codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE FIRST SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Washington D.C., 27-31 October 1986

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INTRODUCTION

1. The First Session of the Codex Committee on Residues of Veterinary Drugs in Foods was held from 27th to 31st October 1986 in Washington, D.C., by courtesy of the Government of the United States of America. The Chairman of the Session was Dr. Lester M. Crawford, Associate Administrator, Food Safety and Inspection Service, USDA. Representatives and Observers from 34 countries and 10 international organizations were present.

2. A list of participants including officers of FAO and WHO is attached as Appendix I to this Report.

OPENING OF THE SESSION (Item 1)

3. The Chairman of the Committee introduced Dr. Donald L. Houston, Administrator, Food Safety and Inspection Service of the USDA who formally opened the Session.

4. Dr. Houston welcomed delegates to this First Session of an important new Committee. He gave the background to the reasons for the establishment of the Committee and recalled the international efforts which had been made over the years in various fora to arrive at solutions for the problems related to the residues of veterinary drugs in foods.

5. Dr. Houston underlined the many implications on health and trade matters which required a coordinated international approach and expressed the hope that through the activities of this Committee it would be possible to find common ground on appropriate measures for the control of veterinary residues in foods.

6. The full text of Dr. Houston's presentation is attached as Appendix II to this Report.

7. Mr. Eddie F. Kimbrell, the Chairman of the Codex Alimentarius Commission reminded the Committee of the objectives of the Joint FAO/WHO Food Standards Programme and its wide impact on health and trade issues. He expressed his appreciation for the active participation of FAO and WHO in the work of this new Committee. He further emphasized that the work of Codex also depended to an increasing extent on making the consumer more aware of Codex work.

8. He joined Dr. Houston in expressing the hope that the Committee which represented an internationally acknowledged body of expertise would be able to make substantive recommendations to the Commission on all matters related to residues of veterinary drugs in foods.

9. Mr. Kimbrell extended a special welcome to Mr. John R. Lupien, the recently appointed Chief of the Joint FAO/WHO Food Standards Programme.

10. The Committee considered a request to admit a member of the press to its Session and decided that, in line with the Guidelines for Codex Committees, this Session should be closed to the public.

Appointment of Rapporteur

11. The Committee agreed to appoint Dr. Arpad Somogyi (Federal Republic of Germany) to serve as Rapporteur for the Session.

ADOPTION OF THE AGENDA (Item 2)

12. The Committee had before it the Provisional Agenda for the meeting (CX/RVDF 86/1).

13. The Delegation of Senegal proposed that the problems associated with the studies of residues of veterinary drugs in foods in the region of Africa should receive specific attention. It was noted that the Coordinating Committee for Africa could play an important role in establishing priorities on a regional basis.

14. The Committee agreed to give further consideration to this matter under Item 10 - "Other Business".

15. The Committee adopted the provisional agenda without change.

Establishment of an Ad-Hoc Working Group on Priority Criteria

16. The Chairman of the Committee proposed to limit the possible number of Ad-Hoc working groups in order to achieve full consideration of all items in plenary. He pointed out, however, that in exceptional cases the nature of the problems to be resolved might require the establishment of an Ad-Hoc working group with well-defined terms of reference. The Committee agreed with the proposal of the Chairman that a working group was appropriate to examine the relevant part of the working papers and proposals by delegations concerning the criteria for including veterinary drugs in the priority list for evaluation by a joint FAO/WHO expert committee.

17. It was also agreed that the above Ad-Hoc Working Group should recommend such draft criteria for examination in plenary under Item 6(a).

18. The Committee agreed that the priority list would be established by the plenary session.

19. For details of the report of the Ad-Hoc Working Group on Criteria for the Inclusion of Veterinary Drugs in a Priority List (see paras 148-162).

BACKGROUND TO THE ESTABLISHMENT OF THE COMMITTEE AND MATTERS OF INTEREST ARISING FROM THE 16TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Item 3)

20. The Committee had before it CX/RVDF 86/2 which provided information on matters relevant to the establishment of the Committee.

21. The Committee noted that the Codex Committee on Pesticide Residues had established, within its regular programme of work, maximum residue limits and guideline levels in products of animal origin for a large number of pesticides directly applied to animals. However, it was only in connection with the elaboration of the Draft International Code of Principles for Ante-Mortem and Post-Mortem Judgement of Slaughter Animals and Meat that the 4th Session of the Codex Committee on Meat Hygiene (CC/MH) had given consideration to residues in meat in a wider context, arising from the use of pesticides, antibiotics and other veterinary drugs, trace metals and other trace contaminants, anabolic agents, radioactive materials, poisonous plants and other substances (Appendix III to the Revised Draft of 1979).

22. CCMH had referred the substances, with the exception of pesticide residues which were already covered by the work of the Codex Committee on Pesticide Residues, to the relevant Committees and consequentially the Codex Committees on Food Additives and Pesticide Residues had discussed responsibility for evaluating these substances.

23. The 5th Session of CCMH had decided that the details included in Appendix III of the "Judgement" Code should not form part of the Code but be issued as a supplement only. The Committee had urged that, within the Codex framework, work should be undertaken on anabolic agents and antibiotics as well as on pesticide residues which were already covered by the Codex Committee on Pesticide Residues (paras 133-134 of ALINORM 83/32).

24. The Codex Committee on Food Additives (CCFA) had been divided in its view whether the question of veterinary drug residues in foods could be handled within that Committee. It had agreed with CCMH that a consultant should advise the Commission on how to tackle the problem. CCFA had proposed very comprehensive terms of reference for the consultant's work and had offered to examine the resulting report (paras 234-237 of ALINORM 83/12A).

25. At its 14th Session the Committee on Pesticide Residues had considered a submission from Australia, requesting the Committee to examine the possibility to evaluate chemicals used for the mass medication of food producing animals. It had been pointed out that these substances could leave residues in meat and meat products, milk and eggs which gave rise to problems in a very extensive area of international trade. The Committee had recognized the need for an appropriate scientific advisory body and had decided to bring the complex matter before the Commission (paras 248-252 of ALINORM 83/24A).

26. The 15th Session of the Commission had considered the views of the three above Committees and agreed that "the subject was urgent and timely" and, as suggested by the 30th Session of the Executive Committee, that in view of the complex scientific and technological aspects, the matter should be examined by a Joint FAO/WHO Expert Consultation.

27. The Commission had also noted that CCFA had already to deal with a very heavy workload and had agreed that the Consultation's recommendations might be best examined by a new Committee (paras 156-162 of ALINORM 83/43).

28. At the request of the Codex Alimentarius Commission, FAO and WHO had convened an Expert Consultation from 29 October to 5 November 1984 at FAO Headquarters in Rome, Italy. The tasks before the consultation had been:

(i) To examine the problems associated with residues in foods arising from the use of veterinary drugs and other chemicals in food producing animals.

(ii) To advise the Codex Alimentarius Commission on how to consider these problems.

(iii) To examine the ways and means of regulatory control.

(iv) To suggest priorities for substances to be considered.

29. The Consultation had defined "veterinary drug" for its considerations and had recognized that a large number of other substances, if they enter food products, could be of public health concern or lead to difficulties in international trade. The Consultation had recommended elaboration of a definition for "residues of veterinary drugs".

30. In conclusion the Expert Consultation had recognized the complex nature of occurrence and safety evaluation of residues of veterinary drugs in foods of animal origin and the world-wide scope of the problem. In view of the significant public health and consumer concern and the problems related to trade originating from residues of veterinary drugs in foods the Expert Consultation had recommended the establishment of a Codex Committee on Residues of Veterinary Drugs in Foods to determine priorities in the area, recommend maximum residue levels and to develop codes of practice.

31. Specific recommendations had been directed to WHO and FAO regarding the need for convening an appropriate scientific body with well established responsibilities. The two Organizations had been also requested to provide assistance in the fields of training, information and other support to developing countries.

32. Recommendation to Member Governments concerned regulatory approaches including advice to users of veterinary drugs through labelling and advertising matters related to withdrawal periods and educational programmes.

33. The Consultation had identified the need for reliable analytical methods which should be simple, economic and, as far as possible, validated.

34. The Report of the Joint FAO/WHO Expert Consultation on Residues of Veterinary Drugs in Foods had been published as Food and Nutrition Paper No. 32 and was distributed as a document for this Session of the Committee.

35. The 16th Session of the Commission had strongly supported the recommendations of the Expert Consultation and established the Codex Committee on Residues of Veterinary Drugs in Foods. The Commission also established terms of reference for the Committee which will be discussed under Agenda Item 5.

36. The Committee noted the Commission's recommendation to liaise closely with the Codex Committee on Methods of Analysis and Sampling (CC/MAS) and to take into account the work already undertaken by other bodies such as the Council of Europe.

37. The Committee also noted that the Commission had urged FAO/WHO to convene an appropriate body to provide independent expert advice to the Committee.

38. The Committee decided to defer any consideration of its terms of reference (Appendix I to CX/RVDF 86/2) to Item 5.

39. The Committee expressed its appreciation for the information provided in CX/RVDF 86/2 and agreed to discuss the working relationship with other subsidiary bodies of the Commission and its proper organizational structure under the next agenda items.

ACTIVITIES OF FAO, WHO, OIE AND OTHER INTERNATIONAL ORGANIZATIONS OF INTEREST TO THE COMMITTEE (Item 4)

FAO Activities, WHO Activities and Joint Activities of the Two Organizations

40. The Secretariat explained current programmes within the Food Quality and Consumer Protection Group of FAO which assisted countries in developing and implementing their own food laws and regulations. Technical and advisory services for the monitoring and control of food contaminants and residues of chemicals used in agricultural production were available through these programmes. The Group was the focal point within FAO for the Joint FAO/WHO Food Contamination Monitoring Programme, which was associated with the Global Environmental Monitoring System (GEMS) operated by the UNEP; the Joint FAO/WHO Expert Committee on Food Additives; the Joint FAO/IAEA/WHO Expert Committee on Food Irradiation; and the Second FAO/WHO/UNEP Conference on Mycotoxins to be held in April 1987. The Group was responsible for the organization within FAO of the Joint FAO/WHO Expert Consultation of Residues of Veterinary Drugs in Foods held in Rome in October 1984.

41. The Food Quality and Consumer Protection Group of FAO has also assisted thirty developing countries to strengthen their laboratory services specializing in food contamination control in the past few years.

42. The Committee was informed of the working procedures of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). It was noted that the Plant Production and Protection Division of FAO (AGP) provided the Joint Secretary for JMPR and that the working procedures had been under review by the last session of JMPR which had taken place in September this year.

43. The Secretariat further explained that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) had been established in 1956 by the Food and Agriculture Organization and the World Health Organization following the First Conference on Food Additives held in Rome in 1955. As of June 1986, the Committee had met on 30 occasions, and had considered more than 600 substances used or proposed for use as food additives, and several contaminants. The Committee has a close working relationship with the Codex Committee on Food Additives, although it was independent of it and was responsible only to the Directors-General of FAO and WHO.

