, 1985) Report of the Audits of the Studies on the Carcinogenic Potential of Succinic Acid 2.2-Dimethylhydrazide (Daminozide) and 1.1-Dimethylhydrazine in Swiss Mice, Studies Conducted at the Eppley Institute, the University of Nebraska Medical Center, Omaha, Nebraska

⁶ U.S. EPA. OPP (April 22, 1985), ibid.

⁷ U.S. EPA (September 24, 1986) Guidelines for Carcinogenic Risk Assessment, EPA Publication No. EPA/600/8-87/045). These guidelines were published in the Federal Register on September 24, 1986 (51 FR 33992), and were products of a two-year Agency development and review process, where drafts were peer-reviewed by experts from academia, industry, public interest groups, and other governmental agencies. Proposed guidelines were published in the **Federal Register** (49 FR 46294. November 23, 1984), reviewed by special panels of EPA's Science Advisory Board, and revised to take into account public and SAB comments, as well as being reviewed by the Office of Management and

^{*} U.S. EPA (September 24, 1986) Guidelines for Carcinogenic Risk Assessment, ibid.

^{*} U.S. EPA (September 24, 1986) Guidelines for Carcinogenic Risk Assessment. ibid.

that EPA uses to evaluate the effects of toxicants, that require any minimal survival rate at different stages of a bioassay.

In addition, survival rates in the Toth study did not demonstrate that the MTD was exceeded. Among male mice, the survival rate was lower than in the untreated animals, but only after more than 50 weeks of exposure. Since 84 percent of the animals in this group developed vascular tumors and 78 percent lung tumors, with average latencies of 42 and 53 weeks, respectively, it is highly likely that cancer induction itself was responsible for mortality after 50 weeks. Among male hamsters, in which the latency for tumor development was longer with fewer incidences, the survival rate was the same for treated and control animals. If adjustments are made for very early mortality in female hamsters, then the long term survival rate was also equivalent in treated animals and controls.

Excessive noncancer liver pathology was not reported in the Toth study, nor was it found by the EPA audit of this study, as would be expected if the MTD were exceeded.

Based upon the mortality results and lack of reported pathology, there is little direct evidence that the MTD was exceeded.

c. Uniroyal challenged the validity of the Toth study because complete necropsy records were not maintained, and portions of the study were conducted by technicians in the absence of direct supervision.

Response: The audit performed by EPA considered in detail this problem with the Toth study, noting that there was a large turnover of technicians, and that none of the observations, calculations or other records for the necropsy histopathology report sheets were dated, signed, or initialled. Despite these deficiencies noted by the auditors, the CAG ¹¹ concluded that the Toth study was still adequate for a risk assessment, since no evidence was found to suggest that errors were made by the technicians under these conditions.

d. Uniroyal contended that animal randomization was inadequate to prevent in-breeding (a condition that could lead to heightened sensitivity to carcinogens as a result of genetic drift).

Response: According to the EPA Guidelines, 12 humans are assumed to be as sensitive to the agent as the most sensitive strains of animal species, unless there is knowledge otherwise. As a result, this allegedly possible change in sensitivity of the colony of mice maintained by Dr. Toth's laboratory would not alter the weight-of-evidence determination for UDMH.

Furthermore, there is no evidence from pathological data on the control animals evaluated in Dr. Toth's laboratory to suggest that any genetically enhanced susceptibility to spontaneous carcinogenesis (carcinogenesis that occurs without the intentional administration of a test substance) has occurred due to genetic drift. If there was such heightened sensitivity, then increased spontaneous carcinogenesis in the control animals would be expected to accompany any genetically enhanced susceptibility to exogenously induced carcinogenesis (carcinogenesis that occurs as the result of the administration of a test substance). The EPA audit of the Toth study did not reveal any increased rate of spontaneous carcinogenesis in the control animals maintained by Dr. Toth's laboratory compared to animals of the same species maintained by other laboratories and the supplier. This fact discredits Uniroyal's theory of inbreeding leading to enhanced susceptibility to carcinogenesis to exogenous carcinogens.

In addition, the rate of spontaneous carcinogenesis was seen to be identical for the control groups maintained by Dr. Toth's laboratory two years prior to the UDMH bioassay as at the same time as the UDMH bioassay. This further supports the conclusion that there was no genetic drift over time due to inbreeding or other factors in the animals tested.

Furthermore, the Swiss albino strain of mice used in the Toth study are highly susceptible to carcinogenesis. This facilitates the development of tumors over the short life span of this rodent species. As a result, any genetic drift that would occur in these mice is likely to lead to decreased sensitivity, not the other way around. Thus, the results of the Toth study are not compromised by any alleged enhanced sensitivity of the animals to carcinogens.

e. Uniroyal contended that another deficiency in the Toth study was a lack of suitable analytical verification of the test material during the study.

