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ANALYSIS OF REPLIES RECEIVED FROM DEPOSITARY INSTITUTIONS TO THE WIPO QUESTIONNAIRE ON DEPOSITS OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

prepared by the International Bureau

This document contains an analysis of replies, received from institutions that accept deposits of microorganisms for the purposes of patent procedure, to the International Bureau's questionnaire relating to the organization and activities of those institutions and the conditions applied with respect to deposits of microorganisms for the purposes of patent procedure.

1. Reference is made to documents DMO/III/2 and 3 containing a Draft Treaty and Draft Regulations on the international recognition of the deposit of microorganisms for the purposes of patent procedure. The system of recognition provided for in those drafts is based on the requirement that deposits be made with "internationally recognized depositary authorities." In order to obtain the status of an internationally recognized depositary authority, a depositary institution would have to fulfill conditions of a technical, organizational and legal nature (see in particular Articles 5 and 6 of the Draft Treaty and Rules 2, 6, 8, 10, 11, 12 and 13 of the Draft Regulations).

2. In order to assess the present methods of operation and relevant conditions of depositary institutions which accept deposits of microorganisms for the purposes of patent procedure, the International Bureau has undertaken a survey on those institutions. For that purpose, the International Bureau submitted on October 7, 1974, a questionnaire to all such institutions known to it on that date. The questions appear in this document.

3. By January 20, 1975, fourteen institutions had replied to the questionnaire, indicating that they accepted--regularly or only occasionally--deposits of microorganisms for the purposes of patent procedure. They are the following:

Abbreviations used in this document	Name and address
ARS	Agricultural Research Service Culture Collection Northern Regional Research Laboratory Peoria, Illinois 61604 (United States of America)
ATCC	American Type Culture Collection 12301 Parklawn Drive, Rockville Maryland 20852 (United States of America)
CBS	Central Bureau Voor Schimmelcultures Oosterstraat 1, Baarn (Netherlands)
CCAP	Culture Centre of Algae and Protozoa 36 Storey's Way, Cambridge, CB3 0DT (United Kingdom)
CCM	Czechoslovak Collection of Microorganisms J.E. Purkyně University, třída Obránců Míru 10, Brno (Czechoslovakia)
CMI	Commonwealth Mycological Institute Ferry Lane, Kew, Surrey (United Kingdom)
FRI	Fermentation Research Institute Inage, Chiba City (Japan)
IF	Institute for Fermentation 17-85 Juso-honmachi, 2 chome Yodogawa-ku, Osaka 532 (Japan)
IHE	Institute for Hygiene and Epidemiology Šrobárova 48, Prague 19 (Czechoslovakia)
ISCD	Institute for State Control of Drugs Bul. VI Zaimov 26, Sofia (Bulgaria)

NCIB	National Collection of Industrial Bacteria Torry Research Station, PO Box No 31 135 Abbey Road, Aberdeen AB9 8DG (United Kingdom)
NCL	National Chemical Laboratory Poona-411008 (India)
NCTC	National Collection of Type Cultures Colindale Avenue, London NW9 5HT (United Kingdom)
NIH	National Institute of Hygiene 2-6 Budapest (Hungary)

As can be seen, of the fourteen institutions, one is located in Bulgaria, two in Czechoslovakia, one in Hungary, one in India, two in Japan, one in the Netherlands, four in the United Kingdom, and two in the United States of America. The full texts of any of the replies may be obtained from the International Bureau on request.

4. The analysis of the replies received follows the order of the questions contained in the questionnaire.

I. GENERAL

Question 1. Is your institution a government agency or a private entity?

5. Ten institutions[1] replied that they were government agencies and two indicated that they were private entities.[2] One institution[3] indicated that it was partly governmental and partly a foundation and one specified that it was an intergovernmental agency.[4]

Question 2. Is your institution supervised or controlled by a government agency? If so, which agency?