44. It was noted that the members of the JECFA were individual experts appointed in their personal capacity. They did not represent their governments, nor the organizations nor institutions for which they work. Although the numbers varied from meeting to meeting, approximately half of the experts were appointed by FAO and half by WHO.

45. Although within the JECFA the experts appointed by WHO had the principal responsibility for the toxicological evaluation of the substances under consideration, while the experts appointed by FAO were principally responsible for the establishment of specifications of identity and purity of the food-grade materials and technological aspects of the use of the food additive, it was emphasized that the conclusions of the Committee were collegial decisions arrived at by the Committee as a whole.

46. In most cases a request for the evaluation of a substance was made at a session of CCFA. The CCFA also considered requests made in response to Codex Circular Letters on this subject and consolidated these requests in the form of a Priority List, which might also include substances proposed for inclusion in individual Codex commodity standards. The Priority List was communicated to the Joint Secretariat of JECFA. JECFA had been unable to evaluate a number of substances due to the lack of data. The CCFA had agreed that in most cases governments or international organizations which propose substances

for inclusion in the Priority List should undertake to ensure that sufficient data would be available for an evaluation to be made. These data not only refer to the toxicological properties of the substance, but also to its chemical identity and use as a food additive.

47. Dr. Vettorazzi of the International Programme of Chemical Safety, Division of Environmental Health of WHO and Joint Secretary of JECFA and JMPR outlined the background and working procedures of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and specifically the WHO contributions to the Committee. He also described the various WHO units and committees which had considered the use and assessed the safety of veterinary drugs and their residues during the past two decades. At its twelfth meeting in 1968, JECFA had evaluated the safety and developed specifications for certain antibiotics in food of animal origin. In October 1973, a WHO Working Group had considered public health aspects of antibiotics in feedstuff. In 1981, JECFA had devoted considerable attention to the safety assessment of hormones in animal production. Finally in 1982 and 1983, JECFA had carried out a detailed toxicological evaluation of two xenobiotic anabolic agents, namely, trenbolone acetate and zeranol.

48. Dr. Vettorazzi furthermore informed that provisions have been made by FAO and WHO to hold two meetings of JECFA during 1987, one of which will exclusively deal with the evaluation of the residues of those drugs appearing on the priority list compiled by this Committee.

49. The Chief of the Joint FAO/WHO Food Standards Programme explained that JECFA is an ad hoc expert body constituted by international experts whose membership and agenda can be accommodated to tackle aspects other than direct food additives and whose terms of references have been extended to consider also food contaminants by the Third Joint FAO/WHO Conference on Food Additives and Contaminants in 1973.

50. Dr. J. Debbie, Veterinary Public Health Unit, Division of Communicable Diseases of WHO, expressed the interest of the Unit in matters related to the use of veterinary drugs. In cooperation with other units of WHO, the VPH Unit was particularly concerned with the effects of the use of antibiotics in animal husbandry with emphasis on standardization of analytical methods to detect drug residue and the mechanisms of resistance transfer.

51. Dr. J. Dunne, Chief, Pharmaceutical Unit of WHO, explained the steps of the normative, advisory and informational activities of WHO with reference to pharmaceutical products. WHO (and its governing bodies) had become increasingly concerned, in recent years, with promoting the rational use of drugs in human medicine. Activities included:

(a) assigning internationally recognized non-proprietary names to drugs;

(b) promulgating standards of good manufacturing practice;

(c) providing specifications in the International Pharmacopoeia for assuring the quality of drug substances; and

(d) promoting international exchange of information on regulatory decisions among countries.

52. The Secretariat explained the activities of FAO Animal Production and Health Division which had expressed interest in the work of CC/RVDF. Special attention was called to an expert consultation on the use of stimulants of animal growth and lactation which might be held during the 1988/89 biennium.

53. The Secretariat further explained that the Codex Committee on Fish and Fishery Products was considering development of a Code of Practice for Aquaculture. A basic working paper was being prepared by the Fisheries Division of FAO for submission to the next session of that committee. It could be expected that such a code might include reference to veterinary drugs used in aquaculture.

54. The Delegation of Brazil commented on the Statements included in the various parts of CX/RVDF 86/3 and made, in particular, the following remarks: Brazil shared the

concern with the use of anabolic agents (natural steroids) in meat as well as the use of xenobiotic anabolic agents. Concerning pesticides used directly on animals, Brazil has prohibited the use of bendiocarb, captan, fenvalerate, hexochlorobenzene, lindane, methidathion, phosmet and phokim.

International Office of Epizooties (OIE)

55. The Observer of OIE described the activities of the International Office of Epizooties (OIE). Two of the fundamental tasks of OIE were to inform member countries about the means used to control animal diseases and to standardize health regulations applicable to international trade in animal and animal products. OIE had set up a working group to study, in collaboration with the International Technical Consultation on Veterinary Drug Registration (ITCVDR) the establishment of an information network on the harmful effects of veterinary drugs and an information programme on the control of veterinary drugs and toxicological accidents. At the Third ITCVDR held in Paris in the Spring of 1986, OIE had determined that its programme of work should deal with activities not taken into account by other international organizations.

Council of Europe

56. The Rapporteur, although not as an official representative of this organization, summarized the activities of the Council of Europe in the field of residues of veterinary drugs. He pointed out that the Public Health Committee (Partial Agreement) of the Council of Europe established in 1982 a multidisciplinary Expert Committee to deal with the human health aspects of residues of veterinary drugs in food of animal origin. Between 1982 and 1986, this Expert Committee had held six sessions and had reached consensus on the principles of the safety evaluation of residues. In addition, it had identified issues of special concern such as the use in food-producing animals of nitrofurans, chloramphenicol, neuroleptic drugs as well as beta-adrenergic blocking agents to reduce losses due to the stress of transportation in animals before slaughter. Residue problems related to individual animal species such as the consequence of drug therapy in fish and laying birds have been dealt with by the Expert Committee as well. Recently, the final report of this Committee has been published by the Council of Europe under the title "Residues of Veterinary Drugs in Food of Animal Origin" (Strasbourg, Council of Europe, Publications Section, ISBN 92-871-0907-9, 1986).

Association of Official Analytical Chemists (AOAC)

57. The Observer of AOAC presented the views of the AOAC. The AOAC believed that reliable precise collaborative methods were important and that a requirement should be made that interlaboratory collaborative studies be performed and published on analytical methods before their use. AOAC was seeking cooperative relationship in developing analytical methods.

International Technical Consultation on Veterinary Drug Registration (ITCVDR)

58. The Observer of ITCVDR informed the Committee that ITCVDR had held three consultations for officials concerned with the registration of veterinary drugs to exchange information and experience in the regulation area.

59. After a first meeting held in Columbia, Maryland, United States, in January 1983 and a second meeting in Oslo, Norway, in June 1984, ITCVDR had organized a third session in Paris in June 1986. This meeting had been attended by about 100 participants representing 40 countries and 8 international organizations.

60. The main items on the agenda of the consultation concerned national legislation, public health (safety of residues) and animal health problems. It had been proposed that the fourth session of the ITCVDR would take place in Australia.

European Economic Community (EEC)

61. The Observer of the EEC summarized the activities of the European Economic Community relating to Residues of Veterinary Medicines in Foods. In accordance with the objectives of the EEC Treaty, the Community had the task of securing the free movement of

both veterinary medicinal products and foodstuffs of animal origin within the Community. A summary of the legislation which had been adopted in this area by the EEC was presented. A Working Party on the Safety of Residues had issued recommendations on residues of chloramphenicol, sulphonamides and nitrofurans. Particular attention was also being given in the EEC to problems resulting from the use of veterinary medicines in fish and in laying birds and to the quality, safety and efficacy of old veterinary drugs (CRD 7).

International Dairy Federation (IDF)

62. The Observer of IDF informed the Committee that IDF had more than 30 member countries from all over the world. The work was performed in nearly 100 groups of experts (10-20 members on average) which were partly joint groups of IDF, ISO and AOAC.

63. The work of the following three groups was closely related to residues of veterinary drugs in milk:

(a) Residues and Contaminants in Milk and Milk Products (a compendium from 1979 being revised at present)

(b) Methods for the Detection of Pesticides (including Organophosphorus Compounds).

(c) Antibiotics.

64. The latter group had worked out a compendium of methods for the detection of inhibitors in milk and the identification of specific antibiotics on a very low level (immunoassays and microbial receptor tests included).

65. The above publication was expected to be available later this year.

Bureau Européen d'Information pour le Développement de la Santé Animale (D.S.A.)

66. The Observer of DSA informed the Committee that the Bureau Européen d'Information pour le Développement de la Santé Animale (DSA) was composed of twenty five research-oriented multinational pharmaceutical companies. The objectives of DSA were to identify issues and provide information on questions related to animal health and production. It was noted that DSA has sponsored two international symposia:

(1) Quality and Safety of Wholesome Food (1984)

(2) Future of Production Productivity; Science vs Politics (1986).

67. The Observer stated that DSA maintained contact with regulatory agencies, the animal production industry and consumer organizations. It also sponsored basic research concerning the safety of residues.

68. The Observer further stated that DSA was the nucleus along with national trade organizations of the European Federation of Animal Health Industries (F.E.D.S.A.) which would become operational in 1987.

CONSIDERATION OF TERMS OF REFERENCE OF THE COMMITTEE AS ESTABLISHED BY THE 16TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Agenda Item 5)

69. The Committee had before it Appendix I to CX/RVDF/86/2 containing the Committee's terms of reference as established by the 16th Session of the Commission. The paper also contained a definition for the term "veterinary drug" elaborated by the Expert Consultation for the purposes of the Consultation and some advice on a term for "residues of veterinary drug".

70. The Secretariat informed the Committee that it was the usual practice for a new Committee to review its terms of reference in the light of its programme of work.

71. The Committee noted that if it were concluded that the present terms of reference did not adequately cover its work programme, the Committee could propose appropriate amendments to the terms of reference to the Commission.

72. The Committee also noted that an annex to the paper provided a number of basic definitions developed by the Codex Alimentarius Commission for reference purposes. Information on the Committees on Pesticide Residues and Food Additives was provided in Appendices II and III to CX/RVDF 86/2.

Terms of References

Clause (b)

73. The Rapporteur informed the Committee that the terms of reference had been based on the recommendations and conclusions of the Expert Consultation and had, after careful consideration, been approved by the Commission.

74. The Delegation of the Federal Republic of Germany drew attention to the difficulties which might arise from Clause (b) of the terms of reference which at present referred to maximum residue levels. The Delegation was of the opinion that health considerations should be the determining criteria for the establishment of permissible residue levels; this view was shared by the Committee.

75. The Representative of WHO explained the concept of ADIs and MRLs. ADIs were established on the basis of a safety evaluation and toxicological data. MRLs on the other hand reflected levels which could be achieved through Good Agricultural Practice. It was the function of the CCPR to ascertain through the data derived from intake studies that the MRLs did not represent a hazard to health.