Response: The EPA auditors recognized that the overall analytical verification of the study did not conform to today's General Laboratory Practice standards, 13 but concluded that despite the deficiencies, there was no reason to doubt that the mice received the test substances (UDMH and Alar*) at the indicated dosage levels. The EPA auditors found, however, that the UDMH purchased from Aldrich Chemical Company had been analyzed for chemical composition by Aldrich. In addition, the auditors found that the UDMH mixed with water in known proportions were in fact analyzed for chemical composition, and that these were the mixtures that were administered to the animals in the Toth study.

The EPA auditors as well as CAG concluded that despite the uncertainties with the analytical method, there was no evidence to suggest that the UDMH/ water solutions did not contain the concentrations reported in the study. This is because even in the absence of analytical verification, laboratory methods for making solutions of known concentrations by the addition of accurately measured portions of a substance (UDMH in this instance) have historically been found to be capable of great accuracy, in the absence of any decomposition or other losses of the substance from the water. Any deterioration of the UDMH/water solutions, through hydrolysis or volatilization of the UDMH, would have resulted in decreased cancer rates, not the other way around.

In addition, even if the analysis of the UDMH obtained from Aldrich Chemical Company, the supplier, were inaccurate, as impliedly alleged by Uniroyal, it was known that Aldrich itself had analyzed the UDMH for purity. There is no evidence that the UDMH contained any toxic contaminants, or that any toxic contaminants were present in sufficient concentration or of sufficient potency to have confounded the observations of the carcinogenic effects of UDMH.

f. Uniroyal contended that even if the Toth study were valid, then the estimated risk from UDMH exposure was lower than the value derived by EPA, based on that study. The q₁* (carcinogenic potency) value of 8.66 (mg/kg/day) ⁻¹ was calculated using an observed carcinogenic response of 42 out of 50 mice by EPA. Uniroyal claimed, however, that only 25 of 48 mice were diagnosed as having blood vessel tumors, basing this contention on an audit performed for Uniroyal.¹⁴

¹⁰ U.S. EPA (September 24, 1986) Guidelines for Carcinogenic Risk Assessment, *ibid*.

¹¹ U.S. EPA, CAG (January 7, 1987), ibid.

² U.S. EPA (September 24, 1986). ibid.

¹³ U.S. EPA, OPP (April 22, 1985), ibid.

¹⁴ Vesselinovitch, S.D., Report to Uniroyal, Inc. (1984).

Response: EPA's audit 15 of the Toth study confirmed the tumor incidence found by Dr. Toth. In addition, CAG 18 has concluded that since the control animals lived longer [not suffering the acute toxic effects from UDMH that resulted in premature death, thus presumably having more time to develop tumors) the potency of UDMH as a carcinogen may even be underestimated using data from the Toth study. Moreover, even if the incidence of tumors was the lower rate contended by Uniroyal, that rate is still highly significant and would not alter the determination that UDMH is a category B2 carcinogenic.

g. Uniroyal expressed the position that EPA cannot list the UDMH manufacturing wastes as hazardous until the scientific validity of the carcinogenicity study conducted by Toth was ascertained or repeated. Uniroyal noted that EPA itself was currently conducting an audit of the Toth study as a result of comments on the study submitted by Uniroyal regarding proposed regulations under FIFRA, and suggested that EPA should take the results of this audit into account.

Response: The results of the EPA audit 17 referred to by Uniroyal became available after Uniroyal submitted its comments on the proposed UDMH listings. As discussed earlier, this audit, although acknowledging certain deficiencies in the Toth study, noted that the increases in the tumor incidences were so striking that even if the controls had been dropped from the study, it would not weaken the findings of the study in any regard. The audit team found that data obtained from missing pathology slides that were subsequently located further substantiated the tumor incidences stated in the publication by Dr. Toth. Thus, this audit does not provide any support for Uniroyal's position that the Toth study is invalid for performing a carcinogenic risk assessment.

2. Use of the Interim Results of Studies on UDMH Carcinogenicity Currently Being Conducted by Uniroyal

As part of its review of the pesticide manufactured from UDMH, Daminozide (Alar®), under the Re-registration Process under FIFRA, EPA required Uniroyal Corporation to conduct additional studies on the health effects of both UDMH AND Daminozide. Based on the interim results of the data submitted by Uniroyal, EPA proposed to cancel certain pesticide product registrations under FIFRA.18

On August 17, 1989, EPA announced its intent to use this new interim data developed by Uniroyal as part of the basis for listing wastes from the manufacture of UDMH as hazardous under RCRA, 19 since EPA believed that this data provided strong evidence that UDMH is a carcinogen. Uniroyal responded to the August 17, 1989 Notice of Data Availability with the following contentions that the data did not support a determination that UDMH was a probable human carcinogen. The specific challenges to the significance of these data for a carcinogenicity determination are given below.

a. Uniroyal claimed that the biological significance of the interim results of the UDMH and Daminozide study are questionable. For example, while positive tumorigenic results were seen in mice, no significant increases in tumor incidences were detected in any of the exposed groups of rats.