6. One institution[5] answered in the negative. Four institutions[6] indicated that they were controlled by the Ministry of Health, two by the Ministry of Education[7] and two by the Department of Agriculture.[8] Five institutions specified that they were controlled by different bodies, such as: Natural Environment Research Council;[9] Academy of Sciences and Letters;[10] Agency of Industrial Science and Technology;[11] Council of Scientific and Industrial Research;[12] Executive Council of Representatives of Contributing Countries.[13]

Question 3. How is your institution financed?

7. Eight institutions[14] indicated that they were financed by their respective governments and one stated that it received mixed contributions (70% from the government and 30% from other sources).[15] One institution[16] indicated that it was financed by the Ministry of Construction and Technics and one by the Ministry of Education.[17] Three institutions reported that they were financed from the following different sources: fees for services and government contracts;[18] private company;[19] annual budget of unspecified source.[20]

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1. ARS; CCAP; CCM; FRI; IHE; ISCD; NCIB; NCL; NCTC; NIH. 2. ATCC; IF. 3. CBS. 4. CMI. 5. ATCC. 6. CMI; IHE; ISCD; NCTC. 7. CCM; IF. 8. ARS; NCIB. 9. CCAP. 10. CBS. 11. FRI. 12. NCL. 13. CMI. 14. ARS; CCAP; CMI; ISCD; NCIB; NCL; NCTC; NIH. 15. CBS. 16. IHE. 17. CCM. 18. ATCC. 19. IF. 20. FRI.

Question 4. (a) What is the total number of staff employed by your institution?

(b) How many scientists with a university degree are employed?

8. The replies received indicated that the total number of staff employed ranged from a maximum of 450 to a minimum of nine. The proportion of staff members who were scientists with university degrees averaged around 43%.

Question 5. What is the size of the building(s) used by your institution?

9. The replies to this question varied in the sense that a first group of eight institutions[21] expressed the size of their buildings in square meters (or square feet), whilst a second group of five institutions[22] answered by giving a more general description of their premises. With respect to the first group of institutions, the size of the buildings ranged from a maximum of 5000 m^2 to a minimum of 280 m^2. As for the second group of institutions, the composition of the buildings ranged from a maximum of 16 to a minimum of of three laboratory rooms. Within the second group of institutions, two of them[23] specified that the buildings included a vivarium, autoclave premises, a collection room and a library. One institution[24] reported that its buildings covered an area of 7.5 acres.

II. ACTIVITIES

Question 6. Which kinds of microorganisms does your institution deal with?

10. The replies to this question varied considerably, since each institution indicated that it dealt with several kinds of microorganisms at the same time. Therefore, the replies received had been analyzed in terms of the kinds of microorganisms most frequently mentioned. Those were, in order of frequency: BACTERIA (mentioned by ten institutions,[25] one institution indicating that it dealt with agricultural and industrially important bacteria[26]); FUNGI (mentioned by six institutions,[27] one institution indicating that it dealt with non-pathogenic fungi,[28] one institution with microfungi of interest to pathology, industry, biodegradation studies, biochemical research and education[29] and one institution with fungi of medical significance[30]); YEASTS (mentioned by four institutions,[31] one institution adding that it dealt with agriculturally and industrially important yeasts[32]); ACTINOMYCETES (mentioned by four institutions,[33] one institution indicating that it dealt with agriculturally and industrially important actinomycetes[34]); VIRUSES (mentioned by three institutions,[35] one institution specifying that it dealt with animal and plant viruses[36] and one with animal viruses only[37]); ALGAE (mentioned by three institutions,[38] one institution indicating that it dealt with algae other than large seaweeds[39]); PROTOZOA (mentioned by two institutions,[40] one institution specifying that it dealt with free-living protozoa[41]); MOLDS (mentioned by two institutions,[42] one institution adding that it dealt with agriculturally and industrially important molds[43]); BACTERIOPHAGES (mentioned by two institutions[44]). Other kinds of microorganisms, each of which was mentioned by one institution, were the following: CELL LINES;[45] FAGES;[46] MYCOPLASMAS;[47] patent-oriented MICROBES;[48] MICROORGANISMS pathogenic for human beings;[49] ENTEROBACTERIACEAE and PSEUDOMONAS AERUGINOSA.[50]

