codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 78/23

CODEX ALIMENTARIUS COMMISSION
Twelfth Session, Rome, 17-28 April 1978

REPORT OF THE TENTH SESSION OF THE
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Budapest, 24-28 October 1977

Introduction

1. The Codex Committee on Methods of Analysis and Sampling held its Tenth Session from 24 to 28 October 1977 in Budapest by courtesy of the Government of Hungary. The Session was opened by Dr. K. Sütő, President of the Hungarian National Codex Committee and Vice-President of the Hungarian Office for Standardization, who welcomed the participants and emphasized the importance of collaboration between international organizations in the elaboration of methods of analysis and sampling for Codex Standards. He introduced the Chairman of the Session, Professor R. Lasztity of the Department of Biochemistry and Food Technology of the Technical University of Budapest.

2. The Session was attended by delegates from 23 countries and observers from six international organizations. The list of participants including officers from FAO is attached as Appendix I to this Report.

Adoption of the Agenda

3. The Committee agreed the adoption of the agenda with minor amendments to allow for discussion of documents submitted for consideration immediately before the meeting. It considered that the papers CX/MAS 77/2-Add. 2 and CX/MAS 77/3 could be linked in discussion under item 5 of the Agenda and further that the topics covered in these were of such importance that they needed discussion by the whole Committee in plenary session. It therefore agreed to defer the appointment of the ad hoc Working Group on Sampling for the Determination of Net Contents until the above discussions were completed.

Appointment of Rapporteurs

4. The Committee agreed to the appointment of Mr. R. Sawyer of the delegation of the United Kingdom and Mme Castang of the delegation of France as rapporteurs.

Matters arising from the Commission and Codex Committees

5. The Committee had before it document CX/MAS 77/2 containing information of interest to the Committee. The various items are discussed below.

Codex Committee on Methods of Analysis and Sampling

6. The Committee noted, following endorsement of a general method for the determination of crude fat (ALINORM 76/23 paras 56-60) that at the Eleventh Session of the Commission (ALINORM 76/44 paras 167, 168) the delegation of Thailand had observed that fat could become bound to soya protein during processing and had asked whether the method endorsed would determine total crude fat in baby food containing soya protein. The Committee pointed out that the method endorsed

(Weibull-Stoldt) include an acid hydrolysis stage which ensure the separation of protein and fat. The method was therefore suitable for the determination of crude fat in baby food containing soya protein.

Codex Committee on Fats and Oils

7. The Committee was informed that the above Committee had requested IUPAC to coordinate activities and to institute a collaborative study on the analysis of oils for linoleic acid content. It was noted also that analysis for erucic acid and examination of butter fat was to be included in the studies. The delegate of the USA informed the Committee that this work was now in progress.

8. With regard to the Standard for Margarine - Method of Analysis for Water Content (ALINORM 76/19, para. 13a), the Committee noted that the description of the method included the word "empirical". This was regarded as unnecessary and it agreed to amend the title accordingly (see para 74 of this report).

9. With regard to para. 13b of ALINORM 76/19, the Committee noted that in the opinion of some delegations the phrase "well ventilated" was being interpreted as "equipped with forced draught". It was agreed, however, that as the description "well ventilated" was sufficiently general to include both forced draught and ventilation by convection, to make no change in the text pending further information. The Committee noted that the French text, which referred to a dessicator rather than an oven, needed appropriate amendment.

10. The delegation of the Netherlands drew attention to a problem in para. 14 of ALINORM 76/19. They did not agree that glass or porcelain vessels were suitable for use in a rapid method for determination of loss on drying, since such materials have a low thermal conductivity and high heat capacity and had been shown in laboratory studies to give wide variability of results. The Committee agreed that the use of non corrodible metal dishes should be specified in the method.

11. With regard to the standard for olive oils and the alternative method for determination of tocopherols (paras 29, 30 of ALINORM 76/19), the Committee was informed that the proposed IOOC method had failed an IUPAC ring test. It was agreed that this information would be put before the Fats and Oils Committe, in view of the fact that IOOC had requested that the method be adopted for tocopherol in olive oil. It was also agreed that there was a need for a general method for determination of tocopherols.

12. In relation to the use of the Bömer value in the Standard for Lard (para. 39 of ALINORM 76/19), the delegation of the Netherlands regretted the attempt to discard this value since it was widely used in trade and for Customs purposes. They also pointed out that an improved text of the method for the Bömer value was now available - ISO 3577-76.

Codex Methods of Analysis and Sampling and Future Work Programme

13. The Committee had before it document CX/MAS 77/2-Add. 2 containing an extract from the report of the Twenty-Third Session of the Executive Committee entitled "Review of current work load, practices and procedures in connection with the elaboration of Codex methods of analysis and sampling and appraisal of the needs of the Food Standards Programme in this area of activity" to which was attached a document on the above topic. This had been prepared by the Secretariat, on the instructions of the Eleventh Session of the Commission, for consideration by the Executive Committee and referenced as CX/EXEC 77/23/7. The Committee also had before it document CX/MAS 77/3 entitled "Codex Methods of Analysis and Sampling and Future Work Programme" which was prepared by the Secretariat subsequent to the Twenty-Third Session of the Executive Committee.

14. The essential features of document CX/EXEC 77/23/7 were set out in the report of the Twenty-Third Session of the Executive Committee (ALINORM 78/3, paragraphs 48 to 60).

15. During the course of the discussion on the nature and role of Codex methods of analysis and sampling, the Executive Committee posed some fundamental questions concerning the work of the Committee. Misgivings had been expressed concerning the need for and usefulness of the work being carried out. The Executive Committee had noted that even though the concept of referee methods of analysis and sampling had been part of the Codex system for a very long time, the concept appeared to be based on the assumption that there would be international disputes to settle. The Executive Committee had commented that, in fact, very few disputes took place which could not be settled by the parties involved. Therefore it was questionable whether there was a need for referee methods of analysis and sampling or whether the amount of time and effort put into this work was worthwhile. The point was also made in the Executive Committee that the continued input of further resources, time and effort would not achieve commensurate results.

16. The statement of the Legal Adviser of FAO, as recorded in the Executive Committee's report, had indicated that there might be still some matters to be considered in regard to the legal implications of methods of analysis laid down in recommended Codex standards.

17. The Executive Committee had decided that the attention of governments should be drawn to the discussions in the Executive Committee on this subject and that their views should be requested on the need for and usefulness of the work of developing referee methods of analysis and sampling. If governments were of the opinion that the Codex Committee on Methods of Analysis and Sampling should continue to function, they should consider what changes or improvement they would wish to see in the programme of work to be carried out by that Committee and suggest appropriate amendments to its terms of reference.

18. In summary, governments would be asked, on the instructions of the Executive Committee, whether the work of the Codex Committee on Methods of Analysis and Sampling justified its continued existence or whether the Committee's programme of work, and therefore, its terms of reference should be restricted to the most essential needs, in which case governments should specify such needs.

19. The Committee, at its present session, noted that the circular letter to be sent to governments, as mentioned in the previous paragraph, would be issued very shortly.

20. Addressing itself to the main question put by the Executive Committee, the Committee agreed that there was a need for Codex methods of analysis and sampling. It was pointed out that in a number of countries including Member States of the EEC increasing use was being made of Codex standards and methodology.

21. The point was also made that the work of developing methodology having international standing was considered to be sufficiently important to justify the continued existence of the Codex Committee on Methods of Analysis and Sampling. Several delegations also stressed the particular importance of developing a common, harmonized approach to sampling.

22. There was general agreement that, in the interest of facilitating international trade in food, it was important to develop properly evaluated and tested methodology which would be acceptable on a world-wide basis.

23. The Committee then considered the concept of referee methods of analysis and sampling. The Committee noted that this concept had always been part of the Codex system and was defined as follows in the General Principles for the Establishment of Codex Methods of Analysis (Procedural Manual of the Commission, 4th Edition):

> "The methods of analysis and sampling contained in the Codex Alimentarius are international referee methods intended for use in case of disputes. These methods will not preclude the use of existing methods for routine inspection or other control purposes.

"Where criteria in Codex standards are related to certain methods of analysis, these methods will be the referee methods."

"If further methods have been proven as being equivalent to these methods, they may be adopted as alternative methods."

24. The Committee also noted that the term "dispute" had been explained as follows by the Executive Committee at its 18th Session (ALINORM 72/3, paras 28 and 29):

"(a) "dispute" should be taken to mean dispute involving any aspect of the analysis or sampling used in connection with imported food and involving the authorities of the importing country and the exporter or exporter country of the food, when the parties in dispute cannot agree on a suitable method; and

(b) it was not the purpose of the Commission to influence national authorities in their choice of methodology for the settlement of internal disputes concerning analytical procedures".

25. The Secretariat, in a working paper for the Twenty-Third Session of the Executive Committee, stated that it considered that included in the obligations which a government assumed in accepting a Codex method for referee purposes was an undertaking to use that Codex referee method in cases of litigation when the parties involved are unable to agree on the method to be used to settle the dispute. This means that, in the view of the Secretariat, a country when accepting a Codex method would be obliged to consider the method to be an official method to be given a special status in national legislation for the dispute situation described above regardless of other existing national standard methods. The Committee also took note of the remarks of the FAO Legal Adviser on this subject, as recorded in paragraphs 56 to 58 of the report of the Twenty-Third Session of the Executive Committee.

26. A number of delegations indicated that acceptance of the concept of referee methods, with the requirement that the referee method be translated into national legislation would present great difficulties. There were countries in which analytical methodology for foodstuffs did not form part of the national legislation, whereas there were others where it did. Several delegations explained the nature of legislative difficulties which would be involved for their countries. In view of these difficulties and also because of the legal uncertainties surrounding the acceptance of the concept of referee methods, the Committee agreed that this concept be re-examined. The view was expressed that Codex methods should be regarded as reference or recommended methods, the main requirement being that the methods be collaboratively tested for reliability and practicability, so that they could be used in international dispute situations and for other purposes. There would be no obligation on governments to accept and enact them into national legislation.

27. Attention was drawn to the fact that there was a class of methods which formed an integral part of the specification and that these would be subject to acceptance as part of the standard.

28. The Committee considered whether it would be necessary for this latter category of methods, called "defining methods", to be subjected to the endorsement procedure. Opposing views were expressed on the necessity of endorsement, but it was generally agreed that there was a necessity to meet the basic criteria for acceptance of the methods as Codex methods.

29. The Committee considered that one of the main tasks was to establish appropriate criteria for the guidance of Commodity Committees when selecting analytical methods. The delegation of Norway considered that the Committee should concern itself with methods which were not being elaborated by Commodity Committees and in particular should concern itself with methods of general applicability.

30. On the proposal of the delegation of Australia, the Committee agreed to establish an ad hoc Working Group to consider:

(i) The two categories of methods discussed
(ii) The criteria for selection and acceptance of methods
(iii) The procedures to be adopted by Commodity Committees

31. The Committee decided to suspend discussion of this item until it received the report of the Working Group. The Committee agreed that the delegations of Australia, Finland, Hungary, Norway, United Kingdom and United States of America would be represented on the Working Group.

32. The Committee resumed discussion following a verbal account of the main features of the report of the Working Party, which had been chaired by Dr. A. Randell (Australia), (see Appendix II). The Committee noted that it had been found desirable to provide for four categories of methods instead of two.

33. In considering the verbal report on the work of the Working Group, which was given by Mr. P. Khan (USA), the delegation of Australia pointed out that it had made available to the Secretariat a compendium of methods of analysis contained in Codex standards, together with a statement concerning the status of endorsement. The delegation added that it was clear that attention must be paid to the outstanding matters.

General Principles for the Selection of Codex Procedures for Sampling

Sampling for the Determination of Net Contents

34. The Committee had before it document CX/MAS 77/5 which arose as a result of the work of a working group coordinated and presented by the delegation of the United Kingdom. The following countries collaborated by correspondence: Australia, Canada, Hungary, Netherlands, Norway, Poland, Switzerland.