76. There was considerable discussion as to whether the term "MRLs" should be re-defined for the purposes of this Committee or whether a new term should be developed. It was also pointed out in this context that the Expert Committee which would be charged with the safety evaluation of veterinary drugs might not be in a position to establish ADIs for all different classes of veterinary drugs and that another approach might have to be taken in some cases.

77. The Committee agreed that it was appropriate to amend Clause (b) to refer to "acceptable residue levels". The Committee agreed further to review its terms of reference again at the end of the session after full examination of its programme of work.

Clause (d)

78. The Delegation of Norway enquired whether Clause (d), as presently drafted, would limit the activities of the Committee to establishing criteria for analytical methods as it did not seem to permit development and consideration of methodology as such.

79. Members of the Expert Consultation informed the Committee of the existence in scientific literature of well-established criteria for the performance of methods. Dr. Ellis of the United States of America expressed the view that appropriate performance standards and characteristics should be provided by the Committee; however individual methods need not necessarily be identified.

80. The Secretariat pointed out that other Committees such as the Codex Committees for Methods of Analysis and Sampling and for Food Hygiene had developed criteria for the application of methods of analysis to foods.

81. The Committee was reminded that full consideration to matters pertaining to methods of analysis and sampling would be given under item 6(c) and agreed to consider clause (d) further at a later stage. (See paras 184-193)

82. The Committee agreed that the amended version of the terms of reference should be provided in full together with a summary of the Committee's programme of work (see para. 211).

Definition of Veterinary Drugs

83. The Delegation of Poland requested that the definition as given in para 2 of the paper should include specific reference to growth promoting agents.

84. It was pointed out that the term "modification of physiological function" covered such substances and there was no need to make specific reference to growth promoting agents.

85. The Delegation of Poland, while agreeing with the above view, thought that the proposed amendment would provide valuable advice to regulatory authorities.

86. The question was also raised of whether vitamins and minerals were covered by the definition. The Committee agreed that under certain circumstances they might be covered and that this could be further discussed under the item dealing with "codes of practice".

87. It was also questioned whether disinfectants used in veterinary practice and giving rise to residues in, for example, milk would fall under the definition. The Committee concurred with the view that disinfectants used directly on animals were covered by the definition; however, if employed in animal quarters, they would not fall under the definition.

88. The Committee, having considered these questions, decided not to include explanatory footnotes to the definition.

89. The Committee considered at great length whether it would be feasible to draw a line in the definition between pesticides used directly on animals and other veterinary drugs. It was noted that there appeared to be differences on how this was dealt with in national regulations.

90. The Committee agreed that, in general, any compound used in or on food-producing animals for the indications enumerated in the definition of veterinary drugs should be considered a veterinary drug and it appeared that certain substances could be classified as both pesticides and veterinary drugs, depending on the purpose for which they were used.

91. Several delegations felt that it might be impracticable to include this concept in the definition and proposed instead that the Committee should closely liaise with CCPR and the appropriate expert body concerning the evaluation of such substances with multiple functions.

92. The Committee recognized that in certain cases where chemical substances had dual functions (additives, pesticides, veterinary drugs) a pragmatic approach should be followed in order to avoid unnecessary duplication in the evaluation of such substance. It should, however, be kept in mind that some of the criteria for the evaluation might be different depending on the particular application of the chemical concerned.

93. The Committee agreed to make an editorial amendment to the definition. It also recognized that veterinary drugs could consist of a combination of substances; however this was already covered by the present wording. The Committee agreed that the definition, as amended, should read as follows:

> "Veterinary Drug" is defined as any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour.

Definition of Residues of Veterinary Drugs

94. The Committee noted that the Expert Consultation had provided advice on certain aspects to be included in the above definition.

95. The attention of the Committee was drawn to the definition of "pesticide residue" which appeared to be more comprehensive. The Committee decided that the definition of

pesticide residues was not suitable for veterinary drugs and agreed to improve the text as contained in paragraph 3 of the paper.

96. It was pointed out by the Delegation of the United Kingdom that residues could also be derived from inactive ingredients used for pharmaceutical reasons (i.e. formulation) and a proposal was made to add the following words:

> "or of any inactive ingredient contained in the formulation of a veterinary product"

97. Several delegations held, however, the view that this approach was not practicable since different formulations resulted in an enormous number of different adjuvants. It was pointed out that many excipients/adjuvants were not harmful and reference should only be made to substances which were considered to be of toxicological significance. A similar phraseology had been used by CCPR. The consideration of this aspect was primarily the responsibility of national authorities.

98. The Representative of WHO expressed the view that the function of the Committee was to deal with the active substance of the veterinary drug and not with drug preparations.

99. On the other hand, the toxicological significance as applicable to impurities in veterinary drugs was clearly recognized.

100. Several delegations held the view that the definition was still not specific enough in relation as to whether the residues were of toxic or potentially toxic significance or concern.

101. The Committee agreed to amend the definition editorially in the following manner:

> "the term 'residues of veterinary drugs' includes the parent compounds and/or their metabolites in any edible portion of the animal product, and includes residues of associated impurities of the veterinary drug concerned."

102. The Committee recognized that it might be necessary to elaborate other definitions as the occasion arose.

CONSIDERATION OF PROPOSALS FOR THE PROGRAMME OF WORK AND ESTABLISHMENT OF WORKING PROCEDURES FOR THE COMMITTEE (Agenda Item 6)

103. The Committee had before it working paper CX/RVDF 86/4 and Conference Room Documents Nos. 1 and 2 on the above subject.

104. In introducing the document the Secretariat indicated that the Expert Consultation had provided extensive guidance on possible items for inclusion in the programme of work of the Committee (Part A).

105. In addition, the paper outlined briefly the working mechanisms of other Codex Committees dealing with chemicals in foods. Furthermore it was proposed that the Committee should decide on fundamental procedural and structural matters in order to integrate it fully into the Codex framework. In addition to agreeing on the type of appropriate residue levels, there appeared to be a need to propose to the Commission procedures for the elaboration of such levels and of an acceptance procedure. It was proposed in the process that it was also essential to arrive at recommendations concerning the working relationship with other Codex Committees (Part C).

106. Since it had been recognized that the most important contributions for the determination of the programme of work were the matters of priorities identified by Governments, a Circular Letter (CL 1986/2) had been issued to Governments and International Organizations requesting information on:

(a) A listing of veterinary drugs to which priority should be given by the Committee.

(b) Problems with residues of veterinary drugs in food being encountered in their respective countries of organization and

(c) Other matters of specific concern.

107. The Committee noted with appreciation that a considerable number of replies had been received which contained detailed proposals to the programme work (Argentina, Australia, Belgium, Canada, Chile, Cuba, Federal Republic of Germany, Japan, Malaysia, Mexico, Netherlands, New Zealand, Norway, Poland, Spain, Trinidad and Tobago, United Kingdom, United States, EFPIA, DSA, Apimondia in Part B of CX/RVDF 86/4 and CRDs I and II). The Committee agreed that the replies to CL 1986/2 should be considered in connection with the relevant sub-items of Item 6, where possible; proposals not pertinent to those sub-items would be identified and taken up under this item at a later stage.

Matters of Concern Identified by the Expert Consultation

108. The Consultation had identified and included in its report a number of potential problems arising from the use of veterinary drugs including the following:

- Veterinary Drugs in Prophylactic and Therapeutic Medicine
- Veterinary Drugs for Growth Promotion
- Control of Reproduction
- Preslaughter Control of Stress
- General Problems
- Safety Evaluation of Veterinary Drugs in Foods
- Regulatory Control of Residues

109. The Expert Consultation had recognized the complexity of problems related to residues of drugs in food producing animals and had pointed to the need to provide recommendations similar to those elaborated to ensure the safe use of pesticides and food additives, including the establishment of Maximum Residue Limits (MRLs). This would imply a need to:

(a) agree on the nature of the residue to which the MRL applies;

(b) define affected commodities in trade for which MRLs are desirable;

(c) agree on the residue data needed for the establishment of MRLs.

110. The Expert Consultation had also agreed that, in order to establish internationally applicable MRLs, different requirements in individual countries have to be taken into account and proposed the use of the work carried out on pesticides as a model, having, however, regard to the specific aspects of veterinary drugs.

111. The Expert Consultation had proposed that generally acceptable criteria should be established for the safety evaluation of residues of veterinary drugs in foods.

112. The Expert Consultation had also proposed that veterinary drugs should be evaluated on a priority basis on their significance in human health and their potential to create problems in international trade. The following substances or groups of drugs had been identified as being of immediate concern:

- Antibiotics (specifically chloramphenicol)
- Anabolic agents
- Sulfonamides; e.g., sulfamethazine
- Nitrofurans

- Benzimidazoles

- Nitroimidazoles

- Synthetic dyes used as marker compounds and as therapeutic agents

- Carbadox

- Cryomazine

113. The Committee agreed that the above points derived from the Expert Consulation were important for consideration under the programme of work and might indicate some long term concerns to be taken up at future sessions. (For details of the above matters see the report of the Expert Consultation, Food and Nutrition Paper No. 32).

Matters of Concern Identified by Member Governments and International Organizations

114. The Committee noted the responses to CL 1986/2 which related to proposals for priority considerations, problems encountered with veterinary drugs and other matters of concern with regard to residues of veterinary drugs in foods. Detailed information on the responses is contained in Part B of CX/RVDF 86/4 and Conference Room Documents Nos. 1 and 2. In addition to the above information the following delegations presented further information verbally at the session on matters of priority:

115. The Delegation of Zimbabwe indicated that in African countries in general there was extensive use of trypanocides.

116. The Delegation of Kenya pointed out that problems existed in African countries with residues of acaricides for tick control and that there was therefore a need to consider with some urgency acaricide residues.

117. The Committee was in favour of including trypanocides in the first list of priorities in order to assure that these substances would be dealt with as soon as possible and to keep the acaricides under review. It was agreed to give attention, at a future meeting, to drugs used at a regional level, since they could also cause obstacles to international trade.

118. The Delegations of Argentina, Zimbabwe and Kenya emphasized the need not only for the evaluation of these substances, but also for the establishment of an appropriate infrastructure to lower the operating costs of control measures in developing countries which are the limiting factor in these countries in controlling the use of veterinary drugs and the presence of their residues in foods. This was especially important to countries which were exporters of foods of animal origin, to assure that their products would not be rejected by those importing countries which had more detailed regulations on residues of veterinary drugs.

119. It was noted that assistance was needed to provide appropriate training of personnel and analytical equipment. The Committee agreed with the view of the Secretariat that this Committee could serve as a forum for an exchange of information on the needs of member countries for food control measures and any relevant action taken by the parent organizations of the Codex Alimentarius Commission.

120. Several delegations pointed to the need for screening tests that is, rapid inexpensive methodology for the detection of residues of veterinary drugs. It was agreed that this would be further discussed under Item 6(c).