Response: The lack of detectable effects in rats cannot be construed as evidence for noncarcinogenicity. Only an extremely potent carcinogen would be expected to induce an increase in tumor incidence as early as 12 months from the start of exposure. In fact, the positive results seen in mice as early as 8 months, suggest that UDMH is not only a carcinogen, but a rather potent one. Furthermore, it is generally recognized that species may differ in sensitivity to an applied dose, so the interim results with rats is not inconsistent with this expectation.

b. Uniroyal argued that there was no increase in the number and severity of liver islands, as would be expected if an agent was a carcinogen.

Response: The liver is made up of liver cells called hepatocytes. In the liver island assay most of the liver is removed to stimulate rapid cell division among the remaining hepatocytes. Subsequent administration of a potentially carcinogenic agent may induce genetic changes resulting in the gain or loss of specific enzyme systems in the hepatocytes. Since the cells are rapidly dividing, one enzymatically altered cell will reproduce to form an "island" of similar cells. These islands can be made visible by differential staining techniques. The assay is regarded as a test for probable carcinogenicity since the enzymatic changes are considered by many investigators to be early steps in the

progression of cellular changes leading to cancer.

The tumors resulting from exposure to UDMH, however, occur in blood vessels. a different type of tissue than located in the liver. Thus, the lack of any increase or severity of the liver islands does not negate the carcinogenicity determination.

c. Uniroyal argued that since positive results were seen in mice only at 40 and 80 ppm, dosages that Uniroyal claims are clearly in excess of the maximum tolerated dose (MTD), any conclusions on the carcinogenicity of UDMH based on results from tests which exceeded the MTD are not valid.

Response: According to established Guidelines 20 using body weight gains, survival, etc., EPA believes that the MTD was not exceeded. Mortality that did occur during the first 12 months of exposure was considered by the EPA reviewers 21 to more likely be the result of cancer rather than liver necrosis. Since tumor increases were detected in intermediate dosed males as well as in females, in which the pathological effects and other toxic signs were minimal, the results are not considered to be invalidated by the alleged overdosage.

Even if the MTD was exceeded, the data can be used in assessing carcinogenicity according to EPA's risk assessment Guidelines, if the results are carefully reviewed to ensure that responses are not due to factors operating only at levels above MTD.22 These include effects such as metabolic activation at high concentrations and hormonal changes. There is little information to indicate that UDMH requires this type of activation, however, which would call into question the possibility that the observed effects were due to an exceedance of the MTD. In addition, there is also no data to indicate that important hormonal changes are taking place, another effect that could be caused if the MTD were exceeded.

The pathological changes in the liver would be of serious concern in evaluating whether the MTD had been exceeded if the liver itself was the primary target organ for the carcinogenic effects of UDMH. The possible genetic alterations with increased cell turnover rates resulting from the pathological changes could lead to tumor induction in some cases.

¹⁵ U.S. EPA. OPP [April 22, 1985], ibid.

¹⁶ U.S. EPA, CAG [January 7, 1987], ibid.

¹⁷ U.S. EPA. OPP (April 22, 1985), ibid.

^{18 54} FR 22558, May 24, 1989.

^{19 54} FR 33942.

²⁰ U.S. EPA (September 24, 1986), ibid.

²¹ U.S. EPA, OPP (May 15, 1989), Second Peer Review of Daminozide (Alar) and UDMH (Unsymmetrical 1.1-dimethylhydrazine).

²² U.S. EPA (September 24, 1986), ibid., pp. 1-5

UDMH, however induces tumors in blood vessels and not in the liver itself. As a result, the changes in the liver do not confound the observations of carcinogenic effects in other organs, the blood vessels.

Thus, EPA does not believe that the MTD was exceeded in the recent Uniroyal studies. Secondly, even if the MTD has been exceeded, EPA's careful review of the data has ascertained that the carcinogenic effects were independent of any physiological changes which could have been caused by an exceedance of the MTD. The results, therefore, still may be used to determine that UDMH is a carcinogen.

d. Uniroyal claimed that the carcinogenic effects were accompanied by a variety of hematological, liver enzyme and liver pathology changes that may well have been responsible for the tumor induction. Thus, the commenter contended that the tumors should not be considered to be the result of a carcinogenic effect of UDMH.