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21. ATCC; CCAP; CCM; CMI; FRI; IF; NCIB; NCTC. 22. CBS; IHE; ISCD; NCL; NIH. 23. CBS; ISCD. 24. ARS. 25. ARS; ATCC; CBS; CCM; IF; IHE; NCIB; NCL; NCTC; NIH. 26. ARS. 27. ATCC; CBS; CCM; CMI; IHE; NCL; 28. NCL; 29. CMI. 30. IHE. 31. ARS; CBS; IF; NCL. 32. ARS. 33. ARS; CBS; IF; NCIB. 34. ARS. 35. ATCC; CCM; IHE. 36. ATCC. 37. CCM. 38. ATCC; CBS; CCAP. 39. ATCC. 40. ATCC; CCAP. 41. CCAP. 42. ARS; IF. 43. ARS. 44. ATCC; IF. 45. ATCC. 46. IHE. 47. CCM. 48. FRI. 49. ISCD. 50. NIH.

Question 7. How many different strains are contained in your collection?

11. The replies to this question indicated that the number of strains contained in each collection ranged from a maximum of 50,000 to a minimum of 2,000 different strains. However, for nine institutions,[51] the number of different strains contained in their collections ranged between 2,000 and 4,000 (one institution stated that its collection contained 3,000 listed and about 20,000 unlisted strains); for two institutions[52] the figure was between about 7,500 and 6,300; one institution[53] indicated that its collection contained about 19,000 different strains, another institution[54] about 20,000 strains and yet another institution[55] 50,000 different strains.

Question 8. (a) How many deposits are made each year?

12. The answers received to this question were very varied. A group of six institutions[56] specified that they received between 50 and 100 deposits a year. Two institutions[57] indicated that the number of deposits each year ranged between 900 and 2000. Two institutions[58] reported that they received between 200 and 400 deposits a year, one institution[59] indicated an average of 600 deposits a year and two institutions[60] stated that they received between 10 and 20 deposits each year. One institution[61] indicated that the number of deposits varied considerably, depending on a number of factors.

Question 8. (b) How many deposits relate to patent cases?

13. The replies to this question also varied considerably. The number of deposits relating to patent cases ranged between a maximum of about 600 and a minimum of four deposits a year. However, for eight institutions[62] the deposits concerning patent cases ranged between four and 50 a year. Two institutions[63] specified that they received between 100 and 200 deposits a year in connection with patent cases. One institution[64] pointed out that the average number of deposits relating to patent cases was around 600 a year. One institution[65] indicated that the deposits relating to patent cases amounted to about 10% of all the deposits made in a year. Two institutions[66] reported that at present they did not receive any deposits for patent purposes.

Question 8. (c) How many deposits are made by foreigners

(i) in general?

14. One institution[67] did not reply to this question. For nine institutions[68] the deposits made in general by foreigners (regardless of whether they were for patent or other purposes) ranged between a maximum of 80% and a minimum of 20% of all the deposits. Four institutions[69] indicated that no deposits were made in general by foreigners.

Question 8. (c) How many deposits are made by foreigners

(ii) in patent cases?

15. Two institutions[70] did not reply to this question. Seven institutions[71] indicated that no deposits were made by foreigners in patent cases. Five institutions[72] reported percentages which ranged between a maximum of 65% and a minimum of 10% of the total number of deposits.

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51. CCAP; CCM; FRI; IHE; ISCD; NCIB; NCL; NCTC; NIH. 52. CMI; IF. 53. ATCC. 54. CBS. 55. ARS. 56. CCAP; CCM; IHE; NCIB; NCL; NCTC. 57. ATCC; CBS. 58. CMI; IF. 59. FRI. 60. ISCD; NIH. 61. ARS. 62. CCM; CMI; IF; IHE; ISCD; NCIB; NCL; NIH. 63. ATCC; CBS. 64. FRI. 65. ARS. 66. CCAP; NCTC (these institutions, however, did not exclude the possibility of deposits for patent purposes). 67. CBS. 68. ARS; ATCC; CCAP; CCM; CMI; IF; IHE; NCIB; NCTC. 69. FRI; ISCD; NCL; NIH. 70. CMI; ISCD. 71. CCAP; CCM; IF; IHE; NCL; NCTC; NIH. 72. ARS; ATCC; CBS; FRI; NCIB.