121. The Committee noted that in addition to the specific matters to be discussed under individual sub-items the following points of concern had emerged from the written and oral comments of delegates:

A number of specific commodities had been identified in which residues of certain drugs presented a problem, for example, residues in fish, eggs and milk, residues of neuroleptic agents and of beta-blockers used in pigs before transportation to reduce losses due to stress.

122. The Committee agreed that special attention should be given to these problems when requesting priority evaluation for the above mentioned drugs and their occurrence in foods of animal origin.

123. The Committee noted that it had been proposed to carry out a survey of veterinary drugs permitted in individual countries to establish a list of compounds currently in use in veterinary practice. The Committee recognized that this might be a difficult undertaking because of the enormous number of compounds and even larger number of formulations in use in different countries.

124. The Committee noted that a similar exercise had been contemplated by WHO with regard to human drugs some years ago but this had been discontinued. It was also pointed out in this context that it would be a major undertaking to keep such a list up-to-date and that it could therefore discriminate against new preparations. The representative of WHO informed the Committee that in the field of human drugs regular exchange of several national drug compendia had been organized. Many countries now notified WHO of new drug information, this information was collected and disseminated to national registration authorities on a monthly basis. He suggested that this could be extended to cover veterinary drugs as well. The Committee expressed its appreciation to the Representative of WHO for the information provided.

125. The Committee was also informed that a compendium on veterinary drugs was being prepared for the Americas and was nearing completion. Further work on the compendium might be taken over a by a commercial enterprise. The Committee expressed its interest in the compendium and accepted the kind offer of the Delegation of the United States to make copies available for the information of this Committee.

126. It was agreed that the proposal of a survey or compendium on veterinary drugs should be further discussed after this Committee had had an opportunity to examine the above compendium.

127. The Committee agreed with the Delegation of Canada that it would be useful to develop a glossary of terms of importance to the work of this Committee and accepted the kind offer of the Delegation of Canada to coordinate work on this topic by correspondence between sessions of the Committee. The delegations of Australia, Ireland, Norway, Netherlands and the United Kingdom offered to participate in the work.

128. It was agreed that the Delegation of Canada would draft terms and definitions and request comments thereon from the delegations which indicated their wish to participate in the exercise.

129. It was further proposed that analogous to the work in CCPR, the Committee might consider establishing a classification of those commodities and parts of food in which residues of veterinary drugs could occur and that the task undertaken by several delegations and coordinated by Canada might include such classification. The Committee was of the opinion that such an exercise was valuable but not as urgent as in the case of pesticide residues. The Committee, therefore, agreed to await the deliberations of the Expert Committee at its 1987 session and to reconsider this question at a future date.

130. The Committee recalled that several delegations had expressed concern at the consequences of adding antibiotics to feedstuffs in low doses to increase feed efficiency. It was noted that the Expert Consultation had thoroughly considered the problems arising from such practices and had thus identified matters of public health concern.

131. The Committee agreed that it should deal only with problems related to the residues of veterinary drugs in foods and not to the possibility of transferring resistant strains to human beings. It was agreed that the latter was a matter of food hygiene which could be referred to the appropriate Codex Committee. The Committee noted that this subject had been the subject of several expert consultations in WHO.

132. The Committee recognized that there was concern regarding numerous aspects of methods of analysis for veterinary drugs in foods and acceptable residue levels. The

Committee agreed that these matters should be taken up under the relevant Items 6(b) and 6(c).

133. In connection with the elaboration of residue levels, several delegations and observers expressed concern with regard to the availability of data for the evaluation of veterinary drugs. It was pointed out by delegations that, in some cases, experience in the field of pesticide residues had shown that lack of data and reluctance to provide data had seriously handicapped the evaluation of pesticide residues. The failure to obtain data was often related to the fact that industry would not provide proprietary data without a guarantee of proper handling and security of these data.

134. The Committee was informed that procedures had been developed between the industry association (GIFAP) and WHO (International Programme on Chemical Safety) to deal with the commercial sensitivity of data on pesticide residues. The Committee agreed that similar arrangements should also be made for the evaluation of veterinary drugs.

135. The Committee noted that several delegations had been in favour of developing codes of practice on the use of veterinary drugs either in general or for specific purposes (for example, aquaculture). It was agreed to refer the matter to Item 7.

136. Furthermore, governments had indicated their concern on appropriate monitoring of certain veterinary drugs, such as hormonal growth promotors.

137. The Committee recalled that information had been supplied under Item 4 on international monitoring efforts; however the Committee agreed that matters related to monitoring activities could also be examined in connection with consideration of intake studies under Item 8(a).

138. Having regard to the concerns expressed by the Delegations of Argentina and Brazil with regard to realistic control measures by importing countries, the Committee decided to take up this issue under Item 8(b). (See also para 119)

139. The Committee identified several topics which appeared to be outside its terms of reference, such as the need for acceptable residue levels for disinfectants in milk and matters related to material aspects of the control of residues of veterinary drugs (requests for training facilities, provision of analytical equipment and standard reference material, designation of reference centres, etc.)

140. The Committee agreed that the above topics should be brought to the attention of the relevant units of FAO and WHO.

141. The Committee agreed to exchange information on these matters by including an appropriate item in future agendas. In this context it was pointed out that countries wishing to receive assistance on food control matters should direct their requests to FAO/WHO through their government authorities. The Committee noted that assistance was already provided by the UN agencies, frequently involving bilateral assistance.

Establishment of appropriate Working Procedures within the Codex Framework

142. The Committee was informed by the Secretariat that the Commission had not yet considered specific working procedures for the new Committee which were necessary, since residues of veterinary drugs were not covered by the existing procedures as e.g. for MRLs for pesticides and provisions for food additives.

143. The Committee noted that relevant adjustments had to be made to several sections of the Procedural Manual to include specific reference to residues of veterinary drugs in foods.

144. It was pointed out that in addition thereto, a procedure had to be developed on the action to be taken on the acceptable residue levels elaborated by the Expert Committee (Step Procedure) and on appropriate acceptance procedures for the finalized levels.

145. The Committee concluded that there was a need to elaborate recommendations on the above matters for submission to the Commission; however, this could be done only after

further discussion of the subsequent agenda items. The Committee agreed to take a decision on this point under Item 9.

Working relationships with other Codex Committees

146. The Committee noted that the 16th Session of the Commission had recommended close relations with CCMAS; while agreeing in principle with these recommendations, the Committee deferred a decision until the involvement of this Committee in the development of methods of analysis and sampling had been clarified (Item 6(c)). The Committee recalled that it had already referred to the Codex Committee on Food Hygiene certain matters related to antibiotic resistance. The Committee also noted that it had agreed to a pragmatic approach concerning the direct use of pesticides on animals (see paras 89-93) but agreed that the relationship with CCPR might have to be further considered to avoid duplication of work.

147. The Committee agreed that the same principle should be applied to potential relationships with other Committees and requested the Secretariat to prepare a working paper for the next session of the Committee on proposals as to how the drafts concerning procedural and organizational matters should be presented to the Commission for inclusion in the Procedural Manual.

DETERMINATION OF PRIORITIES FOR THE CONSIDERATION OF RESIDUES OF VETERINARY DRUGS IN FOODS (Item 6(a))

148. The Committee had before it a list of veterinary drugs proposed by Codex member countries (CX/RVDF 86/4 Add I parts 1 and 2 and CRD's 1 and 2) and a paper concerning the establishment of criteria for the determination of priorities (CX/RVDF 86/4 Add 2).

149. The Committee agreed that the first step to be taken was to establish the criteria and subsequently examine the list of government proposals in the light of these criteria.

150. As decided earlier in the Session, an Ad-Hoc Working Group was convened to develop criteria for selection of veterinary drugs by this Committee for consideration by the Expert Committee. The Working Group under the chairmanship of Dr. G. Guest (United States) proposed that the following criteria be accepted by the plenary body of the CC/RVDF:

"Criteria for the Selection of Veterinary Drugs for the Establishment of Acceptable Residue Levels*

In order to be placed on the CC/RVDF's priority list for the development of an acceptable residue level*, the candidate veterinary drug, when used in accordance with Good Veterinary Practices*, should meet some, but not necessarily all, of the following criteria:

(i) the drug results in residues in the food commodity;

(ii) the drug or its residues are a matter of public health concern;

(iii) the residues of the drug affect international trade to a significant degree;

(iv) the residues of the drugs are creating or have a potential to create commercial problems;

(v) the drug is available for use as a commercial product.

In addition,

(a) there must be a firm indication that relevant data will be made available for evaluation.

(b) CC/RVDF should take into account any work on residues of the drug undertaken or completed by other Codex Committees.

*NOTE: These terms remain under consideration by the Committee.

151. The Working Group further recommended that the selection of drug substances be conducted in the plenary session.

152. In the course of the Working Group discussion, the following items were identified as requiring additional discussion in the plenary session:

- In the future, the absence of current and relevant data may become a more important issue than the presence of current and relevant data when considering a drug substance for review.

- Whether as a minimum, both public health and trade issues must be apparent in order for a drug substance to be selected for consideration.

153. The Committee had a lengthy discussion on the proposed criteria and especially on whether criterion (i) should always be complied with or whether all the criteria should have equal weight. It was agreed that the chemical substance under consideration should meet some but not necessarily all of the five criteria listed.

154. The Committee was of the opinion that in certain cases criteria other than health or trade issues could determine the inclusion of the substance in the priority list and decided therefore not to introduce the aspect as a minimum requirement health and trade issues.

155. The Delegation of Finland enquired whether under the criteria veterinary drugs used for treating dairy cows against mastitis and their residues would be considered to fulfill the criteria since in its view the presence of those residues were in most cases of technological importance rather than of public health concern. It was also noted that for technological reasons lower levels might be necessary than for health reasons. It was agreed that the use of the milk from treated cows constituted a technological and public health problem which would be best considered by the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products.

156. The Committee noted the working procedures of that Committee which included cooperation between IDF and the Secretariat.

157. The Committee placed emphasis on the need to observe provision (b) of the criteria which required that work undertaken by other committees should be taken into account when selecting priority drugs.

158. Concerning the question raised by the Working Group on the availability of data, the Committee was informed that CCPR had long standing experience with obtaining suitable data related to the above criteria and that a similar approach (the issue of circular letters to governments) could be taken up by this Committee.

159. Several delegations expressed concern about the availability of data for the evaluation of veterinary drugs.

160. The Representative of WHO informed the Committee that established procedures existed by which manufacturers could supply the necessary data. He outlined the problems arising from ownership of data encountered particularly with new drugs covered by patents. Another problem might arise where the patents on old drugs had expired and no sponsors were available to supply up-to-date data. It was also noted that the Expert Committee finalized the evaluation of substances only when it was satisfied with the available data and sometimes requested the submission of additional data on specific points.

161. The Committee agreed that it was advantageous if submissions for inclusion of veterinary drugs in the priority list were accompanied by a firm indication that relevant data were available for their evaluation. (See also para. (b) of the Criteria)

162. The Committee adopted the above Criteria for the Selection of Veterinary Drugs for the Establishment of Acceptable Residue Levels and agreed that they should be used for the establishment of the priority list.