35. At its Ninth Session (ALINORM 76/23, paras 22-24), the Committee had discussed document CX/MAS 75/4 which contained the draft criteria prepared by the United Kingdom for selection of appropriate sampling plans.

36. The Committee also had available CX/MAS 77/2-Add. 1, which had been prepared by the United States of America, following discussions in the Codex Committee on Processed Fruits and Vegetables on the application of the sampling plans set out in CAC/RM 42-1969 (Sampling Plans for Prepackaged Foods).

37. The Committee noted that both the Committee on Processed Fruits and Vegetables and the Committee on Fish and Fishery Products were of the opinion that sampling plans for certain products (see ALINORM 78/20, paras 110-112 and also CX/MAS 77/2-Add. 1 and ALINORM 78/18A paras 105-107) should be so designed that the least amount of product was destroyed commensurate with retaining efficiency.

38. After some preliminary discussion the Committee agreed that the general principles were closely connected with the question of sampling for the determination of net contents and requested the ad hoc Working Group to include both subjects in its deliberations.

39. In regard to general principles for the selection of Codex procedures for sampling, the delegation of Bulgaria pointed out the importance of sampling in conjunction with the general problem of contaminants in foods and other health-related matters. It was suggested that this matter be kept in mind and reviewed in a future meeting of this Committee along with the current sampling problems of quality factors and net weight.

40. The Committee heard an oral report from the Chairman of the Working Group Mr. G. E. Anderson (Canada) which is attached as Appendix III to the present report.

41. It noted that the Working Group had offered for consideration a moderate acceptance plan for net content determination of a general nature and that more details and data were required to give the plan practical value. The Committee agreed that a questionnaire should be sent to Governments to ascertain whether they are in favour of the broad principles upon which the plan is based before more detailed work is undertaken.

42. The Committee also agreed that the background documents "The Problem of non-Normal distributions in Official Statistical Inspections" and "Official Statistical Inspection of Adaptable Severity - A Building Block Approach" prepared by the delegation of Switzerland were essential to the proper understanding of the discussion of the Working Group and decided to attach them to the present report as Appendices IV and V respectively.

Methods of Sampling for determination of Pesticide Residues

43. The Committee had before it document CX/MAS 77/6 containing a recommended method adopted by the Codex Committee on Pesticide Residues at its Ninth Session (see also ALINORM 78/24, Appendix III).

44. The Committee noted that the guidelines concerning the endorsement of methods of analysis and sampling require methods of sampling elaborated by Codex Committees to be submitted to this Committee for examination (see Guidelines for Codex Committees, para. 13(c) Procedural Manual of the Commission).

45. One delegation was of the opinion that a considered judgement could not be made without supporting evidence of the practicability of the plan. It was pointed out that since the problem was of non-homogeneity of the Commodity, sampling must be arbitrary.

46. The Committee noted that the sampling plan represented a pragmatic approach to the problem. It considered that the plan had great practical value and agreed to its endorsement.

Endorsement of Methods of Analysis Proposed by Codex Commodity Committees

47. The Committee considered document CX/MAS 77/7 and Conference Room Document No. 1 together with supplementary reports by the delegation of the Netherlands on matters arising from the Report of the Ninth Session of the Committee (ALINORM 76/23, paras 105, 106 and 108).

CODEX COMMITTEE ON FRUIT JUICES

Recommended International Standard for Concentrated Apple Juice (CAC/RS 63-1972)

Expression of results as m/m

48. The delegation of Austria explained that the provision was required to allow for conversion of analytical results obtained on a m/v basis to m/m. The Committee recommended endorsement after editorial amendment of the text to explain the need.

Test for fermentability

49. The provision was endorsed for fruit juices in general.

Determination of soluble solids

50. The delegation of the United States of America pointed out that the reference leading to appropriate temperature corrections in the Official Methods of Analysis 1975 edition needed amendment. The appropriate sequence should be 22.019, 31.009 and 52.010. The method was endorsed as amended.

Determination of ethanol

51. The question of alternative methods and use of the OIMC alcohol tables was raised. In view of the levels of alcohol to be found in these products it was agreed that further study of methods was justified. However, in the light of endorsement in other standards, the Committee agreed to the endorsement of the provision in the standards under review at the present time.

Determination of volatile acids

52. The Committee endorsed the provision without comment.

Determination of arsenic

53. The appropriate reference A.34/F was inserted in the text and the Committee endorsed the provision.

Determination of lead

54. The provision was temporarily endorsed pending development of Codex general methods.

Determination of copper

55. The delegation of the Netherlands wished to draw the attention of the Joint ECE/Codex Alimentarius Group of Experts on Standardization of Fruit Juices to the fact that the complex formed with zinc diethyldithiocarbamate was unstable to light. The Committee noted the fact and endorsed the provision.

Determination of zinc

56. The delegation of the Netherlands drew attention to the ease of carrying out the atomic absorption method for zinc by comparison with the proposed colorimetric method.

57. It was agreed that the alternative proposal AOAC, 1975, 25.136-25.142 (Codex general method for zinc at Step 3) which was based on AAS, should be brought to the attention of the IFJU Working Group chaired by the delegate from Austria, with the recommendation that the method be considered for general use in fruit juice analysis. The Committee agreed endorsement of the current method pending further consideration of AAS methods by IFJU.

Determination of iron

58. The provision was endorsed.

Determination of tin

59. The delegation of the Netherlands drew attention to errors in the text of the ISO Recommended Method No. 2447. In the light of these comments, the Committee could not recommend endorsement. It considered that the attention of the Working Group should be drawn to other procedures, especially those of the Analytical Methods Committee of the Society for Analytical Chemistry, London, and the collaborative studies on the atomic absorption method currently under evaluation by the AOAC.

Determination of sulphur dioxide

60. The provision was endorsed.

Determination of mineral impurities insoluble in hydrochloric acid

61. The Committee agreed to the deletion of the penultimate sentence of the submitted text in 8.1.13 of CX/MAS 77/7. The method was endorsed with this amendment.

Determination of soluble solids

62. The Committee endorsed the provision.

Determination of water capacity and fill of containers

63. The delegation of Norway drew attention to the need to unify methods for this provision, since it is common to many of the Codex Standards. The delegation of the United States of America agreed to conduct a review of the various methods in Codex Standards and to prepare a paper on the topic. Endorsement was suspended.

Determination of ascorbic acid

64. A number of delegations drew attention to work on newer methods for ascorbic acid which could lead to improvements in the determination. The delegation of Austria agreed to prepare a review paper and then arrange collaborative studies of any appropriate new methods; governments interested in participation were requested to write to the delegate of Austria. In the interim the Committee agreed endorsement of the method.

Determination of carbon dioxide

65. The method was endorsed without comment.

Recommended International Standards for Fruit Juices

66. The comments elaborated in paras 48 to 65 of this report were regarded as applicable to the submissions in respect of Recommended Standards for Concentrated Orange Juice (CAC/RS 64-1972), Grape Juice (CAC/RS 82-1976), Concentrated Grape Juice (CAC/RS 83-1976) and Pineapple Juice (CAC/RS 85-1976; Draft Standards for Non-Pulpy Blackcurrant Nectar (ALINORM 78/14, Appendix III), Sweetened concentrated Labrusca Type Grape Juice (CAC/RS 84-1976) and Pulpy Nectars of certain Small Fruits (ALINORM 78/14, Appendix IV).

67. The Committee recommended endorsement of the provisions subject to comments made in the discussions on the Recommended International Standard for Concentrated Apple Juice.

CODEX COMMITTEE ON PROCESSED MEAT PRODUCTS

68. The delegation of the United States of America indicated that many of the methods adopted by the Committee on Processed Meat Products were from ISO; the U.S.A. had recently become a participant in the work of ISO/TC 34. Because of the backlog of methods to be reviewed, the U.S.A. had developed a policy of obtaining from voting on methods which had not been subject of published collaborative study. A joint programme of work was being developed between ISO and AOAC to provide the required studies.

Draft Standard for Cooked Cured Hams

Draft Standard for Cooked Cured Pork Shoulder

Protein (ISO 937)

69. The delegation of Australia pointed out that the same provision in the Standard for Canned Corned Beef was awaiting endorsement. The Committee agreed to endorse the method.

Determination of total fat content (ISO R 1443)

70. The Committee endorsed the method.

Nitrite, Nitrate (ISO 2918 1975 and ISO 3091 1975)

71. The Committee endorsed both methods.

Draft Standard for Cooked Cured Chopped Meat

72. The Committee endorsed the methods for total fat and nitrite since they are the same methods agreed in paras 70 and 71.

Draft Standard for Luncheon Meat

Determinationof total fat (ISO R 1443)

73. The Committee endorsed the method.

CODEX COMMITTEE ON FATS AND OILS

Recommended International Standard for Margarine

Determination of Water Content

74. The Committee endorsed the method but agreed that the title should be changed to read "Determination of Loss of Mass on Drying" (see also paragraph 8 of this Report).

Determination of Sodium Chloride Content

75. The Committee did not endorse the proposed method by the Mohr procedure but agreed to draw the attention of the Fats and Oils Committee to the Codex general method for determination of chloride.

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

Recommended International Standard for Citrus Marmalade
Sampling

76. The Committee agreed that there would be no change in the position.

CODEX COMMITTEE ON QUICK FROZEN FOODS

Recommended International Standard for Quick Frozen Raspberries

Determination of Net Weight

77. The Committee endorsed the method.

Recommended International Standard for Quick Frozen Spinach
Sampling

78. There was some doubt as to the full extent of the applicability in this standard of the Sampling Plan for Prepackaged Foods (AQL-6.5) (Ref. No. CAC/RM 42-1969) - in particular differing views were expressed on the question of whether the Sampling Pians applied to net weight. It was suggested that the wording adopted in the case of the Recommended Standard for Citrus Marmalade would be more appropriate, namely that "the method be held pending a discussion on the general principles of sampling". The Committee decided not to endorse at this time sub-section 8.1 of the standard, which reads "Sampling shall be carried out in accordance with the Sampling Plans for Prepackaged Foods (AQL-6.5) (CAC/RS 42-1969)" and to seek from the Commodity Committee concerned an explanation as to what constituted a "defective" in terms of the Sampling Plan. The Committee also decided to withhold endorsement of this provision in the other standards for quick-frozen foods which were before it.

Thawing procedure

79. The Committee endorsed the method.

Determination of net weight

80. The Committee endorsed the method.

Determination of Salt-free dry matter

81. The Committee agreed to delete alternative method (b) from the text of 8.4.2 and with this amendment endorsed the method.

Determination of mineral impurities

82. The delegation of Czechoslovakia proposed that the expression of the composition of the sodium chloride reagent be amended to 15 g/100 ml. The Committee noted that the proposed text was not in accordance with a previously endorsed method ISO R 763.

83. In view of practical difficulties arising in the application of the ISO method, the Committee agreed to the endorsement of the proposed text in sub-section 8.5 of the standard for quick frozen spinach, with the amendment noted above.

Recommended Standard for Quick Frozen Bilberries

Determination of mineral impurities

84. The Committee endorsed the method in the light of para. 83 above.

Draft Standard for Quick Frozen Blueberries
Draft Standard for Quick Frozen Cauliflowers
Draft Standard for Quick Frozen Broccoli
Draft Standard for Quick Frozen Leeks

85. With the exception of the provision for Sampling see para. 78 above, the Committee endorsed the methods submitted.

CODEX COMMITTEE FOR SPECIAL DIETARY USES

Special Dietary Foods with low Sodium Content

Determination of sodium content

86. The delegation of the Netherlands drew attention to the tabled report and to the comments of the delegation of Switzerland. The Committee agreed to the endorsement of the method.

CODEX COMMITTEE ON SUGARS

87. On the understanding that with one exception the methods proposed in the draft standard for Fructose were in agreement with those endorsed in other sugars standards, the Committee agreed to the endorsement of the methods. The delegation of the United Kingdom pointed out that the conductivity ash provision had been substituted for the sulphated ash provision of the other standards. The Committee endorsed the method.