Response: The hematological, liver enzyme, and liver pathology changes are considered by EPA to be a result of tumor growth, and thus not responsible for their induction. In other words, these changes in the liver and blood are considered to be the result of the carcinogenic effects of UDMH, and not due to any direct action of UDMH by a toxicological mechanism unrelated to carcinogenesis. In addition, it should be noted that tumors were induced in females in which alterations of liver enzyme activity and hematological parameters were minimal. Finally, increased tumor incidences were also seen in the lungs, an organ showing few indications of pathological changes. Thus, the Agency does not agree that the observation of hematological and liver changes negates a conclusion that UDMH should be considered a causative agent for carcinogenesis.

e. In general, Uniroyal contended that the weight-of-evidence from the interim results of the studies on UDMH carcinogenicity did not support a determination that UDMH should be classified as a category "B2" carcinogen, a "probable human carcinogen."

Response: Given that significant increases in tumor incidences were seen at more than one site, in both sexes of mice, and to occur very early, and because the responses occurred in the lungs even at lower, relatively non-toxic doses, the newer, interim data is considered by the Agency to be consistent with the earlier data regarding the carcinogenicity of UDMH.

According to EPA's Guidelines for cancer risk assessment, a chemical is classified into category B2 when there is

sufficient evidence for carcinogenicity in animals, but insufficient data in humans. Sufficient evidence for carcinogenicity in animals occurs when there is an increased incidence of malignant or combined benign and malignant tumors (a) in multiple strains or species (b) in multiple experiments (e.g., with different dose levels) or (c) to an unusual degree in a single experiment. The interim results of the studies satisfy both categories "a" and "c" in that significant tumor increases occurred in both mice and hamsters and the response occurred to an unusual degree, e.g., 84 percent incidence of hemangiosarcomas in male mice. Thus, since human data is inadequate, while animal data is sufficient, UDMH is still considered to fit the classification weight-of-evidence category B2.

f. Uniroyal claimed that the interim data were also inadequate to establish a quantitative, or dose-response, risk estimate for UDMH.

Response: The Agency need not develop quantitative weight-of-evidence for a potential carcinogen as a necessary basis for a determination that a toxicant of concern or wastes containing that toxicant should be regulated as hazardous under RCRA. The available study on UDMH does indicate that it is a potent carcinogen. The final studies on UDMH carcinogenicity to be submitted to EPA in the future are not likely to alter this evaluation.

g. Uniroyal also claimed that the results from the interim studies being conducted by Uniroyal demonstrated that UDMH was not mutagenic.

Response: A total of 5 mutagenicity studies were submitted by Uniroyal to EPA during 1989 as part of the interim results on UDMH oncogenicity. The following three tests were considered to be negative and acceptable: (1) The Ames Salmonella test, (2) unscheduled DNA synthesis, and (3) primary rat hepatocyte and CHO/aberration. The use of an unusual solvent (0.25 Normal hydrochloric acid) in these tests, however, limits the use of the results of these tests to predict mutagenesis that may occur under more usual test conditions.

Two CHO/hprt gene mutation assays have also been submitted by Uniroyal, one using the hydrochloric acid solvent. In the second, an attempt was made to buffer the solution. In these latter two studies there were enough instances of elevated frequencies to suggest that there may be mutagenic activity. Taken as a whole, therefore, the results must be considered to be equivocal, rather than negative.

The interim results of the mutagenicity studies being conducted by Uniroyal also do not call into question the validity of the earlier UDMH tests that were positive for mutagenicity, since the conditions used by Uniroyal differed from those in earlier tests. The positive results of earlier mutagenicity studies are discussed in the background documentation for this final rule as well as in the May, 1988 technical support document developed by EPA as part of the FIFRA reregistration review of Alar.²³

In summary, after carefully evaluating the comments, the Agency believes that the available evidence supports a determination that UDMH is carcinogenic, mutagenic, and teratogenic.

C. Additional Waste Streams

The commenter, the generator of the four wastes covered by today's rulemaking, supplied information on the generation of two additional wastestreams, both having the potential for significant UDMH contamination. As a result of this new information, the Agency, in an accompanying action in today's Federal Register, is proposing to add two additional waste streams from the manufacture of UDMH from carboxylic acid hydrazides to the list of hazardous wastes.

V. Relation to Other Regulations

A. Toxicity Characteristics (TC)

As one of the mandates of HSWA, the Agency expanded the toxicity characteristics (TC) by including additional toxic organic chemicals. Under the March 29, 1990 final rule (55 FR 11796), hazardous waste listings will not be affected by the toxicity characteristic-that is, all the listings will remain in effect, including those listings that were based on the presence of TC constituents. It is EPA's intention that the hazardous waste listings will continue to complement the TC. Although the TC currently does not include UDMH as a toxicity characteristic contaminant, any future addition of UDMH to the TC may capture other wastes contaminated by UDMH that are not covered by wastes K107, K108, K109 and K11O. In addition, the recently promulgated TC may capture other wastes generated by the UDMH manufacturing industry that contain the current toxicity characteristic contaminants that are not covered by wastes K107, K108, K109 and K110.