Proposals for Inclusion in the Priority List

163. The Committee examined in detail the proposals made in writing and contained in the above-mentioned documents (see para. 148) and decided that the list of substances proposed by member countries should be appended to this report for future reference (Appendix III). Additional proposals were submitted by the following delegations:

Sweden:	Benzimidazoles, carbadox, chloramphenicol, anabolic agents, sulphonamides
Australia:	Febantel, Clobantel
Brazil:	Agreed with paras 15-17 of CX/RVDF 86/4 Add 1, but does not feel that tranquilizers and beta-blocking agents should be on priority list
People's Rep. of China	Antibiotics (chloramphenicol, penicillins, streptomycin, tetracyclines, oxytetracyclines) sulphonamides (sulphadiazine, sulphamethazine, sulphaquinoxaline) nitrofurans, clopidol, amprolium, anthelmintics, levamisole, pesticides (including DDT and chlorinated hydrocarbons)
France	Agrees with list of the Expert Consultation (Section 8) and proposed: antibiotics, sulphonamides, nitrofurans, benzimidazoles, tranquilizers and beta-blockers.
Kenya (speaking for countries of the African region	Acaricides (organophosphates and chlorinated hydrocarbons)
Zimbabwe) Senegal) Kenya) Ghana)	trypanocides: isometamidium, prothidium, pro salt of quinuronium sulphate, diminazene aceturate, imidocarb, trypan blue.

164. Before proceeding to establishing a priority list for submission to JECFA the Committee discussed extensively whether the list should include single substances or categories of veterinary drugs. The Representative of WHO expressed the view that for the safety evaluation it might be favourable to consider a category of veterinary drugs with similar characteristics since this would make better use of the limited resources available. However, attention was drawn to the fact that acceptable residue levels would have to be established for individual drugs and, in order to achieve this, governments and interested parties would have to be informed exactly which drugs were under consideration.

165. The Committee also noted that zeranol and trenbolone acetate had already received a partial evalution by JECFA and that it might be appropriate to finalize the evaluation of these drugs as a first step.

166. The Committee was also informed that JECFA had to develop procedures for the establishment of acceptable residue levels in individual foods which was a new task for the Expert Committee.

Establishment of Priority List

167. The Delegation of the United Stated stated that it had carefully studied the written proposals from governments and had prepared a list containing the ten most frequently proposed substances. The next 10 most frequently proposed had also been identified. It was noted that the US list referred to individual substances.

168. Several delegations were of the opinion that this first priority list should relate to individual compounds of immediate concern and should include other substances as categories to facilitate their evaluation. Proposals were made to include also beta-lactam antibiotics because of their allergenic properties and the sulphonamides since they were of considerable health concern. The Committee decided not to include beta-lactam antibiotics in this first list.

169. The Committee agreed that the following substances be included in the priority list:

chloramphenicol
anabolic agents (estradiol, progesterone, testosterone, trenbolone acetate, zeranol)
sulphonamides
nitrofurans
nitroimidazoles
quinoxaline-di-N-oxides
trypanocides

170. The Observer of AHI speaking on behalf of the veterinary drugs industries (DSA, EFPIA and AHI) expressed satisfaction with the decision of the Committee to focus its attention on those priority compounds which were causing both an international trade problem and a public health concern.

He endorsed the decision to give high priority to the group of hormonal analbolic agents and expressed the opinion that the recent EEC hormone ban was an example of a non-tariff trade barrier which had no scientific basis whatsoever.

Other compounds, such as antibacterials etc., were considered by the industry to be of secondary priority.

171. The Observer of the International Union of Consumer Unions (IOCU) made a statement on IOCU's concern with the use of certain veterinary drugs (hormonal growth promoters, sub-therapeutic use of antibiotics in animal feed).

She pointed out the need for consumer protection as IOCU's primary consideration but recognized that unharmonized regulation could constitute barriers to trade.

The Observer emphasized the important role that Codex could play in the field of residues of veterinary drugs in foods.

RELATIONSHIP WITH THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES, (Item 6(b))

172. The Committee had before it working paper CX/RVDF 86/4 ADD 3 which provided selected information on the working procedures of JECFA and the JMPR. The Committee noted that further information on these Committees was also contained in CX/RVDF 86/2 Appendices II and III and in Part I of CX/RVDF 86/3.

173. The Committee recalled that it has received information that a specific session of JECFA held in summer 1987 will evaluate residues of veterinary drugs. The Committee noted that the experts for the committee would be chosen on the grounds of their specific expertise on the compounds to be evaluated. The Committee thought that it was not within its competence to advise the Expert Committee on working procedures. The Committee confirmed, however, that it wished to receive from the Expert Committee recommendations for acceptable residue levels of individual drugs in specific foods.

174. While there was general appreciation that provisions had been made for an extra session of JECFA, the Committee expressed the view that JECFA was not the appropriate body for the evaluation of residues of veterinary drugs in foods and that the number of experts would have to be considerably increased for that purpose, adding to the cost of holding the meeting. Concern was also expressed that the additional work could delay JECFA's action on additives and contaminants. The Committee felt that it was appropriate to establish a new expert committee for the evaluation of veterinary drugs in foods.

175. The Representative of WHO explained the procedures used by WHO to select experts for the WHO part of the JECFA activities. He also pointed out that proposals for evaluation were submitted not only by Codex but also by other bodies. The representative indicated the way in which the agenda of JECFA was drafted, how data were obtained and processed and the timing of submissions to the Committee.

176. Attention was drawn to the general criteria for the selection of methods of analysis included in the procedural manual (5th Edition page 78).

177. The Chief of the Joint FAO/WHO Food Standards Programme informed the Committee that budgetary constraints might not permit at present the establishment of an additional expert committee and that any such request would have to be reviewed by the World Health Assembly and the FAO Conference. He also pointed out that the 3rd Joint FAO/WHO Food Additives Conference (1973) had expanded the terms of reference of JECFA beyond food additives.

178. The Committee recognized the difficulties outlined above, but concluded that, in view of the importance of residues of veterinary drugs in foods, strong representations should be made to the Commission to pursue with FAO and WHO the establishment of a new expert committee.

179. The Secretariat recalled that JMPR was setting MRLs based on Good Agriculture Practice and invited the Committee to consider whether there was a need to define "Good Practices for the Use of Veterinary Drugs".

180. The Committee agreed that it was necessary to elaborate such a definition and invited the views of WHO on this matter because of that Organization's experience in similar guidelines for human drugs.

181. The Delegation of the Netherlands kindly offered to prepare, in cooperation with WHO, a first draft of a definition for "Good Practices for the Use of Veterinary Drugs" for consideration by the Committee at its next session. It was noted that the Expert Committee would also give attention to what constituted good practices. It was agreed that the paper to be prepared by the Netherlands and WHO, would also incorporate the Expert Committee's views.

182. The attention of the Committee was also drawn to an Appendix to CX/RVDF 86/4 Add 3 which outlined the type of data required for the evaluation of pesticide residues by JMPR (user practices and residues) and by JECFA for the evaluation of food additives. This provided an indication of the type of data which might be required for the setting of acceptable residue levels.

ESTABLISHMENT OF WORKING PROCEDURES FOR THE SELECTION OF ANALYTICAL METHODS AND SAMPLING FOR THE CONTROL OF VETERINARY DRUG RESIDUES IN FOODS (Item 6(c))

183. The Committee had before it a working paper on this matter (CX/RVDF 86/4 Add 4) which outlined the views of the Expert Consultation on different types of methods for the detection of residues of veterinary drugs in foods of animal origin. The Committee had also before it the main working paper on this issue presented to the Expert Consultation.

184. The Author, Dr. R. Ellis (United States) highlighted the important issues before the Committee. It was noted that the methods could be classified as screening methods, quantitative methods and confirmatory methods. Dr. Ellis stated that "the most important performance characteristics are demonstrated by evaluating accuracy, precision, reliability, cost effectiveness, ruggedness and sensibility in multi-laboratory validation studies."

185. It was noted that the Expert Consultation had recommended that the Expert Committee should also deal with certain aspects of analytical methods, in particular their availability.

186. Replies to CL 1986/2 indicated the interest of governments in the development of internationally recognized methods which had a high reliability. A proposal had also

been made to establish a Working Group to deal with criteria for analytical methods and the sampling of drug residues.

187. The Committee was informed that CCMAS exercised an endorsement function for methods of analysis and sampling in Codex commodity standards; however, methods for pesticide residues, additives and microbiological criteria had been exempted from endorsement. The Committee proposed that methods for residues of veterinary drugs should also be exempted for the reasons given above.

188. The Committee recalled that the Delegation of Norway had required clarification of clause (d) of the terms of reference which related to methods of analysis. The Committee agreed that it should also deal not only with criteria but also with the methods of analysis and sampling concerned and that clause (d) should be amended accordingly. Several delegations also pointed out that it was necessary to establish the relationship vis-à-vis CCMAS. They emphasized the highly specialized expertise which was necessary to deal with methods of analysis and sampling for residues of veterinary drugs.

189. The Committee decided to establish an Ad Hoc Working Group on Methods of Analysis and Sampling under the Chairmanship of Dr. Ellis (United States) to elaborate and recommend to the plenary session methods of analysis and sampling, as appropriate. It was agreed that the Working Group should also consider the suitability of the criteria referred to above.

190. The Delegations of Australia, Canada, People's Republic of China, France, Federal Republic of Germany, Ireland, Netherlands, New Zealand, Norway, Poland, Switzerland, United Kingdom, United States of America and the observers of AOAC offered to participate in the Working Group. It was also agreed that other member countries could indicate their interest to the Chairman of the Working Group.

191. Dr. Ellis agreed to coordinate the preparatory work for the meeting of the Working Group. Details of the first meeting which would be held in conjunction with the next session of the Committee would be communicated by Circular Letter.

CONSIDERATION OF NEED FOR AND FEASIBILITY OF ELABORATING CODES OF PRACTICE FOR CERTAIN ASPECTS OF THE USE OF VETERINARY DRUGS (RELATED TO RESIDUES OF VETERINARY DRUGS) (Item 7)

192. The Committee had before it a document on the above subject (CX/RVDF 86/6) which reported that the Codex Alimentarius Commission had adopted a considerable number of Codes of Practice, covering hygienic and/or technological aspects of processed foods. The documents were advisory texts and not subject to acceptance under the Codex Procedure. The purpose of codes of practice was, in general, to assist governments to ensure that foods are prepared under conditions of good manufacturing practice, in particular under sound hygienic conditions, and to facilitate international trade.

193. Member countries had indicated that they attached great importance to the Codex Codes of Practice for use in industry, by government regulatory authorities and in the drafting of new laws on foods. In particular, the Codex Codes of Practice were considered valuable in meat and fish inspection by national food control authorities.

194. The Secretariat proposed that, if a Code was elaborated, particular attention should be paid to the terms of reference of the Committee when selecting matters for inclusion in the Code. The Secretariat also drew attention to the comments made by FAO Divisions for Fisheries and Animal Production and Health concerning their possible involvement.