Question 9. Does your institution issue any publications? (If so, please forward specimens.)

16. One institution[73] replied in the negative. All the other institutions indicated that they issued publications (in most of the cases a list or a catalogue of cultures). Most of them forwarded samples of publications issued.

III. PROCEDURE CONCERNING DEPOSITS FOR THE PURPOSES OF PATENT PROCEDURE

A. Acceptance of Cultures for Deposit

Question 10. What are the requirements for acceptance of cultures for deposit as regards

(a) the sample of the culture transmitted by the depositor?

17. The information supplied varied considerably. Seven institutions[74] indicated that they requested that the culture sample should be deposited in ampoules or agar slants, freeze-dried (or "lyophilized"). The number of samples for each deposit ranged between 2 and 20. Two institutions[75] stated that there were no special requirements. Four institutions[76] indicated the following different requirements: the sample should be non-pathogenic; it should be pure, viable and authentic; it should be transmitted by the depositor; it should be a pure culture and lyophilizable.

Question 10. What are the requirements for acceptance of cultures for deposit as regards

(b) any indications to be given by the depositor?

18. The replies received showed a certain uniformity. One institution[77] indicated that, at present, no indication was to be given by the depositor. Seven institutions[78] gave detailed information as to the indications the depositor was requested to supply. They can be summarized as follows: name of strain, name of isolator, reference number given by isolator, name of laboratory, date and place of isolation, conditions as to growth and maintenance, properties and applications, pathogenicity, method of shipment and storage. For five institutions[79] the indications to be given by the depositor ranged from the indication of the main features of the culture to the indication of the strain number, media for maintenance and growth conditions.

Question 11. Does your institution give an access number in advance?

19. Eleven institutions[80] replied that they did not give any access number in advance. One institution[81] replied in the affirmative.

Question 12. What fees are to be paid by the depositor?

20. Seven institutions[82] indicated that no fees were charged; however, two of them[83] indicated that the matter of fees was under consideration. Six institutions[84] reported that annual fees were charged which ranged between a maximum of 80 and a minimum of 30 US dollars per deposit. One of them[85] added that the initial fee per deposit, including preservation for one year, was 115 US dollars.

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73. FRI. 74. ARS; ATCC; CBS; CMI; FRI; IF; NCIB. 75. CCAP; IHE. 76. CCM; ISCD; NCL; NIH. 77. IHE. 78. CCAP; CCM; CMI; FRI; IF; NCIB; NCL. 79. ARS; ATCC; CBS; ISCD; NIH. 80. ARS; ATCC; CBS; CCAP; CCM; CMI; IF; IHE; ISCD; NCIB; NCL. 81. NIH. 82. ARS; CCM; CMI; IHE; ISCD; NCIB; NCL. 83. CMI; NCIB. 84. ATCC; CBS; CCAP; FRI; IF; NIH. 85. ATCC.

Question 13. (a) Does your institution issue a receipt to the depositor?

(b) If so, what are the contents of the receipt? (Please forward a specimen.)

21. Eight institutions[86] indicated that they issued a receipt, a certificate or a similar document to the depositor. Two institutions[87] indicated that a letter was written to the depositor acknowledging receipt of the culture. Three institutions[88] reported that no receipt or certificate was issued at present; however, one of them[89] specified that, where the deposit was made by mail, a letter of acknowledgement was sent.

22. The institutions that replied in the affirmative to question 13(a) above gave particulars as regards the contents of the receipt, which can be summarized as follows: five institutions[90] specified that the receipt or the certificate contained the access number and the date of access; one of them[91] indicated that the certificate contained also the viability test. Three institutions[92] reported that the receipt included a statement regarding the treatment of the deposited cultures for the purposes of patent procedure.

B. Viability Test

Question 14. Does your institution test the viability of deposited cultures of microorganisms

(a) on its own initiative?

