

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NATIONAL BEEF PACKING COMPANY, LLC,
Petitioner

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.,
Patent Owner

Case No. IPR2024-00183
Patent No. 7,534,584 C1

Case No. IPR2024-00185
Patent No. 8,822,143 B2

Case No. IPR2024-00186
Patent No. 9,637,771 B2

DECLARATION OF JAMES L. MULLINS, PH.D.

TABLE OF CONTENTS

I.	INTRODUCTION.....	6
II.	QUALIFICATIONS	6
III.	LEGAL STANDARDS.....	9
IV.	BACKGROUND.....	11
V.	DOCUMENTS	17
A.	Exhibit 1012 – ICMSF 2002.....	17
1.	Authenticity of ICMSF 2002.....	18
2.	Public Accessibility of ICMSF 2002.....	20
3.	Conclusion Re ICMSF 2002.....	23
B.	Exhibit 1013 – ICMSF 1986.....	23
1.	Authenticity of ICMSF 1986.....	23
2.	Public Accessibility of ICMSF 1986.....	26
3.	Conclusion Re ICMSF 1986.....	29
C.	Exhibit 1014 – Gombas	29
1.	Authenticity of Gombas.....	30
2.	Public Accessibility of Gombas	32
3.	Conclusion Re Gombas	34
D.	Exhibit 1015 – Hughes 1999.....	35
1.	Authenticity of Hughes 1999.....	35
2.	Public Accessibility of Hughes 1999.....	37
3.	Conclusion Re Hughes 1999	41
E.	Exhibit 1016 – Hughes 2003.....	41

1.	Authenticity of Hughes 2003.....	42
2.	Public Accessibility of Hughes 2003.....	44
3.	Conclusion Re Hughes 2003	47
F.	Exhibit 1017 – Price.....	48
1.	Authenticity of Price.....	48
2.	Public Accessibility of Price.....	50
3.	Conclusion Re Price	53
G.	Exhibit 1018 – Stewart.....	53
1.	Authenticity of Stewart.....	54
2.	Public Accessibility of Stewart.....	56
3.	Conclusion Re Stewart	59
H.	Exhibit 1019 – Fratamico.....	60
1.	Authenticity of Fratamico.....	60
2.	Public Accessibility of Fratamico.....	63
3.	Conclusion Re Fratamico	66
I.	Exhibit 1020 – D’Haese.....	66
1.	Authenticity of D’Haese.....	67
2.	Public Accessibility of D’Haese.....	69
3.	Conclusion Re D’Haese.....	72
J.	Exhibit 1021 – D’Aoust.....	72
1.	Authenticity of D’Aoust	73
2.	Public Accessibility of D’Aoust.....	75

3.	Conclusion Re D'Aoust.....	79
K.	Exhibit 1022 – BAM 2003.....	79
1.	Authenticity and Public Accessibility of BAM 2003	80
2.	Conclusion Re BAM 2003	84
L.	Exhibit 1023 – FSIS Directive.....	84
1.	Authenticity and Public Accessibility of FSIS Directive	85
2.	Conclusion Re FSIS Directive.....	87
M.	Exhibit 1024 – Midura	88
1.	Authenticity of Midura	88
2.	Public Accessibility of Midura	90
3.	Conclusion Re Midura.....	95
N.	Exhibit 1028 – MLG 2003	95
1.	Authenticity and Public Accessibility of MLG 2003	96
2.	Conclusion Re MLG 2003.....	101
O.	Exhibit 1029 – MLG 1998.....	102
1.	Authenticity and Public Accessibility of MLG 1998	102
2.	Conclusion Re MLG 1998.....	108
P.	Exhibit 1032 – BAM 1969.....	108
1.	Authenticity and Public Accessibility of BAM 1969	109
2.	Conclusion Re BAM 1969	115
Q.	Exhibit 1033 – JAOAC 1967.....	115
1.	Authenticity of JAOAC 1967	116

2.	Public Accessibility of JAOAC 1967	118
3.	Conclusion Re JAOAC 1967.....	121
VI.	RIGHT TO SUPPLEMENT	122
VII.	CERTIFICATION.....	122

I. INTRODUCTION

I, James L. Mullins, am above the age of majority and hereby declare under penalty of perjury:

1. I have been retained by Petitioner National Beef Packing Company, LLC (“National Beef”) to provide expert opinions in connection with petitions requesting *inter partes* review (IPR) of U.S. Patent Nos. 7,534,584 (“the ’584 Patent”), 8,822,143 (“the ’143 Patent”), and 9,637,771 (“the ’771 Patent”), which are each owned by the Institute for Environmental Health, Inc. (“IEH”) and are collectively referred to as the “IEH Patents.”

2. I am being paid my usual hourly rate of \$275 per hour. My compensation in no way depends on the content of my testimony or the outcome of the proceedings.

3. In this declaration, I opine on the authenticity of certain documents referenced herein and explain when and how these documents were disseminated or otherwise made publicly available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located each document.

II. QUALIFICATIONS

4. I am the Founder and Owner of Prior Art Documentation Librarian Services, LLC (“PADLS”) at 205 Saint Cuthbert, Williamsburg, VA 23188. Attached as Appendix A is a true and correct copy of my Curriculum Vitae describing my

background and experience. Further information about my firm, PADLS, is available at <https://www.priorartdoclib.com>.

5. I am currently Dean Emeritus of Libraries and Esther Ellis Norton Professor Emeritus at Purdue University, 2018 – present. I was previously employed as follows:

- a. Dean of Libraries and Professor and Esther Ellis Norton Professor, Purdue University, West Lafayette, IN, 2004 – 2017;
- b. Assistant/Associate Director for Administration, Massachusetts Institute of Technology (“MIT”) Libraries, Cambridge, MA, 2000 – 2004;
- c. University Librarian and Director, Falvey Memorial Library, Villanova University, Villanova, PA, 1996 – 2000;
- d. Director of Library Services, Indiana University South Bend, South Bend, IN, 1978 – 1996;
- e. Part-time Associate Professor, School of Library and Information Science, Indiana University, Bloomington, IN, 1979 – 1996;
- f. Associate Law Librarian, and associated titles, Indiana University School of Law, Bloomington, IN, 1974 – 1978; and
- g. Catalog Librarian, Assistant Professor, Georgia Southern College (now University), Statesboro, GA, 1973 – 1974.

6. During my more than forty-four years as an academic librarian and library science scholar, I have gained extensive experience with techniques and systems for cataloging and indexing printed materials in the library setting, including catalog records and online library management systems (“LMS”) built using Machine-Readable Cataloging (“MARC”) standards.

7. Additionally, throughout my career, I have been an active researcher and writer. I am an author of numerous publications in the field of library science and have given presentations in library sciences at national and international conferences. I am a member of the American Library Association (“ALA”) where I served as the chair of the Research Committee of the Association of College and Research Libraries (“ACRL”). My service to ALA included service on the editorial board of the most prominent library journal, *College and Research Libraries*. I also served on the Standards Committee, College Section of the Association of College and Research Libraries, where I was instrumental in developing a re-issue of the *Standards for College Libraries* in 2000.

8. As an academic library administrator, I ensured that students were educated to identify, locate, assess, and integrate information garnered from research library resources. I have also facilitated the research of faculty colleagues either directly or through the provision of and access to the requisite print and/or digital materials and services at the universities where I worked.

9. For this declaration, I have reviewed the documents and appendices referenced herein. These materials are records created in the ordinary course of business by publishers, libraries, indexing services, and others in my field. From my years of experience, I am familiar with the process for creating many of these records, and I know that these records are created by people with knowledge of the information contained within the record. Further, these records are created with the expectation that researchers and other members of the public will use and rely on them. All materials cited in this declaration and its appendices are of a type that experts in my field would reasonably rely upon and refer to in forming their opinions.

III. LEGAL STANDARDS

10. ***Authentication.*** I am informed by counsel and understand that an item is considered authentic if there is sufficient evidence to support a finding that the item is what it is claimed to be by the proponent of the item. I am also informed that authenticity can be established based on the properties of the item itself, such as the appearance, content, substance, internal patterns, or other distinctive characteristics of the item.

11. ***Public Accessibility.*** I am informed by counsel and understand that a given reference qualifies as publicly accessible if it were disseminated or otherwise made available such that persons interested in and ordinarily skilled in the relevant subject matter could locate it through the exercise of ordinary diligence. I understand that

one way that public accessibility can be shown is if a publication is cataloged and indexed by a library such that a person interested in the relevant subject matter could locate it. I also understand that there are other ways that a given reference may be deemed publicly accessible, including where that reference is cited by others in the field.

12. ***The Critical Date.*** I have been informed by counsel that for the purpose of this declaration I should consider evidence of public accessibility prior to August 6, 2004. As described further below, I have concluded that each of the references discussed herein was publicly accessible, including to a person of ordinary skill in the art, prior to August 6, 2004.

13. ***The Person of Ordinary Skill in the Art.*** I have been informed by counsel that a person of ordinary skill in the art at the time of invention (“POSA”) is a hypothetical person who is presumed to be familiar with the relevant field and its literature at the time of invention. This hypothetical person is also one of ordinary creativity capable of understanding the scientific principles applicable to the pertinent field.

14. In addition, I have been informed by counsel that as relevant to these proceedings, the POSA at the time of invention would have a working knowledge of microbiology and would have been involved in developing sampling and testing methodologies for analysis of food products (“validation methodologies”). The

POSA would most likely have an advanced degree in microbiology, food science, or animal science and at least two years of work experience but may alternatively have a bachelor's degree in those areas and at least four years of experience with validation methodologies. The POSA, more likely than not, would have been familiar with relevant scientific literature and industry regulations, directives, and guidelines relating to validation methodologies.

IV. BACKGROUND

15. ***Periodical Publications.*** A periodical publication is a published work in a series, for example, a journal article. A library typically creates a catalog record for a periodical publication when the library receives its first issue. When the institution receives subsequent issues or volumes of the periodical, the issues or volumes are checked in, often using a date stamp, added to the institution's holding records, and made available very soon thereafter, normally within a few days of receipt or at most within a few weeks of receipt.

16. ***Monograph Publications.*** Monograph publications are written on a single topic, presented at length, and distinguished from an article. They include books, dissertations, proceedings of a conference, and technical reports. A library typically creates a catalog record when the monograph is acquired by the library. First, it will search the Online Computer Library Center ("OCLC") to determine if a record has already been created by the Library of Congress or another OCLC institution.

17. If a record is found in OCLC, the record is downloaded into the library's management system that typically includes the online public access catalog ("OPAC"). Once the item is downloaded into the library's management system, the library adds its identifier to the OCLC database so when a search is completed on WorldCat, the library will be indicated as possessing the publication. Once a record is created in a library's management system, it is searchable and viewable through the library's OPAC, typically by author, title, and subject heading, at that library and from anywhere in the world through the internet by accessing that library's OPAC.

18. ***Indexing.*** A common way to search for a publication is to search for relevant information in an index of periodicals and other publications. Having found relevant material, the researcher will then normally obtain it online, look for it in libraries, or purchase it from the publisher, a bookstore, a document delivery service, or other provider. Indexing services use a wide variety of controlled vocabularies to provide subject access and other means of discovering the content of documents. The formats in which these access terms are presented vary from service to service. Online indexing services commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document is evidence that

the document was publicly available and in use by researchers no later than the publication date of the citing document.

19. **MARC.** The MARC standard is an industry-wide standard method of storing and organizing library catalog information. MARC practices have been consistent since the MARC format was developed by the Library of Congress in the 1960s, and by the early 1970s became the U.S. national standard for disseminating bibliographic data. By the mid-1970s, MARC format became the international standard, and persists through to the present. A MARC-compatible library is one that has a catalog consisting of individual MARC records for each of its items. The underlying MARC format underpins the OPAC that is available to library users to locate a particular holding of a library. Today, MARC is the primary communications protocol for the transfer and storage of bibliographic metadata in libraries. The MARC practices discussed below were in place during the time frames relevant to the documents referenced herein.

20. Libraries worldwide use the machine-readable MARC format for catalog records. MARC-formatted records include a variety of subject access points based on the content of the document being cataloged. A MARC record for a particular work comprises several fields, each of which contains specific data about the work. Each field is identified by a standardized, unique, three-digit code corresponding to the type of data that follows.

21. When a MARC record is created by the Library of Congress or an OCLC member institution, the date of creation for that record is automatically populated in the MARC Field 008 with characters 00 through 05 in year, month, day format (YYMMDD).¹ Therefore, the MARC record creation date reflects the date on which the publication associated with the record was first cataloged. The local library will enter the date of cataloging the item into its OPAC in the MARC Field 005 and once entered the local library's computer system may automatically update the date in this field every time the library updates the MARC record. For example, the MARC Field 005 may be updated when there is a change in location of the item or when a replacement library computer system is installed, which will likely reflect that date in the MARC Field 005 for all items held by the local library at that time.

22. **OCLC.** OCLC is a not-for-profit worldwide consortium of libraries. Like MARC standards, OCLC's practices have been consistent since the 1970s up to the present. Accordingly, the OCLC practices discussed below were in place during the relevant timeframe discussed herein. Among other services, OCLC and its members are responsible for maintaining the WorldCat database used by libraries throughout the world.

¹ Some of the newer library catalog systems also include hour, minute, second (HHMMSS).

23. ***HathiTrust.*** Founded in 2008, HathiTrust is a not-for-profit collaborative of academic and research libraries preserving over 18 million digitized items. HathiTrust offers reading access to the fullest extent allowable by U.S. copyright law, computational access to the entire corpus for scholarly research, and other emerging services based on the combined collection. HathiTrust members steward the collection — the largest set of digitized books managed by academic and research libraries — under the aims of scholarly, not corporate, interests. More information about HathiTrust is available at <https://www.hathitrust.org>.

24. ***Internet Archive/Wayback Machine.*** The Internet Archive is a digital archive/library that began in 1996 to “scrape” publicly accessible webpages. The Internet Archive created a service called the Wayback Machine that enables public access to surf more than 450 billion webpages stored in the Internet Archive. Searches on the Wayback Machine can be undertaken by URL or entity name. If an archive record for a URL is available, it will be shown. Through the Wayback Machine it is possible to view a specific webpage at a URL and see that page on that date as it then appeared. It is essentially a “snapshot” of the website on that date. More information about the Internet Archive and the Wayback Machine is available at <https://www.archive.org>.

25. ***Monthly Catalog of U.S. Government Publications (“Monthly Catalog”).*** The Monthly Catalog is a monthly-issued index that lists all the publications

produced by the U.S. Government Printing Office from 1895 to 2004. It is organized by issuing agency and includes a variety of other indexes to provide additional access. Indexes refer to the entry number in the main section of the volume. Over time, the information in the entries and the indexes have changed, but there is usually at least an annual subject index with each volume. Author and title indexes are included with some ranges of years, and a United States Congressional Serial Set Supplement was issued with separate subject, author, and title indexes for several years. More information about the Monthly Catalog is available at <https://www.govinfo.gov/collection/monthly-catalog>.

26. ***Springer Link***. Providing researchers with access to millions of scientific documents from journals, books, series, protocols, reference works, and proceedings. More information about Springer Link is available at <https://link.springer.com>.

27. ***WorldCat***. WorldCat is the world's largest public online catalog, maintained by the OCLC, and built with the records created by the thousands of libraries that are members of OCLC. OCLC provides bibliographic and abstract information to the public based on MARC-compliant records through its OCLC WorldCat database. WorldCat requires no knowledge of MARC tags and codes and does not require a login or password. WorldCat is easily accessible to all who wish to search it at <https://www.worldcat.org>.

28. **ASM Journals.** ASM Journals from the American Society for Microbiology are the most prominent publications in the field, delivering up-to-date and authoritative coverage of both primary and clinical microbiology. More information about ASM Journals is available at <https://www.journals.asm.org>.

29. **Wisconsin TechSearch (“WTS”).** WTS offers an array of article delivery and research services to individuals and organizations, including those not affiliated with the University of Wisconsin. More information about WTS is available at <https://www.wts.wisc.edu>.

V. DOCUMENTS

A. Exhibit 1012 – ICMSF 2002

30. I have been asked to opine on the authenticity and public accessibility of a book titled “*Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*” released by the International Commission on Microbiological Specifications for Foods and published by Springer (formerly Kluwer Academic/Plenum Publishers) in 2002 (“ICMSF 2002”).

31. I have assessed the authenticity and public accessibility of ICMSF 2002: (1) by reviewing Exhibit 1012 provided by counsel; and (2) by requesting WTS obtain scans from a print copy of ICMSF 2002 owned and held by the Library of Congress, attached as Appendix A-1.

1. Authenticity of ICMSF 2002

32. I reviewed and assessed Exhibit 1012 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1012 is compared with scans of ICMSF 2002 I retrieved to verify authenticity.

33. Appendix A-1 includes scans of: the cover of ICMSF 2002 with labels on the spine of the book that read “CBN BRNCH GenColl QR 115 .I46 2002 Copy 1” as shown below; internal flyleaf page with a stamp that reads “THE LIBRARY OF CONGRESS 1800” as shown below; title page with handwritten note that reads “International Commission on Microbiological Specifications for Foods” as shown below; Table of Contents, pages v-ix; blank page; Introduction, pages xi-xiii; Chapter 6, “Concepts of Probability and Principles of Sampling,” pages 113-121; Chapter 10, “Experience in the Use of Two-Class Attributes Plans for Lot Acceptance,” pages 183-197; Chapter 12, “Sampling, Sample Handling, and Sample Analysis,” pages 225-236; Chapter 15, “*Salmonella* in Dried Milk,” pages 273-284; Chapter 16, “*Listeria monocytogenes* in Cooked Sausage (Frankfurters),” pages 285-312; and Chapter 17, “*E. coli* O157:H7 in Frozen Raw Ground Beef Patties,” pages 313-332:



*International Commission on Microbiological Specifications
for foods.*

34. All identifying characteristics of Appendix A-1, including labels, stamps, and handwritten notations, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

35. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps observed on Appendix A-1 are consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the Library of Congress.