195. Comments received from governments supported the development of appropriate codes of practice or guidelines for the use of veterinary drugs.

196. Delegations present at the Session supported the proposal to develop a Code of Practice for the Use of Veterinary Drugs which should be directed to the farmer/producer of foods as well as veterinarians. It was suggested that the code might consist of two different sections to accommodate both producers and supervisers.

197. The Delegation of Kenya proposed the development of guidelines as a first step.

198. Several delegations expressed the opinion that a Code of Practice for the Safe Use of Veterinary Medicines on Farms already developed in the United Kingdom provided guidance and could be used as a model for an international Code of Practice for the Use of Veterinary Drugs. The Committee accepted the kind offer of the Delegation of the United Kingdom to prepare a first draft of such a Code for consideration by the Committee at its next session.

CONSIDERATION OF NEED TO COMMENCE WORK ON: (A) INTAKE STUDIES ON RESIDUES OF VETERINARY DRUGS IN FOODS; and (B) GUIDELINES FOR REGULTORY PRINCIPLES CONCERNING RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Items 8(a) and (b))

(A) Intake Studies

199. The Committee had before it the above paper CX/RVDF 86/7 which provided some information on the work undertaken by and on the experience of the CCFA and CCPR concerning dietary intake studies particularly in the field of contaminants and pesticide residues. These data were necessary to apply the maximum residue levels established by the relevant committees to individual foods. It was also recalled that earlier in the Session concern had been expressed on appropriate international monitoring of veterinary drugs in foods (see paras 136-137).

200. It was suggested that the Committee give consideration to the need to consider dietary intake studies in the context of its work and review already existing international activities related to dietary intake studies. Attention was drawn to the WHO Guidelines for the Study of Dietary Intake of Chemical Contaminants and to the work of the Joint FAO/WHO Food Contamination Monitoring Programme.

201. The Delegation of Australia informed the Committee of the work on intake studies undertaken by CCPR and indicated that at each Session of that Committee there was a report from individual countries on such studies which was received with great interest by participating countries. It also pointed to the work on monitoring carried out by WHO which provided a large amount of international data. The Delegation proposed that such studies should be extended to cover veterinary drugs.

202. The Delegation of the United States of America agreed with the view expressed above and suggested that a survey be carried out of the monitoring activities of member countries concerning residues of veterinary drugs in foods. This was supported by other delegations.

203. The Committee accepted the kind offer of the Delegation of the United States of America to initiate such a survey in cooperation with the Secretariat and to evaluate the data for the next session of the Committee.

(B) Regulatory aspects

204. The Committee noted the work undertaken by CCPR which was contained in the "Guide to Codex Recommendations concerning Pesticide Residues" and, in particular, Part 9 of the document entitled "Recommended National Regulatory Practices to facilitate Acceptance and Use of Codex Maximum Limits for Pesticide Residues in Foods".

205. The Committee also recalled that the Delegations of Argentina and Brazil had expressed concern about restrictive regulatory measures in importing countries and had recommended that international guidance be provided on these matters.

206. The Committee expressed the opinion that it might be premature to consider the elaboration of regulatory guidance documents at such an early stage of the Committee's work programme, reminding the Committee that CCPR had elaborated these guidelines at only a very advanced stage of its work.

207. The Committee agreed to keep this item on its programme of work but to defer consideration to a future session, when appropriate.

PROGRAMME OF WORK AND WORK ASSIGNMENTS FOR NEXT SESSION (Item 9)

208. The Committee agreed that the agenda for its next session should include the following items:

- Matters of interest
- Activities of International Organizations
- Working paper on Procedural Matters (Proposal for Amendment of Procedural Manual, Step Procedure, Acceptance Procedure and Working Relationships with other Codex Committees)(Secretariat)
- Report on Progress concerning Glossary of Terms and Definitions (coordinated by Canada)
- Report on Definitions for Good Practice in the Use of Veterinary Drugs (Netherlands/WHO)
- Review of Priority List based on replies to circular letter
- Report of JECFA including consideration of Acceptable Residue Levels, if available
- Report of Ad Hoc Working Group on Methods of Analysis and Sampling
- First Draft of a Code of Practice for the Use of Veterinary Drugs (United Kingdom)
- Discussion on Compendium of Veterinary Drugs for the Americas (to be distributed by the Delegation of USA)
- Survey of Intake Studies (USA/Secretariat).

209. The Committee agreed with the following amended terms of reference and decided that they be brought to the attention of the 16th Session of the Commission for approval:

(a) to determine priorities for the consideration of residues of veterinary drugs in foods;

(b) to establish acceptable residue levels for such substances:

(c) to develop codes of practice and/or guidelines as may be required;

(d) to consider methods of sampling and analysis for the determination of residues of veterinary drugs in foods.

OTHER BUSINESS (Item 10)

Statement by the Delegation of Senegal

210. The Delegation of Senegal presented the following statement:

"At the request of the Delegation of Senegal it had been agreed earlier at the session that consideration would be given to certain specific aspects of the situation in Africa with regard to veterinary drug residues.

As the Delegation of Senegal had emphasized during the session the detection of residues was a heavy task which required:

- Equipment
- and well trained personnel.

Human health was of the first importance but unfortunately the need for the monitoring of veterinary drug residues in animal food was not yet widespread; public authorities were at present more concerned with increased production.

The Delegation of Senegal though that at the present time, with the exception of a few countries, they were at a stage where education was needed. As much information as possible was required on:

- Essential veterinary drugs
- Types of toxicity and consequent secondary effects
- Need for regulation for the use of these drugs.

The Delegation of Senegal proposed that a seminar should be organized in Africa to discuss:

- Secondary effects and dangers associated with the misuse of veterinary drugs.

It was proposed that this Committee recommend that international organizations concerned organize such a seminar.

211. The concern of the Delegation of Senegal was shared by the Delegations of Ghana, Kenya, Côte d'Ivoire and Zimbabwe. Furthermore, the Delegation of the Côte d'Ivoire expressed the following two wishes:

(1) To see the Coordinating Committee for Africa involved more closely in the preparation for an auspicable holding of a Seminar on Veterinary Residues.

(2) To re-activate the Coordinating Committee for Africa, at least concerning the Codex Committee on Residues of Veterinary Drugs in Foods, in such a way that an African regional study plan shall be developped and studied in advance, if necessary. This would avoid a duplication of work and give the possibility to better expose to this Committee the problems which are of main concern at the moment in due time.
In this instance we give our support to the Delegation of Senegal on the necessity of paying a special attention to the problems submitted by the Study of Veterinary Residues.

212. The Delegation of the People's Republic of China completely supported the statement made by the Delegation of Senegal. In the past few years WHO, FDA and the Food Quality and Consumer Protection Group has assisted thirty developing countries to strengthen their laboratory services specializing in food contamination control. China as a developing country would like to receive some information and educational advice, for example through seminars, expert consultations from the Codex Committee. China would also like to get some assistance to strengthen laboratory services specializing in food contamination control in the form of analytical equipment and appropriately trained personnel. The country needs to establish regulations for food practice in the use of veterinary drugs including feed additives, including tolerance levels of residues in the tissues and products of food-producing animals, withdrawal times of veterinary drugs and feed additives for different kinds of food producing animals.

213. The Secretariat informed the Committee that a possible way of organizing a seminar of the type proposed by the delegation of Senegal would be to arrange to hold such a meeting in conjunction with the Codex Coordinating Committee for Africa.

214. This approach had already proved to be useful and successful in the region of Latin America and the Caribbean where workshops dealing with topics related to food hygiene had been held sponsored by PAHO in conjunction with the sessions of the Codex Coordinating Committee for Latin America and the Caribbean.

215. The delegations of the African region were informed that their national authorities should approach the regional offices of FAO and WHO.

216. The Committee as a whole expressed strong support to the request of the African countries present and urged the two Agencies to take appropriate action.

217. The Chief of the Joint FAO/WHO Food Standards Programme and the Chairman of the Committee undertook to pursue the matter.

DATE AND PLACE OF NEXT SESSION (Item 11)

218. The delegations present at the Session expressed the view that annual sessions were necessary at least in the initial stages of the Committee to achieve viable results as quickly as possible. Caution was expressed by some delegations that considerable time was needed for efficient preparation of sessions of this Committee.

219. The Committee was informed that only one session had been foreseen for the biennium 86/87 and that the Commission would have to decide on any substitution or addition of meetings of Codex Committees.

220. The Committee agreed that it favoured holding its Second Session in 1987 and decided to request the Host Country and the Secretariat to make appropriate recommendations to the Commission.

221. It was noted that the Second Session could be held in Washington D.C. at a date to be communicated.

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OPENING ADDRESS BY
DR. DONALD L. HOUSTON, ADMINISTRATOR FSIS (USDA)

Good morning and welcome to the United States. It is truly a pleasure for me to open this historic first meeting of the Codex Committee on Residues of Veterinary Drugs in Foods - established little more than a year ago by the 16th Session of the Codex Alimentarius Commission.

The healthy attendance is a measure of the importance of our task. We expect that the final count will show representation from at least 33 countries, 10 observer organizations, and a total of at least 130 attendees. This strong participation speaks well for the importance of the issue and the desire of many countries to help find solutions for the problems now facing us.

The Codex Alimentarius Commission is the internationally recognized forum for resolving food trade issues that are also food safety issues, and today's meeting is of course not the first Codex effort to deal with the issue of veterinary drug residues. Two United Nations Organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) - as well as the Commission itself - have long recognized the significance of the issue from many perspectives.

Public Health, Trade and Consumer Concerns

First, veterinary drug residues are a persistent public health concern about which we should never become complacent. Second, differences among nations in the use and regulation of various animal drugs and hormones present troubling implications for world trade. As the Commission has recognized, the use of increasingly more sensitive methods of analysis can inhibit trade to those countries that needlessly impose a "zero" tolerance for certain residues. Unfortunately, advances in science can be used punitively - as technical barriers to trade.

Perhaps if this Committee had been formed five years ago, my country - and potentially yours - would not be faced with resolving the trade difficulties now before us.

Finally, residues of veterinary drugs are a major concern to consumers. Many of those consumers are very uninformed, and may be too quick to define residues as always a "problem" rather than a necessary "concern". Yet who can really blame them for their perceptions in the wake of the unaccountable use of diethylstilbestrol (DES) some 30 years ago? It was not until 1979 that the last major nation banned the use of DES, and today we are still dealing with the "public health residue" of DES use. This problem therefore casts a much greater shadow in the minds of many consumers than the decades of proper and judicious use of veterinary preparations which have followed. We cannot ignore that shadow; we must find a way to clear it away through education.

Laying the Groundwork

Recognizing the importance of harmonious and positive international approaches to the prevention of unsafe levels of drug residues in animal food products, international scientific and technical groups have held discussions over the past 25 years on various aspects of the issue.