Report of the Delegation of the Netherlands concerning
(a) Loss on drying in foods and
(b) Ash in food

88. The Committee took note of the above two reports which were prepared by the Delegation of the Netherlands following replies to CL 1976/5 in which governments were requested to supply data on methods used for the above "determination" in foods for infants and children. It noted that replies had been received only from Australia and Egypt and agreed with the conclusions of the rapporteur that the methods for the determination of loss on drying (AOAC XI - 7003) and that for the determination of ash (AOAC XI - 7010) could be endorsed.

Governments Replies to Circular Letter CL 1976/5

89. The Committee had before it a Conference Room Document dealing with item 4 of the circular letter, which had called for comment on a number of matters arising from the business of the Ninth Session of the Committee in 1975. The comments received were directed in particular towards the proposed Codex Methods for determination of heavy metals.

Mercury

A number of governments had reported explosions when using the teflon lined bomb for digestions of foodstuffs with nitric acid. It was pointed out that the risk of explosion could be eliminated by restricting the size of sample, by allowing the digestion to start in the cold and continue overnight, by preliminary freeze drying of the sample or by use of a bomb with a safety valve.

Lead

The delegation of Poland drew attention to the need for a collaboratively studied method with a limit of detection below 2 mg/kg. It was pointed out that some AOAC methods were specifically designed for lower levels than 2 mg/kg, and also that the method of standard additions could be successfully employed in cases of difficulty.

General

The Committee noted the comments received and agreed that there was a need for proper documentation of these together with any further comments on the Codex general methods which were being elaborated. Attention was also drawn to the need for coordination of comments and documentation in the light of the Report of the Joint FAO/WHO Expert Consultation on Methods of Analysis and Sampling of Contaminants in Food mentioned under Agenda Item 7b of the agenda and discussed under para. 90 of this Report.

Methods of Sampling and Analysis of Contaminants in Food (Report of a Joint FAO/WHO Expert Consultation in collaboration with UNEP)

90. The above report (ESN: FC/76/3; FAO Food Control Series No. 3 and WHO Food Control No. 3) was introduced by Dr. W. Horwitz (U.S.A.), who had chaired a Joint FAO/WHO Expert Consultation in collaboration with UNEP (United Nations Environment Programme) held in Rome in January 1976. Dr. Horwitz drew attention to the salient features of the report including the summary table of contaminants and food products dealt with. The report had previously been circulated to all Codex Contact Points and participants at the previous session of this Committee. In particular he referred to the recommendations of the Consultation as given in paragraph 10 of the report. He indicated that the Committee was, in fact, taking action at this session in regard to the sixth recommendation which was addressed to the Codex Alimentarius Commission and in which the Consultation recommended that the Commission "may wish to examine procedures for the elaboration of Codex methods of analysis and sampling and to examine the implications of and need for Codex methods in the light of the obligations undertaken by governments when accepting Codex methods".

91. The Committee took note of the report with interest and agreed that the recommendations in paragraph 10 of the report should be reproduced and appended to the report of this session (see Appendix VI).

Referee Methods for the Determination of Nitrogen and Crude Fibre in Baby Food

92. The Committee noted that the determination of nitrogen had been the subject of correspondence between ISO and AOAC and that no paper was available for this meeting. The subject would, however, be discussed at the next session of the Codex Committee on Foods for Special Dietary Uses.

Other Business

International Organizations Working in the Field of Analysis

93. The Committee had before it a document (CX/MAS 77/9) prepared by the delegation of the Federal Republic of Germany, which contained corrections, changes and amendments to its previous paper on the subject (CX/MAS 75/9) presented at the Ninth Session of the Committee (ALINORM 76/23, paras 53-55).

94. The Committee expressed its appreciation to the delegation of the Federal Republic of Germany for the preparation of the document and noted that because of the considerable work involved Section 4 "Individual methods in preparation or already available originating from different institutions" had not yet been completed.

Future Work

95. No specific proposals were put forward under this item of the Agenda. The Committee noted that there would be a sufficient number of matters of importance arising from the reports of the Working Groups.

APPENDIX I

LIST OF PARTICIPANTS *
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

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* The Heads of delegations are listed first.
Les chefs de délégations figurent en tête.
Figuran en primer lugar los Jefes de las delegaciones.

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APPENDIX II

REPORT OF THE AD HOC WORKING GROUP ON DETERMINATION AND CRITERIA OF METHODS OF ANALYSIS

1. The Ad hoc Working Group on Determination and Criteria of Methods of Analysis met in the Department of Biochemistry and Food Technology University, Budapest, on 25 October 1977 and again on 26 October 1977 at the Conference Building.

2. The following participants attended:

A. Zsigmond	Hungary
A.W. Randell	Chairman/Australia
W. Horwitz	USA/AOAC
J. Yeransian	USA
G.D. Usher	United Kingdom
R. Wood	United Kingdom
Fred T. King	USA
Esko Pajunen	Finland
Svein Nossen	Norway
Olaf R. Braekkan	Norway
Paul Khan	USA/Rapporteur

3. The Working Group was asked by the Committee to discuss and to define the:

(i) Two types of methods of analysis ("Defining" and "Reference")
(ii) Criteria for selection and application for such methods
(iii) Procedures to establish appropriate relationships between other Codex Committees and the Codex Committee on Methods of Analysis and Sampling.

A. TYPES OF METHODS

4. The Working Group, chaired by A.W. Randell (Australia), developed the following tentative definitions for four (rather than just two) groups of methods.

Type I - METHOD - Definition:

5. A method which defines a specification in terms of the method per se.
Examples: Howard mould count, Iodine value, Brix, Reichert-Meisel value.
Possible terms: Defining, Pre-emptive, Mandatory, Obligatory, Designated, Exclusive.

Type II - METHOD - Definition:

6. A Type II Method is the one designated Reference Method. It is selected from one or more types III Methods (as defined below). It is to be used in cases of international disputes and for calibration purposes.

Examples: Potentiometric method for chlorides.
Possible terms: Reference method, Referee method.

Type III - METHOD - Definition:

7. A Type III Method is one which meets all of the criteria required by the Codex Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.

NOTE: Type III Methods are alternatives to the Reference/Referee Method but are not intended for resolution of disputes or for calibration.

Examples: Volhard Method or Mohr Method for Chlorides
Possible terms: Codex-, Alternative-, Optional-, Acceptable-, Recommended-, Approved-, etc.

Type IV - METHOD - Definition:

8. A Type IV Method is a method which has been used traditionally or else has been recently introduced but for which the full criteria required by the Codex Committee on Methods of Analysis and Sampling have not yet been determined. In many cases the missing information would be the reproducibility based on collaborative studies.

Examples: -
Possible terms: tentative, candidate.

NOTE: Sufficient information should be available to assess the usefulness and application of the method.

B. CRITERIA FOR METHODS OF ANALYSIS

9. The Codex Committee on Methods of Analysis and Sampling recommends that every method be evaluated on the following criteria:

(i) Accuracy
(ii) Precision (i.e. - Repeatability, - Reproducibility)
(iii) Limit of detection
(iv) Sensitivity
(v) Applicability
(vi) Practicability

10. A Codex Committee shall, wherever possible, provide to the Codex Committee on Methods of Analysis and Sampling all known information for each individual test method relating to each of the criteria listed above as applicable.

11. Where a new method of Type III or Type IV is submitted and where a Type II (Reference) method already exists, a comparison of the criteria of the proposed method and the accepted Type II method shall be provided. Type IV methods are subject to review against General Criteria where no current method may exist, or where it is intended to be developed as a Type I method.

C. RELATIONSHIP BETWEEN THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING AND OTHER CODEX COMMITTEES

12. The Working Group noted that Appendix II of ALINORM 74/23 has previously addressed this subject. This report further attempts to clarify differences in Codex Methods and suggests that changes will be necessary in the text of the Codex Procedural Manual, so as to make appropriate reference to the four types of Codex methods discussed above.

13. The Working Group also proposed the following procedures which should lighten the burden of the Codex Committee on Methods of Analysis and Sampling and at the same time increase the relevance of its work:

(a) At the earliest step possible, certainly at step 4 and again at step 7, the Codex Committees should discuss and report on matters connected with:

(i) Provisions in a standard which require analytical procedures;
(ii) Any provisions for which methods of analysis are outstanding and require elaboration;
(iii) Provisions which are defined by the method used, together with the proposed method and supporting information which will assist the CCMAS in its consideration of the method;
(iv) Other provisions, together with proposed methods and supporting information; and
(v) Any request for assistance or advice in reference to any method.

(b) General subject committees, or the Commission, should inform the Codex Committee on Methods of Analysis and Sampling of any provisions in any standard, or in general terms, of any provisions considered to require a reference method of analysis.

(c) The Codex Committee on Methods of Analysis and Sampling should undertake a coordinating role in the use of recommended and reference methods.

(d) Methods should be elaborated by the Commodity Committee in consultation, if necessary, with an appropriate expert body. The Codex Committee on Methods of Analysis and Sampling should maintain an overview of such activities.

(e) The Codex Committee on Methods of Analysis and Sampling should request elaboration of methods by organizations having expertise when advised by Commodity Committees or the the Commission that this is necessary.

(f) It is recognized that the terms of reference of certain Codex Committees allow for the elaboration and endorsement of methods entirely within these committees.

14. The Working Group urges that a way be found to keep the CCMAS informed of all planned and completed collaborative studies so as to maximize all available resources.

CRITERIA FOR CODEX METHODS

(Examples)

Type of method	Collaborative study	Accuracy	Precision	Limit of detection	Sensitivity	Applicability	Practicability	Comments
I	Required	Defined	Determinated by collaborative studies	inherent in the method	As determined by collaborative study	Specified and may be specific	Experience + use reference	Defined by the terms of the method
II	Required	Specified	Based on collaborative study and may relate to application	to be indicated whenever applicable	to be indicated whenever applicable	Should be broadly applicable but may be limited	Must be sufficiently practicable to be used in a variety of laboratories	Used for reference and/or calibration
III	Required	Specified	Based on collaborative study and may relate to application	to be indicated whenever applicable	to be indicated whenever applicable	Could be limited	Could be limited	Not for reference or calibration but satisfactory for control, enforcement, inspection, etc.
IV	To be organized	Judgemental	May not be known	May not be known	May not be known	Suggested	Not established	May become a new method or may be revoked

APPENDIX III

REPORT OF THE AD HOC WORKING GROUP ON ACCEPTANCE SAMPLING PLANS FOR THE DETERMINATION OF NET CONTENTS OF PREPACKAGED COMMODITIES AND ON GENERAL PRINCIPLES FOR THE SELECTION OF CODEX PROCEDURES FOR SAMPLING

INTRODUCTION

1. On the second day of the Tenth Session of the Codex Committee on Methods of Analysis and Sampling, held in Budapest, 24-28 October 1977, the Chairman requested that the ad hoc Working Group on Acceptance Sampling Plans for the Determination of Net Contents of Prepackaged Commodities be reconvened. In addition to continuing its study of net contents sampling plans, the Working Group was charged with examining certain aspects of Codex document CX/MAS 77/5, "General Principles for the Selection of Codex Procedures for Sampling".

2. The membership of the reconvened Working Group consisted of the following representatives:

CANADA	G.E. Anderson (Chairman)
AUSTRALIA	A.W. Randell
DENMARK	K. Snoer
EGYPT	L.I. Hanna
FINLAND	Mrs. P.L. Penttila
HUNGARY	B. Czakó
	L. Poós
NETHERLANDS	W.J. de Koe
NORWAY	A.O. Hougen
SWITZERLAND	P. Koch
	B. Kovaliv
	H.U. Pfister
USA	C.H. Brokaw
	B. Levy
	Mrs. M.G. Natrella
	J.S. Winbush

PREAMBLE

3. At the Ninth Session held in Budapest, 27-31 October 1975, the Working Group reported that after considerable discussion it was proposed that a "Moderate Acceptance Probability" (MAP) plan should be developed. This plan should take into consideration the strengths and weaknesses of the 50-50 Indifference Quality Level (IQL) plans used in Australia, Canada and the U.S.A.; and the "High Acceptance Probability" (HAP) plans used by the EEC and certain other countries. An essential characteristic of this MAP plan should be that it could be re-applied sequentially to questioned lots in order to increase the confidence level of any decision finally reached.