36. Appendix A-2 is a download of ICMSF 2002 that I made on December 18, 2023 as an emeritus faculty member at Purdue University through the Purdue University Libraries from Springer Link at this URL:

[https://link-springer-com.ezproxy.lib.purdue.edu/book/10.1007/978-1-4684-8369-](https://link-springer-com.ezproxy.lib.purdue.edu/book/10.1007/978-1-4684-8369-7)

7. This download is also available for a fee at the following URL:

<https://link.springer.com/book/10.1007/978-3-319-68460-4>.

37. I have compared Exhibit 1012 with Appendix A-1 obtained from the Library of Congress and Appendix A-2 obtained from Springer Link through Purdue University Libraries. I found no difference between Exhibit 1012 and Appendices A-1 and A-2. Therefore, I conclude that these copies of ICMSF 2002, Exhibit 1012 and Appendices A-1 and A-2, are the same.

38. This conclusion supports my opinion that Exhibit 1012 is an authentic, true, and correct copy of ICMSF 2002.

39. Further supporting my opinion of Exhibit 1012's authenticity, Appendices A-1 and A-2 were found within the custody of libraries, the Library of Congress and the Purdue University Library via Springer Link, the most likely sources of authentic copies of ICMSF 2002.

2. Public Accessibility of ICMSF 2002

40. Appendix A-3 is a true and correct copy of the WorldCat entry for ICMSF 2002. I obtained Appendix A-3 by completing a search for ICMSF 2002 on WorldCat on December 15, 2023.

41. Appendix A-3 shows that ICMSF 2002 is the document associated with this WorldCat entry, as verified by the releasing agency/authors International

Commission on Microbiological Specifications for Foods, title *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, date 2002, and ISBN 0306472627.

42. ICMSF 2002 could have been located on WorldCat by searching for the title *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management* and/or by searching the subject headings Food Microbiology, Food Microbiology standards, Food Standards, and/or HACCP, among others.

43. When I searched WorldCat for holdings of ICMSF 2002 in Washington, D.C., the Library of Congress was first on the list among the 132 libraries shown as holding ICMSF 2002 worldwide.

44. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat through August 6, 2004.

45. Appendix A-4 is a true and accurate copy of the Library of Congress online OPAC catalog record for ICMSF 2002 that I downloaded on December 17, 2023.

46. On the second page of Appendix A-4 there is a note toward the bottom of the page that reads “Item Availability CALL NUMBER QR115 .I46 2002 CABIN BRANCH Copy 1” as shown below:

Item Availability

CALL NUMBER

QR115 .I46 2002 CABIN BRANCH
Copy 1

47. ICMSF 2002 could have been located in the Library of Congress OPAC by searching the title *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management* and/or by searching the subject headings Food--Microbiology and/or Food--Standards, among others.

48. Thus, in my opinion, ICMSF 2002 was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding ICMSF 2002 from its publication in 2002 until August 6, 2004.

49. Appendix A-1 has a date of receipt stamped on the copyright page that reads “LIBRARY OF CONGRESS JUNE 11 2002 CIR” as shown below:



50. The stamp above is evidence that ICMSF 2002 was received by the Library of Congress on June 11, 2002. From my experience, it would then require no more than a week to ten days for processing and transfer to the shelf where it would be publicly accessible, therefore ICMSF 2002 would have been publicly accessible no later than June 21, 2002.

3. Conclusion Re ICMSF 2002

51. Based on the evidence presented above, it is my opinion that Exhibit 1012, ICMSF 2002, is an authentic publication that was publicly accessible at least as early as June 21, 2002.

B. Exhibit 1013 – ICMSF 1986

52. I have been asked to opine on the authenticity and public accessibility of a book titled “*Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications*,” Second Edition, released by the International Commission on Microbiological Specifications for Foods and published by University of Toronto Press in 1986 (“ICMSF 1986”).

53. I have assessed the authenticity and public accessibility of ICMSF 1986: (1) by reviewing Exhibit 1013 provided by counsel; and (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix B-1.

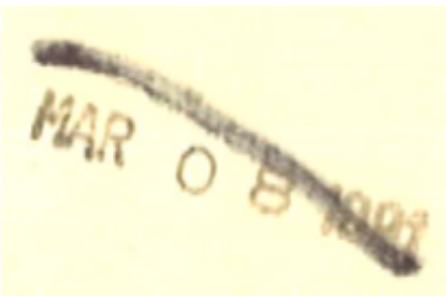
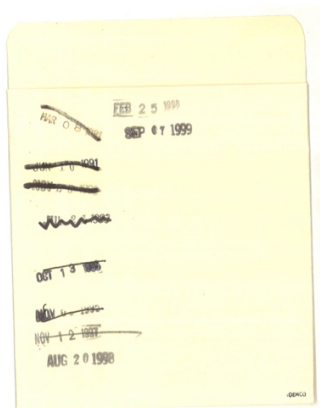
1. Authenticity of ICMSF 1986

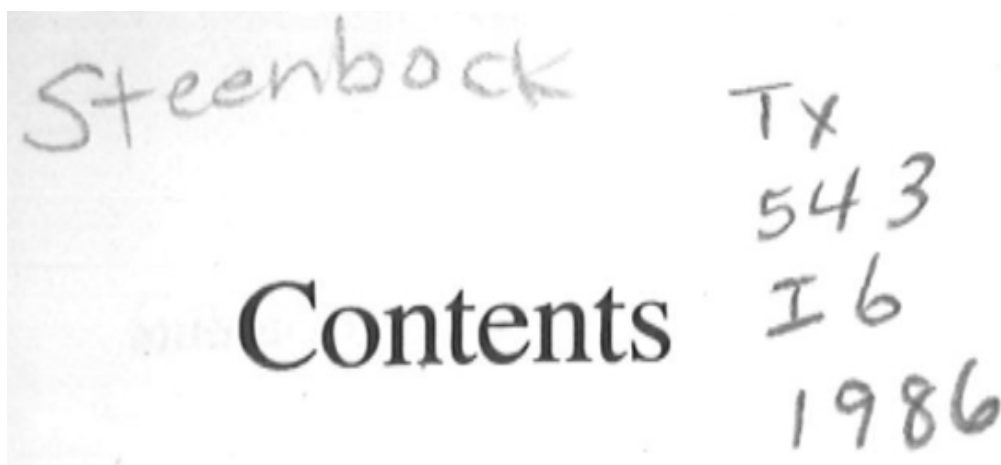
54. I reviewed and assessed Exhibit 1013 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion.

Exhibit 1013 is compared with scans of ICMSF 1986 I retrieved to verify authenticity.

55. Appendix B-1 includes scans of: the cover of ICMSF 1986; internal flyleaf page with a stamp that reads “STEENBOCK MEMORIAL LIBRARY” and a date due pocket with various date stamps, the earliest one with the date “MAR 08 1991” as shown below; title page; verso of the title page (i.e., the copyright page) with a stamp that reads “UNIVERSITY OF WISCONSIN – MADISON LIBRARY” as shown below; Contents, with “Steenbock” and a call number that reads “TX 543 I6 1986” handwritten as shown below, pages v-x; Tables, pages xi-xii; Preface to the second edition, pages xv-xvii; Preface to the first edition, pages xix-xxii; Abbreviations of societies and agencies, pages xxiii-xxiv; Chapter 9, pages 114-123; and Glossary, pages 275-278:

STEENBOCK MEMORIAL LIBRARY





56. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

57. All identifying characteristics of Appendix B-1, including stamps and handwritten notations, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

58. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps observed on Appendix B-1 are consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

59. I have compared Exhibit 1013 with Appendix B-1 obtained from the University of Wisconsin – Madison Library, having found no difference between the two, I conclude that Exhibit 1013 and Appendix B-1 are the same.

60. This conclusion supports my opinion that Exhibit 1013 is an authentic, true, and correct copy of ICMSF 1986.

61. Further supporting my opinion of Exhibit 1013's authenticity, Appendix B-1 was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of ICMSF 1986.

2. Public Accessibility of ICMSF 1986

62. Appendix B-2 is a true and correct copy of the WorldCat entry for ICMSF 1986. I obtained Appendix B-2 by completing a search for ICMSF 1986 on WorldCat on December 15, 2023.

63. Appendix B-2 shows that ICMSF 1986 is the document associated with this WorldCat entry, as verified by the releasing agency/authors International Commission on Microbiological Specifications for Foods, title *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Application*, edition 2nd ed, date 1986, and ISBN 0802056938.

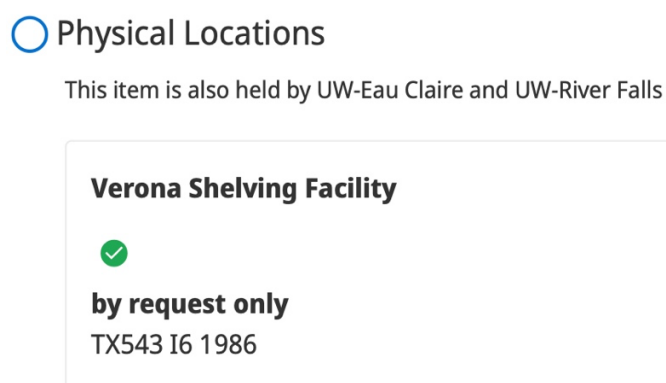
64. ICMSF 1986 could have been located on WorldCat by searching for the title *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications* and/or by searching the subject headings Food Analysis and/or Food Microbiology, among others.

65. When I searched WorldCat for holdings of ICMSF 1986 in Wisconsin, the University of Wisconsin – Madison General Library System was first on the list among the 221 libraries shown as holding an edition of ICMSF 1986 worldwide.

66. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

67. Appendix B-3 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for ICMSF 1986 that I downloaded on December 17, 2023.

68. On the first page of Appendix B-3 there are notes toward the bottom of the page that read “Physical Locations This item is also held by UW-Eau Claire and UW-River Falls” and “Verona Shelving Facility by request only TX543 I6 1986” as shown below:

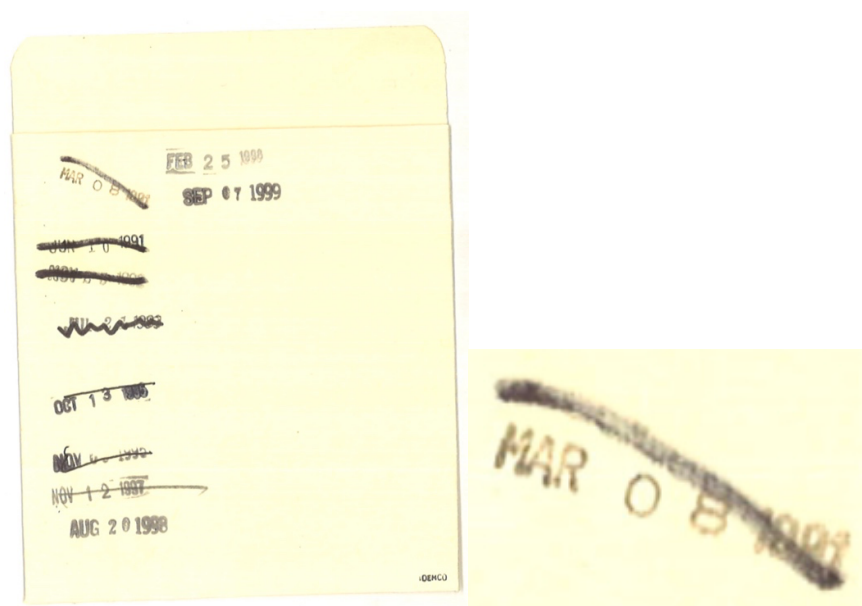


69. ICMSF 1986 could have been located in the University of Wisconsin – Madison Library OPAC by searching the title *Microorganisms in Foods 2: Sampling*

for Microbiological Analysis: Principles and Specific Application and/or by searching the subject headings Food -- Analysis, Food -- Microbiology, Food Analysis, and/or Food Microbiology.

70. Thus, in my opinion, ICMSF 1986 was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding ICMSF 1986 from its publication in 1986 until August 6, 2004.

71. Appendix B-1 has the check-out/return date slip with the earliest date of March 8, 1991 stamped, more likely than not, by staff of the University of Wisconsin – Madison Libraries as shown below:



72. The stamp above is evidence that ICMSF 1986 was publicly accessible no later than March 8, 1991, but more likely than not, several weeks earlier depending

upon the loan period in place at the library since that date is when Appendix B-1 was due back to the library after the loan period ended on March 8, 1991.

3. Conclusion Re ICMSF 1986

73. Based on the evidence presented above, it is my opinion that Exhibit 1013, ICMSF 1986, is an authentic publication that was publicly accessible at least as early as March 8, 1991.

C. Exhibit 1014 – Gombas

74. I have been asked to opine on the authenticity and public accessibility of an article authored by David E. Gombas and others titled “*Survey of Listeria monocytogenes in Ready-to-Eat Foods*” and published in the Journal of Food Protection, Volume 66, Number 4, 2003 on pages 559-569 (“Gombas”).

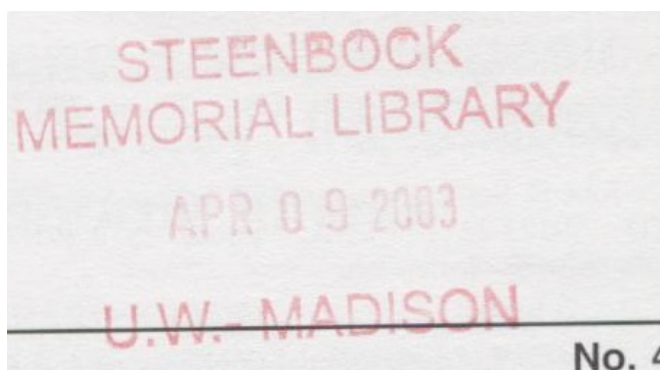
75. For consistency and clarity, it is understood that Gombas not only indicates the article under review, but also, when appropriate within the context of this declaration, Gombas refers to the issue of the Journal of Food Protection in which the article was published.

76. I have assessed the authenticity and public accessibility of Gombas: (1) by reviewing Exhibit 1014 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix C-1; and (3) by downloading Gombas from an open access website, attached as Appendix C-2.

1. Authenticity of Gombas

77. I reviewed and assessed Exhibit 1014 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1014 is compared with scans of Gombas I retrieved to verify authenticity.

78. Appendix C-1 includes scans of: the cover of the Journal of Food Protection, Volume 66, Number 4, 2003; contents page with an ownership and date stamp that reads “STEENBOCK MEMORIAL LIBRARY APR 09 2003 U.W.-Madison” as shown below; and the Gombas article on pages 559-569:



79. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

80. All identifying characteristics of Appendix C-1, including the stamp, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

81. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamp on the contents page of Appendix C-1 is consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

82. Appendix C-2 is a download of Gombas that I made from Science Direct at the following open access URL:
<https://www.sciencedirect.com/science/article/pii/S0362028X22030964>.

83. I have compared Exhibit 1014 with Appendices C-1 and C-2. That is, I compared the copy of Gombas obtained from the University of Wisconsin Library System with the copy of Gombas I downloaded from the Science Direct website, and I conclude that these two copies of Gombas are the same, and when compared to Exhibit 1014, it is also the same.

84. This conclusion supports my opinion that Exhibit 1014 is an authentic, true, and correct copy of Gombas.

85. Further supporting my opinion of its authenticity, Gombas was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of an academic journal like the Journal of Food Protection.

2. Public Accessibility of Gombas

86. Appendix C-3 is a true and correct copy of the WorldCat entry for the Journal of Food Protection which published Gombas. I obtained Appendix C-3 by completing a search for the Journal of Food Protection on WorldCat on November 16, 2023.

87. Appendix C-3 shows that the Journal of Food Protection is the document associated with this WorldCat entry, as verified by the title Journal of Food Protection and the ISSN 0362-028X.

88. The Journal of Food Protection could have been located on WorldCat by searching for the title Journal of Food Protection and/or by searching the subject headings Food adulteration, Food adulteration and inspection Periodicals, Milk hygiene, and/or Milk hygiene Periodicals.

89. When I searched WorldCat for holdings of the Journal of Food Protection in Wisconsin, the University of Wisconsin – Madison General Library System was first on the list among the 1,350 libraries shown as holding the Journal of Food Protection worldwide.

90. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

91. Appendix C-4 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for the Journal of Food Protection that I downloaded on November 16, 2023.

92. The second page of Appendix C-4 indicates that the Journal of Food Protection began publication with this specific title in January 1977 with Volume 40 and has been continually published since 1977.