²³ U.S. EPA. OPP (May, 1989). ibid.

B. Land Disposal Restrictions

HSWA mandated that EPA promulgate under a specific schedule land disposal restrictions for all wastes listed or identified as hazardous prior to the enactment of HSWA (see RCRA section 3004(g)(4)(C)). HSWA also requires the Agency to make a land disposal prohibition determination for any hazardous waste that is newly identified or listed after November 8, 1984, within six months of the date of identification or listing (RCRA section 3004(g)(4), 42 U.S.C. 6924(g)(4)). However, the statute does not provide for an automatic prohibition of the land disposal of such wastes if EPA fails to meet this deadline. The Agency is evaluating treatment standards for newly listed wastes K107, K108, K109, and K110.

VI. Test Methods to Be Added to Appendix III

Appendix III of 40 CFR part 261 is a list of test methods that are approved for use in demonstrating that the constituents of concern in listed wastes are not present at concentrations of concern. The Agency is designating Method 8250 for testing for UDMH, and is adding this method to Appendix III of part 261. The proposed regulation proposed the use of Method 8250 for testing for UDMH in the wastes (49 FR 49556); no comments were received regarding the use of this method for this purpose. Method 8270 is also believed to be a suitable method since most commercial laboratories now prefer to use the capillary column chromatography specified in this method to improve the chromatographic resolution. The only difference between these two methods is the use of a capillary column gas chromatography technique instead of a packed column technique.

Persons wishing to submit delisting petitions must use one of these methods (or an equivalent one) to demonstrate the concentration of UDMH in their wastes. ²⁴ (See 40 CFR 260.22(d)(1).) As part of their petitions, EPA requests submission of quality control data demonstrating that the methods they have used yield acceptable recovery (i.e., >80% recovery at concentrations above 1 µg/g) on spiked aliquots of their waste.

The above methods are in "Test Methods for Evaluating Solid Waste: Physical/Chemical Methods," SW-846,

24 Petitioners may use other methods to analyze for UDMH if, among other things, they demonstrate the equivalency of these methods by submitting their quality control and assurance information along with their analysis data. (See 40 CFR 260.21.) 3rd Ed., as updated, available from: Superintendent of Documents, Government Printing Office, Washington, DC 20402, (202) 783–3238, Document Number: 055–002–81001–2.

VII. CERCLA Impacts

All listed hazardous wastes, as well as any solid waste that exhibits one or more of the characteristics of a hazardous waste (as defined in 40 CFR 261.21 through 261.24), are hazardous substances under section 101(14)(C) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). (CERCLA hazardous substances are listed in Table 302.4 at 40 CFR 302.4. along with their reportable quantities (RQs).) CERCLA section 103(a) requires that persons in charge of vessels or facilities from which a hazardous substance has been released in a quantity that is equal to or greater than its RQ immediately notify the National Response Center of the release [at [800] 424-8802 or in the Washington, DC metropolitan area at (202) 426-2675]. In addition, section 304 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) requires the owner or operator of a facility to report the release of a hazardous substance to the appropriate state emergency response commission (SERC) and to the local emergency planning committee (LEPC) when the amount released equals or exceeds the RQ for the substance.

According to the "mixture rule" used for notification under CERCLA and SARA (50 FR 13463, April 4, 1985), the release of mixtures must be reported when the amount released equals or exceeds the RQ for the waste, unless the concentrations of the constituents of the waste are known. When the concentrations of the individual constituents of a hazardous waste are known, the release of the hazardous waste would need to be reported to the NRC and to the appropriate LEPC and SERC when the RQ of any of the hazardous constituents is equaled or exceeded. RQs of different hazardous substances are not additive under the mixture rule (except for radionuclides, see 54 FR 22536, May 24, 1989), so that spilling a mixture containing half an RQ of one hazardous substance and half an RQ of another hazardous substance does not require a report.

Under Section 102 of CERCLA, all hazardous wastes newly designated under RCRA will have a statutorily-imposed RQ of one pound unless and until adjusted by regulation under CERCLA. In order to coordinate the RCRA and CERCLA rulemaking with respect to new waste listings, the

Agency also proposed on December 20, 1984 regulatory amendments under CERCLA authority in connection with the proposed listings to: (1) Designate wastes K107 to K110 based on the hazardous substances under section 102 of CERCLA; and (2) adjust the RQs of wastes Kl07 to K110 based on the application of the RQ adjustment methodology under section 102(a) (49 FR 49556).

The RQs for each waste and for each of the hazardous constituents are identified in the table below. The constituent of concern, UDMH, has an RQ that has undergone adjustment since the proposed listing of UDMH production wastes. On August 14, 1989, EPA adjusted the RQ for UDMH from one pound to 10 pounds (54 FR 33426).