4. The Committee in plenary session requested the Working Group, under the Chairmanship of Mr. G.E. Anderson, to develop details of such plan. It was further agreed that the plan should be sent to governments for comment after consideration by the Committee at the Tenth Session.

PROCEEDINGS

5. The Swiss delegation distributed for consideration a technical paper entitled "Official Statistical Inspection with Adaptable Severity: A Building Block Approach". This paper describes the broad outlines of a procedure which can be considered to be a "Moderate Acceptance Probability" plan and which appears to meet many of the criteria which had been specified by the Working Group during the Ninth Session. Details of the plans are given in the appended paper.

6. A supplemental paper entitled, "The Problem of Non-Normal Distribution in Official Statistical Inspections" was also submitted by the Swiss delegation. This paper, which is also appended, is intended to outline the basic philosophy underlying the first mentioned paper.

7. The Working Group also examined the document CX/MAS 77/5 "General Principles for the Selection of Codex Procedures for Sampling" and reached conclusions which are given below.

COMMENTS ON THE SWISS PAPER

8. The sampling plan as outlined in the Swiss papers is intended to be used by the governmental inspection services of a country (e.g. Weights and Measures inspectors) to establish the acceptability or non-acceptability of lots of prepackaged commodities for sale within that country. The plan is suitable for inspections intended to be carried out at random and infrequent times but it is not intended for use as a procedure for the continuous "on the line" control of net contents.

9. Among the important features which are characteristic of the Swiss plan are the following:

(i) The standard deviation of the frequency distribution of the net content of each package in an acceptable lot must not exceed a maximum value, σ_o to be specified. Limiting the width of the frequency distribution through the use of σ_o in place of tolerance limits is an important feature of the plan. This feature permits a considerable reduction in the sample size and also permits greater uniformity of legal requirements among various countries. σ_o is approximately one half of the value of the tolerance limits employed in the EEC and other European sampling plans.

(ii) Inspection by attributes or by variables is possible provided the selected plan has an "Operating Characteristic" (O.C.) curve equivalent to that to be specified.

(iii) The plan makes provision for the repetition of inspections up to three (3) inspections in order that a decision might be reached giving a very high level of confidence in the result - which might be necessary in order to establish in a court of law "beyond any reasonable doubt" that an infraction of the law had indeed occurred. The inspection may be made repeatedly on the same lot for evaluation of that lot. The inspection may also be done at various intervals of time on different lots from the same packer, in order to judge the characteristics of the following process.

(iv) The plan is such that a decision could be made after the first or the second or the third inspection, with increasing levels of confidence at each successive step, so that the number of steps chosen would be appropriate to the importance of the enforcement action contemplated, i.e. warning, severe reprimand or fine and confiscation of goods.

(v) The plan differs from many other plans in current use in that the sample size is independent of lot size and is constant, once certain choices are made, e.g. whether inspection is by attributes or by variables or by single, double or sequential sampling, etc.

RECOMMENDATIONS re : NET CONTENTS SAMPLING

10. Because the plan submitted by the Swiss delegation appears to meet in large measure the characteristics described in the report of the Working Group prepared in October 1975 (see ALINORM 76/23, Appendix III), the following steps are therefore recommended to the Committee:

(i) That the two papers prepared by the Swiss delegation be printed as appendices to the report of the 10th Session.

(ii) That the papers be submitted for comment by member nations, with a view to proceeding to Step 3 if the comments appear to warrant such action.

(iii) That a questionnaire be prepared by the Working Group and distributed to member nations through official Commission channels.

(iv) That the questionnaire be so worded as to elicit, among other matters, a statement by each respondent country as to the feasibility and possibility of the Swiss plan being employed in the respondent country (perhaps suitably modified) and also the parameters (such as AQL, producers' risk or consumers' risk, etc.) which that country would wish to use if the plan were to be employed therein.

COMMENTS ON THE PAPER CX/MAS 77/5 re: GENERAL PRINCIPLES FOR SELECTION OF SAMPLING PLANS

11. The time available for study by the Working Group of the above-mentioned papers was limited but the following points should be noted:

(i) The field of application of the document CAC/RM 42-1969 is restricted but nevertheless it would appear that the document has upon occasions been used more widely than, or in circumstances outside of, the restricted field intended;

(ii) In particular, the limitations implicit in section 2.1 of CAC/RM 42-1969 should be closely observed;

(iii) The amendment to the above-mentioned document, as given in CX/MAS 77/2-Add.1, should be adopted.

12. In preparing sampling plans, Commodity Committees should give consideration to the following suggestions:

(i) Sampling plans should be adopted only after careful examination of:

(a) the hazards to health or the economic risks which might result from incorrectly accepting a defective lot;

(b) the economic losses due to the destruction of sample items or which might be due to delays experienced during the carrying out of tests or analyses;

(c) the costs of the sampling and analytical procedures.

(ii) Various sampling plans are often available for use and the plan chosen should be appropriate to the parameters which are intended to be controlled.

(iii) Proposed sampling plans should be submitted to the CCMAS for evaluation together with the following information:

(a) scope
(b) field of application
(c) confidence levels
(d) level of quality which should be accepted at the designated confidence level
(e) details of plans, such as O.C. curves

RECOMMENDATIONS re: GENERAL PRINCIPLES FOR THE SELECTION OF SAMPLING PLANS

13. The Working Group wishes to acknowledge the valuable contributions made by the delegations of the Netherlands and of the United Kingdom in the preparation of CX/MAS 77/5 and would recommend to the Committee that the Working Group continue its activities in this area with the United Kingdom acting as convenor.

APPENDIX IV

THE PROBLEM OF NON-NORMAL DISTRIBUTIONS IN OFFICIAL STATISTICAL INSPECTIONS

by the
Delegation of Switzerland

1. Outline of the situation:

In the framework of the present study, an official statistical inspection is understood as a sporadic act aimed at the determination of statistical parameters on a batch of units in order to decide on the manufacturer's reliability.

(a) As the inspections are done at very large intervals, the system is not a quality control method in the normally accepted meaning of the term.

(b) Since for each inspected lot a great number of others pass without test, the fate of that particular lot does not influence the average quality of traded goods. What is important is the conclusion drawn on the manufacturer, in so much as he may be forced to observe certain "rules of the game". Handling of the lot can be used to bring pressure on him, but cannot achieve more.

(c) It follows from (b) that the efficiency of such a statistical inspection method can only be estimated if one takes into account the frequency of inspections, the applicable sanctions and the requirements on the lot.

2. The requirements

Definition of a legally sufficient production:

Since the State can test only a very small fraction of the produced units, its requirements to the manufacturer must be suitable for checks on small-sized samples. For a given characteristic such requirements might be that:

- There be no evidence for the mean value being below a given limit;
- There be no evidence for any unit being below a given standard;
- There be no evidence for more than a small percentage of all produced units being below a given standard;
- There be no evidence for the difference between very good and very bad units surpassing a given limit.

This list could be lengthened. The important feature is the term "evidence" which purposely was repeated 4 times. The aim of the statistical inspection is a judgement, to be perhaps followed by sanctions. The findings of the court should be free from errors in evaluation of the statistical facts. There is always a small probability of the sample not being sufficiently representative of the whole population. On the other hand, there are cases where decisions must be based on sampling. What is the least bad solution ?

3. Judgment based on sampling:

3.1 Distribution shapes

The characteristics on which a judgment of a production is based can be very different: accuracy of a measuring instrument; life expectancy of a car tyre; pesticide content of a shipment of salad; net weight of prepacked goods; etc.

Generally, every characteristic when considered over a very long production time will tend towards a determined mean value. This can be rather well controlled by the manufacturer and it seems reasonable to formulate whenever possible requirements on the mean value of relevant characteristics. These mean values are also the parameters easiest checked statistically.

On the other hand, every single value of a characteristic will deviate from the mean. From a given point of view it will be once better, once worse than the required mean.

The question is now: how much "worse" than the required mean may a single piece be ? Or more specifically: how many percent of the production may lie at how much quality units below the required mean ?

These questions lead to consider how the values are distributed around the average.

One can imagine very extreme distributions. If I throw a coin once I get either hundred percent head and zero percent tail or the opposite, although the mean would be 50% head and 50% tail. Other distributions show an astonishing preference for the mean value. Consider for example the net weight of single chocolate tablets of the same make.

A graph showing the percentage of units presenting a given deviation from the mean versus the values of deviation may take very different shapes: in the first example one would have two vertical lines at head and tail with 50% as the average probability for "head", in the second example the different machines or dispenser would show each its individual distribution, which could, according to their width and disposition fuse to a bell-shaped curve or, standing side by side, form something like a rectangle. The ideal case for the mathematician is the bell-shaped normal or Gauss' distribution. This distribution is entirely defined by two numbers: the position of its summit (mean value) and its "waist width", or more precisely the distance between the two points with the steepest slope.

Non-normal distributions may require more than these two values for their description, the number increasing with complexity of the shape. In such case we are faced with the problem of how to formulate the legal requirements on the population.

3.2 The simplest distribution parameters

The quantile (p%-quantile). A parameter so constructed that p% of all single units are of worse quality, (but how much worse is not known).

The median (middle value; 50% quantile). This value is chosen in such a way that just as many single pieces lie above as below.

The mean value (of the measurements). This value is chosen in such a way that the sum of all positive differences is just equal to the sum of all negative differences. (This implies that all differences can be measured or "weighed").

The root mean square error (from the mean value). The differences from the mean value to each single element are squared, these squares are summed and this sum is divided by the total number of elements. The result is called the mean square error (therefore a square) and the root of this square is the equivalent average deviation, in other words the root mean square error.
Forgetting the finer statistical points, one can say that the root mean square error of a normal distribution is equal to half its "waist" and is called standard deviation. Non-normal distributions also have a root mean square error but do not necessarily have a "waist width".

Moments of a higher order are built in the same way as the mean square error (which is of second order), only the differences are not squared but elevated to a higher power. Such moments give a measure for the skew and the steepness of the distribution curve.

3.3 Judgement by values and by attribute

Some of the mentioned parameters require an exact measurement on each unit: the mean value, the root mean square error and the moments of higher order. A judgement "worse" or "better" is sufficient for the different quantiles. At first glance this may seem the easiest solution because all the problems of measurement and calculation seem to disappear. The problems will be shown in an example: I would buy a car-load of melons with the acceptance condition that no more than 1% of the melons be rotten. The questions are:

(a) when is the criterium "rotten" fulfilled? Where lies the exact boundary? Quite a lot concerning the decision depends on this;

(b) how many pieces must I inspect in order to be able to judge with a reasonable confidence "more than 1%" or "less than 1%"? (Certainly more than 100 pieces).

Judgement by values is completely different to the judgement by attribute presented above. There is more work to be done with this method because not only must the judgement "good" or "bad" be given, but a quantitative measure of it must be taken. On the other hand, whenever such a quantitative measure is possible, each piece yields more information than with the test by attribute. But then this increase in information for each checked piece often makes it possible at the same confidence level to give a judgement on the whole population with less pieces than would be necessary with a test by attribute. Statisticians' experience shows in most cases the proportion of units to be checked is approximately 1:2. In extreme cases it is even more marked:

If we want to be convinced (in the statical sense of the word) that out of one million numbers not more than 50 are smaller or equal to 1, we would have to check some 20,000 numbers with a test by attributes. But if we were to find by measuring that the mean value of these numbers is 10, that they are probably normally distributed, and that their standard deviation is about 2.2, then we could see that a number smaller or equal to 1 lies about 9 units, that is to say about 4 times the standard deviation below the mean value and that the probability of occurrence of such an event in the normal distribution is about 32 parts in 1 million. Such an estimation of a mean value and standard deviation requires, depending on the accuracy wanted, 25 to perhaps 200 units. (The numbers in the example describe the number of "head"-results for series of 20 coin throws. For the result "0 head" and "1 head" the probabilities are 1 and 20 times 2^{-20} which is approximately equal to 1 and 20 times 10^{-6}.