(b) only on request?

23. Nine institutions[93] indicated that they tested the viability of deposited cultures of microorganisms on their own initiative and one of them[94] added that it also made additional viability tests on request. Three institutions[95] specified that they tested the viability of deposited cultures of microorganisms only on request; however, one of them[96] indicated that it sometimes tested the viability of the deposited cultures on its own initiative.

Question 15. If the answer to question 14 is affirmative, please indicate:

(a) when the viability test is made

24. Eight institutions[97] reported that the viability test was made after receipt of the culture for deposit. Other replies indicated the date of the test as being one month from deposit,[98] at the time of preparation of the culture for freeze-drying,[99] within 20 days after freeze-drying,[100] or at regular intervals at the request of the depositor.[101]

Question 15. If the answer to question 14 is affirmative, please indicate:

(b) whether, after the first test, further tests are made and, if so, at what intervals.

25. The answers to this question were again very varied. Four institutions[102] indicated that after the first test further tests were made at intervals of between six months and one year; one of them[103] specified that, depending on

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86. ARS; ATCC; CBS; CCM; FRI; IF; ISCD; NIH. 87. CMI; NCIB. 88. CCAP; IHE; NCL. 89. NCL. 90. CCM; FRI; IF; ISCD; NIH. 91. ISCD. 92. ARS; ATCC; CBS. 93. ARS; CBS; CCAP; CCM; CMI; IHE; ISCD; NCIB; NIH. 94. NCIB. 95. ATCC; IF; NCL. 96. ATCC. 97. ARS; ATCC; CBS; CCAP; CCM; CMI; FRI; NCIB. 98. IHE. 99. ISCD. 100. NIH. 101. NCL. 102. CBS; CCM; FRI; IHE. 103. CCM.

the character of the strain, further tests might take place at intervals of one to five years. Two institutions[104] indicated that further tests were made according to the nature of the culture and the method of maintenance. In addition, the following replies were given: further tests are sometimes made, but not at regular intervals;[105] further tests are made at intervals at the request of the depositor;[106] further tests are made when necessary;[107] viability tests are automatically made in the preparation of material for lyophilization, and immediately after lyophilization;[108] the intervals of further tests are set according to the result of a heat test after freeze-drying.[109]

Question 16. In addition to the viability test, does your institution make other kinds of tests relating to deposited cultures of microorganisms?

26. Seven institutions[110] reported that they made other kinds of tests in addition to the viability test. Six institutions[111] replied in the negative to this question; one of them[112] added, however, that observations of characteristics were made in preparation for lyophilization, and one institution[113] stated that sometimes the purity and identity of deposited cultures were checked.

Question 17. If the answer to question 16 is affirmative, please indicate the kinds of tests your institution makes.

27. Six institutions[114] indicated that they made purity tests; four of them[115] added that they also made identity tests and one of them[116] fertility tests. Three institutions[117] reported as follows: one[118] indicated that, if necessary, examination under an electronic microscope was made, another[119] that biochemical, serological and morphological tests were made, and the third[120] that only tests which were adequate to maintain the strains were made.

Question 18. (a) Does your institution issue a certificate on the viability test or on any other test?

(b) If so, what are the contents of the certificates?

28. Eight institutions[121] replied that they did not issue any certificate on the viability test or other tests made; however, three of them[122] added the following information: two[123] notified the depositor when the strains were dead or contaminated on receipt, and one[124] returned the revivified specimen to the depositor for confirmation and received an identification report from him. Two institutions[125] replied that they issued certificates relating to viability tests. Three institutions[126] indicated that a certificate was normally not issued or was issued only on request.

29. Among the institutions which replied in the affirmative to question 18(a) above, one[127] indicated that the certificate contained the data communicated by the depositor as compared with those resulting from the viability test.