Many of these meetings have been held under the umbrella of Codex, particularly the Joint FAO/WHO Expert Committee on Food Additives. The Expert Committee has considered the toxicological implications of the use of several of the substances we are concerned about today. For example, the Committee issued a report addressing the toxicology of antibiotic residues as far back as 1969.

However, as public concern and world trade implications have assumed more prominence, the interest of the international scientific and regulatory community in veterinary drug residues has intensified in this decade. Perhaps of singular importance have been the three meetings of the International Consultation on Veterinary Product Registration, held at Columbia, Maryland (1983); Oslo (1984) and Paris (1986). The alliance between that Group and the OIE is also welcomed.

Also, the Expert Committee on Food Additives addressed veterinary hormones in 1981 and 1984 reports. The 1981 report of a World Health Organization Working Group summarized certain health aspects of residues of anabolics in meat. Likewise, the OIE Symposium on Anabolics in Animal Production helped pave the way toward international cooperation.

Many of you here today have been involved in that earlier foundational work - whether it was performed in connection with Codex or not - and you deserve to be commended for it. In that regard, I am particularly pleased to see Doctors Crawford and Somogyi as Chairman and Rapporteur of this Session.

Joint FAO/WHO Expert Consultation

That groundwork culminated in the 1984 Rome Meeting of the Joint FAO/WHO Expert Consultation on Residues of Veterinary Drugs in Foods. The Consultation, requested by the 15th Session of the Commission, was charged with considering the "urgent and timely" subject of veterinary drug residues and providing independent technical and scientific advice to the Commission. The specific tasks before the Consultation were:

(a) To examine the problems associated with residues in foods arising from the use of veterinary drugs and other chemicals in food producing animals;

(b) To advise the Codex Alimentarius Commission on how to consider these problems;

(c) To examine the ways and means of regulatory control; and

(d) To suggest priorities for substances to be considered.

Formation of the CC/RVDF

The Consultation recommended the formation of a new Codex Standing Committee on Veterinary Drug Residues as the best vehicle for accomplishing these objectives, and the Commission unanimously approved the formation of this Committee in July of last year.

This week the Committee will consider the terms of reference, or scope of work, approved by the Commission. Those terms of reference are:

(1) To determine priorities for the consideration of residues of veterinary drugs in foods;

(2) To recommend maximum residue levels of such substances;

(3) To develop codes of practice as may be required; and

(4) To determine criteria for analytical methods used for the control of veterinary drug residues in foods.

The Commission also called upon FAO and WHO to consider formation of an appropriate expert body to provide independent scientific advice to the Committee from time to time, as recommended by the Consultation.

This request recognizes the interdisciplinary nature of the study of veterinary drug residues, which is not the same as the science of veterinary medicine. In the days before mass-medication of food animals, the veterinarian may have been the best analyst of animal drug residues. But today, answering the many questions about the ramifications of veterinary drug use - including hormones - is perhaps best described as a young subdiscipline of pharmacology. The study also requires the skills of toxicologists, animal scientists, microbiologists, immunologists, analytical chemists, biochemists, endocrinologists, physiologists, and others.

Agenda

And so we are here today to begin our mission. The proposed agenda for the week is broad and ambitious, but I believe that we can accomplish it.

Priority List of Drugs. The eyes of the world are upon us, and I believe that the development of a first list of veterinary drugs for priority review is a vital objective if the Committee is to be effective over the long term. Obviously, many if not most of you agree. Many of the countries represented today have submitted your priority lists of veterinary drugs. A few examples of the preparations on those lists are hormones such as trenbolone and estradiol; drugs such as chloramphenicol; certain anthelmintics and antibiotics; and even the sulfonamides.

However, before we can establish the Committee's priority list, we must agree on the criteria for a veterinary drug to "make the list". Those criteria will no doubt include considerations of public health, trade, and practicality.

Once we have agreed on criteria and the actual list of priority drugs for review, we will have taken a pivotal step toward the sane and orderly determination of Average Daily Intakes (ADI's).

Expert Advisory Committee. Another agenda item of critical importance is the nature of the expert advisory committee and our working relationship with the group. Continuing progress toward Codex Maximum Residue Levels (MRL's) for drugs of public health and trade significance will be inextricably linked with the progress of this group. For the expert advisory body will be expected to determine:

(1) an acceptable daily intake for total residues of the drug;

(2) a maximum residue level for each commodity in which the drug might appear;

(3) a withdrawal time, if necessary, for each species; and

(4) a recommended analytical method for monitoring residues of the drug.

In order to refine the Committee's views on the constitution of the expert body as well as our relationship with it, we will ask many questions this week. For example, is it feasible to convene a new separate joint expert committee on veterinary drugs? Or should we continue to rely on the Joint Expert Committee on Food Additives, at least for the time being? Can the expert group meet annually? Should the expert group be expected to evaluate the drugs in the priority order we agree upon? And how can we best ensure the timely publication of monographs that will be necessary for the Committee on Veterinary Drug Residues to maintain its momentum in dealing with this issue that has come of age?

It should also be stated that arriving at appropriate Codex ADI's may require access to proprietary data. Much of the data on the safety of food products from animals that have received veterinary drug preparations is unpublished, although it has been submitted to governments for their consideration in registering and licensing the drugs. We do not anticipate problems in this respect. Industry representatives participating in Codex as observers have ably demonstrated their full commitment to this forum, which seeks to balance the interests of health, nutrition, agriculture and trade.

Analytical Methods and Sampling. We also plan to establish working procedures for the selection of analytical methods and sampling for the control of veterinary drug residues in foods. The Commission has recommended that we maintain close liaison with the Committee on Methods of Analysis and Sampling, and that we consider the work already undertaken by other bodies, such as the Council of Europe.

What is our starting point? Can we proceed to development and testing of methodology for directly evaluating the toxicity of small amounts of residues? Do questions remain about the appropriate level of uncertainty in establishing sampling plans? How can we be sensitive to the limited resources and experience of developing countries in analysis, while incorporating the best available methodology? These are some of the questions we will deal with this week.

If you will allow me, I would like to take a slight detour here to discuss public education. The Commission has recommended more public education about residues, and it is in the arena of analysis and sampling that the public is perhaps most misinformed - and therefore frightened. Perhaps the greatest misconception is that if there is any residue in the food, that residue must be unsafe. Because the residue would not be present if veterinary drugs were not used, the consumer falsely concludes that products from animals raised without these drugs might be safer.

In the United States, a number of consumers are buying products allegedly from animals raised without the use of antibiotics or hormones. This trend, while it may be harmless, presents its own regulatory problems. Are consumers getting what the label or advertisement says they are getting? Are any of them (persons with hypersensitivities, for example) placing too much faith in the "residue-free" product? Unfortunately, while we are not yet aware of any problems, the trend offers great opportunities for the unscrupulous.

But the trend also indicates that all of us in the veterinary drug community need to more seriously consider this problem of public perception. Rather than commiserating about the lack of knowledge by consumers who do not understand the difference between a qualitative and a quantitative method, between an action level and a tolerance, we need to try to begin to explain the practical and necessary aspects of residue analysis and sampling. In the past, public perception has played a role in the development of technical barriers to trade, and it could do so again.

Codes of Practice. Illegal or improper use of veterinary drugs can also have a very direct effect on trade. This week we will begin consideration of the need for codes of practice for users of veterinary drugs. Such codes would of course apply to producers as well as veterinarians. Veterinary drugs are used for disease treatment, but they are also used for such disparate uses as disease prevention, growth promotion, control of reproduction, and control of pre-slaughter stress.

Codex codes of practice - basically good manufacturing practice - have been used all over the world to train food personnel. Many believe that the codes of practice will stand as the Commission's most significant contribution to food safety. Yet codes of practice for veterinary drug use would have a very different character than the existing codes of practice, which are very oriented toward hygiene and sanitation.

Codes of practice for users of veterinary drugs could, within the framework of a solid regulatory system, be very helpful in deterring unintentional misuse of veterinary drugs, though they would be unlikely to halt deliberate misuse. They would advise primarily on procedures to achieve the lowest residue content possible, and on appropriate measures to control residues. However, delegations have varying views on the need for formal codes of practice, their scope, and the practical difficulties involved in developing them. This week, we hope to find the common ground on which we can all agree.

Closing

The Codex Alimentarius Commission has for nearly a quarter of a century provided an international forum where regulators, scientists, and business people could find a common ground on the food trade issues that are also food safety issues.

The success of Codex has in a sense reflected the number of committees adjourned because their work is complete. Yet its success is also measured in new beginnings. Any institution must change to reflect the needs of the time, or it will not survive. And while some might argue that Codex is not really an institution but a community, I think few of us would disagree that the formation of this Committee is a signal that the Codex Alimentarius Commission is as vital - as essential and as alive - as it was in 1962.

We have work to do, so let's proceed. Thank you very much.

PROPOSALS FOR INCLUSION IN THE PRIORITY LIST OF VETERINARY DRUGS

In reply to CL 1986/2 (RVDF) and during the First Session of the Codex Committee on Residues of Veterinary Drugs in Foods the following countries and international organizations proposed veterinary drugs for inclusion in the priority list of veterinary drugs to be evaluated:

Argentina, Australia, Belgium, Brazil, Canada, Chile, People's Republic of China, Cuba, France, Federal Republic of Germany, Ghana, Ireland, Japan, Kenya, Malaysia, Mexico, Netherlands, New Zealand, Norway, Poland, Senegal, Spain, Sweden, Trinidad and Tobago, United Kingdom, Unites States of America, Zimbabwe.

The following veterinary drugs were proposed for inclusion in the list (CX/RVDF 86/4-Add. 1 and Part II, CRDs 1 and 2 and para. 163 of the Report).

1. ARGENTINA

Sulphonamides:

- Sulphadimethoxine
- Sulphamethazine
- Sulphathiazole
- Sulphaquinoxaline

Antibiotics:

- Chloramphenicol
- Neomycin
- Erythromycin
- Penicillin
- Tetracycline
- Oxytetracycline
- Chlortetracycline

Hormones

It is suggested that a definition should be made of the chemical compound and its substrate, where it is necessary to determine quantities, in the following groups of substances: oestrogens, androgens, progesterons, corticosteroids and prostaglandins.

Anthelmintics:

- Albendazole
- Cryomazine
- Fenbendazole
- Ivermectin
- Losalocid
- Levamisole

2. AUSTRALIA

- Antibiotics, especially chloramphenicol
- Hormonal growth promotants
- Sulphonamides
- Nitrofurans
- Anthelmintics
- Dimetridazole
- Tranquilizers
- Cryomazine
- Febantel
- Clobantel

3. BELGIUM

- Antibiotics and antimicrobial compounds susceptible of triggering hypersensitivity reactions and appearance of resistence phenomena.
- Nitrofurans
- Chloramphenicol (aplastic anemia)
- Neuroleptic drugs and beta-blockers
- Hormones
- Anthelmintics (embryotoxic properties of benzimidazoles).