This example also outlines the limits of the model of a normal distribution: how can I prove that my population really has a normal distribution ? How accurate can this proof be? (The cat could have swallowed just the second biggest sausage out of a pack containing 10,000, the weight of which were normally distributed. How could I notice that? One must not forget that such an error has a worse influence on the distribution when it concerns an extreme and rare value than when it concerns a middle, strongly represented value).

3.4 Practical consequences

Let us consider the net quantity filled in prepacked goods: there is an ever increasing tendency to demand of the manufacturer that he hold a determined mean value and, at the same time, that the distribution of his filling quantities be not broader than a given measure, so that underfilled packages would not have a net quantity smaller than the declared mean minus a given margin. We now come to the problem of the exact formulation, bearing in mind that this formulation has a direct influence on the choice of a test, on the work involved and on the amount of destroyed packages.

The regulation has the aim to protect the consumer against strongly underfilled packages and therefore tends to limit to "seldom" the occurrence of units filled under the margin. The politician would like to replace "seldom" by "never". Since the statistician does not know the word "never", he replaces it by "5%", "2%" or even "1%". We have seen in our example that a test by attribute for a rare occurrence requires as many more units to be checked as the occurrence is scarcer. (This number also increases with the confidence level required for the decision, but this is true of all checking methods). On the other hand, a test by values with a decision taken on the basis of standard deviation requires that the distribution be normal. This could be important in a court of law, because for non-normal distributions, it is not always permissible to conclude from values of the standard deviation to quantiles.

In the European Common Market, it is prescribed for the test of large batches to measure 50 units if the mean value is to be checked. On the other hand, up to 200 units are to be judged by attribute if the condition on the tolerance is to be checked. In this test, it is considered proven with the necessary statistical confidence that more than the permitted 2% of batch units are below the prescribed tolerance when 5 to 6% of the sample units are unsatisfactory. For a normal distribution, applying the same safety factor of 2.5 to 3 on the width of the distribution, one could already judge the observation of the tolerance limit on the base of 8 units checked.

For small batches, the mentioned prescription reduces the sample size, setting forth a value of 30 for the mean value and even 20 for very small batches. In both cases, the the respect of the tolerance is judged by attribute on 20 units with the condition that 1 may lie under the limit. Here, we also have a security factor of 2.5, and at the same time we must wonder how strongly chance can influence the outcome of such a test, bearing in mind that with either 0 or 1 permitted, we are a long way from the "law of great numbers".

All would work better if we could find another criterion for the distribution width, still giving the consumer an idea of his protection, but allowing to reach a conclusion based on the normal distribution, notwithstanding the fact that de facto the checked production is not normally distributed.

There is such a possibility: the use of the central limit theorem.

4. The new criterion for the distribution width:

The central limit theorem can be formulated like this: "Take any distribution, as far from normal as you like (for instance, one with two straight lines as for the case of coin-flipping). Then take a sample of several units (e.g. 100). Repeat that procedure a number of times and calculate each time the mean value of the sample. (For each 100 coin throws the mean value of the head results would be e.g. 48, 51, 50, 47 ...). It can be demonstrated that these mean values always show a nearly normal distribution and tend to be absolutely normal when the number of units in the sample increases beyond limits".

This situation corresponds rather well to the situation of a consumer if, at the end of the year, he were to draw a balance sheet. He has bought during the year a given item several times and got sometimes more, sometimes less than the prescribed mean value. At the end of the year he has paid a certain amount of money corresponding to a certain amount of goods. The mean value of the received goods (per package) is normally distributed to all practical ends.

Given that normality, it is rather simple to calculate the risk that a given consumer at the end of a year got for his money a given amount of goods less that he was entitled to. If this definition of underfilling is used, statistical inspections can be made with a noticeably smaller amount of work and destruction, or, more products can be watched at equal cost, and this again is to the advantage of the consumer.

Let us once more outline the difference between the two criteria:

Up to now: If 100 consumers each buy 1 pack, on average 2 consumers will each get 1 unit filled below the margin set by the old tolerance (T_{old}).

New: If 100 consumers each buy 16 packs, on average 2 will get a mean quantity of goods per pack lying below the new margin set by the new tolerance. The new tolerance would be approximatively 1/4 of the old.

Remark: The number of 16, which determines the proportion between the new tolerance and the old one has only been chosen as an example. In order to use the central limit theorem, the number of units should be somewhat larger than 10 but not so large that it would seem to be unrealistic as a number of purchases.

5. Mathematical consequences

Although the definition of underfilling is based on an assumed number of purchases (here 16), the checks need not be based on the measurement of groups of 16 units. In fact, it can be shown that the root mean square error of the new distribution of mean values, nearly normal due to the central limit theorem, is equal to the root mean square error of the original distribution divided by the square root of the number of units considered in the definition (here $\sqrt{16}$). A fair estimate of this error can be obtained from a relatively small number of units. It is at the same time the best possible estimate of the standard deviation in the new distribution.

Another consequence is that we now have a measure common to all distributions to express their width: the root mean square error from the mean. For a production of reasonable size the r.m.s. error will be practically identical to the standard deviation σ. On the other hand σ is the measure we need to define consumer's risks following the new proposal. And again, the r.m.s. error or the standard deviation are parameters well known to the producer if at all he does statistics. So it would be practical to replace the tolerance limits (which in different countries may correspond to different quantiles) by r.m.s. error, which would allow for an international standardization of the legal requirements.

Let us compare different ways of expressing distribution width, taking figures corresponding exactly to the same production if it were normally distributed (σ will always be the standard deviation of the individual units).

For the producer and the inspector:

2%-quantile $T(2\%) = 2{,}054\ \sigma \triangleq 21$ g
5%-quantile $T(5\%) = 1{,}645\ \sigma \triangleq 16$ g
16%-quantile $T(16\%) = 1{,}000\ \sigma \triangleq 10$ g

(this would be the r.m.s. error, as limited by regulations).

For the consumer, buying 16 units:

r.m.s. error of the average: $\frac{\sigma}{\sqrt{16}} \triangleq 2.5$ g

2%-quantile of the average distribution:

$$2{,}054 \cdot \frac{\sigma}{\sqrt{16}} \triangleq 5 \text{ g}$$

(the risk of getting an average low by σ $(=4 \cdot \frac{\sigma}{\sqrt{16}})$ corresponds to a theoretical quantile of 0,003%).

The remaining problem is to effectively enforce limitation on standard deviation. The generally accepted idea is to define an upper limit for it, up to which it is sufficient for the manufacturer to respect the mean value condition. If for any reason his r.m.s. error shows to be larger than that limit, he must compensate for it by shifting his mean value upwards in order to hold the percentage of units allowed to be below the tolerance limit. If now we have decided to think in terms not of single units but of the average from a reasonable number of units, we must reduce the percentage of precisely those "defective averages". But this does not change the mathematical procedure, since σ of these averages is proportional to σ of the individuals. The proportionality factor $\frac{1}{\sqrt{n}}$ makes tests on distribution width less stringent, but this we may compensate by asking for narrower tolerance limits of smaller percentages, if we want to.

Summary

Instead of describing admitted distribution width by a quantile in the original distribution (a percentage of units allowed to be below a given tolerance limit), it is suggested to define the width of the distribution for the average of a "reasonable number" of units. In this way, use is made of the central limit theorem, the distribution we have to consider will be practically a normal one, prescriptions and judgements may be done by measurement and evaluation of the standard deviation. This allows for more economic test procedures and eliminates the risks of discussions about normality or non-normality of a product's error. Methematics underlying the test procedures remain of the same kind and procedures themselves reduce to the simpler case of normal populations. Defining allowable standard deviation is an approach to an international unification of rules.

APPENDIX V

OFFICIAL STATISTICAL INSPECTION OF ADAPTABLE SEVERITY: A BUILDING BLOCK APPROACH

by the
Delegation of Switzerland

SUMMARY

A Working Group of the Organisation Internationale de Métrologie Légale has studied the possibility of defining predetermined operation characteristics for legal statistical inspections. A family of three such curves is suggested, with the special feature that they may be obtained by repetitive application of one basic test. Different test procedures resulting in practically the same operation characteristic for that basic test are described. It is felt that by this approach it could be possible to unify statistical requirements without giving up the liberty for different administrations to chose the testing method judged most appropriate for their staff.

The discussed OC's are shown in figures 1 to 4.

Official Statistical Inspection of Adaptable Severity: A building block approach

Note: these ideas were presented in Spring 1977 to a working group of the Organisation Internationale de Métrologie Légale (OIML) concerned with official statistical inspections.

Summary:

1. Outline of the problem

The mathematical efficiency of any statistical inspection scheme may be described by its operational characteristic, showing the acceptance probability for the inspected batch versus the average value of the inspected property. When drawn on special paper showing a probabilistic scale for the acceptance and a linear one for the measure of the property checked, the curve is a straight or nearly straight line. This implies that the whole description of the test may be reduced to 2 parameters: one point of the OC-curve and either a second one or, rather, just the slope of the curve.

Steepness of the curve depends on qualitative parameters of the test - as the choice of the mathematical evaluation method or the choice between a single step, multistep or sequential testing - and one quantitative parameter, the number of units checked during

evaluation. These parameters on one hand may provide efficiency to the test, on the other hand they fix its costs, viz. working expenses or the expenses incurred through destruction of tested material.

At least one point of the OC-curve must be given by its coordinates and this may be for instance the acceptance probability for the batch when the average of the relevant property is just sufficient to a given requirement. In the case of prepacked goods this would mean that the average of the filled quantity is just equal to the declared quantity, provided that no other characteristic has to be considered. Let us call that point of the OC-curve the acceptance probability for the marginal quality.

For better qualities the acceptance probability will be higher, for worse quality it will be lower.

Now this acceptance probability for marginal quality will always be the result of some compromise, weighing the interests of the buyer against those of the manufacturer. As long as legal consequences may result from the check, the manufacturer which is just in a legally correct situation may claim for a reasonable probability of acceptance, that is to say a practically negligible risk of being rejected.

Since the slope of the OC-curve is limited, this claim for safety from one manufacturer implies that another one, willing to run a slightly higher risk, can aim slightly below the limit which was meant to be defined by the marginal quality. There is no remedy against this situation: if two producers are ready for different risks at the test, they can and must bring to it batches of different quality. The layout of the procedure can either protect the first one and allow the other to cheat, or it can set very bad rules, refraining the second from his tendency but imposing on the more prudent one to produce a better quality than the margin. This results either in higher costs to the consumer or in a cynical way of calculating the inspection risks and comparing them to the possible gain on a production slightly below the standard.

2. Legal action

Most systems of laws are made with the idea of progressive enforcement: the first time an offence is done, there will be a warning, may be a more or less symbolic penalty. If the offence is repeated by the same subject, reaction will be stronger. On the other hand, for the strongest reactions there must be a certain evidence of a purposely done action.

It is normally asked that this evidence be "beyond any reasonable doubt". Criticism on possible proofs is a way of eliminating doubt; considering the number of repetitions for a given act is another one. Reasonable doubt is also a different measure depending on the reaction intended: there must be another level of confidence to give you a fine for extended parking or to withdraw your driving licence. Theoretically, the first reaction also should come only after the situation has been cleared beyond any doubt. But as this clearing would cost the community and even the presumptive offender a lot of time and money, there is a commonly established acceptance for a less exacting procedure.

In the domain of legal statistic inspections we need a similar consideration of an action's importance. There should be at least 2 types of tests with different operating characteristics: one, representing an economic way of looking for "weak points", would not have so rapid a slope and so good a power of selection between "good" and "bad". It would be used only to give warnings and to decide on further inspection; but it should have only a limited acceptance probability for marginal quality in order that not too many of the "sub-marginal" producers may pass undetected.