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104. CCAP; CMI. 105. ATCC. 106. NCL. 107. NCIB. 108. ARS. 109. NIH. 110. ATCC; CCAP; CCM; FRI; IHE; NCIB; NIH. 111. ARS; CBS; IF; ISCD; NCL; NIH. 112. ARS. 113. CMI. 114. ATCC; CCM; CMI; FRI; NCIB; NIH. 115. CMI; FRI; NCIB; NIH. 116. CCM. 117. ARS; CCAP; IHE. 118. CCAP. 119. IHE. 120. ARS. 121. ARS; CCM; CMI; FRI; ISCD; NCIB; NCL; NIH. 122. ARS; FRI; NCIB. 123. ARS; NCIB. 124. FRI. 125. IF; IHE. 126. ATCC; CBS; CCAP. 127. IHE.

C. Storage of Cultures

Question 19. (a) For what (minimum) duration does your institution store deposited cultures of microorganisms?

30. Six institutions[128] replied that they stored the deposited cultures for an unlimited period. Two institutions[129] indicated that they stored deposited cultures for the life of the patent; two institutions[130] make the duration of storage dependent on the payment of annual storage fees. For two institutions,[131] the minimum period of storage of deposited cultures is five years, and for one other institution,[132] it is one year.

Question 19. (b) Does the duration depend on the payment of fees by the depositor? (If so, please indicate the amount of those fees).

31. Six institutions[133] indicated that the duration of storage of deposited cultures depended on the payment of fees, and four[134] of them qualified their reply by adding the following information: one[135] charged an annual fee of 30 US dollars for maintenance exceeding one year; another[136] charged an annual fee of 85 US dollars only until the patent to which the deposited culture related was issued; the third[137] charged an annual fee of 58 US dollars for cultures of restricted release; the fourth[138] charged annual fees which, depending on the type of culture deposited and for periods of maintenance exceeding one year, ranged from 9 to 12 US dollars. Two institutions[139] replied that, at present, the duration of storage of deposited cultures did not depend on payment of fees; one institution[140] indicated that cultures were usually maintained even after the payment of annual fees was discontinued.

Question 20. Please indicate the method used by your institution for storing deposited cultures of microorganisms, in particular as regards the precautions taken to ensure that they are kept viable and uncontaminated.

32. Nine institutions[141] reported that freeze-drying was used as a method of storing deposited cultures of microorganisms; five of them[142] indicated that storage under liquid nitrogen was also used. Four institutions[143] reported on various methods of storage: one[144] indicated that six samples were lyophilized, two were kept on agar slant and one under mineral oil; another[145] stated that lyophilization was used for all bacteria, liquid nitrogen for some viruses and maintenance media for some fungi that could not be lyophilized; the third[146] indicated that lifeless media were employed and, if the cultures were spore-formers, they were preserved under soil; in addition, the culture was maintained under paraffin oil; the fourth[147] specified that the strains were immediately lyophilized and, if they could not be lyophilized, they were kept on agar slants and periodically transferred.

33. As regards the precautions taken to ensure that the deposited cultures of microorganisms were kept viable and uncontaminated, one institution[148] indicated that sealed ampoules were used.

Question 21. Under what circumstances does your institution consent to the depositor's request for the return of a deposited culture or to the depositor's instructions to destroy the deposited culture?

34. The answers received were very varied. Three institutions[149] indicated that they consented to the depositor's request for the destruction or return of deposited cultures; this would occur either on receipt of a written statement from the depositor that the patent was abandoned, or in the event of withdrawal or non-

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128. ARS; CCAP; CMI; ISCD; NCIB; NCL. 129. ATCC; FRI. 130. IF; NIH (as regards NIH, see, however, also footnote 140). 131. CCM; IHE. 132. CBS. 133. ATCC; CBS; CCAP; CCM; FRI; IF. 134. ATCC; CBS; CCAP; FRI. 135. CBS. 136. ATCC. 137. CCAP. 138. FRI. 139. ARS; CMI. 140. NIH. 141. ATCC; CCAP; CCM; CMI; FRI; IF; ISCD; NCIB; NIH. 142. ATCC; CCAP; CCM; CMI; NCIB. 143. ARS; CBS; IHE; NCL. 144. CBS. 145. IHE. 146. NCL. 147. ARS. 148. NCIB. 149. ATCC; CCM; FRI.