93. On the first page of Appendix C-4 there is a note that reads “This Location Has v.40(1977)-v.69(2006)” as shown below. These dates and volumes are inclusive of the date and volume in which Gombas was published in the Journal of Food Protection:

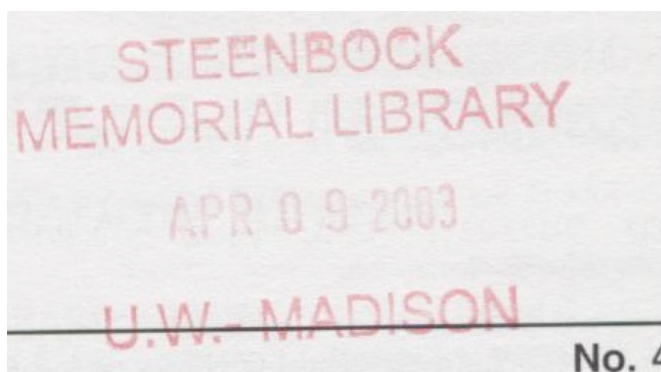
**This Location Has
v.40(1977)-v.69(2006)**

94. The Journal of Food Protection could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Journal of Food Protection and/or using the Chemical Abstracts database as indicated on the bottom of the second page of Appendix C-4.

95. Thus, in my opinion, Gombas was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable

diligence, would have had no difficulty finding Gombas from its publication in the Journal of Food Protection in April 2003 until August 6, 2004.

96. Appendix C-1 has the date of receipt of April 9, 2003 by the University of Wisconsin – Madison Libraries on the contents page of the Journal of Food Protection, Volume 66, Number 4, 2003 as shown below:



97. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, Gombas would have been available no later than April 21, 2003.

3. Conclusion Re Gombas

98. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1014, Gombas, is an authentic document that was publicly accessible at least as early as April 21, 2003.

D. Exhibit 1015 – Hughes 1999

99. I have been asked to opine on the authenticity and public accessibility of an article authored by Denise Hughes and others titled “*Salmonella in Foods—A New Enrichment Procedure for Use with the TECRA Salmonella Visual Immunoassay: Collaborative Study*” and published in the Journal of AOAC International, Volume 82, Number 3, 1999 on pages 634-647 (“Hughes 1999”).

100. For consistency and clarity, it is understood that Hughes 1999 not only indicates the article under review, but also, when appropriate within the context of this declaration, Hughes 1999 refers to the issue of the Journal of AOAC International in which the article was published.

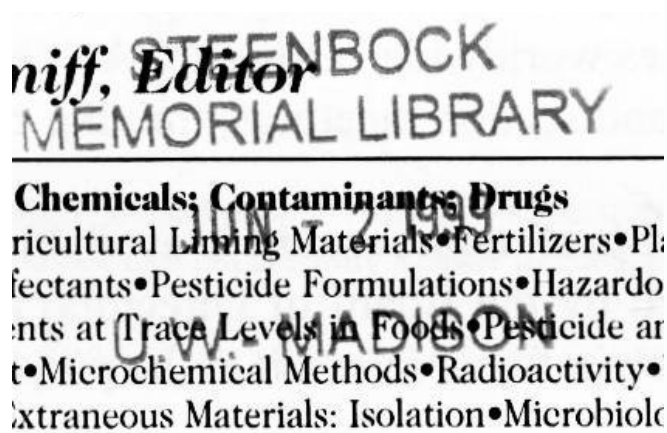
101. I have assessed the authenticity and public accessibility of Hughes 1999: (1) by reviewing Exhibit 1015 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix D-1; and (3) by downloading Hughes 1999 from an open access website, attached as Appendix D-2.

1. Authenticity of Hughes 1999

102. I reviewed and assessed Exhibit 1015 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion.

Exhibit 1015 is compared with scans of Hughes 1999 I retrieved to verify authenticity.

103. Appendix D-1 includes scans of: the cover of the Journal of AOAC International, Volume 82, Number 3, May/June 1999; internal page with an ownership and date stamp that reads “STEENBOCK MEMORIAL LIBRARY JUN – 2 1999 U.W. - MADISON” as shown below; table of contents pages 35A-37A; and the Hughes 1999 article on pages 634-647:



104. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

105. All identifying characteristics of Appendix D-1, including the stamp, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

106. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamp observed on the internal page of

Appendix D-1 is consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

107. Appendix D-2 is a download of Hughes 1999 that I made from the Oxford University Press at the following open access URL: <https://academic.oup.com/jaoac/article/82/3/634/5683815>.

108. I have compared Exhibit 1015 with Appendices D-1 and D-2. That is, I compared the copy of Hughes 1999 obtained from the University of Wisconsin Library System with the copy of Hughes 1999 I downloaded from the Oxford University Press website, and I conclude that these two copies of Hughes 1999 are the same, and when compared to Exhibit 1015, it is also the same.

109. This conclusion supports my opinion that Exhibit 1015 is an authentic, true, and correct copy of Hughes 1999.

110. Further supporting my opinion of its authenticity, Hughes 1999 was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of an academic journal like the Journal of AOAC International.

2. Public Accessibility of Hughes 1999

111. Appendix D-3 is a true and correct copy of the WorldCat entry for the Journal of AOAC International which published Hughes 1999. I obtained Appendix D-3 by

completing a search for the Journal of AOAC International on WorldCat on November 15, 2023.

112. Appendix D-3 shows that the Journal of AOAC International is the document associated with this WorldCat entry, as verified by the title Journal of AOAC International and the ISSN 1060-3271.

113. The Journal of AOAC International could have been located on WorldCat by searching for the title Journal of AOAC International and/or by searching the subject headings Agricultural chemistry and/or Agricultural chemistry Periodicals, among others.

114. When I searched WorldCat for holdings of the Journal of AOAC International in Wisconsin, the University of Wisconsin – Madison General Library System was fourth on the list among the 1,426 libraries shown as holding the Journal of AOAC International worldwide.

115. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

116. Appendix D-4 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for the Journal of AOAC International that I downloaded on November 16, 2023.

117. The second page of Appendix D-4 indicates that the Journal of AOAC International began publication with this specific title in January/February 1992, with Volume 75, Number 1, and has been continually published since 1992.

118. On the first page of Appendix D-4 there is a note that reads “This Location Has v.75(1992)-v.95(2012)” as shown below. These dates and volumes are inclusive of the date and volume in which Hughes 1999 was published in the Journal of AOAC International:

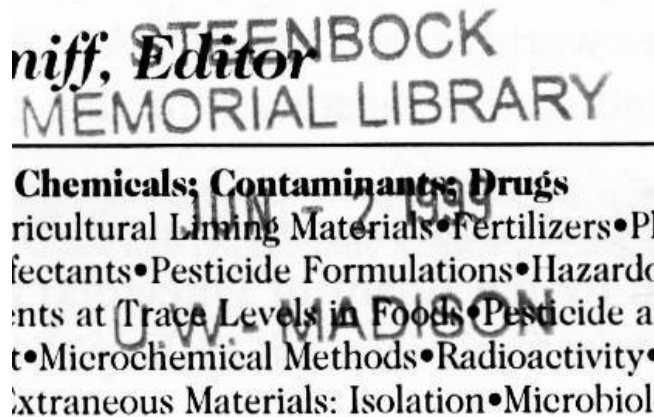
**This Location Has
v.75(1992)-v.95(2012)**

119. The Journal of AOAC International could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Journal of AOAC International and/or using the databases listed on the second page of Appendix D-4 as shown below:

- Biological & agricultural index
- Abstract bulletin of the Institute of Paper Chemistry
- Bibliography of agriculture
- Biological abstracts 1992-
- Canadian Environment
- Chemical abstracts
- Energy information abstracts
- Energy research abstracts
- Environment abstracts
- Excerpta medica
- GeoRef
- Index medicus
- International packaging abstracts
- Life sciences collection
- PESTDOC
- Reference sources
- RINGDOC
- Selected water resources abstracts
- VETDOC
- Nuclear science abstracts

120. Thus, in my opinion, Hughes 1999 was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding Hughes 1999 from its publication in the Journal of AOAC International in May/June 1999 until August 6, 2004.

121. Appendix D-1 has the date of receipt of June 2, 1999 by the University of Wisconsin – Madison Libraries on the internal page of the Journal of AOAC International, Volume 82, Number 3, May/June 1999 as shown below:



122. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, Hughes 1999 would have been available no later than June 14, 1999.

3. Conclusion Re Hughes 1999

123. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1015, Hughes 1999, is an authentic document that was publicly accessible at least as early as June 14, 1999.

E. Exhibit 1016 – Hughes 2003

124. I have been asked to opine on the authenticity and public accessibility of an article authored by Denise Hughes and others titled “*Salmonella in Foods: New Enrichment Procedure for TECRA Salmonella Visual Immunoassay Using a Single RV(R10) Only, TT Only, or Dual RV(R10) and TT Selective Enrichment Broths*

(AOAC Official Method 998.09): Collaborative Study” published in the Journal of AOAC International, Volume 86, Number 4, 2003 on pages 775-790 (“Hughes 2003”).

125. For consistency and clarity, it is understood that Hughes 2003 not only indicates the article under review, but also, when appropriate within the context of this declaration, Hughes 2003 refers to the issue of the Journal of AOAC International in which the article was published.

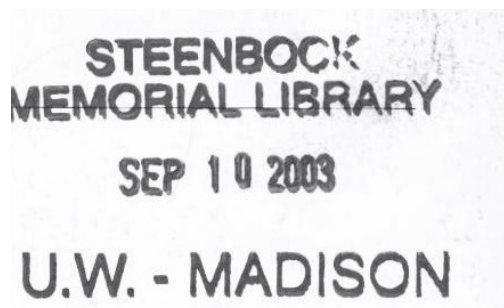
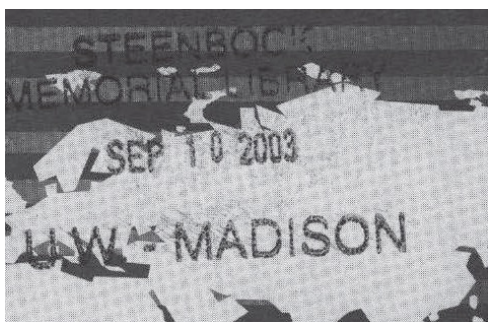
126. I have assessed the authenticity and public accessibility of Hughes 2003: (1) by reviewing Exhibit 1016 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix E-1; and (3) by downloading Hughes 2003 from an open access website, attached Appendix E-2.

1. Authenticity of Hughes 2003

127. I reviewed and assessed Exhibit 1016 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1016 is compared with scans of Hughes 2003 I retrieved to verify authenticity.

128. Appendix E-1 includes scans of: the cover of the Journal of AOAC International, Volume 86, Number 4, July/August 2003 with an ownership and date

stamp that reads “STEENBOCK MEMORIAL LIBRARY SEP 10 2003 U.W. - MADISON” as shown below; table of contents page with an ownership and date stamp that reads “STEENBOCK MEMORIAL LIBRARY SEP 10 2003 U.W. - MADISON” as shown below; additional table of contents pages 58A-60A; and the Hughes 2003 article on pages 775-790:



129. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

130. All identifying characteristics of Appendix E-1, including the stamps, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

131. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps observed on the cover and the table of contents page of Appendix E-1 are consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

132. Appendix E-2 is a download of Hughes 2003 that I made from the Oxford University Press at the following open access URL: <https://academic.oup.com/jaoac/article/86/4/775/5657033>.

133. I have compared Exhibit 1016 with Appendices E-1 and E-2. That is, I compared the copy of Hughes 2003 obtained from the University of Wisconsin Library System with the copy of Hughes 2003 I downloaded from the Oxford University Press website, and I conclude that these two copies of Hughes 2003 are the same, and when compared to Exhibit 1016, it is also the same.

134. This conclusion supports my opinion that Exhibit 1016 is an authentic, true, and correct copy of Hughes 2003.

135. Further supporting my opinion of its authenticity, Hughes 2003 was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of an academic journal like the Journal of AOAC International.

2. Public Accessibility of Hughes 2003

136. Appendix E-3 is a true and correct copy of the WorldCat entry for the Journal of AOAC International which published Hughes 2003. I obtained Appendix E-3 by completing a search for the Journal of AOAC International on WorldCat on November 15, 2023.

137. Appendix E-3 shows that the Journal of AOAC International is the document associated with this WorldCat entry, as verified by the title Journal of AOAC International and the ISSN 1060-3271.

138. The Journal of AOAC International could have been located on WorldCat by searching for the title Journal of AOAC International and/or by searching the subject headings Agricultural chemistry and/or Agricultural chemistry Periodicals, among others.

139. When I searched WorldCat for holdings of the Journal of AOAC International in Wisconsin, the University of Wisconsin – Madison General Library System was fourth on the list among the 1,426 libraries shown as holding the Journal of AOAC International worldwide.

140. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

141. Appendix E-4 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for the Journal of AOAC International that I downloaded on November 16, 2023.

142. The second page of Appendix E-4 indicates that the Journal of AOAC International began publication with this specific title in January/February 1992, with Volume 75, Number 1, and has been continually published since 1992.

143. On the first page of Appendix E-4 there is a note that reads “This Location Has v.75(1992)-v.95(2012)” as shown below. These dates and volumes are inclusive of the date and volume in which Hughes 2003 was published in the Journal of AOAC International:

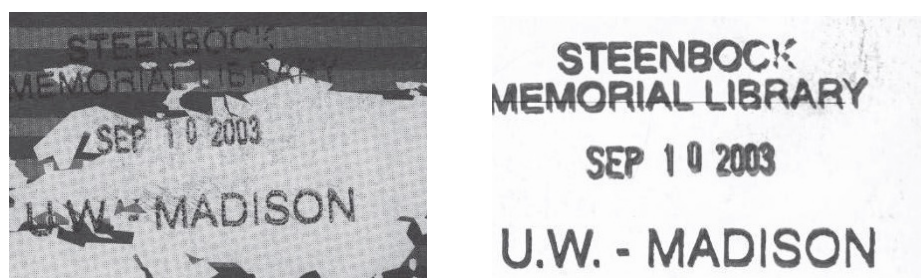
**This Location Has
v.75(1992)-v.95(2012)**

144. The Journal of AOAC International could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Journal of AOAC International and/or using the databases listed on the second page of Appendix E-4 as shown below:

- Biological & agricultural index
- Abstract bulletin of the Institute of Paper Chemistry
- Bibliography of agriculture
- Biological abstracts 1992-
- Canadian Environment
- Chemical abstracts
- Energy information abstracts
- Energy research abstracts
- Environment abstracts
- Excerpta medica
- GeoRef
- Index medicus
- International packaging abstracts
- Life sciences collection
- PESTDOC
- Reference sources
- RINGDOC
- Selected water resources abstracts
- VETDOC
- Nuclear science abstracts

145. Thus, in my opinion, Hughes 2003 was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding Hughes 2003 from its publication in the Journal of AOAC International in July/August 2003 until August 6, 2004.

146. Appendix E-1 has the date of receipt of September 10, 2003 by the University of Wisconsin – Madison Libraries on the cover and table of contents page of the Journal of AOAC International, Volume 86, Number 4, July/August 2003 as shown below:



147. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, Hughes 2003 would have been available no later than September 22, 2003.

3. Conclusion Re Hughes 2003

148. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a

scholarly database, it is my opinion that Exhibit 1016, Hughes 2003, is an authentic document that was publicly accessible at least as early as September 22, 2003.

F. Exhibit 1017 – Price

149. I have been asked to opine on the authenticity and public accessibility of an article authored by W. R. Price and others titled “*Salmonella Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples*” and published in Applied Microbiology, Volume 23, Number 4, April 1972 on pages 679-682 (“Price”).

150. For consistency and clarity, it is understood that Price not only indicates the article under review, but also, when appropriate within the context of this declaration, Price refers to the issue of Applied Microbiology in which the article was published.

151. I have assessed the authenticity and public accessibility of Price: (1) by reviewing Exhibit 1017 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix F-1; and (3) by downloading Price from an open access website, attached as Appendix F-2.

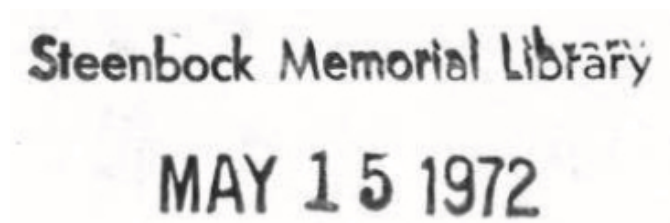
1. Authenticity of Price

152. I reviewed and assessed Exhibit 1017 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner

with no apparent interruption in sentence structure or paragraphs caused by deletion.

Exhibit 1017 is compared with scans of Price I retrieved to verify authenticity.

153. Appendix F-1 includes scans of: the cover of Applied Microbiology, Volume 23, Number 4, April 1972 with an ownership and date stamp that reads “Steenbock Memorial Library MAY 15 1972” as shown below; title page; editorial board page; contents pages; and the Price article on pages 679-682:



154. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

155. All identifying characteristics of Appendix F-1, including the stamp, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

156. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamp observed on the cover of Appendix F-1 is consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

157. Appendix F-2 is a download of Price that I made from the American Society for Microbiology at the following open access URL:
<https://journals.asm.org/doi/10.1128/am.23.4.679-682.1972>.

158. I have compared Exhibit 1017 with Appendices F-1 and F-2. That is, I compared the copy of Price obtained from the University of Wisconsin Library System with the copy of Price I downloaded from the American Society for Microbiology website, and I conclude that these two copies of Price are the same, and when compared to Exhibit 1017, it is also the same.

159. This conclusion supports my opinion that Exhibit 1017 is an authentic, true, and correct copy of Price.

160. Further supporting my opinion of its authenticity, Price was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of an academic journal like Applied Microbiology.