The other OC-curve would be used in important cases, being able of an effective discrimination between good and bad, and giving the inspected party a high level of statistical confidence. On the other hand rejection in this test would be a strong proof of non-conformity to regulation and could therefore induce substantial reactions.

It may be desirable to define a third OC situated between the two we have just described.

3. Suggestion for a choice among 3 operating characteristic curves

During its discussions, the Working Group OIML SP2/SR5 decided to define 3 preferred operating characteristic curves resulting in risks of 16%, 2,5% and 0,4% for batches of marginal quality. These confidence levels were considered appropriate for screening and warning, for light administrative repression and for bringing a case to a court of law. Furthermore it was decided to give the curves different slopes and to arrange things so that the same basic test could be applied repetitively, resulting in

- the first grade OC when applied once,
- the second grade OC when applied a second time if the first result was a rejection,
- the third grade OC when applied a third time if the results of both previous tests were rejections.

This implies that for given average values of the considered property, rejection risks are the first, second and third powers of the risk given by the basic test, and these would be

- for marginal quality: 15,87%; 2,5%; 0,4%
- for a given lower quality: 50%; 25%; 12,5%

see fig. 1

That lower quality limit has to be set by some regulation and will be different for different applications, this resulting simply in a change of scale for the representation of the variable describing the quality.

Taking this for granted, we see that the three suggested OCs have increasing slopes for increasing grade of the test. We remember that the difference between the quality variable leading to 50% acceptance and the same variable at 84,13% acceptance correspond to $t \cdot \sigma / \sqrt{n}$.

Assuming n to be sufficiently large to have little influence on t, we see that slope increases proportionally to $\sqrt{n}$. An inspection shows that for the three suggested curves, the equivalent values for n would be in the proportions 1 : 1,65 : 2,3 and not 1 : 2 : 3 as could be expected from the fact of having repeated 2 or 3 times the basic test. The reason is simple: if after the first test a continuation is deemed necessary, the second test is done as a new and independent one. The result of the first one is "thrown away", that is, it is reduced to the information "was bad" or "was good". This fact reduces the information of each former test with respect to the final decision.

One could next regret that loss and think it would be better to make single tests of relative sample size 1, 2 and 3. But then the system would not be a repetitive one, starting with a simple test and ending when necessary with a more complete one. We would have to decide in advance on the severity. Another solution would be not to forget the values gained in former tests, but to record them and then to continue the same computation with the results of the second and the third test. But this recording of old results would make the whole thing more difficult for the inspector and (this is the important thing!) it would discourage the manufacturer from bettering his production. We prefer to give him a new chance at each test and so to lead him to reconsider his policy, since the aim of our actions is not to earn money by fines or to better such a thing as an average "outgone" quality, but rather to influence market policies for the future.

4. Equivalence of test prescriptions

4.1 Preliminary remark

The suggested basic operating characteristic may be realized by different statistical tests, from attributive ones to simple tests by variable and to sequential methods. We try here to find out the parameters of such tests resulting in that same OC.

First we only discuss the conditions which regulate average value at small standard deviations, and do not yet elaborate a second condition limiting s or forcing the manufacturer to shift to higher values when $s > \sigma_0$. σ_0 is a standard fixed by law to protect the

consumer against strong negative variations. We furthermore assume to have normal distributions. A discussion of why it could be possible to defend this assumption is given elsewhere. 1/

4.2 A simple test by $(\bar{x}, s)$ using the most probable dispersion limits

If we define by D the declared (marginal) value of the tested property (resulting in an acceptance probability of 84,13%) we may put, using student's variable t :

$$\bar{x} + t \cdot \frac{s}{\sqrt{n}} \geq D$$

if $n = 12$ $\qquad t\ (12/84{,}13\%) = 1{,}05$

this leads to

$$\bar{x} \geq D - 0{,}3\ s \qquad \text{for } s \leq \sigma_0.$$

4.3 Test by $(\bar{x}, s)$ on 12 using safe limits of variation

4.2 describes the most probable distribution of the most probable estimate for σ.

If we assume that in our test we can get for s a value smaller than the real dispersion σ, we must allow for more than $\pm / \sqrt{n}$ times this s between D and the average $\bar{x}$ we found.

Since the basic test works at an α of 15,87%, corresponding to $\mu = 1$, it seems reasonable to take the same risk for under-estimation of σ. The relation of σ^2 and s^2 is described by X^2 which we have to calculate for 11 degrees of freedom and a confidence level of 84,13%, leading to a value of $X^2 = 15{,}6$ and to a possible under-estimation of σ by roughly 20%. Therefore the safer conditions would be, for n = 12:

$$\bar{x} > = D - 0{,}35\ s \quad / \quad s < \sigma_0.$$

4.4 Limiting the dispersion

For $s \geq \sigma_0$, where σ_0 is a limit given by the law, $\bar{x}$ must be shifted upwards. This has been done up to now by providing that the 2% - quantile of the distribution does not go lower than D-E where E (often named T) is a given tolerance limit. For a normal distribution, the 2% - quantile corresponds to $T = 2{,}054\ \sigma_0$ and this point of the distribution is used as a "pivot" for the shifting. There are three disadvantages to that:

- the resulting overfill is very important and one might ask if so much is really necessary and right, as in some way the consumer has to pay for it,
- the "pivot" is very far out from the center of the distribution, at a point where the slope of the curve is small, resulting in a large statistical uncertainty,
- mathematics related to this question are not so simple, since correctly one should consider again the safe limits of variation and not the most probable ones.

A much simpler way to enforce a certain overfilling in cases of too large a standard deviation is to ask that the point of 50% acceptance does not shift lower than in the case of the limit σ_0 set by law.

Then we get for our basic test on 12 units:

$(\bar{x} \geq D - 0{,}3\ \sigma)$ equivalent to:
$\bar{x} \geq D - 0{,}35\ s$ if $s \leq \sigma_0$
$\bar{x} \geq D - 0{,}35\ \sigma_0$ if $s > \sigma_0$.

Figure 2 shows the overfilling enforced by these conditions.

1/ The problem of non-normal distributions in official statistical inspections (article by P. Koch). (See Appendix IV of this Report).

4.5 A test by attributes

4.5.1 First case: small values for σ.

As shown in 4.2 the manufacturer is given at the test a bonus of roughly 0.3 s to reach 84,13% acceptance with a production average just equal to D. Running production lower by these 0.3 s must reduce his acceptance probability to 50%.

We may translate this into a prescription for an attributive test, knowing that in the production proportions of units above D must be 50% for 84,13% acceptance and at least P(-0.3) = 38.21% for 50% acceptance.

These proportions are not small, so that we should consider rather the binomial distribution than that of Poisson. Then we find as a suitable single step plan

$$(n-c) = (20-13)$$

in other words, out of a sample of 20 units we must find not more than 13 which are below D (or: at least 7 above D).

With this plan we do not however, check the width of the distribution. In order to do so, we must add a second test, and now the cumulative probability to pass both tests must be 84.13%, for a producer working just within the limits of the law.

4.5.2 Second case - Checking the distribution width

In order to reduce the possible amount of statistically induced underfilling, prescriptions can be set up limiting the relative number of units filled below a given limit, regardless of what average the manufacturer is aiming at, and what is his dispersion.

A production running at exactly $\mu = D$ and $\sigma = \sigma_0$ would satisfy any one of the following prescriptions:

- not more than 2% of units below $D-2.054\ \sigma_0$
- not more than 15.87% units below $D-1\ \sigma_0$
- not more than 30.86% units below $D-0.5\ \sigma_0$
- not more than 38.21% units below $D-0.3\ \sigma_0$

the first of these suggestions corresponds to the mostly adopted solution up to now. To check for a 2% proportion requires however very large sample sizes.

The last suggestion would fix the quality corresponding to 50% acceptance in the proposed basic plan. Allowing for a high proportion of defectives, it needs only a very moderate number of units in the sample.

After thinking the question over, we propose the second alternative (15.87% below $D - 1\sigma_0$) just for the simplicity of the criterion, after our idea to have the regulations fix values for σ_0.

4.5.3 Combining both tests

A test of (20-5) at $D - 1\sigma_0$ for the distribution width gives 91.59% acceptance probability to the "marginal producer". This must be combined with the probability of passing the first test (20 - 13) at $D \pm 0$. These two probabilities are not independent, so simply making their product is only an approximation to the correct result (94.23% x 91.59% = 86.31%).

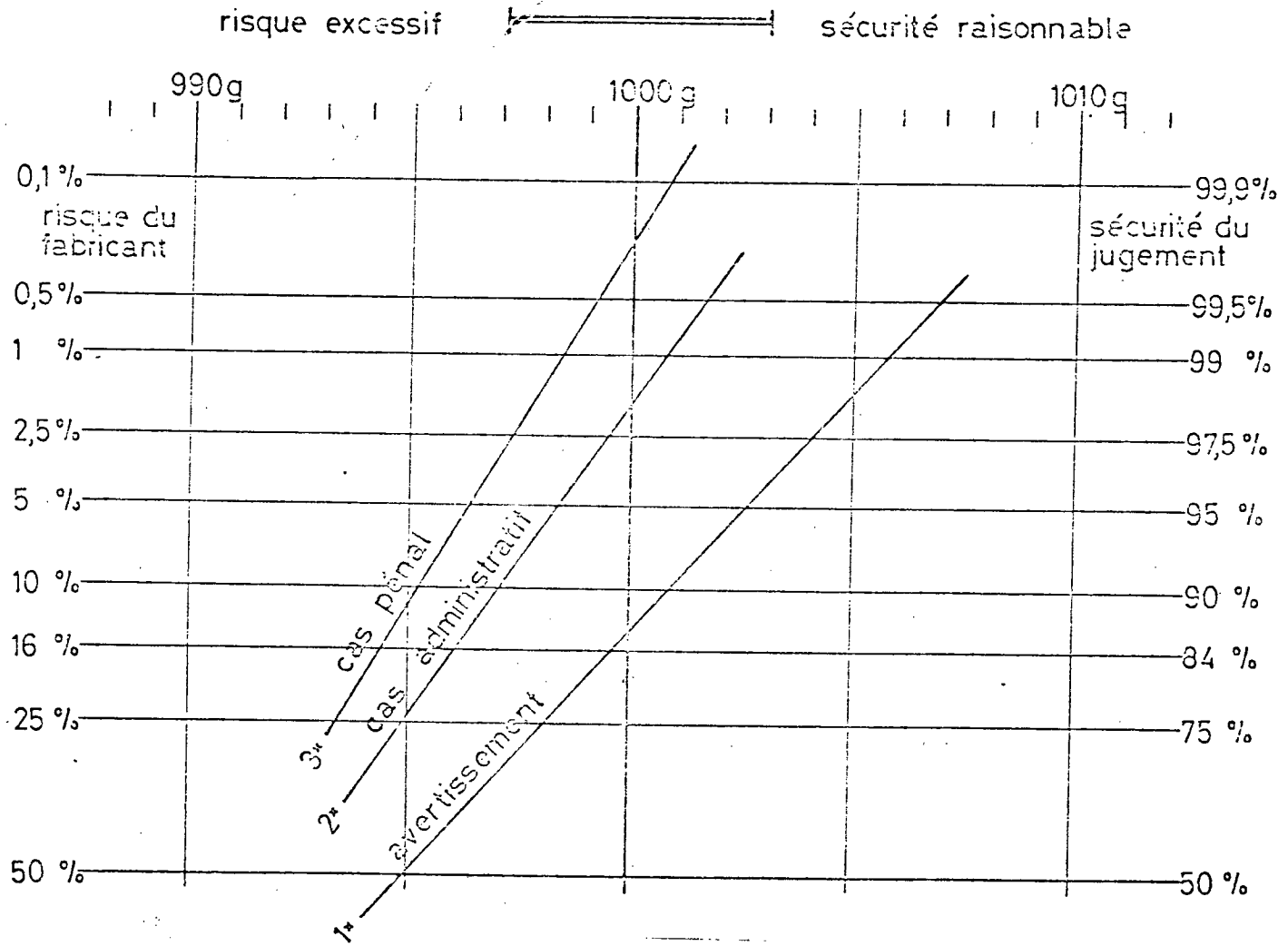
More elaborate computation however leads to the value of 87% for the cited case. So we suggest for a single step attributive plan the simultaneous fulfillment of both the following conditions:

- (20 - 13) at $D \pm 0$ (not more than 13 out of 20 below D)
- (20 - 5) at $D - \sigma_0$ (not more than 5 out of 20 below $D - \sigma_0$).