The adjustment of the RQs of wastes K107, K108, K109 and K110 from the statutory one-pound level is based on the current RQ of the constituent in these listings. Because the only toxic constituent of concern in the wastes (UDMH) has an RQ of 10 pounds, the RQs of the four wastes likewise are being set today as 10 pounds. These RQs will become effective on the effective date of today's action, when the wastes simultaneously become hazardous substances under CERCLA.

Hazardous substance	Con- stituent	RQ		
Waste No. K107	THE RESERVE OF THE PERSON NAMED IN	The second second		
Waste No. K108	UDMH	Chicago Indiana		
Waste No. K109	UDMH	The state of the s		
	UDMH	10 lbs.		
Waste No. K110	UDMH			

VIII. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR part 271 for the standards and requirements for authorization.) Following authorization, EPA retains enforcement authority under sections 3007, 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in the State that the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obliged to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time that they take effect in nonauthorized States. EPA is directed to implement those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

Today's rule is promulgated pursuant to section 3001(e)(2) of RCRA, a provision added by the HSWA. Therefore, these wastes have been added to Table 1 in 40 CFR 271.1(j). which identifies the Federal program requirements that are promulgated pursuant to HSWA, and that take effect in all States, regardless of their authorization status. States may apply for either interim or final authorization for the HSWA provisions identified in Table 1, as discussed in the following section of this preamble. Because EPA promulgated rules regarding the timing for HSWA listings after this rule was proposed, the existing regulatory time frames supersede the discussions in the preamble to the proposed rule.

B. Effect on State Authorizations

As noted above, EPA will implement today's rule in authorized States until they modify their programs to adopt these rules, and the modification is approved by EPA. Because the rule is promulgated pursuant to HSWA, a State submitting a program modification may apply to receive either interim or final authorization under section 3006(g)(2) or 3006(b), respectively, on the basis of regulations that are substantially equivalent or equivalent to EPA's. The procedures and schedule for State program modifications under section 3006(b) are described in 40 CFR 271.21. The same procedures should be followed for section 3006(g)(2).

Section 271.21(e)(2) requires that States that have final authorization must modify their programs to reflect Federal program changes and must subsequently submit the modifications to EPA for approval. State program modifications to conform to today's rule must be made by July 1, 1991, if only regulatory changes are necessary, or by July 1, 1992, if statutory changes are necessary. See 40 CFR 271.21(e)(2)(iv) and 271.21(e)(2)(v). These deadlines can be extended in exceptional cases. See 40 CFR 271.21(e)(3).

States with authorized RCRA programs already may have regulations similar to those in today's rule. These State regulations have not been assessed against the Federal regulations being promulgated today to determine whether they meet the tests for authorization. Thus, a State is not authorized to implement these regulations in lieu of EPA until the State program modification is approved. Of course, States with existing regulations may continue to administer and enforce their regulations as a matter of State law. In implementing the Federal program, EPA will work with States under cooperative agreements to minimize duplication of efforts. In many cases, EPA will be able to defer to the States in their efforts to implement their programs, rather than take separate actions under Federal authority.

States that submit official applications for final authorization less than 12 months after the effective date of these regulations are not required to include standards equivalent to these standards in their applications. However, a State must modify its program by the deadlines set forth in 40 CFR 271.21[e]. States that submit official applications for final authorization 12 months after the effective date of these standards must include standards in their application. Section 271.3 sets forth the requirements a State must meet when submitting its final authorization

application.

IX. Compliance Dates

A. Notification

Under section 3010 of RCRA, EPA may waive the notification requirement otherwise applicable to persons managing newly-regulated hazardous waste. The Agency has decided to waive the RCRA section 3010 notification requirement for only those persons who generate, transport, treat, store, or dispose of hazardous wastes subject to today's rule that have previously notified EPA or an authorized State of hazardous waste activities and have received an identification number. The Agency believes that most, if not all, persons who manage these wastes have already notified EPA and received an EPA identification number and therefore will not have to re-notify.

However, any person who generates, transports, treats, stores, or disposes of these wastes has not previously notified and received an identification number, that person must notify EPA or an authorized State no later than July 31, 1990, of these activities pursuant to section 3010 of RCRA. Notification instructions are set forth in 45 FR 12746, February 26, 1980.

B. Permitting

Because HSWA requirements are applicable in authorized States at the same time as in unauthorized States. EPA will regulate K107-K110 until States are authorized to regulate these wastes. Thus, once this regulation becomes effective, EPA will apply Federal regulations to these wastes and to their management in both authorized and unauthorized States. Facilities that treat, store, or dispose of K107-K110, but that have not received a permit pursuant to section 3005 of RCRA and are not operating pursuant to interim status, might be eligible for interim status under HSWA (see section 3005(e)(1)(A)(ii) of RCRA, as amended). In order to operate pursuant to interim status, the eligible facilities are required to possess an EPA ID number pursuant to 40 CFR 270.70(a). and will be required to submit a Part A permit application by November 2, 1990.