2. Public Accessibility of Price

161. Appendix F-3 is a true and correct copy of the WorldCat entry for Applied Microbiology which published Price. I obtained Appendix F-3 by completing a search for Applied Microbiology on WorldCat on November 14, 2023.

162. Appendix F-3 shows that Applied Microbiology is the document associated with this WorldCat entry, as verified by the title Applied Microbiology and the ISSN 0003-6919.

163. Applied Microbiology could have been located on WorldCat by searching for the title Applied Microbiology and/or by searching the subject headings 58.31 technical microbiology, Bacteriology, and/or Bacteriology Periodicals, among others.

164. When I searched WorldCat for holdings of Applied Microbiology in Wisconsin, the University of Wisconsin – Madison General Library System was first on the list among the 1,081 libraries shown as holding Applied Microbiology worldwide.

165. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

166. Appendix F-4 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for Applied Microbiology that I downloaded on November 14, 2023.

167. The second page of Appendix F-4 indicates that Applied Microbiology began publication with this specific title in January 1953, with Volume 1, Number 1, and was continually published until Volume 30, Number 6, December 1975.

168. On the first page of Appendix F-4 there is a note that reads “This Location Has v.1(1953)-v.30(1975)” as shown below. These dates and volumes are inclusive of the date and volume in which Price was published in Applied Microbiology:

**This Location Has
v.1(1953)-v.30(1975)**

169. Applied Microbiology could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Applied Microbiology. Before the advent of digital databases and publishing Price would have been retrievable, more likely than not, through several print indices that included Energy information abstracts, Environmental abstracts, and Chemical abstracts, among others listed on the second page of Appendix F-4 as shown below:



Energy information abstracts
Environment abstracts
Chemical abstracts

170. Thus, in my opinion, Price was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding Price from its publication in Applied Microbiology in April 1972 until August 2004.

171. Appendix F-1 has the date of receipt of May 15, 1972 by the University of Wisconsin – Madison Libraries on the cover of Applied Microbiology, Volume 23, Number 4, April 1972 as shown below:

Steenbock Memorial Library
MAY 15 1972

172. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, Price would have been available no later than May 25, 1972.

3. Conclusion Re Price

173. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1017, Price, is an authentic document that was publicly accessible at least as early as May 25, 1972.

G. Exhibit 1018 – Stewart

174. I have been asked to opine on the authenticity and public accessibility of an article authored by Diana S. Stewart and others titled “*Comparison of Assurance Gold Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of Salmonella in Alfalfa Sprouts and Sprout*

Irrigation Water” and published in the Journal of AOAC International, Volume 85, Number 2, 2002 on pages 395-403 (“Stewart”).

175. For consistency and clarity, it is understood that Stewart not only indicates the article under review, but also, when appropriate within the context of this declaration, Stewart refers to the issue of the Journal of AOAC International in which the article was published.

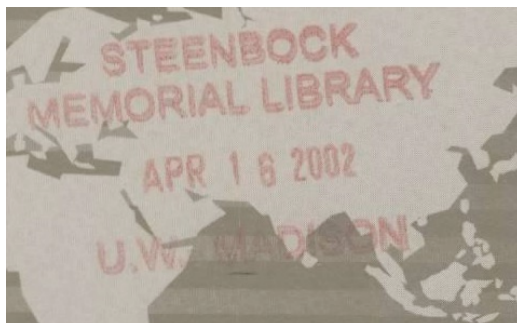
176. I have assessed the authenticity and public accessibility of Stewart: (1) by reviewing Exhibit 1018 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix G-1; and (3) by downloading Stewart from an open access website, attached as Appendix G-2.

1. Authenticity of Stewart

177. I reviewed and assessed Exhibit 1018 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1018 is compared with scans of Stewart I retrieved to verify authenticity.

178. Appendix G-1 includes scans of: the cover of the Journal of AOAC International, Volume 85, Number 2, March/April 2002 with an ownership and date stamp that reads “STEENBOCK MEMORIAL LIBRARY APR 18 2002 U.W. -

MADISON” as shown below; table of contents page; additional table of contents pages 20A-21A; and the Stewart article on pages 395-403:



179. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

180. All identifying characteristics of Appendix G-1, including the stamp, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

181. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamp observed on the cover of Appendix G-1 is consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

182. Appendix G-2 is a download of Stewart that I made from the Oxford Academic Press at the following open access URL:
<https://academic.oup.com/jaoac/article/85/2/395/5656505>.

183. I have compared Exhibit 1018 with Appendices G-1 and G-2. That is, I compared the copy of Stewart obtained from the University of Wisconsin Library System with the copy of Stewart I downloaded from the Oxford University Press website, and I conclude that the two copies of Stewart are the same, and when compared to Exhibit 1018, it is also the same.

184. This conclusion supports my opinion that Exhibit 1018 is an authentic, true, and correct copy of Stewart.

185. Further supporting my opinion of its authenticity, Stewart was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of an academic journal like the Journal of AOAC International.

2. Public Accessibility of Stewart

186. Appendix G-3 is a true and correct copy of the WorldCat entry for the Journal of AOAC International which published Stewart. I obtained Appendix G-3 by completing a search for the Journal of AOAC International on WorldCat on November 15, 2023.

187. Appendix G-3 shows that the Journal of AOAC International is the document associated with this WorldCat entry, as verified by the title Journal of AOAC International and the ISSN 1060-3271.

188. The Journal of AOAC International could have been located on WorldCat by searching for the title Journal of AOAC International and/or by searching the subject headings Agricultural chemistry and/or Agricultural chemistry Periodicals, among others.

189. When I searched WorldCat for holdings of the Journal of AOAC International in Wisconsin, the University of Wisconsin – Madison General Library System was fourth on the list among the 1,426 libraries shown as holding the Journal of AOAC International worldwide.

190. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

191. Appendix G-4 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for the Journal of AOAC International that I downloaded on May 3, 2024.

192. The second page of Appendix G-4 indicates that the Journal of AOAC International began publication with this specific title in January/February 1992, with Volume 75, Number 1, and has been continually published since 1992.

193. On the first page of Appendix G-4 there is a note that reads “This Location Has v.75(1992)-v.95(2012)” as shown below. These dates and volumes are

inclusive of the date and volume in which Stewart was published in the Journal of AOAC International:

This Location Has
v.75(1992)-v.95(2012)

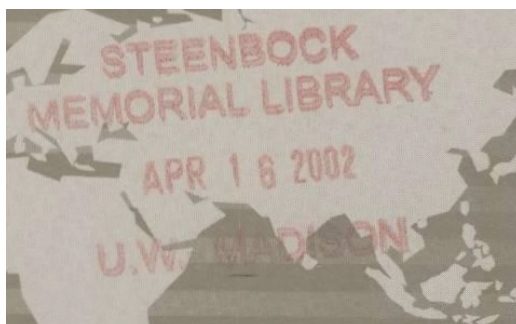
194. The Journal of AOAC International could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Journal of AOAC International and/or using the databases listed on the second page of Appendix G-4 as shown below:

- Biological & agricultural index
- Abstract bulletin of the Institute of Paper Chemistry
- Bibliography of agriculture
- Biological abstracts 1992-
- Canadian Environment
- Chemical abstracts
- Energy information abstracts
- Energy research abstracts
- Environment abstracts
- Excerpta medica
- GeoRef
- Index medicus
- International packaging abstracts
- Life sciences collection
- PESTDOC
- Reference sources
- RINGDOC
- Selected water resources abstracts
- VETDOC
- Nuclear science abstracts

195. Thus, in my opinion, Stewart was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable

diligence, would have had no difficulty finding Stewart from its publication in the Journal of AOAC International in March/April 2002 until August 6, 2004.

196. Appendix G-1 has the date of receipt of April 18, 2002 by the University of Wisconsin – Madison Libraries on the cover of the Journal of AOAC International, Volume 85, Number 2, March/April 2002 as shown below:



197. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, Stewart would have been available no later than April 29, 2002.

3. Conclusion Re Stewart

198. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1018, Stewart, is an authentic document that was publicly accessible at least as early as April 29, 2002.

H. Exhibit 1019 – Fratamico

199. I have been asked to opine on the authenticity and public accessibility of an article authored by Pina M. Fratamico and others titled “Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method” and published in Food Microbiology, Volume 9, Number 2, 1992 on pages 105-113 (“Fratamico”).

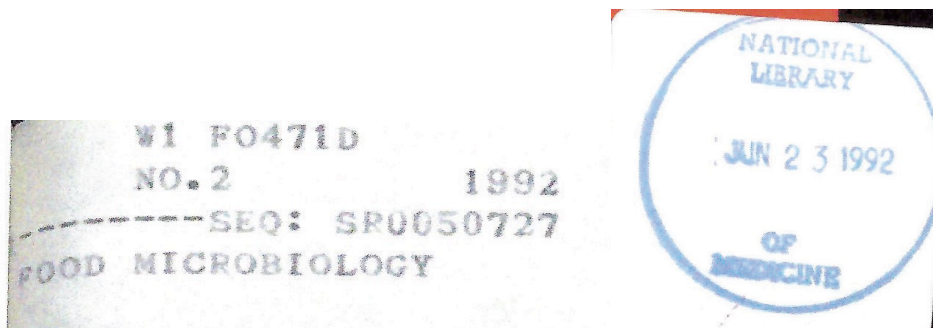
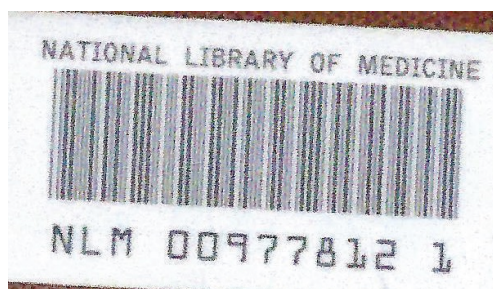
200. For consistency and clarity, it is understood that Fratamico not only indicates the article under review, but also, when appropriate within the context of this declaration, Fratamico refers to the issue of Food Microbiology in which the article was published.

201. I have assessed the authenticity and public accessibility of Fratamico: (1) by reviewing Exhibit 1019 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the National Library of Medicine, attached as Appendix H-1; and (3) by downloading Fratamico from Science Direct through the Purdue University Libraries, attached as Appendix H-2.

1. Authenticity of Fratamico

202. I reviewed and assessed Exhibit 1019 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1019 is compared with scans of Fratamico I retrieved to verify authenticity.

203. Appendix H-1 includes scans of: the cover and spine of Food Microbiology, Volume 9, Number 2, 1992 with markings on the spine that read “FOOD MICROBIOLOGY 9 1992 W1 FO471D” and a barcode label that reads “NATIONAL LIBRARY OF MEDICINE NLM 00977812 1” as shown below; published cover with a label that reads “W1 FO471D NO.2 1992 -----SEQ: SR0050727 FOOD MICROBIOLOGY” and another label with stamp that reads “NATIONAL LIBRARY OF MEDICINE JUN 23 1992” as shown below; journal information and copyright page; contents page; and the Fratamico article on pages 105-113:



204. All identifying characteristics of Appendix H-1, including the markings, labels, and stamps, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

205. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the label with a stamp on the published cover of Appendix H-1 is consistent with labels with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the National Library of Medicine.

206. Appendix H-2 is a download of Fratamico that I made from Science Direct through the Purdue University Libraries as an emeritus faculty member of Purdue University using the following open access URL:
<https://www.sciencedirect.com/science/article/abs/pii/074000209280018Y>.

207. I have compared Exhibit 1019 with Appendices H-1 and H-2. That is, I compared the copy of Fratamico I obtained from the National Library of Medicine with the copy of Fratamico I downloaded from the Science Direct website, and I conclude that these two copies of Fratamico are the same, and when compared to Exhibit 1019, it is also the same.

208. This conclusion supports my opinion that Exhibit 1019 is an authentic, true, and correct copy of Fratamico.

209. Further supporting my opinion of its authenticity, Fratamico was found within the custody of a research library, the National Library of Medicine, one of the most likely sources of an authentic copy of an academic journal like Food Microbiology.

2. Public Accessibility of Fratamico

210. Appendix H-3 is a true and correct copy of the WorldCat entry for Food Microbiology which published Fratamico. I obtained Appendix H-3 by completing a search for Food Microbiology on WorldCat on March 26, 2024.

211. Appendix H-3 shows that Food Microbiology is the document associated with this WorldCat entry, as verified by the title Food Microbiology and the ISSN 0740-0020.

212. Food Microbiology could have been located on WorldCat by searching for the title Food Microbiology and/or by searching the subject headings Food Contaminants Microorganisms, Food Microbiology, and/or Food Microbiology Periodicals, among others.

213. When I searched WorldCat for holdings of Food Microbiology in Washington, D.C., the National Library of Medicine was seventh on the list among the 884 libraries shown as holding Food Microbiology worldwide.

214. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

215. Appendix H-4 is a true and accurate copy of the National Library of Medicine online OPAC catalog record for Food Microbiology that I downloaded on March 26, 2024.

216. Appendix H-4 indicates that Food Microbiology began publication with this specific title in January 1984 with Volume 1, Number 1 and has been continually published since 1984.

217. On Appendix H-4 there is a note that reads “LOCATION ITEMS NLM Available, General Collection; W1 FO471D Summary holdings: v.1(1984)-v.3(1986),v.5(1988)-v.34(2013),v.35:no.2(2013),v.36(2013)-v.76(2018)” as shown below. These dates and volumes are inclusive of the date and volume in which Fratomico was published in Food Microbiology:

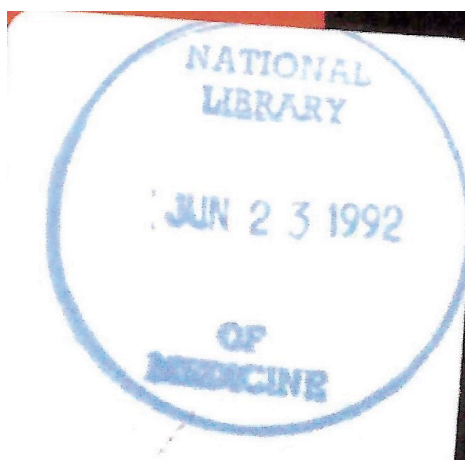
LOCATION ITEMS
NLM
Available, General Collection ; W1 FO471D
Summary holdings: v.1(1984)-v.3(1986),v.5(1988)-v.34(2013),v.35:no.2(2013),v.36(2013)-v.76(2018)

218. Food Microbiology could have been located in the National Library of Medicine OPAC by searching the title Food Microbiology and/or by searching the

MESH Subjects (i.e., Medical Subject Headings) Food Microbiology as indicated on Appendix H-4.

219. Thus, in my opinion, Fratamico was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding Fratamico from its publication in Food Microbiology in June 1992 until August 6, 2004.

220. Appendix H-1 has the date of receipt of June 23, 1992 by the National Library of Medicine on the front cover of Food Microbiology, Volume 9, Number 2, June 1992 as shown below:



221. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, Fratamico would have been available no later than July 3, 1992.

3. Conclusion Re Fratamico

222. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1019, Fratamico, is an authentic document that was publicly accessible at least as early as July 3, 1992.

I. Exhibit 1020 – D’Haese

223. I have been asked to opine on the authenticity and public accessibility of an article authored by Eva D’Haese and Hans J. Nelis titled “*Rapid Detection of Single Cell Bacteria as a Novel Approach in Food Microbiology*” and published in the Journal of AOAC International, Volume 85, Number 4, 2002 on pages 979-983 (“D’Haese”).

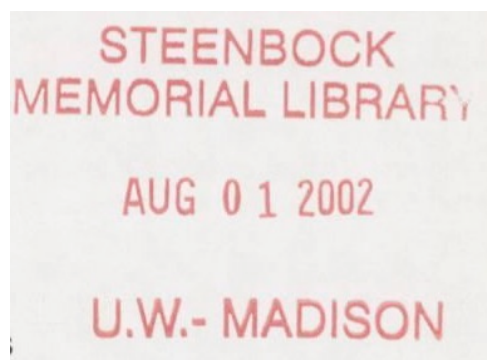
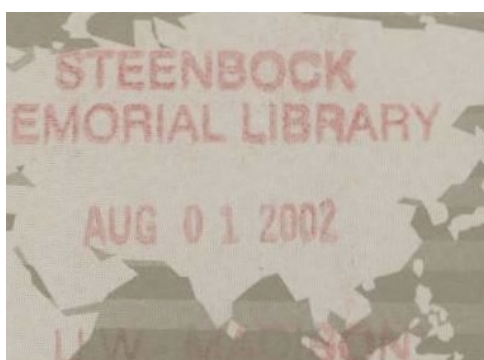
224. For consistency and clarity, it is understood that D’Haese not only indicates the article under review, but also, when appropriate within the context of this declaration, D’Haese refers to the issue of the Journal of AOAC International in which the article was published.

225. I have assessed the authenticity and public accessibility of D’Haese: (1) by reviewing Exhibit 1020 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Steenbock Memorial Library, University of Wisconsin – Madison Libraries, attached as Appendix I-1; and (3) by downloading D’Haese from an open access website, attached as Appendix I-2.

1. Authenticity of D’Haese

226. I reviewed and assessed Exhibit 1020 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1020 is compared with scans of D’Haese I retrieved to verify authenticity.