The resulting OC's for different values of production standard deviation are shown in fig. 3.

4.6 A sequential test by variables

Taking as a base the sequential sampling plan proposed by the Swiss delegation to the Codex Committee on Methods of Analysis and Sampling (CX/MAS 73/13-Rev. - CX/MAS 73/14-Rev. Documents Relating to Sampling (Revised Edition)) and the discussions which the Codex Working Group on Acceptance Sampling Plans held in October 1975, a sequential plan was developed to come out with approximatively the same operation characteristics. These are given in fig. 4. The average number of destroyed units for a production situated just within the limits ($u = D$, $o = o_0$) is about 7 or slightly less and drops below 6 for a producer aiming about 95% acceptance probability.



Exemple : σ limite = 15 g

Fig. 1

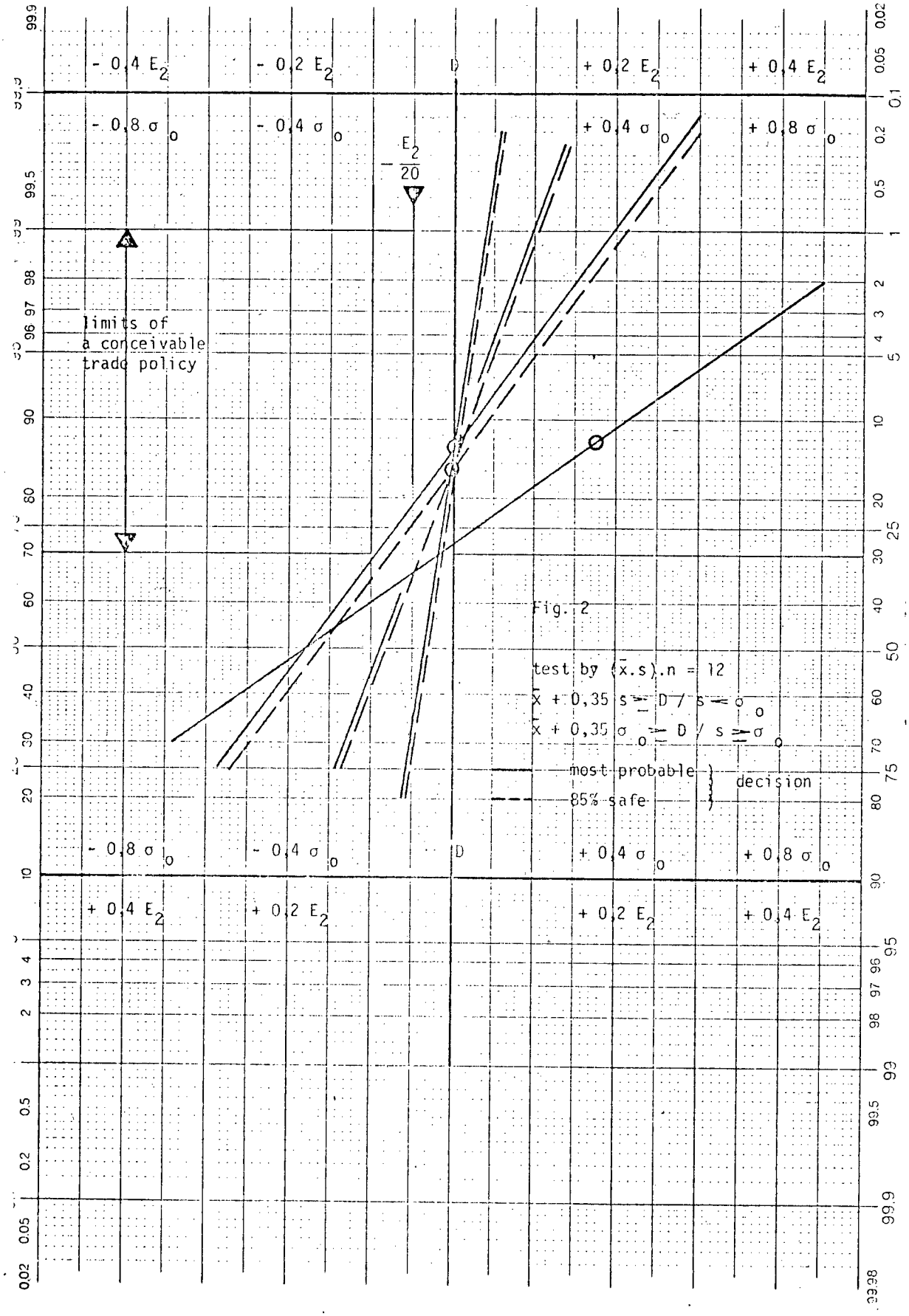

- 0,4 E2
- 0,2 E2
D
+ 0,2 E2
+ 0,4 E2
- 0,8 σo
- 0,4 σo
- E2/20
+ 0,4 σo
+ 0,8 σo
limits of a conceivable trade policy
- 0,8 σo
- 0,4 σo
D
+ 0,4 σo
+ 0,8 σo
+ 0,4 E2
+ 0,2 E2
+ 0,2 E2
+ 0,4 E2
test by (x̄.s).n = 12
x̄ + 0,35 s ≥ D / s ≤ σo
x̄ + 0,35 σo ≥ D / s ≥ σo
most probable
85% safe
decision

