

REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER <i>N1-412-07-27</i>	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		DATE RECEIVED <i>1-8-2007</i>	
1. FROM (Agency or establishment) U.S. Environmental Protection Agency		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 Adisposition not approved or Awithdrawn in column 10.	
2. MAJOR SUBDIVISION Toxic Substances			
3. MINOR SUBDIVISION Headquarters			
4. NAME OF PERSON WITH WHOM TO CONFER John B. Ellis	5. TELEPHONE 202-566-1643	DATE <i>2/11/08</i>	ARCHIVIST OF THE UNITED STATES <i>Ann W. ...</i>
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 <u>3</u> 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, <input checked="" type="checkbox"/> is not required; <input type="checkbox"/> is attached; or <input type="checkbox"/> has been requested.			
DATE <i>12/11/06</i>	SIGNATURE OF AGENCY REPRESENTATIVE John B. Ellis <i>John B. Ellis</i>	TITLE 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 GRS OR SUPERSEDED JOB CITATION	10.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)

TSCA Section 5 Biotechnology Files

N1-412-01-6

re 3/9/08 copies sent to agency, NWML, NWME, NWML, & NR

This schedule is in draft. It may be used to retire records, but may not be used to destroy records. If you have any questions, please contact the Records Help Desk.

EPA Records Schedule 296

Status: Draft, 01/31/2008

Title: TSCA Section 5 Biotechnology Files

Program: Toxic Substances

Applicability: Headquarters

Function: 108-025-06-02 - Manage Toxic Substances

NARA Disposal Authority:

This schedule authorizes the disposition of the record copy in any media (media neutral), excluding any records already in electronic form. Records designated for permanent retention must be transferred to the National Archives in accordance with NARA standards at the time of transfer.

- N1-412-07-27

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; RAD, 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.

Disposition Instructions:

Item a(1): Promulgation of final rule - Nonelectronic

- **Permanent**
- Close inactive records after mandated Agency review period or other decision.
- Transfer to the National Archives 20 years after file closure. If microform, destroy paper after quality assurance is completed.

Item a(2): Promulgation of final rule - Electronic

- **Permanent**

- Close inactive records after mandated Agency review period or other decision.
- Transfer to the National Archives 5 years after file closure, with any related documentation and external finding aids, as specified in 36 CFR 1228.270 or standards applicable at the time.

~~Item b(2): Promulgation of final rule - Electronic copy of records transferred to the National Archives~~

- **Disposable**
- Close file upon transfer to the National Archives.
- Delete after electronic record copy is successfully transferred to the National Archives.

Non-record copy

Item b(1): Pending promulgation of final rule - Nonelectronic

- **Permanent**
- Close inactive records up to 1 year following promulgation of final rule.
- Transfer to the National Archives 20 years after file closure. If microform, destroy paper after quality assurance is completed.

Item b(2): Pending promulgation of final rule - Electronic

- **Permanent**
- Close inactive records up to 1 year following promulgation of final rule.
- Transfer to the National Archives 5 years after file closure, with any related documentation and external finding aids, as specified in 36 CFR 1228.270 or standards applicable at the time.

~~Item b(3): Pending promulgation of final rule - Electronic copy of records transferred to the National Archives~~

- **Disposable**
- Close file upon transfer to the National Archives.
- Delete after electronic copy is successfully transferred to the National Archives.

Non-record copy

Guidance:

The official records are maintained by CBIC, NCIC and the program office.

The collection of records that 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 biotechnology rulemaking docket are to be retained under EPA 149 for regulations, standards, and guidelines and EPA 150 for dockets. The program office is responsible for maintenance and disposition of sensitive information not included in the

NCIC files.

Microform copies are to be produced in accordance with standards in 36 CFR 1230.10 and 1230.20.

Due to the nature of the Section 5 biotech process, the decision documents vary. Based on routine processing, file closures 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, 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.

Specific legal citations include:

- Toxic Substances Control Act, as amended, Sec. 5
- 40 CFR Part 725

Reasons for Disposition:

The disposition instructions have been rewritten as media neutral to allow for maintaining the record copy in EPA's recordkeeping system. Item c for microformed paper copy was deleted and incorporated into items a and b. The retention of the record copy is unchanged.

The following changes were made in the 01/31/2008 version:

- Divided items a and b into three subitems, a(1)-(3) and b(1)-(3).
- Revised the titles of disposition items a(1)-(3) and b(1)-(3).
- Revised the disposition instructions for items a(3) and b(3).

Item d for electronic copies created with word processing and electronic mail applications deleted 08/18/2006 pursuant to NARA Bulletin 2006-04.

Custodians:

Office of Prevention, Pesticides, and Toxic Substances, Chemical Control Division

- **Contact:** Jim Alwood
- **Telephone:** 202-564-8974

Related Schedules:

EPA 149, EPA 150, EPA 261

Previous NARA Disposal Authority:

N1-412-01-6

Entry: 08/02/1994

EPA Approval: 12/19/2006

NARA Approval: Pending