227. Appendix I-1 includes scans of: the cover of the Journal of AOAC International, Volume 85, Number 4, July/August 2002 with an ownership and date stamp that reads “STEENBOCK MEMORIAL LIBRARY AUG 01 2002 U.W. - MADISON” as shown below; table of contents page with an ownership and date stamp that reads “STEENBOCK MEMORIAL LIBRARY AUG 01 2002 U.W. - MADISON” as shown below; additional table of contents pages 68A-69A; and the D’Haese article on pages 979-983:



228. The Steenbock Library is the name of the main research library at the University of Wisconsin – Madison.

229. All identifying characteristics of Appendix I-1, including the stamps, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

230. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps observed on the cover and the table of contents page of Appendix I-1 are consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

231. Appendix I-2 is a download of D’Haese that I made from the Oxford University Press at the following open access URL:
<https://academic.oup.com/jaoac/article/85/4/979/5656863>.

232. I have compared Exhibit 1020 with Appendices I-1 and I-2. That is, I compared the copy of D’Haese obtained from the University of Wisconsin Library System with the copy of D’Haese I downloaded from the Oxford University Press website, and I conclude that these two copies of D’Haese are the same, and when compared to Exhibit 1020, it is also the same.

233. This conclusion supports my opinion that Exhibit 1020 is an authentic, true, and correct copy of D’Haese.

234. Further supporting my opinion of its authenticity, D’Haese was found within the custody of a university library, the University of Wisconsin – Madison Library,

one of the most likely sources of an authentic copy of an academic journal like the Journal of AOAC International.

2. Public Accessibility of D’Haese

235. Appendix I-3 is a true and correct copy of the WorldCat entry for the Journal of AOAC International which published D’Haese. I obtained Appendix I-3 by completing a search for the Journal of AOAC International on WorldCat on November 15, 2023.

236. Appendix I-3 shows that the Journal of AOAC International is the document associated with this WorldCat entry, as verified by the title Journal of AOAC International and the ISSN 1060-3271.

237. The Journal of AOAC International could have been located on WorldCat by searching for the title Journal of AOAC International and/or by searching the subject headings Agricultural chemistry and/or Agricultural chemistry Periodicals, among others.

238. When I searched WorldCat for holdings of the Journal of AOAC International in Wisconsin, the University of Wisconsin – Madison General Library System was fourth on the list among the 1,426 libraries shown as holding the Journal of AOAC International worldwide.

239. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

240. Appendix I-4 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for the Journal of AOAC International that I downloaded on May 3, 2024.

241. The second page of Appendix I-4 indicates that the Journal of AOAC International began publication with this specific title in January/February 1992, with Volume 75, Number 1, and has been continually published since 1992.

242. On the first page of Appendix I-4 there is a note that reads “This Location Has v.75(1992)-v.95(2012)” as shown below. These dates and volumes are inclusive of the date and volume in which D’Haese was published in the Journal of AOAC International:

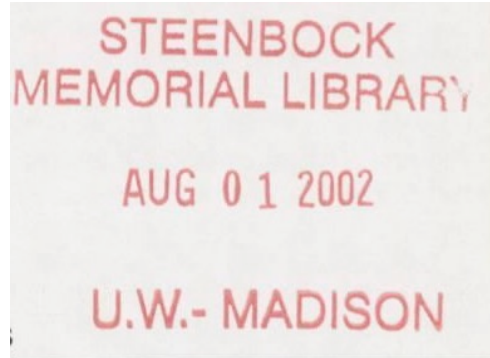
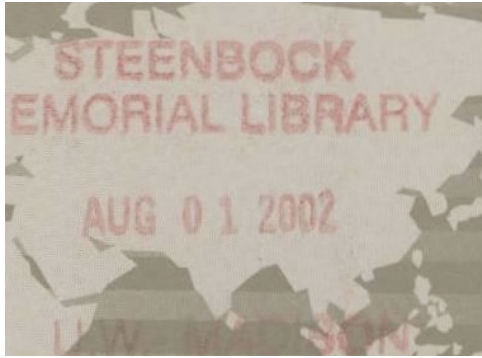
This Location Has
v.75(1992)-v.95(2012)

243. The Journal of AOAC International could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Journal of AOAC International and/or using the databases listed on the second page of Appendix I-4 as shown below:

- Biological & agricultural index
- Abstract bulletin of the Institute of Paper Chemistry
- Bibliography of agriculture
- Biological abstracts 1992-
- Canadian Environment
- Chemical abstracts
- Energy information abstracts
- Energy research abstracts
- Environment abstracts
- Excerpta medica
- GeoRef
- Index medicus
- International packaging abstracts
- Life sciences collection
- PESTDOC
- Reference sources
- RINGDOC
- Selected water resources abstracts
- VETDOC
- Nuclear science abstracts

244. Thus, in my opinion, D’Haese was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding D’Haese from its publication in the Journal of AOAC International in July/August 2002 until August 6, 2004.

245. Appendix I-1 has the date of receipt August 1, 2002 by the University of Wisconsin – Madison Libraries on the cover and table of contents page of the Journal of AOAC International, Volume 85, Number 4, July/August 2002 as shown below:



246. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, D’Haese would have been available no later than August 12, 2002.

3. Conclusion Re D’Haese

247. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1020, D’Haese, is an authentic document that was publicly accessible at least as early as August 12, 2002.

J. Exhibit 1021 – D’Aoust

248. I have been asked to opine on the authenticity and public accessibility of an article authored by Jean-Yves D’Aoust titled “*Update on Preenrichment and Selective Enrichment Conditions for Detection of Salmonella in Foods*” and published in the Journal of Food Protection, Volume 44, Number 5, May 1981 on pages 369-374 and 393 (“D’Aoust”).

249. For consistency and clarity, it is understood that D'Aoust not only indicates the article under review, but also, when appropriate within the context of this declaration, D'Aoust refers to the issue of the Journal of Food Protection in which the article was published.

250. I have assessed the authenticity and public accessibility of D'Aoust: (1) by reviewing Exhibit 1021 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Library of Congress, attached as Appendix J-1; and (3) by downloading D'Aoust from an open access website, attached as Appendix J-2.

1. Authenticity of D'Aoust

251. I reviewed and assessed Exhibit 1021 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1021 is compared with scans of D'Aoust I retrieved to verify authenticity.

252. Appendix J-1 includes scans of: a bound volume cover of the Journal of Food Protection with markings on the spine that read "JOURNAL OF FOOD PROTECTION 44 1981 SF 221 .I532" and a Library of Congress bar code label as shown below; internal flyleaf page of the volume with Library of Congress ownership print, as shown below; the cover of the Journal of Food Protection, Volume 44, Number 5, May 1981; National Sanitation Foundation ad page with a

stamp that reads “COPYRIGHT OFFICE MAY 3 1982 COPY LIBRARY OF CONGRESS” as shown below; table of contents page; and the D’Aoust article on pages 369-374 and 393:



253. All identifying characteristics of Appendix J-1, including the markings, labels, flyleaf, and stamps, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

254. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the bar code label and stamp observed on Appendix J-1 are consistent with bar code labels and stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the Library of Congress.

255. Appendix J-2 is a download of D'Aoust that I made from Science Direct at the following open access URL:
<https://www.sciencedirect.com/science/article/pii/S0362028X23010694>.

256. I have compared Exhibit 1021 with Appendices J-1 and J-2. That is, I compared the copy of D'Aoust obtained from the Library of Congress with the copy of D'Aoust I downloaded from the Science Direct website, and I conclude that these two copies of D'Aoust are the same, and when compared to Exhibit 1021, it is also the same.

257. This conclusion supports my opinion that Exhibit 1021 is an authentic, true, and correct copy of D'Aoust.

258. Further supporting my opinion of its authenticity, D'Aoust was found within the custody of the Library of Congress, one of the most likely sources of an authentic copy of an academic journal like the Journal of Food Protection.

2. Public Accessibility of D'Aoust

259. Appendix J-3 is a true and correct copy of the WorldCat entry for the Journal of Food Protection which published D'Aoust. I obtained Appendix J-3 by completing a search for the Journal of Food Protection on WorldCat on March 8, 2024.

260. Appendix J-3 shows that the Journal of Food Protection is the document associated with this WorldCat entry, as verified by the title Journal of Food Protection and the ISSN 0362-028X.

261. The Journal of Food Protection could have been located on WorldCat by searching for the title Journal of Food Protection and/or by searching the subject headings Food adulteration, Food adulteration and inspection Periodicals, Milk hygiene, and/or Milk hygiene Periodicals.

262. When I searched WorldCat for holdings of the Journal of Food Protection in Washington, D.C., the Library of Congress was ninth on the list among the 1,362 libraries shown as holding the Journal of Food Protection worldwide.

263. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

264. Appendix J-4 is a true and accurate copy of the Library of Congress online OPAC catalog record for the Journal of Food Protection that I downloaded on May 8, 2024.

265. The first page of Appendix J-4 indicates that the Journal of Food Protection began publication with this specific title in January 1977 with Volume 40 and has been continually published since 1977.

266. On the fifth and last page of Appendix J-4 there is a note that reads “Older receipts v.40:no.1-v.46:no.6 (1977:Jan.-1983:June)” as shown below. These dates and volumes are inclusive of the date and volume in which D’Aoust was published in the Journal of Food Protection:

Older receipts

v.40:no.1-v.46:no.6 (1977:Jan.-1983:June)

267. The Journal of Food Protection could have been located in the Library of Congress OPAC by searching the title Journal of Food Protection and/or using the Chemical Abstracts database as indicated near the bottom of the second page of Appendix J-4.

268. Thus, in my opinion, D’Aoust was sufficiently accessible to the public interested in the art, and an ordinarily skilled researcher, exercising reasonable diligence, would have had no difficulty finding D’Aoust from its publication in the Journal of Food Protection in May 1981 until August 6, 2004.

269. One way to verify that an article was accepted as authoritative and publicly accessible is by showing citation to that article in a subsequent published scholarly work as evidence.

270. Appendix J-5 is an article that cites D’Aoust authored by B.M. Mackey and Christine M. Derrick titled “*The effect of sublethal injury by heating, freezing, drying and gamma-radiation on the duration of the lag phase of Salmonella typhimurium*”

and published in the Journal of Applied Bacteriology, Volume 53, 1982 on pages 243–251 (“Mackey”).

271. Appendix J-5 is a download of Mackey that I made from Oxford University Press through the Purdue University Libraries as an emeritus faculty member of Purdue University using the following open access URL:
<https://academic.oup.com/jambio/article-abstract/53/2/243/6729754>.

272. The References section on page 250 of Mackey cites to D’Aoust as shown below:

D’Aoust, J.Y. 1981 Update on pre-enrichment and selective enrichment condition for detection of *Salmonella* in foods. *Journal of Food Protection* **44**, 369–374.

273. Appendix J-1 has the date of receipt of May 3, 1982 by the Library of Congress on the internal ad page of the Journal of Food Protection, Volume 44, Number 5, 1981 as shown below:



274. Allowing for a typical amount of time, that I observed during my professional career, for processing and transfer to the shelf of one week to ten days after receipt by a research library, D'Aoust would have been available no later than May 13, 1982.

3. Conclusion Re D'Aoust

275. Based on the evidence presented here, including publication in a widely held periodical, online indexing and publication, library processing, and availability in a scholarly database, it is my opinion that Exhibit 1021, D'Aoust, is an authentic document that was publicly accessible at least as early as May 13, 1982.

K. Exhibit 1022 – BAM 2003

276. I have been asked to opine on the authenticity and public accessibility of a document released by the U.S. Department of Health and Human Services, U.S. Food and Drug Administration ("FDA"), Center for Food Safety and Applied Nutrition website titled "*Bacteriological Analytical Manual*" including the Table of Contents/Introduction, About the Bacteriological Analytical Manual, Chapter 1, Chapter 5, and Chapter 10 webpages ("BAM 2003").

277. I have assessed the authenticity and public accessibility of BAM 2003: (1) by reviewing Exhibit 1022 provided by counsel; (2) by searching and retrieving BAM 2003 from the Wayback Machine provided by the Internet Archive, attached as Appendices K-1 through K-5.

1. Authenticity and Public Accessibility of BAM 2003

278. I reviewed and assessed Exhibit 1022 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1022 is compared with scans of BAM 2003 I retrieved to verify authenticity.

279. To verify the authenticity and public accessibility of BAM 2003 it is necessary to retrieve evidence from the Wayback Machine. I retrieved Appendices K-1 through K-5 from the Wayback Machine on November 20 through December 10, 2023. Since these were retrieved from the FDA's Center for Food Safety and Applied Nutrition website as it was accessible in April to June, 2003, this is evidence that BAM 2003 is an authentic document. Dates for public accessibility will be shown below for Appendices K-1 to K-5 which correlate with Exhibit 1016.

280. As described above, the Wayback Machine was inaugurated by the Internet Archive to be a permanent repository of webpages available on a specific day. Not every day was archived, but downloads were made on a schedule that was determined by the Internet Archive or were downloaded into the Wayback Machine by the owner of the website. That practice is evident below since different sections of BAM 2003 were archived on different dates.

281. Appendix K-1 is a download from the Wayback Machine of the Table of Contents/Introduction webpage of BAM 2003. Appendix K-1 is comprised of two

parts. The first part is a screen capture of the first page of the Table of Contents/Introduction webpage that shows the date as it appeared on June 3, 2003 as shown below. The second part is a complete download of the Table of Contents/Introduction webpage as it appeared on June 3, 2003.

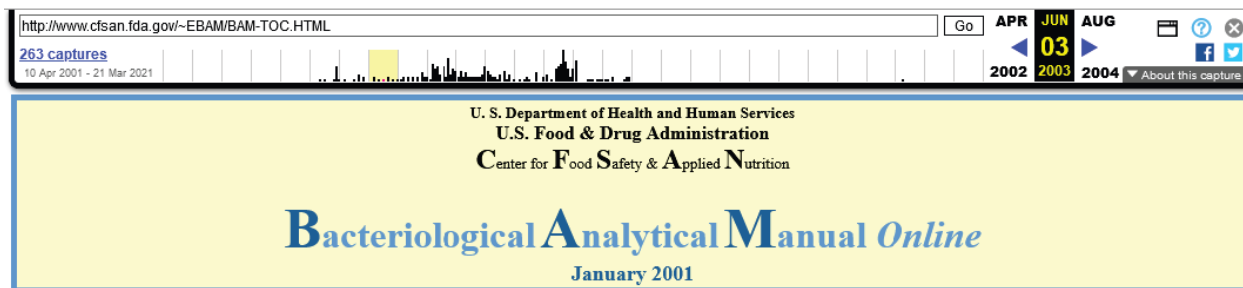
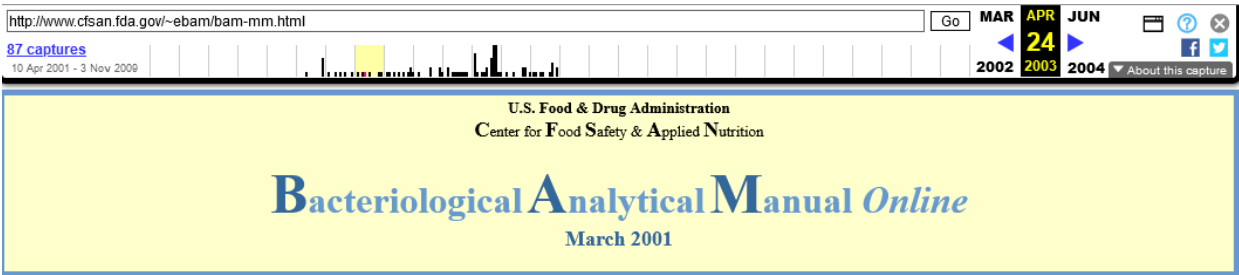


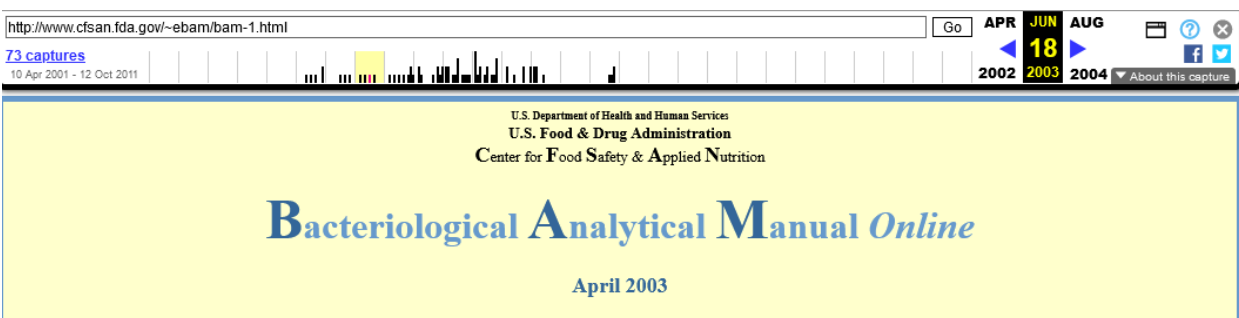
Table of Contents

282. Appendix K-2 is a download from the Wayback Machine of the About the Bacteriological Analytical Manual webpage of BAM 2003. Appendix K-2 is comprised of two parts. The first part is a screen capture of the first page of the About the Bacteriological Analytical Manual webpage that shows the date as it appeared on April 24, 2003 as shown below. The second part is a complete download of the About the Bacteriological Analytical Manual webpage as it appeared on April 24, 2003.



