REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See Instructions on reverse)

TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

LEAVE BLANK (NARA use only)

JOB NUMBER: N1-412-01-6

DATE RECEIVED: 11-13-2000

1 FROM (Agency or establishment)
Environmental Protection Agency

2. MAJOR SUBDIVISION
Office of Prevention, Pesticides, and Toxic Substances

3. MINOR SUBDIVISION
Office of Pollution Prevention and Toxics

4. NAME OF PERSON WITH WHOM TO CONFER
Chris O'Donnell

5. TELEPHONE
202-260-1324

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U S C 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.

DATE: 9-26-01

ARCHIVIST OF THE UNITED STATES: John W. Carlin

6. AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached 4 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

[X] is not required; [ ] is attached; or [ ] has been requested.

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
11/2/00	Chris O'Donnell	Agency Records Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
	See attached schedule U.S. EPA 296 - TSCA Section 5 Biotechnology Files		

cc: NWMD, Agency

DRAFT OF 12/1/00

U.S. EPA RECORDS SCHEDULE

SERIES TITLE: TSCA Section 5 Biotechnology Files

PROGRAM: Toxic Substances

EPA SERIES NO: 296

AGENCY FILE CODE: TOXI 296

NARA DISPOSAL AUTHORITY: N1-412-01-6
(Use this number to retire records to the FRC)

APPLICABILITY: Headquarters

IDENTIFYING INFORMATION:

DESCRIPTION: Records document the review and approval process of genetically modified, viable microorganisms prior to importation or manufacture in the U.S. A typical file could include meeting summaries, reports and internally generated documents, Pre-Notice Consultations Notes/Summaries/Correspondence; Biotech Hazard Screening Team Meeting (BHST); Initiation Meeting; 5(d)2 (Federal Register) Notice; Chemistry Report; Focus Meeting; Mid-Course Meeting; Initial Integrated Risk Assessment; Biotechnology Scientific Advisory Committee Report; HERD, EETD, and CCD Disposition Meetings; Final Integrated Risk Assessment; Inventory Report; Division Director's Briefing Paper and Summary; Evaluation Meeting; Letter to Submitter; Draft and Final 5(e) Consent Orders; Notice of Commencement; Staff Telephone Conversation Logs and public comments.

ARRANGEMENT: Arranged numerically by parent number.

TYPE OF RECORDS:
Case files

SPECIFIC RESTRICTIONS:
Confidential Business Information
Enforcement Sensitive Information

MEDIUM:
Paper, microfilm, electronic

VITAL RECORD:
Yes

FUNCTIONS SUPPORTED:
Regulatory development and public access

SPECIFIC LEGAL REQUIREMENTS:
Toxic Substances Control Act, as amended, Section 5
40 CFR, Parts 720

EPA SERIES NO. 296

DISPOSITION INFORMATION:

FINAL DISPOSITION:	**TRANSFER TO FRC PERMITTED:**
a. Promulgation of Final Rule (microformed or paper): Permanent	Yes
b. Pending Promulgation of Final Rule (microformed or paper): Permanent	Yes
c. Paper copy (microformed): Disposable	No
d. Electronic versions created with electronic mail and word processing systems: Disposable	No

FILE BREAK INSTRUCTIONS:

a. If microformed, break file upon completion of microform quality assurance check. If not microformed, break file after mandated Agency review period or other decision.

b. If microformed, break file upon completion of quality assurance check. If not microformed, break file up to 1 year following promulgation of final rule.

c. Break file when quality assurance check is completed.

d. See disposition instructions.

DISPOSITION INSTRUCTIONS:

a and b. If microformed, keep in office up to 1 year after file break, then retire one silver master and one diazo copy along with finding aids and indexes to the FRC. Transfer to the National Archives 20 years after file break. Retain up to 2 microform copies for office use; destroy copies when no longer needed.

If not microformed, keep in office up to 1 year after file break, then retire to FRC along with finding aids and indexes. Transfer to the National Archives 20 years after file break. Destroy copies when no longer needed.

c. Destroy paper after completion of quality assurance check.

d. Delete when record copy is generated.