acceptance of a patent application relating to the deposited culture. One institution[150] indicated that the depositor's request could be accepted after preliminary consultation with the industrial property office. Four institutions[151] stated that the depositor's request for the destruction or return of deposited cultures was accepted; two of them,[152] however, qualified their replies by adding the following information: only cultures deposited in a restricted way, with payment of fees, were destroyed at the depositor's request;[153] deposited cultures were destroyed or returned on the depositor's legal responsibility.[154] One institution[155] indicated that deposited cultures were available to the depositor, but that no regulations existed on destruction of cultures requested by the depositor. Two institutions[156] specified that the acceptance of the depositor's request for return or destruction depended on the circumstances of each case and on the conditions under which the cultures were deposited. One institution[157] indicated that this matter was not regulated at present, and another[158] said that no deposited cultures were returned or destroyed in toto, except for good reasons (e.g., accession of a virulent pathogen by mistake).

Question 22. Please indicate the period during which your institution keeps deposited cultures of microorganisms secret.

35. In this case too the answers received were very varied. Five institutions[159] indicated that the deposited cultures were kept secret pending the grant of a patent. One institution[160] stated that the cultures were kept secret until the depositor communicated that they were free for distribution, which was supposed to be when the corresponding patent was published; the depositor was responsible for informing the institution of the publication of the patent. Four institutions[161] pointed out that the deposited cultures were kept secret for as long as the depositor requested, and one of them[162] added that this was further subject to payment of the annual fees. Two institutions[163] reported that the period during which the cultures were kept secret was five years and one institution[164] stated that the deposited cultures were kept secret as long as appropriate fees were paid, but that normal deposits could be restricted only for a short period such as might be required for publication of a scientific paper.

D. Release of Samples

Question 23. (a) Under what conditions (authorization of the depositor, certification by the industrial property office) does your institution release samples of deposited cultures of microorganisms to a requesting party?

36. The answers received varied considerably. Seven institutions[165] reported that samples of deposited cultures were released with the authorization of the depositor, one of them adding that only deposits subject to restrictions would require the depositor's authorization[166]. Three institutions[167] indicated that samples of deposited cultures would be released to a requesting party after the publication or grant of the patent; however, one institution[168] added that samples would be released, even before the grant of a patent, with the authorization of the depositor. One institution[169] stated that samples of deposited cultures would be released to a requesting party with the consent of the Patent Office. One institution[170] reported that, when restrictions, possibly imposed by the depositor, were removed, samples of deposited cultures would be obtainable on receipt of a request stating the name of the microorganism and its strain number or providing other satisfactory information. One institution[171] reported that cultures deposited in connection with patent procedure were maintained in

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150. ISCD. 151. CBS; CCAP; CMI; IF. 152. CCAP; CMI. 153. CCAP. 154. CMI. 155. NIH. 156. NCIB; NCL. 157. IHE. 158. ARS. 159. ARS; ATCC; FRI; ISCD; NIH. 160. CMI. 161. CBS; IF; NCIB; NCL; 162. IF. 163. CCM; IHE. 164. CCAP. 165. CBS; CCAP; CCM; IF; IHE; NCIB; NCL. 166. CCAP. 167. ATCC; FRI; NIH. 168. ATCC. 169. ISCD. 170. ARS. 171. CMI.

a reserved collection until the depositor informed the institution that they were free to be distributed or included in the catalogue; this information was expected to be given at the latest after publication of the patent; if a reserved culture was requested, the depositor was informed of the request so as to ensure that the corresponding patent had not been issued without the knowledge of the institution; however, the fact that the patent had been granted did not entitle the institution to release a sample; authorization by the depositor was required in any case.

Question 23. (b) Has the requesting party to subscribe to certain obligations (e.g., not to export the culture and/or to use it only for research purposes)?