About the Bacteriological Analytical Manual

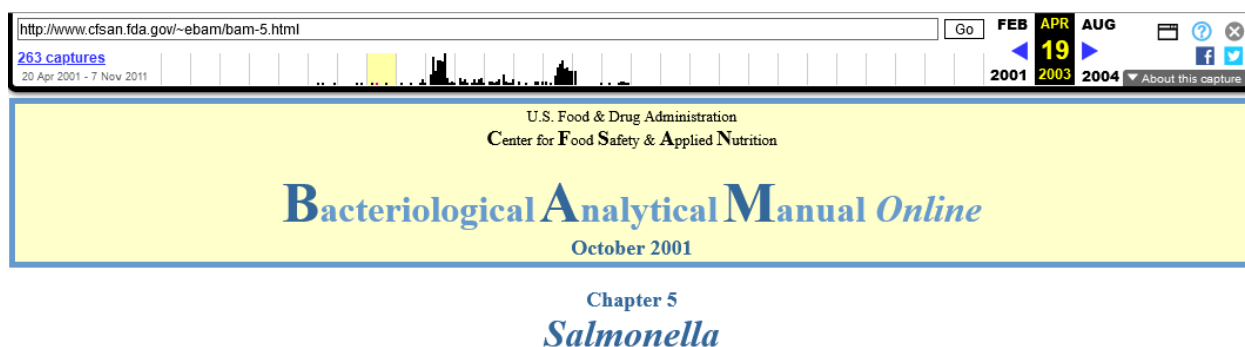
283. Appendix K-3 is a download from the Wayback Machine of the Chapter 1 webpage of BAM 2003. Appendix K-3 is comprised of two parts. The first part is a screen capture of the first page of the Chapter 1 webpage that shows the date as it appeared on June 18, 2003 as shown below. The second part is a complete download of the Chapter 1 webpage as it appeared on June 18, 2003.



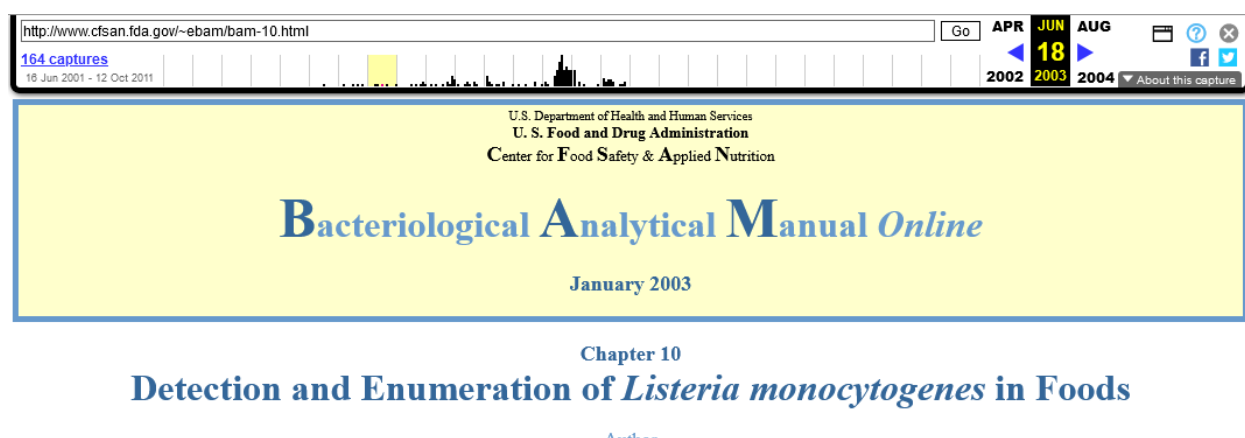
Chapter 1 Food Sampling and Preparation of Sample Homogenate

284. Appendix K-4 is a download from the Wayback Machine of the Chapter 5 webpage of BAM 2003. Appendix K-4 is comprised of two parts. The first part is a screen capture of the first page of the Chapter 5 webpage that shows the date as it

appeared on April 19, 2003 as shown below. The second part is a complete download of the Chapter 5 webpage as it appeared on April 19, 2003.



285. Appendix K-5 is a download from the Wayback Machine of the Chapter 10 webpage of BAM 2003. Appendix K-5 is comprised of two parts. The first part is a screen capture of the first page of the Chapter 10 webpage that shows the date as it appeared on June 18, 2003 as shown below. The second part is a complete download of the Chapter 10 webpage as it appeared on June 18, 2003.



286. I compared Appendices K-1 through K-5 to Exhibit 1022 and the content is the same.

287. The presence of the links for BAM 2003 that correlate Exhibit 1022 with the dates June 3, 2003, April 24, 2003, June 18, 2003, April 19, 2003, and June 18, 2003 and indicate that BAM 2003 would have been available no later than June 18, 2003.

2. Conclusion Re BAM 2003

288. Therefore, based on the evidence presented here, I opine that Exhibit 1022, BAM 2003, is an authentic document that was publicly accessible on the FDA's Center for Food Safety and Applied Nutrition website by at least as early as June 18, 2003.

L. Exhibit 1023 – FSIS Directive

289. I have been asked to opine on the authenticity and public accessibility of a document released on the U.S. Department of Agriculture's Food Safety and Inspection Service ("FSIS") website as "FSIS DIRECTIVE 10,010.1, Revision 1" dated March 31, 2004 with the specific title of "MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES FOR *Escherichia coli* O157:H7 IN RAW GROUND BEEF PRODUCTS AND RAW GROUND BEEF COMPONENTS AND BEEF PATTY COMPONENTS" ("FSIS Directive").

290. I have assessed the authenticity and public accessibility of the FSIS Directive: (1) by reviewing Exhibit 1023 provided by counsel; and (2) by searching and retrieving the FSIS Directive from the Wayback Machine provided by the Internet Archive, attached as Appendices L-1 and L-2.

1. Authenticity and Public Accessibility of FSIS Directive

291. I reviewed and assessed Exhibit 1023 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1023 is compared with scans of the FSIS Directive I retrieved to verify authenticity.

292. To verify the authenticity and public accessibility of the FSIS Directive it is necessary to retrieve evidence from the Wayback Machine. I retrieved Appendices L-1 and L-2 from the Wayback Machine on November 18, 2023. The history and role of the Wayback Machine has been described above in this declaration.

293. Appendix L-1 is a screen capture I made on November 18, 2023 from the Wayback Machine of the FSIS's website on the Regulations and Directives Development webpage dated May 20, 2004 as archived by the Internet Archive and made accessible by the Wayback Machine through the following URL: <https://web.archive.org/web/20040520135754/http://www.fsis.usda.gov:80/oppde/rdad/FSISDir10000.htm>.

294. This archived webpage from May 20, 2004 indicates, toward the bottom of Appendix L-1, that FSIS Directive series "10,010.1 Rev 1" entitled "Microbiological Testing Program for *Escherichia Coli* O157:H7 in Raw Ground Beef Products and

Raw Ground Beef Components and Beef Patty Components” is 28 pages and “New!”

295. By clicking on the live hyperlink “10,010.1 Rev 1” shown by Appendix L-1 I was taken to a webpage archived by the Wayback Machine on July 25, 2004 which is shown by the screen capture and download attached as Appendix L-2 for the following Wayback Machine URL <https://web.archive.org/web/20040725051246/http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10.010.1.pdf>.

296. As described above, the Wayback Machine was inaugurated by the Internet Archive to be a permanent repository of webpages available on a specific day. Not every day was archived, but downloads were made on a schedule that was determined by the Internet Archive or were downloaded into the Wayback Machine by the owner of the website.

297. Inserted below are specific indications of the record content retrieved from the Wayback Machine at the URLs above:





298. The first image, May 20, 2004, documents that the FSIS Directive was “New!” at least as early as May 20, 2004 and could be accessed through the live hyperlink “10,010.1 Rev 1.” When clicking on this hyperlink, it retrieved the FSIS Directive as available from <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10.010.1.pdf> on July 25, 2004, as shown by the second image, July 25, 2004, above.

299. The presence of the hyperlink on May 20, 2004 indicates that the FSIS Directive, more likely than not, would have been publicly accessible, however, since I was not able to retrieve the entire FSIS Directive document until the July 25, 2004 date, I can only show as evidence that the FSIS Directive was publicly accessible as of July 25, 2004.

2. Conclusion Re FSIS Directive

300. Therefore, based on the evidence presented here, I opine that Exhibit 1023, FSIS Directive, is an authentic document that was publicly accessible on the FSIS’s website by at least as early as July 25, 2004.

M. Exhibit 1024 – Midura

301. I have been asked to opine on the authenticity and public accessibility of a book chapter authored by Thaddeus F. Midura and Raymond G. Bryant and titled “*Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis*,” Chapter 2, pages 13-23 in the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, released by the American Public Health Association in 2001 (“Midura”).

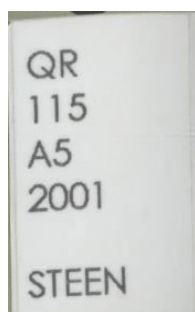
302. For consistency and clarity, it is understood that Midura not only indicates the book chapter under review, but also, when appropriate within the context of this declaration, Midura refers to the edition of the Compendium of Methods for the Microbiological Examination of Foods in which the book chapter was published.

303. I have assessed the authenticity and public accessibility of Midura: (1) by reviewing Exhibit 1024 provided by counsel; and (2) by requesting WTS obtain scans from a print copy owned and held by the University of Wisconsin – Madison Libraries, attached as Appendix M-1.

1. Authenticity of Midura

304. I reviewed and assessed Exhibit 1024 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1024 is compared with scans of Midura I retrieved to verify authenticity.

305. Appendix M-1 includes scans of: the cover of the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001, with a spine label that reads “QR 115 A5 2001 STEEN” as shown below; title page; copyright page with two stamps that read “General Library System University of Wisconsin – Madison 728 State Street Madison, WI 53706-1494 U.S.A.” and “Steenbock Memorial Library University of Wisconsin – Madison 550 Babcock Drive Madison, WI 53706-1293” as shown below; Contents, pages iii-xiii; and Chapter 2, “Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis” by Thaddeus F. Midura and Raymond G. Bryant, pages 13-23:



**General Library System
University of Wisconsin - Madison
728 State Street
Madison, WI 53706-1494
U.S.A.**

Steenbock Memorial Library
University of Wisconsin - Madison
550 Babcock Drive
Madison, WI 53706-1293

306. All identifying characteristics of Appendix M-1, including labels and stamps, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

307. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps observed on the copyright page of Appendix M-1 are consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the University of Wisconsin – Madison Libraries.

308. I have compared Exhibit 1024 with Appendix M-1 obtained from the University of Wisconsin Library System, having found no difference between the two, I conclude that Exhibit 1024 and Appendix M-1 are the same.

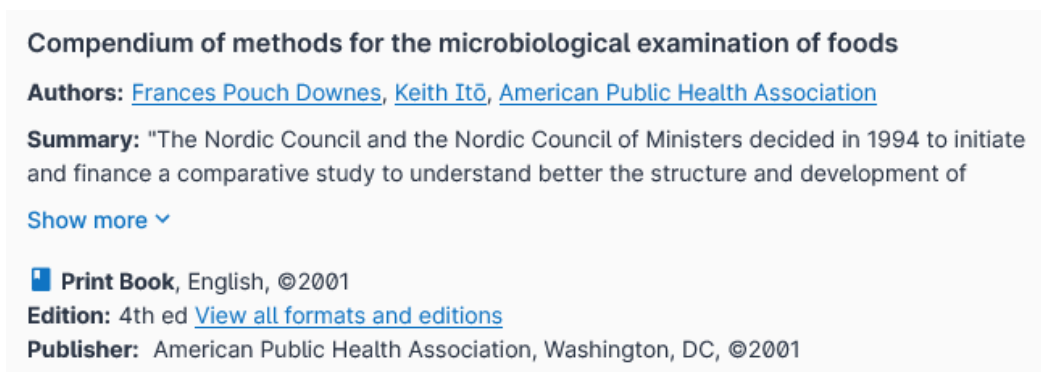
309. This conclusion supports my opinion that Exhibit 1024 is an authentic, true, and correct copy of Midura.

310. Further supporting my opinion of Exhibit 1024's authenticity, Appendix M-1 was found within the custody of a university library, the University of Wisconsin – Madison Library, one of the most likely sources of an authentic copy of the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001.

2. Public Accessibility of Midura

311. Appendix M-2 is a true and correct copy of the WorldCat entry for Midura. I obtained Appendix M-2 by completing a search for the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 on WorldCat on March 11, 2024.

312. Appendix M-2 shows that Midura in the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 is the document associated with this WorldCat entry, as verified by the title, authors, date, edition, and publisher shown in the screen capture below:



313. The Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 could have been located on WorldCat by searching for the title Compendium of Methods for the Microbiological Examination of Foods and/or by searching the subject headings Food Analysis methods, Food Contamination analysis, Food Microbiology, Food Microbiology Methodology, Food Microbiology Technique, among others.

314. When I searched WorldCat for holdings of the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 in Wisconsin, the University of Wisconsin – Madison General Library System was first on the list among the 294 libraries shown as holding an edition of the Compendium of Methods for the Microbiological Examination of Foods.

315. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat through August 6, 2004.

316. Appendix M-3 is a true and accurate copy of the University of Wisconsin – Madison Library online OPAC catalog record for the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 that I downloaded on March 11, 2024.

317. Appendix M-3 indicates that the Compendium of Methods for the Microbiological Examination of Foods was owned and accessible in the University of Wisconsin Steenbock Library and was shelved with call number QR115 A5 2001. This call number corresponds to the call number on the spine label shown in Appendix M-1. The OPAC record indicates that the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 was shelved in the Steenbock Library, the main library of the University of Wisconsin – Madison Libraries, as shown below:

Steenbock Library
Today's hours: 9 a.m.–11:30 p.m.

 **Stacks**
QR115 A5 2001

318. The Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001, including Midura, could have been located in the University of Wisconsin – Madison Library OPAC by searching the title Compendium of

Methods for the Microbiological Examination of Foods, Fourth Edition, 2001 and/or by searching the subject headings Food Microbiology, Food Analysis -- methods, Food Contamination -- analysis, Food -- Microbiology -- Methodology, and Food -- Microbiology -- Technique.

319. Appendix M-4 is the MARC Record of Appendix M-1 from the University of Wisconsin Library OPAC that I retrieved in the same manner as Appendix M-3. Since there is not a date stamp shown in Appendix M-4 for when the University of Wisconsin Library received the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001, it is necessary to identify the date of receipt, cataloging, and indexing through the MARC Record.

320. The MARC Record System uses a specific three-digit numeric code to identify each “field” in a catalog record. For example, MARC Field 008 provides the six-digit date the item was received and/or catalogued by the original cataloging library, more often than not, the Library of Congress. The first six characters of MARC Field 008 are always in the “YYMMDD” format. Descriptions and definitions of all the character positions of MARC Field 008 are outlined at <https://www.loc.gov/marc/bibliographic/bd008a.html>.

321. MARC Field 005 is available to the holding library to indicate the date which the holding library (i.e., the University of Wisconsin Library) entered an item, such as the Compendium of Methods for the Microbiological Examination of Foods,

Fourth Edition, 2001, including Midura, into its online catalog and was therefore available to a researcher. The date structure is not prescribed so each holding library may develop its own date nomenclature, different from the one mandated for MARC Field 008. The MARC 005 and MARC 008 Fields of Appendix M-1 as indicated by Appendix M-4 are shown below:

005	20011129122040.0		
008	010507t20012001dcua	b	001 0 eng

322. MARC Field 008 indicates a date of original cataloging of “010507” (i.e., May 7, 2001).

323. MARC Field 005 indicates a date of cataloging and addition to the OPAC of the University of Wisconsin Library of “20011129” (i.e., November 29, 2001). The remaining digits shown in MARC Field 005 are check digits used by the software program.

324. Therefore, the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001, including Midura, was added to the collections at the University of Wisconsin Library on November 29, 2001, and would have been, after processing and labeling, available to a researcher no later than one week to ten days after that date, consistent with standard library processing time I observed during my years as a professional librarian.

325. Accordingly, the Compendium of Methods for the Microbiological Examination of Foods, Fourth Edition, 2001, including Midura, would have been available in the Steenbock Library at the University of Wisconsin no later than December 10, 2001.

3. Conclusion Re Midura

326. Based on the evidence presented above, it is my opinion that Exhibit 1024, Midura, is an authentic publication that was publicly accessible at least as early as December 10, 2001.

N. Exhibit 1028 – MLG 2003

327. I have been asked to opine on the authenticity and public accessibility of a document released on the U.S. Department of Agriculture's Food Safety and Inspection Service ("FSIS") website in 2003 titled "Microbiology Laboratory Guidebook" including the Introduction/Chapters Available On This Site, Cover, Foreword, General Considerations, Chapter 4.02, Chapter 5.03, and Chapter 8.03 sections ("MLG 2003").

328. For consistency and clarity, it is understood that MLG 2003 not only indicates the documents under review, but also, when appropriate within the context of this declaration, MLG 2003 refers to the edition of the Microbiology Laboratory Guidebook in which those documents were published.

329. I have assessed the authenticity and public accessibility of MLG 2003: (1) by reviewing Exhibit 1028 provided by counsel; (2) by searching and retrieving MLG 2003 from the Wayback Machine provided by the Internet Archive, attached as Appendices N-1 through N-5.

1. Authenticity and Public Accessibility of MLG 2003

330. I reviewed and assessed Exhibit 1028 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1028 is compared with a download of MLG 2003 that I retrieved to verify authenticity.