Currently permitted facilities that manage UDMH wastes must submit Class I permit modifications if they are to continue managing the newly regulated wastes in units that require a permit. The facilities must obtain the necessary modification by the effective date of the rule, or they will be prohibited from accepting additional UDMH wastes.

Interim status facilities that manage UDMH wastes in units that require a permit must file an amended Part A permit application under 40 CFR 270.10(g) if they are to continue managing newly regulated wastes. The facilities must file the necessary amendments by the effective date of the rule, or they will not receive interim status with respect to the UDMH wastes (i.e., they will be prohibited from accepting additional UDMH wastes until permitted).

Newly regulated facilities (i.e., facilities at which the only hazardous wastes that are managed are newly regulated UDMH wastes) must qualify for interim status by the compliance date of the rule in order to continue managing UDMH wastes prior to receiving a permit. Under 40 CFR 270.70, an existing facility may obtain interim status by getting an EPA identification number and submitting a Part A permit

application by the effective date of this rule. To retain interim status, a newlyregulated land disposal facility must submit a Part B permit application within one year after the effective date of the rule and certify that the facility is in compliance with all applicable ground water monitoring and financial responsibility requirements (see RCRA section 3005(e)(3)).

EPA recently promulgated amendments to the procedures for permit modifications for treatment, storage, and disposal facilities (see 53 FR 37934, September 28, 1988). The following discussion assumes implementation in accordance with the new rule. EPA will implement the UDMH listing regulations by using the new permit modification procedures, consistent with EPA policy (see 53 FR

37933, September 28, 1988).

Under the new regulation in 40 CFR 270.42, there are now three classes of permit modifications with different submittal and public participation requirements for each class. In 40 CFR 270.42(g), which concerns newly listed or identified wastes, a permitted facility that is "in existence" as a hazardous waste facility for the newly listed or identified waste on the effective date of the notice must submit a Class 1 modification by that date. Essentially, this modification is a notification to the Agency that the facility is handling the waste. As part of the procedure, the permittee must also notify the public within 90 days of submittal to the

Next, within 180 days of the effective date, the permittee must submit a Class 2 or 3 modification to the Agency. A permittee may submit a Class 2 modification if the newly regulated waste will be disposed in existing TSD units and will not require additional or different management practices from those authorized in the permit. A Class 1 modification requires public notice by the facility owner of the modification request, a 60 day public comment period, and an informal meeting between the owner and the public within the 60 day period. The rule includes a "default provision," so that for Class 1 modifications, if the Agency does not make a decision within 120 days, the modification is automatically authorized for 180 days. If the Agency does not reach a decision by the end of that period, the modification is permanently authorized. If the newly regulated waste requires additional or different management practices, a Class 3 modification is required. The initial public notification and public meeting requirements are the same as for Class

2. However, after the end of the public comment period, the Agency will develop a draft permit modification, open a public comment period of 45 days and hold a public hearing.

X. Regulatory Impact Analysis

Under Executive Order 12291, EPA must determine whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. The generator subject to today's rule, Uniroyal Corporation, is not currently manufacturing UDMH. As a result, none of the wastes covered by this final regulation are currently being generated, and therefore no costs from their management as hazardous would be incurred at the present time.

However, Uniroyal may resume production; when this occurs the total additional incurred cost for disposal of the wastes as hazardous would be less than \$2,000 (based on previous production levels), well under the \$100 million constituting a major regulation. This cost would be insignificant and would result from minimal additional compliance requirements, as these wastes were already handled as if they

were hazardous.

Since EPA does not expect that the amendments promulgated here will have an annual effect on the economy of \$100 million or more, result in a measurable increase in cost or prices, or have an adverse impact on the ability of U.S.based enterprises to compete in either domestic or foreign markets, these amendments are not considered to constitute a major action. As such, a Regulatory Impact Analysis is not required.

The Agency received comments on the economic impact analysis included with the December 20, 1984 proposed regulations. Uniroyal criticized the Agency's economic analysis because it did not consider the impact of codisposal of the aqueous wastes with other plant wastes by deep well injection. Uniroyal contended that in the event that the subject hazardous wastes are mixed with other solid wastes, the resulting mixture would be hazardous wastes by the mixture rule (see 40 CFR 261.3(a)(2)(iii)).

Because the commenter ceased underground injection of their UDMH manufacturing wastes in May, 1985 (because of having ceased the production of UDMH itself), long before promulgation of today's rule, the commenter will not be subject to the permitting requirements of parts 144 and 146 for Class 1 wells receiving hazardous wastes (assuming no other hazardous wastes are being injected). As a result, no additional management costs would

be incurred by a designation as hazardous wastes formerly disposed in this manner. The commenter would still be required to comply with the parts 144 and 146 requirements for Class 1 wells for the disposal of non-hazardous industrial wastes, however, if the deep well continues to receive other wastes from the facility not regulated as hazardous under RCRA.