4. BRAZIL

- Antibiotics (specifically Chloramphenicol)
- Anabolic agents
- Sulphonamides; e.g., sulphamethazine
- Nitrofurans
- Benzimidazoles
- Nitroimidazoles
- Synthetic dyes used as marker compounds and as therapeutic agents
- Carbadox
- Cryomazine

5. CANADA

- Quinoxaline (carbadox)
- 5-nitro-imidazole (dimetridazole, ipronidazole and ronidazole)
- Hormones used for anabolic purposes
- Nitrofurans
- Sulphamethazine

6. CHILE

- Anabolic substances based on synthetic hormones and xenobiotics such as zeranol, trenbolone and melengesterol.
- Antiparasitic agents for external and internal use especially organophosphates and chlorinated hydrocarbons.
- Coccidiostats
- Antibiotics

7. PEOPLE'S REPUBLIC OF CHINA

- Antibiotics (chloramphenicol, penicillins, streptomycin, tetracyclines, oxytetracyclines).
- Sulphonamides (sulphadiazine, sulphamethazine, sulphaquinoxaline)
- Nitrofurans
- Clopidol
- Amprolium
- Anthelmintics (levamisole)
- Pesticides (including DDT and chlorinated hydrocarbons)

8. CUBA

Cuba agrees with the list established by the Expert Consultation (Section 8 of Food and Nutrition Paper No. 32):

- Antibiotics (specifically Chloramphenicol)
- Anabolics
- Sulphonamides; e.g., sulphamethazine
- Nitrofurans
- Benzimidazoles
- Nitroimidazoles
- Synthetic dyes used as marker compounds and as therapeutic agents
- Tranquilizers and beta-adrenogenic blocking agents

and
- Carbadox
- Cryomazine

9. FRANCE

Agrees with list of the Expert Consultation (see para. 8 (Cuba) above) and proposed:

- Antibiotics
- Sulphonamides
- Nitrofurans
- Benzimidazoles
- Tranquilizers and beta-blockers

10. FEDERAL REPUBLIC OF GERMANY

(a) Substances of First Priority:

- Chloramphenicol
- Beta-lactam Antibiotics - Ampicillin, amoxicillin, cloxacillin, dicloxacillin, oxacillin, benzylpenicillin, phenoxymethylpenicillin, phenethamate hydriodide, clemizole penicillin.
- Tetracyclines - Tetracycline, chlortetracycline, rolitetracycline, oxytetracycline.
- Macrolide Antibiotics - Erythromycin, oleandomycin, spiramycin, tylosin, kitasamycin.
- Sulphonamides - Sulphamethazine, sulphaquinoxaline, sulphachlorpyridazine, sulphadiazine, sulphamerazine, sulphathiazole, sulphadoxine, sulphadimethoxine, sulphamethoxypyridazine, sulphaloxic acid, sulphaguanidine, formosulphathiazole, succinylsulphathiazole, phthalylsulphathiazole, sulphamethizole, sulphamethoxazole, sulphapyridine, sulphanilamide, sulphaphenazole, sulphatolamide, sulphisomidine, sulphaethoxypyridazine, sulphalene, sulphaperine.
- Aminoglycoside Antibiotics - Destomycin A, streptomycin, dihydrostreptomycin, gentamycin, kanamycin, neomycin, paromomycin, spectinomycin, apramycin.
- Nitrofurans - Nitrofurathiazide, furazolidone, nitrofurantoin, nitrofurazone, furaltadone, nifurprazine.
- Trimethoprim
- Polypeptide Antibiotics - Polymyxin B, colistin
- Lincomycin
- Rifamycin
- Tiamulin
- Phenothiazines - Acepromazine, chlorpromazine, propionylpromazine, triflupromazine, prothipendyl.
- Griseofulvin
- Pyrimethamine
- Imidazoles - Levamisole, tetramisole
- Anthelmintics - Dichlorvos, trichlorfon
- Nitroimidazoles - Ronidazole, ipronidazole, dimetridazole, metronidazole.

- Glucocorticoides - Dexamethasone, triamcinolone acetonoide, flumethasone.
- Azaperone (tranquilizer)
- Carazolol (beta-adrenergic blocker)
- Antihistaminics - Mepyramine, methapyrilene
- Pyrazolones - Aminophenazone, dipyrone, phenylbutazone, phenazone
- Methyl violet
- Benzimidazoles - (Thiabendazole), parbendazole, cambendazole, albendazole, fenbendazole, oxfendazole, mebendazole, flubendazole.
- Febantel
- Xylazin
- Dapsone
- Fasciolicides - Oxyclozanide, rafoxanide, brotianide, bromfenofos, niclofolan, bithionol, hexachlorophen, nitroxynil, hexachloroethane.
- Diaveridine
- Nystatin, amphotericin B
- Tetrachlorvinphos

(b) Substances of Second Priority:

- Phoxim, coumafos
- Hexachlorcyclohexane, bromocyclen
- Piperonyl butoxyde, diazinon = dimpylate
- Arecoline, praziquantel, piperazine, diethylcarbamazine, kamala (Endoparasitic agents).
- Cyclic Amides - Morantel, pyrantel
- Prednisolon, prednison
- Ethinyl-Oestradiol (VO)
- 19-Norandrostenolone dodecanoate, medroxyprogesterone acetate, 19-norandrosterolone decanoate.
- Chlormadinone acetate
- Prostaglandines - Prostalene, tiaprost, fluprostenol, cloprostenol, prostianol.
- Benzothiadiazines - Hydrochlorothiazide, benzylhydroflumethiazide, trichlormethiazide.
- Acetanilide, phenacetin, acetaminophen, paracetamol (Aniline Derivatives).
- Arsanilic acid, 8-hydroxyquinoline, mercury, clenbuterol, furosemide, isoxsuprine, strychnine, veratrum viride, ergotamine.

11. GHANA

Trypanocides: Isometamidium, prothidium, pro salt of quinuronium sulphate, diminazene aceturate, imidocarb, trypan blue.

12. IRELAND

- Prohibited hormones: stilbenes, thyreostatics, trenbolone, zeranol, other substances having an oestrogenic, androgenic or gestagenic effect.
- Chloramphenicol
- Other antibiotic and substances with antimicrobial effect.

13. JAPAN

Antibiotics:

- Oxytetracycline
- Chlortetracycline
- Tylocine
- Penicillin
- Spiramycin
- Chloramphenicol

Antibacterial Substances:

- Furazolidone (nitrofurans)
- Sulphamonomethoxine
- Sulphadimethoxine
- Thiamphenicol
- Olaquindox
- Carbadox

Hormone Growth Promoters and Corticosteroids

Antimycotics and Antiparasitic Agents:

- Clopidol
- Thiabendazoles

14. KENYA

Kenya (speaking for countries of the African Region) proposed acaricides (organophosphates and chlorinated hydrocarbons) and supported Ghana on trypanocides (see para. 11 (Ghana) above).

15. MALAYSIA

- Antibiotics (e.g., tetracyclines, chloramphenicol)
- Anabolic agents
- Sulphonamides
- Nitrofurans
- Acaricides including DDT and other chlorinated hydrocarbons.

16. MEXICO

- Antibiotics (penicillin, streptomycin, tetracycline, erythromycin, chloramphenicol, novobiocin)
- Hormon-Based Anabolic Agents
- Synthetic Colours used as Therapeutic Agents or as Feed Additives

17. NETHERLANDS

- Antibiotics (chloramphenicol, tetracycline, oxytetracycline, chlortetracycline)
- Sulphonamides

- Nitrofurans (furazolidone, furaltadone)
- Quinoxalines (carbadox, olaquindox)

18. NEW ZEALAND

Anabolic agents including:

- Endogenous hormones, the active ingredient of which is a naturally occurring substance, e.g. oestradiol - 17 B, progesterone and testosterone (all of which are prohibited for sale in New Zealand as growth promotants, but are allowed for veterinary therapeutic purposes);

- oestrogenic stilbenes and their derivatives (which are prohibited for sale in New Zealand);

- exogenous substances or xenobiotics, e.g. zeranol and trenbolone acetate (zeranol only is on sale in New Zealand).

- Antibiotics

- Other Antimicrobial Drugs

19. NORWAY

Antibiotics and Other Antiinfective Drugs:

- Oxytetracyclines
- Sulphadiazine
- Trimetroprim
- Nifurazolidone
- Chloramphenicol (the question of completely banning this drug for veterinary use should be considered)
- Penicillins
- Streptomycines
- Sulphonamides

Antiparasitic Agents, especially:

- Coccidiostats (Amprolium, etc.)
- Ivermectin
- Hexicide and other agents against mange
- Imidazothiol derivatives, benzimidazoles and tetrahydropyrimidines
- Organophosphates, including metrifonate

Substances Acting on the Central Nervous System - Amperozid

20. POLAND

- Chloramphenicol
- Sulphonamides
- Anticoccidial agents
- Hormonal growth promoters

21. SENEGAL

Senegal proposed the evaluation of trypanocides (see para. 11 (Ghana) above).

22. SPAIN

- Anabolic agents
- Antibiotics (chloramphenicol and beta-lactam antibiotics)
- Sulphonamides
- Nitrofurans
- Nitroimidazoles
- Benzimidazoles

- Carbadox
- Antibiotics used as additives in EEC countries.

23. SWEDEN

- Benzimidazoles
- Carbadox
- Chloramphenicol
- Anabolic Agents
- Sulphonamides

24. TRINIDAD AND TOBAGO

- Chloramphenicol
- Tetracycline
- Tylosin
- Penicillin and Streptomycin
- Stilbestrol
- Diethylstilbestrol
- Thyreostatic drugs and associated mastitis preparations.

25. UNITED KINGDOM

(a) Assessment of dietary exposure to residues of:

- Antimicrobial agents: chloramphenicol, sulphonamides, nitrofurans
- Benzimidazole anthelmintic agents
- Nitroimidazoles
- Carbadox
- Those tranquilizers and beta-adrenogenic blocking agents used to facilitate the transport of animals, notably pigs, prior to slaughter.

(b) Assessment of residues of:

- Olaquindox
- Coccidiostats
- Antimicrobial agents not listed under (a) above which are widely used in food-producing animals.

26. UNITED STATES

- Anabolic Agents
- Nitroimidazoles
- Carbadox
- Chloramphenicol
- Sulphamethazine

27. ZIMBABWE

Zimbabwe proposes evaluation of trypanocides (see para. 11 (Ghana) above).

28. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES' ASSOCIATIONS (EFPIA)

- Effects of sub-bacteriostatic levels of oral tetracycline in-vivo and in-vitro, and the relevance, if any, to fixing acceptable safe residue levels for these antibiotics.
- Antibacterials of the nitrofuran and nitroimidazole group.
- Chloramphenicol and thioamphenicol
- Carbaquindox and olaquindox.

29. BUREAU EUROPEEN D'INFORMATION POUR LE DEVELOPPEMENT DE LA SANTE ANIMALE (DSA)

- Growth Promoters (natural hormones and synthetic compounds which have an effect on the metabolism).