APPLICATION GUIDANCE:

REASONS FOR DISPOSITION: The Biotechnology Program is currently operating under the 1986 Statement of Interim which requires the review of certain types of genetically modified, viable microorganisms prior to importation or manufacture for commercial purposes in the U.S. Under Section 5 of TSCA, the review process associated with Biotech submissions are subjected to reviews that are similar in purpose but requirements are different from those to which chemical substances are subjected. (TSCA Section 5 New Chemical Files are scheduled separately as EPA Series No. 261.) The review cycle associated with

the Biotech Premanufacture Notice is totally different from the PMN submitted for the review of a chemical prior to manufacture.

The Biotech PMN and the Section 5 PMN are governed by the same legal and administrative requirements. The final disposition for the Section 5 PMN is permanent, therefore permanent disposition for BioTech documentation is also required.

AGENCY-WIDE GUIDANCE: The official records are maintained by CBIC, NCIC and the program office.
The collection of records which support program decisions regarding the approval and disapproval of genetically modified, viable microorganisms prior to their importation or manufacture for commercial purposes are governed by this schedule. The records associated with the Biotechnology rulemaking docket are to be dispositioned under EPA 149 - Regulations, Standards, and Guidelines and EPA 150 - Rulemaking Dockets. Paper records which are electronically imaged must be dispositioned in accordance with EPA 270 - OPPT Image Processing System.

Microform copies are to be produced in accordance with standards in 36 CFR 1230.10 and 1230.20. If records are not filmed, use disposition a for paper records.

PROGRAM OFFICE GUIDANCE/DESCRIPTIVE INFORMATION: Due to the nature of the Section 5 Biotech process, the decision documents vary. Based on routine processing, file breaks could occur up to 60 days following each document's mandated review period or other Agency decision.

The review periods are as follows:

PMN	90 days
MCAN*	90 days
NOC	date of receipt
Bona fide	30 days
TMEA	45 days
LVE	21 days
SNUN	90 days
Tiered exemptions	45 days
TERA**	60 days

Agency regulatory decisions include:

Revocation of 5(e) order
Focus Drop
Foundon Inventory
Invalid
Disposition Drop
Division Director's Drop
5(e) Consent Order
5(e) Adversarial Order
Incomplete
Excluded from Reporting

EPA SERIES NO. 296

5(f) Order/Rule
Exemption Grants
Exemption Conditionally Granted
Denial

*MCAN - Microbial Commercial Activity Notice - This submission is proposed for use for microorganisms in lieu of PMN following promulgation of the final rule.

**TERA, TSCA Experimental Release Application - This is a completely new type of submission which is specific for biotechnology products which are intended to be tested in the environment.

All records, regardless of media, claimed as confidential business information (CBI) under Section 14 of the Toxic Substances Control Act (TSCA) must be handled in accordance with the 1993 edition of TSCA Confidential Business Information Security Manual.

At close out of the file, all records held by all offices should be retired at the same time. However, the program office may retain a closed file should it be determined that it would be needed for additional information or continuity regarding a related matter. All reference copies can be destroyed when no longer needed to support program operations.

CUSTODIAL INFORMATION:

CONTROLLING UNIT:

Name: OPPTS/OPPT

Location: WSM, NCIC/CBIC

Inclusive Dates: 1985-present

Volume on Hand (Feet):
paper - 33 ft.

Annual Accumulation:
(feet or inches) paper - 3 ft.

CONTACT POINT:

Name: Vanessa Williams

Mail Code: 7407

Telephone: 202-260-3554

Office: IMD/RMB

Room: 725 ET

CONTROL INFORMATION:

RELATED ITEMS: EPA 149, EPA 150, EPA 261

PREVIOUSLY APPROVED BY NARA SCHEDULE NOS:

Approval Date EPA	Approval Date NARA	Entry Date	Last Modified
11/2/00		8/2/94	12/1/00