XI. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. sections 601-612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the impact of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). No regulatory flexibility analysis is required, however, if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The hazardous wastes listed here are not generated by small entities (as defined by the Regulatory Flexibility Act), and the Agency received no comments that small entities will dispose of them in significant quantities. Accordingly, I hereby certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

XII. Paperwork Reduction Act

This rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. section 3501 et seq.

List of Subjects

40 CFR Part 261

Hazardous waste, Recycling.

40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands. Intergovernmental relations, Penalties, Reporting and recordkeeping requirements. Water pollution control. Water supply.

40 CFR Part 302

Air pollution control, Chemicals, Hazardous materials, Hazardous materials transportation, Hazardous substances, Intergovernmental relations. Natural resources, Nuclear materials,

Pesticides and pests, Radioactive materials, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control.

Dated: April 23, 1990. William K. Reilly,

Administrator.

For the reasons set out in the preamble, Title 40 of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

2. In § 261.32, add the following waste streams to the subgroup 'Organic Chemicals':

§ 261.32 Hazardous wastes from specific sources.

Industry and EPA. Hazardous waste hazardous waste				aste				
				to be being				
ganic chemicals:	3. O de la			OF STATE OF				
K107		dumn bottoms from	product separation	from the production	of 1,1-dimethyl-hy	drazine (UDMH) fro	om carboxylic acid	(C,T)
K108	Co			t separation and con	densed reactor ve	ent gases from the	production of 1,1-	(1,7)
K109	Sr			ion from the production	on of 1,1-dimethyll	hydrazine (UDMH) fr	om carboxylic acid	(II)
K110	Co			ediate separation from	n the production	of 1,1-dimethylhydra	zine (UDMH) from	m
		- William - William -					The second	

 Add the following compound and analysis methods in alphabetical order to Table 1 of Appendix III of part 261:

Appendix III—Chemical Analysis Test Methods

TABLE 1.—ANALYSIS METHODS FOR OR-GANIC CHEMICALS CONTAINED IN SW-846

	Composito			No.
1,1-Dimethy	lhydrazine	e (UDMH)		8250

Method

 Add the following entries in numerical order to Appendix VII of part 261:

Appendix VII—Basis for Listing Hazardous Waste

EPA hazardous waste No.	Hazardous constituents for which lis					
	*					
K107	1,1-Dim	ethylhydra	zine (UDM	IH).		
K108	1,1-Dim	ethylhydra	zine (UDM	H).		
K109	1,1-Dim	ethylhydra	zine (UDM	H).		
K110	1,1-Dim	ethylhydra	zine (UDM	H).		
1			10.1			

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

5. The authority citation for part 271 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), and 6926.

 Section 271.1(j) is amended by adding the following entry to Table 1 in chronological order by date of publication:

§ 271.1 Purpose and scope.

(j) * * *

TABLE 1.—REGULATIONS IMPLEMENTING THE HAZARDOUS AND SOLID WASTE AMENDMENTS OF 1984

Promulgation date			Effective date	
May 1, 1990	Listing Wastes from the Production of UDMH from Carboxylic Acid Hydrazides	[insert Federal Register page numbers].	November 2, 1990.	
		A SHOW		

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

7. The authority citiation for part 302 continues to read as follows:

Authority: Secs. 101(1)(14) and 102(b) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 U.S.C. 9601(14) and 9602; secs. 311 and 501(a) of the Federal Water Pollution Control Act. 33 U.S.C. 1321 and 1361.

8. Section 302.4 is amended by adding the waste streams K107, K108, K109, and K110 to Table 302.4.

§ 302.4 Designation of hazardous substances.

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

	UMORIV	Married and		Statutory		Final RQ	
Hazardous substance		Regulatory synonyms	RQ	Code	RCRA waste num- ber	Category	Pounds (kg)
K107	THE REAL PROPERTY.			-	-		TRUE !
Column bottoms from product separation from the production of 1,1-dimethylhy- drazine (UDMH) from carboxylic acid hydrazines.			10	4	K107	×	10 (4.54)
K108			10	4	K108	x	10 (4.54)
K109			10	4	K109	x	10 (4.54)
Spent filter cartridges from product purification from the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazides.	100	A STATE OF THE PARTY OF			State of		
Condensed column overheads from intermediate separation from the production of 1,1-dimethylhydrazine (UDMH) from carboxylic acid hydrazides.			10	4	K110	X	10 (4.54)

^{1.4—}indicates that the statutory source for designation of this hazardous substance under CERCLA is RCRA section 3001.

[FR Doc. 90-9978 Filed 5-1-90; 8:45 am] BILLING CODE 6560-50-M