331. To verify the authenticity and public accessibility of MLG 2003 it is necessary to retrieve evidence from the Wayback Machine. I retrieved Appendices N-1 through N-5 from the Wayback Machine on December 6-11, 2023. The documents shown in Appendices N-1 to N-5 were retrieved by the Internet Archive and downloaded into the Wayback Machine from the FSIS website as it was accessible on dates ranging from April 9, 2003 through February 2, 2004, thereby evidencing that MLG 2003 is an authentic document. Dates for public accessibility will be shown below for Appendices N-1 to N-5 that correlate with Exhibit 1028.

332. As described above, the Wayback Machine was inaugurated by the Internet Archive to be a permanent repository of webpages available on a specific day. Not

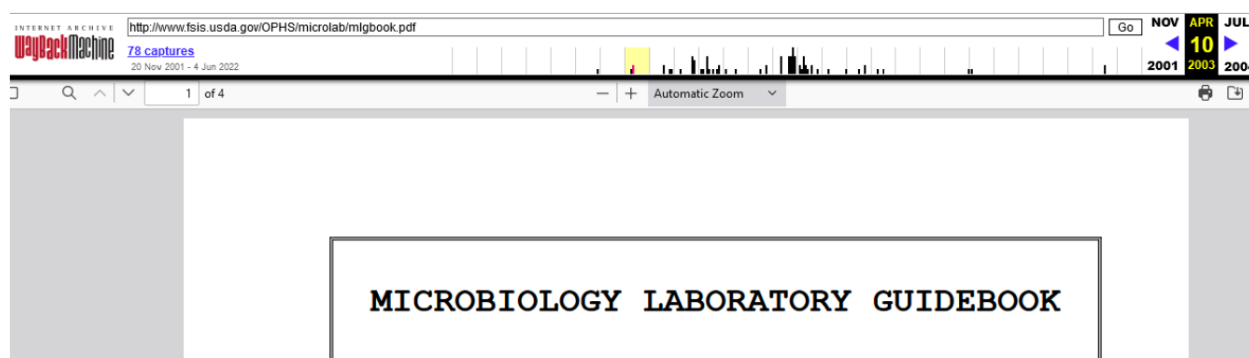
every day was archived, but downloads were made on a schedule that was determined by the Internet Archive or were downloaded into the Wayback Machine by the owner of the website. That practice is evident below since different sections of MLG 2003 were archived on different dates.

333. Appendix N-1 is a download from the Wayback Machine of the FSIS's Microbiology Laboratory Guidebook "Table of Contents" webpage (i.e., Introduction/Chapters Available On This Site section of MLG 2003). Appendix N-1 is comprised of two parts. The first part is a screen capture of the first page of the FSIS's Microbiology Laboratory Guidebook "Table of Contents" webpage that shows the date as it appeared on July 7, 2003 as shown below. The second part is a complete download of the Introduction/Chapters Available On This Site section of MLG 2003 as it appeared on July 7, 2003.



Microbiology Laboratory Guidebook

334. Appendix N-2 is a download from the Wayback Machine of the Cover, Foreword, and General Considerations sections of MLG 2003 as it appeared on April 10, 2003. Appendix N-2 is comprised of two parts. The first part is a screen capture of the Cover of MLG 2003 that shows the date as it appeared on April 10, 2003 as shown below. The second part is a complete download of the Cover, Foreword, and General Considerations sections of MLG 2003 as it appeared on April 10, 2003.



335. Appendix N-3 is a download from the Wayback Machine of the Chapter 4.02 section of MLG 2003 titled “Isolation and Identification of *Salmonella* from Meat, Poultry, and Egg Products” as it appeared on February 2, 2004. Appendix N-3 is comprised of two parts. The first part is a screen capture of the Chapter 4.02 section of MLG 2003 that shows the date as it appeared on February 2, 2004 as shown below. The second part is a complete download of the Chapter 4.02 section of MLG 2003 as it appeared on February 2, 2004.



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of
Public Health
and Science

Laboratory QA/QC Division
950 College Station Road
Athens, GA 30605

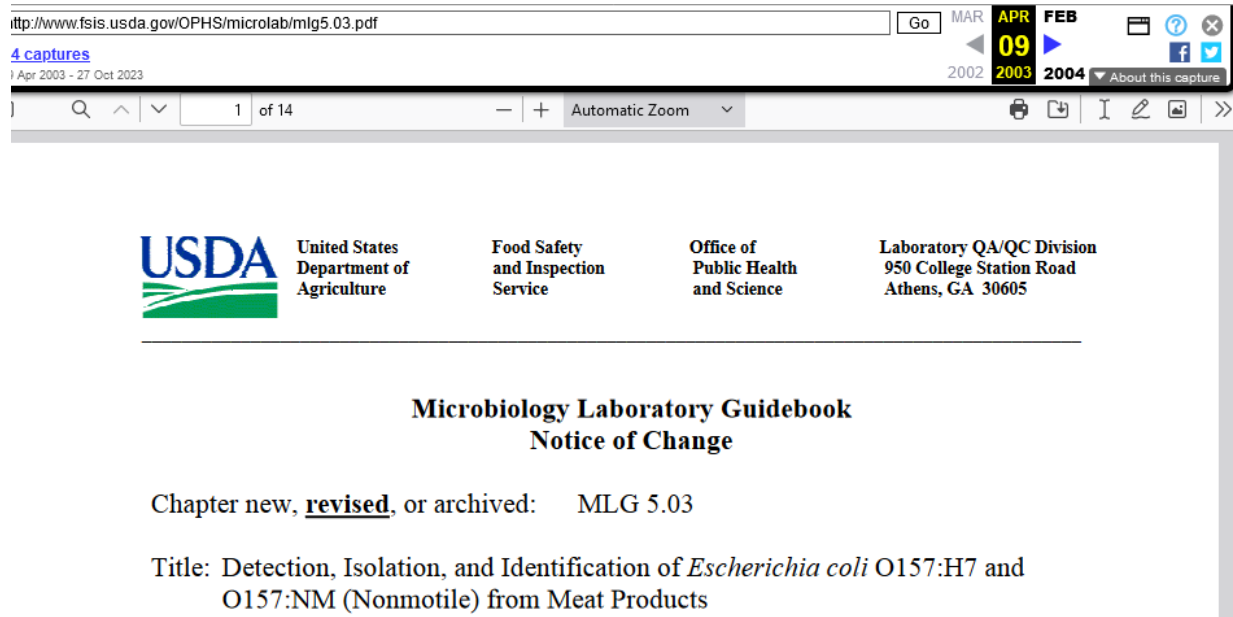
Microbiology Laboratory Guidebook Notice of Change

Chapter new, revised, or archived: MLG 4.02

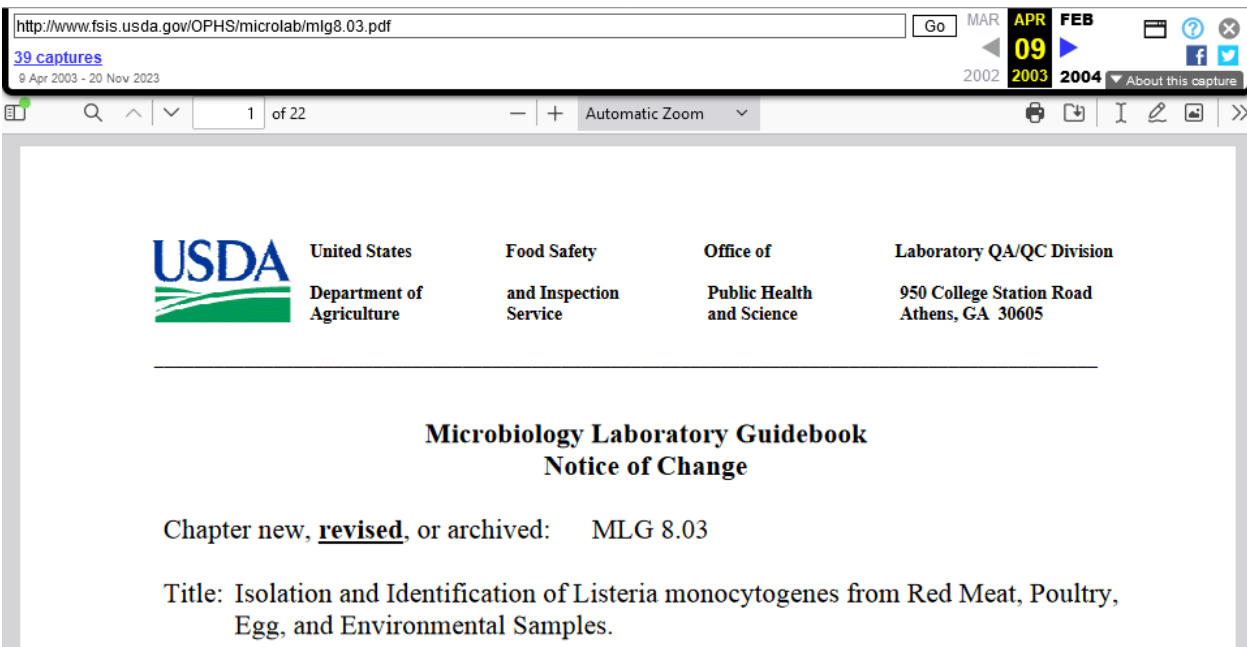
Title: Isolation and Identification of *Salmonella* from Meat, Poultry, and Egg Products

Effective Date: 10/25/02

336. Appendix N-4 is a download from the Wayback Machine of the Chapter 5.03 section of MLG 2003 titled "Detection, Isolation, and Identification of *Escherichia coli* O157:H7 and O157:NM (Nonmotile) from Meat Products" as it appeared on April 9, 2003. Appendix N-4 is comprised of two parts. The first part is a screen capture of the Chapter 5.03 section of MLG 2003 that shows the date as it appeared on April 9, 2003 as shown below. The second part is a complete download of the Chapter 5.03 section of MLG 2003 as it appeared on April 9, 2003.



337. Appendix N-5 is a download from the Wayback Machine of the Chapter 8.03 section MLG 2003 titled “Isolation and Identification of *Listeria monocytogenes* from Red Meat, Poultry, Egg, and Environmental Samples” as it appeared on April 9, 2003. Appendix N-5 is comprised of two parts. The first part is a screen capture of the Chapter 8.03 section of MLG 2003 that shows the date as it appeared on April 9, 2003 as shown below. The second part is a complete download of the Chapter 8.03 section of MLG 2003 as it appeared on April 9, 2003.



338. I compared Appendices N-1 through N-5 to Exhibit 1028 and the content is the same.

339. The presence of the links for MLG 2003 that correlate Exhibit 1028 with the dates July 7, 2003, April 10, 2003, February 2, 2004, April 9, 2003, and April 9, 2003 indicate that MLG 2003 would have been available no later than February 2, 2004.

2. Conclusion Re MLG 2003

340. Therefore, based on the evidence presented here, I opine that Exhibit 1028, MLG 2003, is an authentic document that was publicly accessible on the FSIS's website by at least as early as February 2, 2004.

O. Exhibit 1029 – MLG 1998

341. I have been asked to opine on the authenticity and public accessibility of a document released by the U.S. Department of Agriculture’s Food Safety and Inspection Service (“FSIS”) titled “*Microbiology Laboratory Guidebook*,” Third Edition, 1998, including Chapter 8 titled “ISOLATION AND IDENTIFICATION OF *LISTERIA MONOCYTOGENES* FROM MEAT, POULTRY AND EGG PRODUCTS” (“MLG 1998”).

342. For consistency and clarity, it is understood that MLG 1998 not only indicates Chapter 8 under review, but also, when appropriate within the context of this declaration, MLG 1998 refers to the edition of the Microbiology Laboratory Guidebook in which Chapter 8 was published.

343. I have assessed the authenticity and public accessibility of MLG 1998: (1) by reviewing Exhibit 1029 provided by counsel; and (2) by locating and downloading MLG 1998 from HathiTrust, which provided access to a digitized version of the print copy held by the University of Minnesota Libraries, attached as Appendix O-1.

1. Authenticity and Public Accessibility of MLG 1998

344. Although HathiTrust has been described above in the introductory section of this declaration, to have it clearly understood as it relates to MLG 1998 I will summarize the creation and intent of HathiTrust.

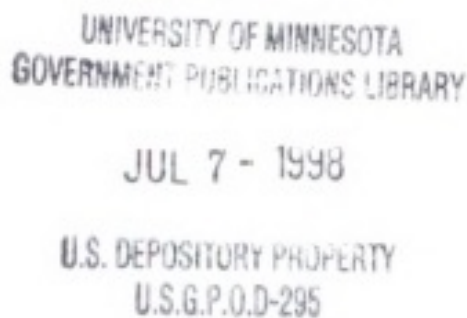
345. During my tenure as dean of libraries at Purdue University, HathiTrust was conceptualized around the 2007-2008 timeframe. The Big Ten University Libraries and Google, Inc., initiated a collaborative effort to digitize library collections from those libraries, which, at that time included the University of Illinois, Indiana University, the University of Iowa, Michigan State University, the University of Michigan, the University of Minnesota, Northwestern University, Ohio State University, Penn State University, Purdue University, and the University of Wisconsin. This collaborative effort was joined by the University of California and Stanford University.

346. The name HathiTrust was chosen to convey long term preservation and memory. Hathi is Hindi for elephant, an animal often identified as having a remarkable memory. The member libraries committed to making their collections available for scanning by Google at its expense to provide access by researchers to collections of these major research libraries.

347. HathiTrust is funded and managed as a non-profit organization by its members. Institutional membership is required to have full access to content. While copyright law may restrict full access to some works, since government publications, such as those of the federal government, are in the public domain, full access to such works is not restricted by copyright law. Thus, copyright law does not restrict full access to MLG 1998.

348. Appendix O-1 is a download of MLG 1998 from HathiTrust that I made on December 16-26, 2023 enabled by my emeritus faculty status at Purdue University through the following URL: <https://babel.hathitrust.org/cgi/pt?id=umn.31951d017531255> (redirected from <https://hdl.handle.net/2027/umn.31951d017531255>).

349. Appendix O-1 is comprised of: a HathiTrust cover page that states “Public Domain, Google-digitized”; title page with a stamp that reads “UNIVERSITY OF MINNESOTA GOVERNMENT PUBLICATIONS LIBRARY JUL 7 – 1998 U.S. DEPOSITORY PROPERTY U.S.G.P.O.D.-295” as shown below; Foreword; General Considerations; Contents, Volumes 1 and 2; and Chapter 8 titled “ISOLATION AND IDENTIFICATION OF *LISTERIA MONOCYTOGENES* FROM MEAT, POULTRY AND EGG PRODUCTS”:



350. All identifying characteristics of Appendix O-1, including the stamp above, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

351. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamp on the title page is consistent with stamps I have observed during my career as a professional librarian.

352. The date stamped on Appendix O-1 is evidence MLG 1998 was received by the University of Minnesota Library on July 7, 1998, more likely than not as a federal depository item. An additional marking at the bottom of all pages of Appendix O-1 but the first page reads “Digitized by Google” and “Original from UNIVERSITY OF MINNESOTA” indicating that this digitized version was obtained by Google, Inc., for digitization from the University of Minnesota.

353. The stamp above is evidence that MLG 1998 was received by the University of Minnesota Library on July 7, 1998. From my experience, it would then require no more than a week to ten days for processing and transfer to the shelf where it would be publicly accessible, therefore MLG 1998 would have been publicly accessible no later than July 17, 1998.

354. I have compared Exhibit 1029 with Appendix O-1. That is, I compared Exhibit 1029 provided by counsel with the copy of MLG 1998 I obtained from

HathiTrust as the digitized version of the University of Minnesota Library print copy, and I conclude that Exhibit 1029 and Appendix O-1 are the same.

355. This conclusion supports my opinion that Exhibit 1029 is an authentic, true, and correct copy of MLG 1998. Further supporting my opinion of its authenticity, MLG 1998 was found within the custody of a university library, the University of Minnesota, one of the most likely sources of an authentic copy of MLG 1998.

356. Appendix O-2 is a true and correct copy of the WorldCat entry for the MLG 1998. I obtained Appendix O-2 by completing a search for MLG 1998 on WorldCat on December 26, 2023.

357. Appendix O-2 shows that the Microbiology Laboratory Guidebook, Third Edition, 1998 is the document associated with this WorldCat entry, as verified by the title, author, edition, date, and publisher shown below:

Microbiology laboratory guidebook

Author: [United States](#)

 Continuously Updated Resource, English, 1998-

Edition: 3rd ed., 1998 [View all formats and editions](#)

Publisher: U.S. Dept. of Agriculture, Food Safety and Inspection Service, Office of Public Health and Science, Microbiology Division : For sale by the U.S. G.P.O., Supt. of Docs., Washington, D.C., 1998-

358. MLG 1998 could have been located on WorldCat by searching for the title Microbiology Laboratory Guidebook, Third Edition, 1998 and/or using the subject headings Agricultural microbiology, Agricultural microbiology United States

Laboratory manuals, Food Microbiology, and/or Food Microbiology United States Laboratory manuals, among others.

359. When I searched WorldCat for holdings of MLG 1998 in Minnesota, the University of Minnesota, Twin Cities was fourth on the list among 121 libraries shown as holding an edition of MLG 1998 worldwide.

360. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

361. Appendix O-3 is a true and accurate copy of the University of Minnesota Library online OPAC catalog record for MLG 1998.

362. Appendix O-3 indicates that the MLG 1998 is owned by and accessible at the University of Minnesota, shelved at the TC Magrath Library with call number Gov Pub (US Docs) ; A 110.8:M 58/V.1-2 as shown below:

LOCATION ITEMS

TC Magrath Library
Available, Gov Pub (US Docs) ; A 110.8:M 58/V.1-2
(1 copy, 1 available, 0 requests)

2. Conclusion Re MLG 1998

363. Therefore, based on the evidence presented here, I opine that Exhibit 1029, MLG 1998, is an authentic document that was publicly accessible by at least as early as July 17, 1998.