37. Six institutions[172] replied that the requesting party had not to subscribe to any obligations. Three institutions[173] answered this question in the affirmative, and two of them[174] added the following information: the requesting party had to provide personal data and a guarantee in writing that the culture would not be used for industrial or business purposes and would not be transmitted to third persons;[175] the requesting party would not transfer the culture to third persons besides the user mentioned in the request.[176] Two institutions[177] indicated that the depositor could specify certain obligations. Moreover, it should be noted in this context that one institution[178] stated that deposited cultures were released only within the country.

Question 23. (c) What fees have to be paid by the requesting party?

38. Five institutions[179] indicated either that no fees were charged or that they were not yet fixed; one of them[180] specified that no fees were charged in the framework of international exchanges. For six institutions[181] the fees ranged from 36 to 5 US dollars for one requested sample. One institution[182] stated that the fees which the requesting party had to pay were determined by the depositor.

Question 24. Does your institution notify the depositor of the release effected?

39. Seven institutions[183] indicated that they notified the release of a deposited culture to the depositor; two of them[184] added that such notification was effected if requested by the depositor. Five institutions[185] reported that they did not notify the release to the depositor, one of them[186], however, mentioning that a notification was made under a special arrangement with the depositor. One institution[187] referred to the condition according to which the depositor's prior authorization was required for the release of samples of deposited cultures.

IV. LEGAL ASPECTS

Question 25. Is the relationship between your institution and the depositor governed by a contract? If so, do you apply any standard contract? (Please forward a specimen.)

40. Five institutions[188] replied that their relations with depositors were not governed by contract. Eight institutions[189] replied in the affirmative to this question and four of them[190] forwarded a specimen of the model contract or equivalent document.

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172. ARS; ATCC; CBS; CCAP; CMI; NIH. 173. CCM; FRI; IHE. 174. FRI; IHE. 175. IHE. 176. FRI. 177. NCIB; NCL. 178. IHE. 179. ARS; CCM; IHE; ISCD; NIH. 180. IHE. 181. ATCC; CBS; CCAP; CMI; FRI; NCIB. 182. NCL. 183. ATCC; CCM; FRI; IF; IHE; NCL; NIH. 184. ATCC; IF. 185. ARS; CBS; CCAP; CMI; ISCD. 186. CCAP. 187. NCIB. 188. CCAP; CMI; IHE; ISCD; NCIB. 189. ARS; ATCC; CBS; CCM; FRI; IF; NCL; NIH. 190. ARS; ATCC; FRI; IF.

Question 26. Is your responsibility vis-à-vis the depositor limited in any respect? (If so, please specify.)

41. Three institutions[191] indicated that their responsibility vis-à-vis the depositor was not limited. Ten institutions[192] specified to what extent their responsibility towards the depositor was limited. Their answers were very varied and can be summarized as follows: four institutions[193] stated that no responsibility was accepted for loss of deposited cultures, one of them[194] adding that this limitation of responsibility also applied to their stability; one institution[195] indicated that the deposit of cultures could be refused if the depositor did not supply them in sufficient quantity and with the necessary technical information; one institution[196] referred in this context to the condition whereby the cultures could not be released without the depositor's consent, and one institution[197] reported that no responsibility was accepted for changes due to possible genetic instability and for damage of an uncontrolled nature. One institution[198] pointed out that it had no obligation to indemnify in case of damage caused to deposited cultures, and one institution[199] replied that it did not accept any legal responsibility. One institution[200] indicated that it did not accept microorganisms which could be considered fastidious, or microorganisms which could not be lyophilized; it also added that depositors should be familiar with national regulations regarding shipments and imports of microorganisms; depositors were also responsible for supplying additional material, if necessary.

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42. The deposit of microorganisms for the purposes of patent procedure is an operation which has only recently started to be performed in practice. This explains the considerable divergencies of procedure reflected in the survey contained in this document. Nevertheless, it should be noted that on a number of essential questions harmonization of procedure already exists or appears to be attainable without difficulty.

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191. ATCC; CBS; ISCD. 192. ARS; CCAP; CCM; CMI; FRI; IF; IHE; NCIB; NCL; NIH. 193. CCAP; IF; NCIB; NIH. 194. CCAP. 195. IHE. 196. NCL. 197. CCM. 198. FRI. 199. CMI. 200. ARS.

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