Fig. 2

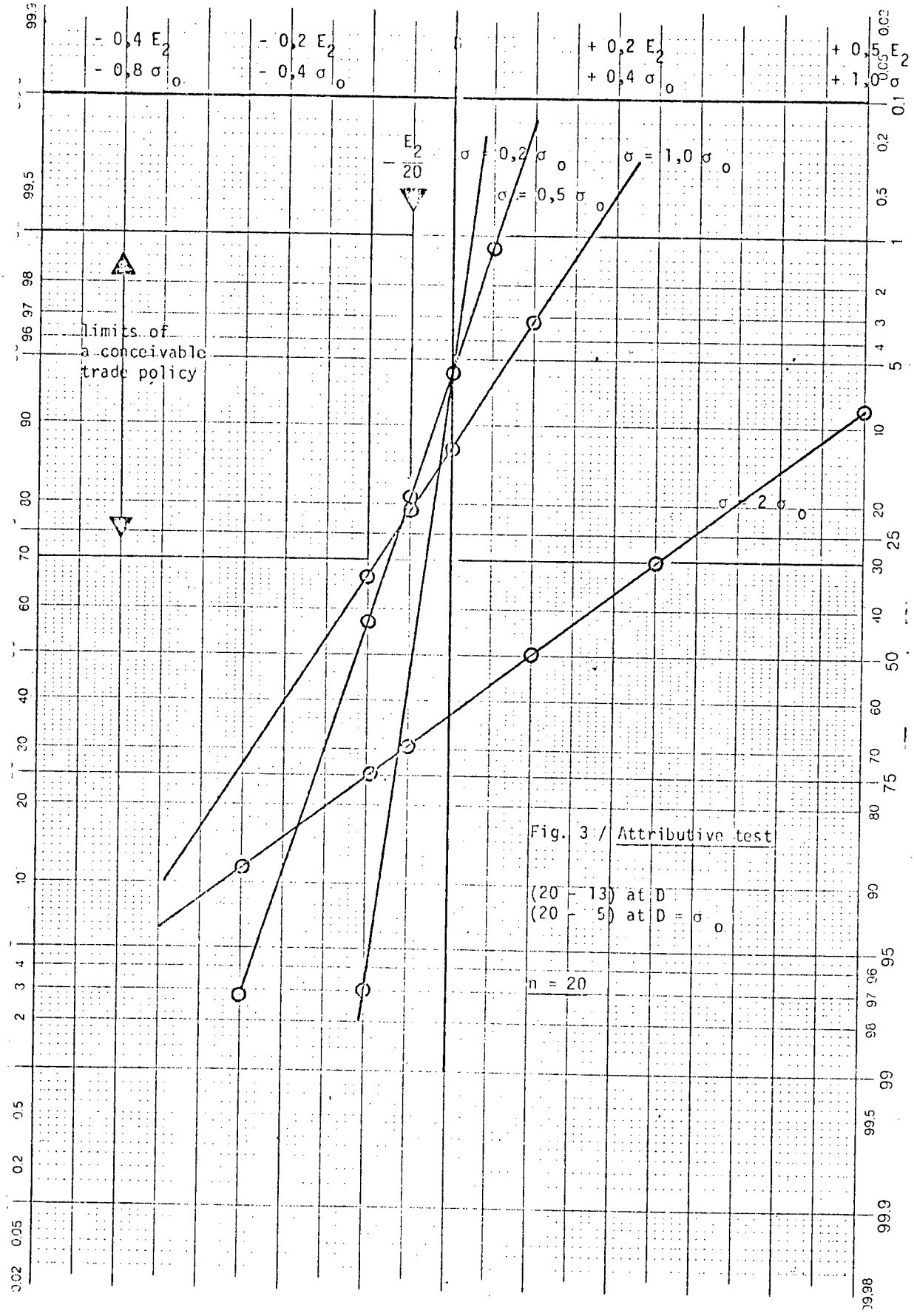


Fig. 3 / Attributive test

(20 - 13) at D
(20 - 5) at D = σ_o

n = 20

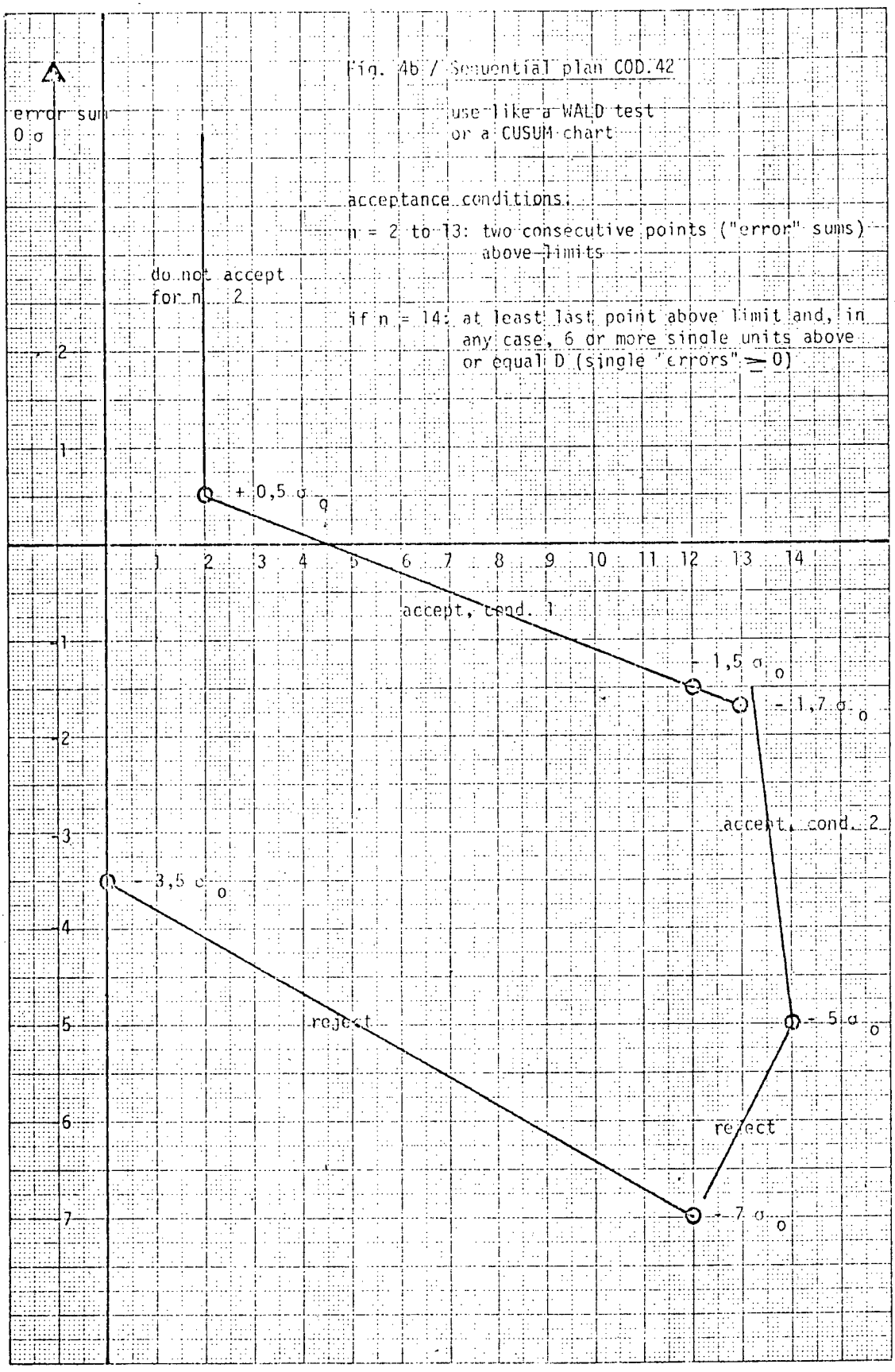


Fig. 4b / Sequential plan COD.42
use like a WALD test
or a CUSUM chart
acceptance conditions:
n = 2 to 13: two consecutive points ("error" sums) above limits
if n = 14: at least last point above limit and, in any case, 6 or more single units above or equal 0 (single "errors" ≥ 0)
error sum
0 σ
do not accept for n 2
+ 0,5 σ o
1 2 3 4 5 6 7 8 9 10 11 12 13 14
accept, cond. 1
- 1,5 σ o
- 1,7 σ o
accept, cond. 2
- 3,5 σ o
reject
- 5 σ o
reject
- 7 σ o
1
2
3
4
5
6
7

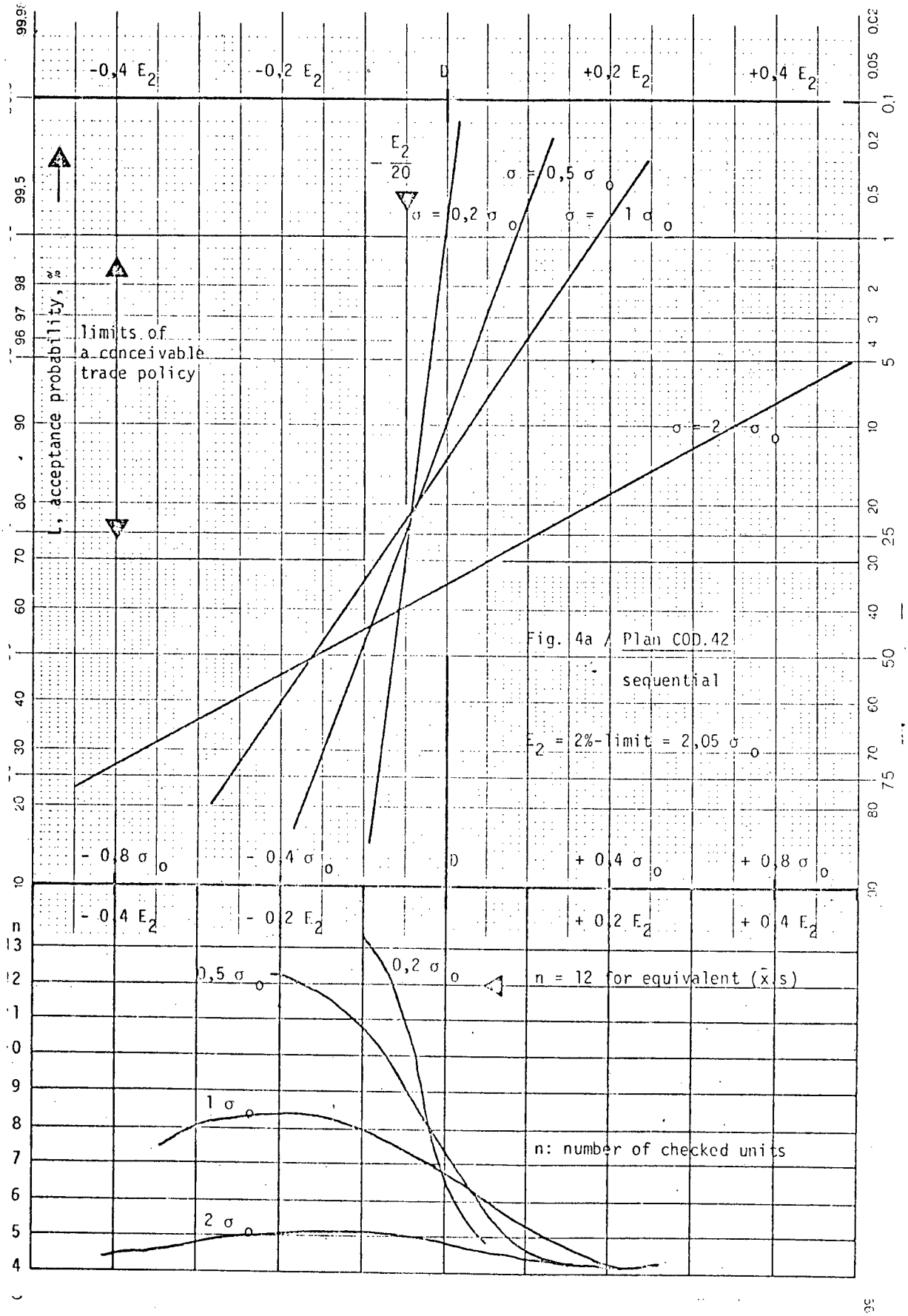


Fig. 4a / Plan COD.42

sequential

E_2 = 2%-limit = 2,05 σ_o

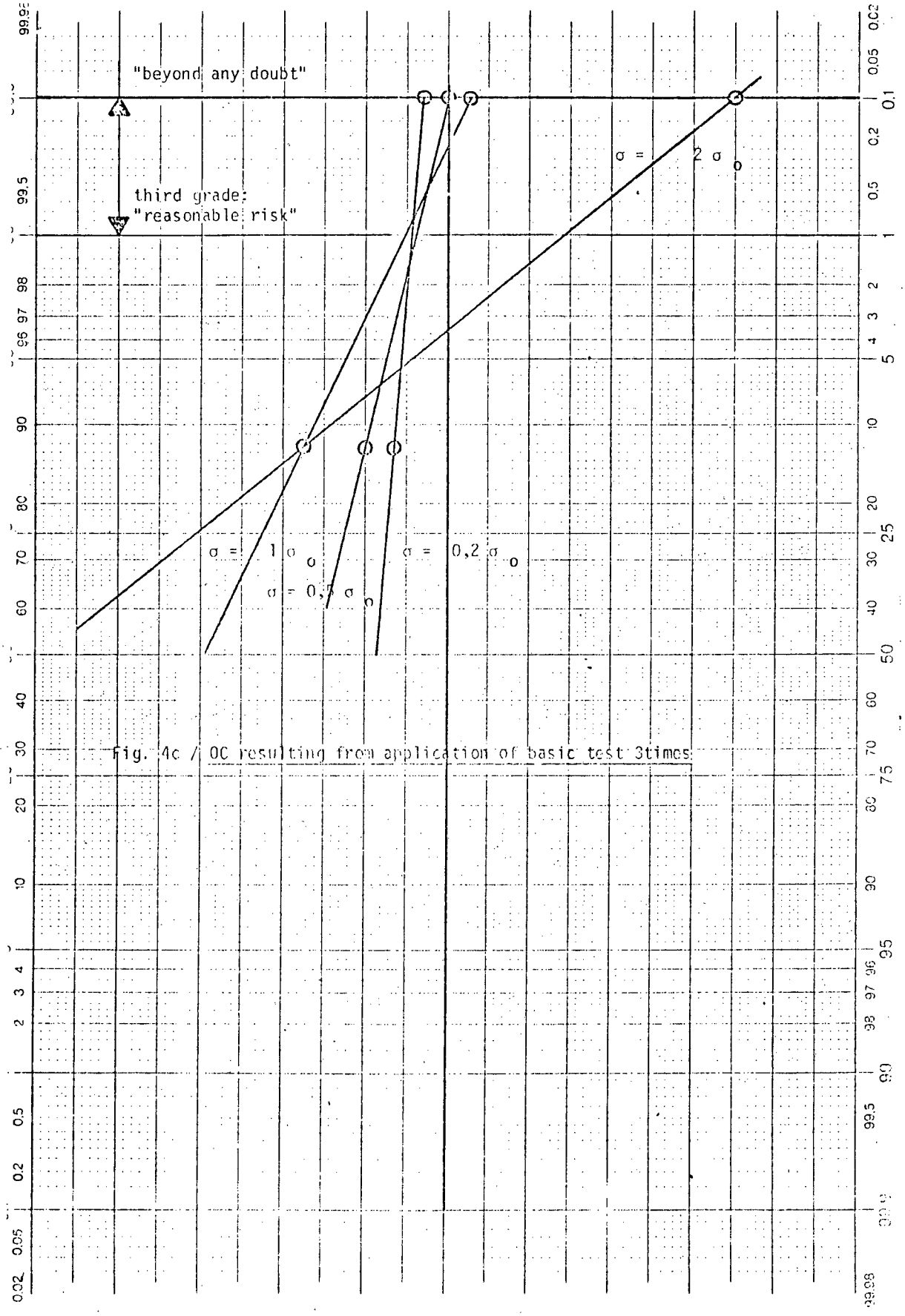


Fig. 4c / OC resulting from application of basic test 3times

APPENDIX VI

EXTRACT FROM REPORT OF A JOINT FAO/WHO EXPERT CONSULTATION ON METHODS OF SAMPLING AND ANALYSIS OF CONTAMINANTS ROME, 12-16 JANUARY 1976

(IN COLLABORATION WITH THE UNITED NATIONS ENVIRONMENT PROGRAMME(UNEP))

"10. RECOMMENDATIONS

The meeting recommends that:

FAO/WHO/UNEP:

1) Call a meeting of the principal international bodies responsible for sponsoring collaborative studies and publishing methods of analysis based on such studies, such as AOAC, ICC, ICUMSA, IDF, IFSU, ISO, IUPAC, NMKLS, OICC, OIV and others, to discuss harmonization of the principles of collaborative studies and the possibility of developing and publishing manuals on methods which will meet the needs of less developed countries as well as international organizations.

2) Encourage national and international research institutions and organizations to undertake further work on those methods of analysis which have so far not been studied collaboratively, where there is a potential for improved reliability or simpler operations, both for the priority contaminants dealt with by the consultation and others.

3) Request pertinent organizations to develop and make available a wide range of standard reference materials suitable for use at the required levels of detection.

4) In recognition of the importance of sampling, to secure agreement on sampling procedures for determination of contaminants in foods moving in trade and to continue to foster work necessary to this end.

5) Convene a further meeting of experts to consider and recommend routine and/or regulatory methods of analysis and sampling for other contaminants than those dealt with by this Consultation, and for up-dating the recommendations of this consultation.

The Codex Alimentarius Commission:

6) May wish to examine procedures for the elaboration of Codex methods of analysis and sampling and to examine the implications of and need for Codex methods in the light of the obligations undertaken by governments when accepting Codex methods.

Governments, scientific and technical organizations, and scientists concerned with levels and limits of contaminants in foods should:

7) Encourage the general use of reference and other suitable quality control standards to check practical performance in analytical work.

8) Stimulate development and dissemination of uniform guidelines for collaborative studies in order to further international agreement on methods and procedures for testing and evaluation, including confirmatory tests and blanks; encourage the extension, as far as possible, of general methods to additional materials and commodities in the interest of efficiency of effort."