P. Exhibit 1032 – BAM 1969

364. I have been asked to opine on the authenticity and public accessibility of a document released by the U.S. Department of Health, Education, and Welfare, Food and Drug Administration (“FDA”) titled “*Bacteriological Analytical Manual*,” Second Edition, 1969, including Chapter 10, Section 10.04 (“BAM 1969”).

365. For consistency and clarity, it is understood that BAM 1969 not only indicates Chapter 10, Section 10.04 under review, but also, when appropriate within the context of this declaration, BAM 1969 refers to the edition of the Bacteriological Analytical Manual in which Chapter 10, Section 10.04 was published.

366. I have assessed the authenticity and public accessibility of BAM 1969: (1) by reviewing Exhibit 1032 provided by counsel; and (2) by locating and downloading BAM 1969 from HathiTrust, which provided access to a digitized version of the print copy held by the University of Minnesota Libraries, attached as Appendix P-1.

1. Authenticity and Public Accessibility of BAM 1969

367. Although HathiTrust has been described above in this declaration, to have it clearly understood as it relates to BAM 1969 I will summarize the creation and intent of HathiTrust.

368. During my tenure as dean of libraries at Purdue University, HathiTrust was conceptualized around the 2007-2008 timeframe. The Big Ten University Libraries and Google, Inc., initiated a collaborative effort to digitize library collections from those libraries, which, at that time included the University of Illinois, Indiana University, the University of Iowa, Michigan State University, the University of Michigan, the University of Minnesota, Northwestern University, Ohio State University, Penn State University, Purdue University, and the University of Wisconsin. This collaborative effort was joined by the University of California and Stanford University.

369. The name HathiTrust was chosen to convey long term preservation and memory. Hathi is Hindi for elephant, an animal often identified as having a remarkable memory. The member libraries committed to making their collections available for scanning by Google at its expense to provide access by researchers to collections of these major research libraries.

370. HathiTrust is funded and managed as a non-profit organization by its members. Institutional membership is required to have full access to content. While

copyright law may restrict full access to some works, since government publications, such as those of the federal government, are in the public domain, full access to such works is not restricted by copyright law. Thus, copyright law does not restrict full access to BAM 1969.

371. Appendix P-1 is a download of BAM 1969 from HathiTrust that I made on December 6, 2023 enabled by my emeritus faculty status at Purdue University through the following URL:
<https://babel.hathitrust.org/cgi/pt?id=umn.31951p010907453> (redirected from <https://hdl.handle.net/2027/umn.31951p010907453>).

372. Appendix P-1 is comprised of: a HathiTrust cover page that states “Public Domain, Google-digitized”; title page with a stamp near the top of the page that reads “UNIVERSITY OF MINNESOTA LIBRARY MAY 26 1969” and a stamp near the bottom of the page that reads “Original from UNIVERSITY OF MINNESOTA” as shown below; Introduction; Contents; Chapters 1-14; Chapters 40-42; and Chapter 43, “References”:



Original from
UNIVERSITY OF MINNESOTA

373. All identifying characteristics of Appendix P-1, including the stamps above, are consistent with standard library practice and procedure that I observed during my career as a professional librarian, and support a conclusion of authenticity.

374. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps on the title page are consistent with stamps I have observed during my career as a professional librarian.

375. The date stamped on Appendix P-1 is evidence BAM 1969 was received by the University of Minnesota Library on May 28, 1969, more likely than not as a federal depository item. The bottoms of all pages of Appendix P-1 but the first page include the stamp that reads "Original from UNIVERSITY OF MINNESOTA," as well as the indication that this document was "Digitized by Google."

376. The stamps above are evidence that BAM 1969 was received by the University of Minnesota Library on May 28, 1969. From my experience, it would

then require no more than a week to ten days for processing and transfer to the shelf where it would be publicly accessible, therefore BAM 1969 would have been publicly accessible no later than June 9, 1969.

377. I have compared Exhibit 1032 with Appendix P-1. That is, I compared Exhibit 1032 provided by counsel with the copy of BAM 1969 I obtained from HathiTrust as the digitized version of the University of Minnesota Library print copy, and I conclude that Exhibit 1032 and Appendix P-1 are the same.

378. This conclusion supports my opinion that Exhibit 1032 is an authentic, true, and correct copy of BAM 1969. Further supporting my opinion of its authenticity, BAM 1969 was found within the custody of a university library, the University of Minnesota, one of the most likely sources of an authentic copy of BAM 1969.

379. Appendix P-2 is a true and correct copy of the WorldCat entry for BAM 1969. I obtained Appendix P-2 by completing a search for BAM 1969 on WorldCat on December 6, 2023.

380. Appendix P-2 shows that BAM 1969 is the document associated with this WorldCat entry, as verified by the title, author, date, and shown below:

BACTERIOLOGICAL ANALYTICAL MANUAL

Author: [United States](#)

 **Print Book**, English, 1969

Edition: [View all formats and editions](#)

Publisher: [UNITED STATES. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE. FOOD AND DRUG ADMINISTRATION], 1969

381. BAM 1969 could have been located on WorldCat by searching for the title.

“Bacteriological Analytical Manual,” Second Edition, 1969.

382. When I searched WorldCat for holdings of BAM 1969 in Minnesota, the University of Minnesota, Twin Cities was first on the list among 213 libraries shown as holding an edition of BAM 1969 worldwide.

383. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

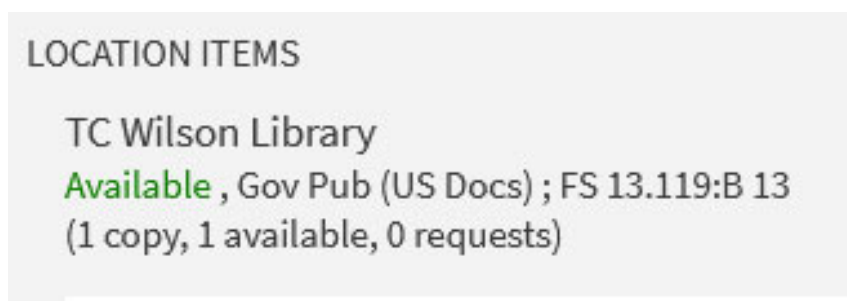
384. When BAM 1969 was released there were no digital databases or even a digital library catalog, like OPAC, in existence. MARC format was only recently developed by the Library of Congress and in the early implementation stage. Therefore, to locate a government publication such as BAM 1969 it would have been necessary to access the Monthly Catalog of United States Government Publications (“Monthly Catalog”) described above in the introduction.

385. The Monthly Catalog was the primary means by which researchers located government publications. It was searchable in print by title, agency, or subject. Typically, a research library that had a large government publications collection also had a librarian who was a specialist in searching and locating government publications. More likely than not, the University of Minnesota Library would have

had such a librarian from the 1960s well into the 21st century. This librarian would have been accessible to assist a researcher to locate BAM 1969.

386. Appendix P-3 is a true and accurate copy of the University of Minnesota Library online OPAC catalog record for BAM 1969.

387. Appendix P-3 indicates that BAM 1969 is owned by and accessible at the University of Minnesota, shelved at the TC Wilson Library with call number Gov Pub (US Docs) ; FS 13.119:B 13 as shown below:



388. This call number corresponds to the stamped call number on the title page of Appendix P-1 as shown below:

GOVU
FS 13.119:B 13

2. Conclusion Re BAM 1969

389. Therefore, based on the evidence presented here, I opine that Exhibit 1032, BAM 1969, is an authentic document that was publicly accessible by at least as early as June 9, 1969.

Q. Exhibit 1033 – JAOAC 1967

390. I have been asked to opine on the authenticity and public accessibility of an article titled “*Changes in Official Methods of Analysis Made at the Eightieth Annual Meeting, October 10-13, 1966*” published in the Journal of the Association of Official Analytical Chemists, February 1967, Volume 50, Number 1, pages 231-239 (“JAOAC 1967”).

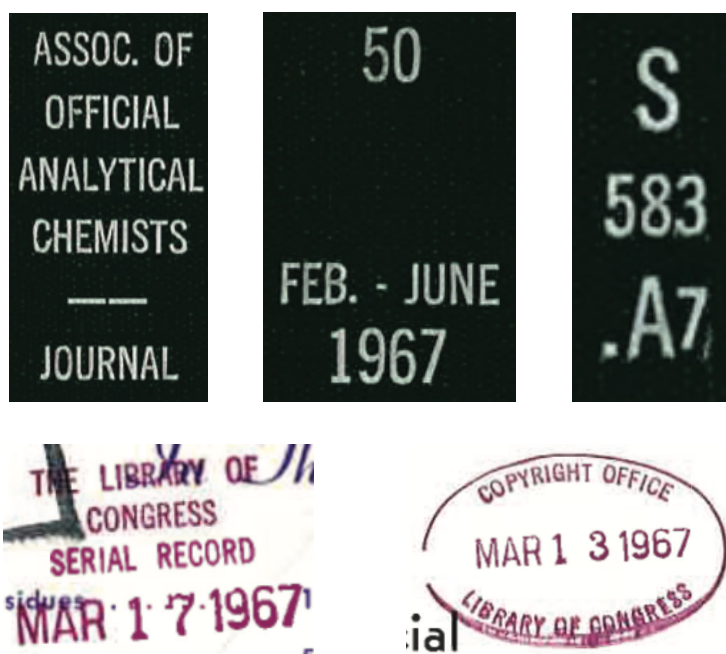
391. For consistency and clarity, it is understood that JAOAC 1967 not only indicates the article under review, but also, when appropriate within the context of this declaration, JAOAC 1967 refers to the issue of the Journal of the Association of Official Analytical Chemists in which the article was published.

392. I have assessed the authenticity and public accessibility of JAOAC 1967: (1) by reviewing Exhibit 1033 provided by counsel; (2) by requesting WTS obtain scans from a print copy owned and held by the Library of Congress, attached as Appendix Q-1; and (3) by requesting through the Purdue University Libraries Interlibrary Loan Department, as an emeritus faculty member, an interlibrary loan request from the Oxford University Press, attached as Appendix Q-2.

1. Authenticity of JAOAC 1967

393. I reviewed and assessed Exhibit 1033 provided by counsel. There does not appear to be text missing, each paragraph and page proceeds in a consistent manner with no apparent interruption in sentence structure or paragraphs caused by deletion. Exhibit 1033 is compared with scans of JAOAC 1967 I retrieved to verify authenticity.

394. Appendix Q-1 includes scans of: a bound cover with markings that read “ASSOC. OF OFFICIAL ANALYTICAL CHEMISTS – JOURNAL 50 FEB.-JUNE 1967 S 583 .A7” as shown below; issue title page with a stamp that reads “THE LIBRARY OF CONGRESS SERIAL RECORD MAR 17 1967” as shown below; contents page with a stamp that reads “COPYRIGHT OFFICE MAR 13 1967 LIBRARY OF CONGRESS” as shown below; and pages 190 and 231-239:



395. Please note that due to the tight binding of the journal volume, the scans of the text of Appendix Q-1 are somewhat difficult to read near the binding, but the text when compared to the text of Exhibit 1033 is legible enough to determine that the text is the same.

396. All identifying characteristics, including the markings and stamps on Appendix Q-1, are consistent with library practice and procedure that I have observed during my career as a professional librarian, and specifically with those items held by the Library of Congress.

397. I have no cause for concern about the authenticity or accuracy of these identifying attributes. In particular, the stamps observed on Appendix Q-1 are consistent with stamps I have observed applied to documents I have retrieved through WTS from numerous libraries, including the Library of Congress.

398. In addition, JAOAC 1967 was found within the custody of a library, the Library of Congress, one of the most likely locations for an authentic publication to be located. Evidence of the ownership of JAOAC 1967 by the Library of Congress is further explored and detailed in the section below on public access.

399. Appendix Q-2 is a download of JAOAC 1967 completed by the Oxford University Press from the request I made to the Purdue University Interlibrary Loan Department as an emeritus faculty member.

400. After comparison between Exhibit 1033 with the corresponding pages of Appendices Q-1 and Q-2, I found no differences between Exhibit 1033 and Appendices Q-1 and Q-2. Therefore, I conclude that these copies of JAOAC 1967, Exhibit 1033 and Appendices Q-1 and Q-2, are the same.

401. This conclusion supports my opinion that Exhibit 1033 is an authentic, true, and correct copy of JAOAC 1967.

2. Public Accessibility of JAOAC 1967

402. Appendix Q-3 is a true and correct copy of the WorldCat entry for JOAOC 1967. I obtained Appendix Q-3 by completing a search for JAOAC 1967 on WorldCat on December 7, 2023.

403. Appendix Q-3 shows that JAOAC 1967 is the document associated with this WorldCat entry, as verified by the title Journal of the Association of Official Analytical Chemists.

404. JAOAC 1967 could have been located in WorldCat by searching for the title the Journal of the Association of Official Analytical Chemists and/or by searching the subject headings 34.20 analytical chemistry: general, Agricultural chemistry, Analytical chemistry, and/or Food Analysis, among others.

405. When I searched WorldCat for holdings of the Journal of the Association of Official Analytical Chemists in the District of Columbia, the Library of Congress

was fifth on the list among the 508 libraries shown as holding the Journal of the Association of Official Analytical Chemists worldwide.

406. From the 1960s through the late 1990s, JAOAC 1967 could have been located by searching print indexes prior to the advent of digital databases. Among these print databases would have been Chemical Abstracts and the Biological and Agricultural Index, among others. These print indexes, from my experience of libraries during the 1960s onward, would have been readily available in research libraries.

407. The search discussed above could have been performed anywhere in the world by anyone who accessed WorldCat or its predecessor database, FirstSearch, through an OCLC member library from the 1990s through August 6, 2004.

408. Appendix Q-4 is a true and accurate copy of the Library of Congress online OPAC catalog record for JAOAC 1967 that I downloaded on December 5, 2023.

409. The document cataloged in this record is JAOAC 1967 as verified by the OPAC record fields including the title Journal of the Association of Official Analytical Chemists.

410. The record of holdings of the Journal of the Association of Official Analytical Chemists held by the Library of Congress is shown in the lines, as shown below, that read “Published/Created [Washington, D.C.] : The Association, 1966-1991.” indicating that the Journal of the Association of Official Analytical Chemists began

publication in 1966 and continued, under this title, until 1991. It succeeded an earlier title the Journal of the Association of Official Agricultural Chemists and was succeeded by the later title of the Journal of AOAC International.

Published/Created

[Washington, D.C.] : The Association, 1966-1991.

411. Evidence that the Library of Congress received and holds JAOAC 1967 is shown in the OPAC record under the heading titled “Older receipts” on the last page of Appendix Q-4, as shown below, which reads “v.49-v.74 (1966:Feb.-1991) Bound volumes: Inventory in progress,” which is inclusive of February 1967, Volume 50, Number 1:

Older receipts v.49-v.74 (1966:Feb.-1991) Bound volumes: Inventory in progress

412. JAOAC 1967 could have been located in the Library of Congress OPAC by searching for the title the Journal of the Association of Official Analytical Chemists and/or by searching the subject headings Agricultural chemistry, Food--Analysis, 35.20 analytical chemistry: general, and/or Analytical chemistry, among others.

413. The date stamped on Attachment Q-1 of March 17, 1967 shown below indicates receipt of JAOAC 1967 by the Library of Congress Serial Record Department after which it would have been sent to the cataloging processing, labeling, stamping, and shelving at the Library of Congress:



414. The physical copy of JAOAC 1967 at the Library of Congress would have been available for public access within one week to ten days after it was received on March 17, 1967. Therefore, JAOAC 1967 would have been available in the Library of Congress no later than March 27, 1967.

415. Once JAOAC 1967 was entered into the general collection of the Library of Congress, members of the public could access the book by having it brought to either the Jefferson or Adams Reading Rooms.

416. Members of the public could read, study, and make notes about a selected work in the Library of Congress Reading Rooms. Further, members of the public were permitted to make photocopies of portions of the work while in the Reading Rooms. Accordingly, a copy of JAOAC 1967 was accessible to the public when it was available at the Library of Congress.

3. Conclusion Re JAOAC 1967

417. Based on the evidence presented here, it is my opinion that Exhibit 1033, JAOAC 1967, is an authentic document that was publicly accessible at least as early as March 27, 1967.

VI. RIGHT TO SUPPLEMENT

418. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to consider new information as it becomes available to me.

VII. CERTIFICATION

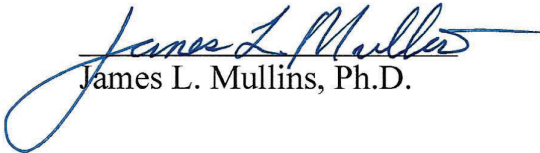
419. In signing this declaration, I recognize that this declaration will be filed in support of the Petitioner in case numbers IPR2024-00183, IPR2024-00185, IPR2024-00186 at the U.S. Patent and Trademark Office.

420. I acknowledge that, as part of these IPRs, if an IPR trial is instituted, I may be subject to cross-examination in the United States regarding the content of this declaration. If cross-examination is required of me, I will make myself reasonably available for cross-examination within the United States during the time allotted for cross-examination.

421. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code.

Dated: May 19, 2024

Respectfully submitted,


James L. Mullins, Ph.D.