

codex alimentarius commission

FOOD AND AGRICULTURE
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WORLD HEALTH
ORGANIZATION

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REPORT OF THE SECOND SESSION OF THE

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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INTRODUCTION

1. The Second Session of the Codex Committee on Residues of Veterinary Drugs in Foods was held from 30 November to 4 December 1987 in Washington, D.C. by courtesy of the Government of the United States of America. The Session was chaired by Dr. Lester M. Crawford, Administrator, Food Safety and Inspection Service, USDA, except that for Items 12 and 13, Dr. Gerald B. Guest, Director, Center for Veterinary Medicine, FDA, was in the chair. Representatives and observers from 40 countries and 12 international organizations were present.
2. The Session was preceded by the meeting of the Ad Hoc Working Group on Methods of Analysis and Sampling which took place on 27 November 1987 under the chairmanship of Dr. Richard Ellis, Director, Chemistry Division, FSIS/USDA. The report of the meeting was presented to the Plenary under Item 9.
3. A list of participants at the session, including officers of FAO and WHO, is attached as Appendix I to this report.

OPENING OF THE SESSION (Item 1)

4. The Session was opened by Dr. Frank Young, Commissioner of the U.S. Food and Drug Administration, who welcomed delegates. Dr. Young highlighted the importance of international agreements on technological and scientific aspects of food production and control which profoundly influenced consumer acceptance of food and international trade matters. He pointed to the need of pooling financial resources and of making optimal use of the scientific expertise available in many countries to establish international acceptable parameters for chemical substances intentionally added to foods or occurring through contamination.
5. Dr. Young confirmed the high priority the Government of the United States was assigning to the work of Codex Committees and, in particular, to the work on residues of veterinary drugs carried out by this Committee. Dr. Young also assured Delegates that the Government of the United States would continue to support the activities of the codex Alimentarius Commission in the Governing Bodies of FAO and WHO. The full text of Dr. Young's speech is attached as Appendix II to this report.
6. The Committee confirmed its view expressed at the First Session that, in line with the guidelines for Codex Committees, this Session should be closed to the public and that members of the press would be met on December 4.

APPOINTMENT OF RAPPORTEUR

7. The Committee appointed Dr. Dieter Arnold of the Federal Republic of Germany, to serve as Rapporteur of the Session.

ADOPTION OF THE AGENDA (Item 2)

8. The Committee had before it the Provisional Agenda for the Session (CX/RVDF 87/1). The Delegation of the United States proposed to introduce a new item dealing with the format of publishing and presenting the MRLs for veterinary drugs which would have to be sent to governments for comments under a specific procedure.
9. The Chairman reminded the Committee that Items 4 to 8 dealt with different aspects of the elaboration of Codex recommendations for residue levels of veterinary drugs in foods. It was pointed out by several delegations that Item 11, concerning a code of practice for the use of veterinary drugs, was also closely related to Item 7 dealing with

principles for good veterinary practice and, that therefore, these two items should be considered together.

10. The Committee noted that whereas Items 4 to 8 concerned the Codex recommendations for veterinary drug residues as such, Item 11, the code, was intended to serve as an auxiliary advisory text. The Committee decided to introduce a new Item 8a to embrace the conclusions of the Committee on Items 4 to 8 and a set of draft recommendations based on the 32nd JECFA report to be sent out for government comments. The Committee decided to leave the remainder of the agenda unchanged.

11. At the request of the Delegation of the United States, the Committee decided to give consideration under the Item "Other Business" to the need and feasibility of developing a Code of Practice on Minimum Standards for Drug Registration and Criteria for the Determination of Residues.¹ It was proposed that a decision also be taken on which organization would be the appropriate body to elaborate such a document.

¹ This proposal was amended to deal with Guidelines for Establishing a Regulatory Programme for the Control of Residues of Veterinary Drugs in Foods. (See paras. 134-141).

12. The Delegation of Hungary proposed that the Committee should consider possibilities to harmonize the application of safety factors in the calculation of ADIs. The Committee noted that this matter could be discussed in connection with Item 8a and if necessary continued under "Other Business". (See paras. 93-100)

13. The provisional agenda was adopted as amended.

MATTERS OF INTEREST ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Item 3a)

14. The Committee had before it Working Paper CX/RVDF 87/2.

Codex Alimentarius Commission, 17th Session (ALINORM 87/39)

15. The Committee noted that the Commission had been informed of the work carried out at its first session and that decisions had been taken on a number of important issues. (Para. 167)

16. The Commission had also been informed that the Committee had given special attention to problems with animal husbandry and residues of veterinary drugs in the region of Africa. The Commission had strongly supported a request that FAO and WHO should consider holding seminars or workshops to assist African countries. It had also been noted that trypanocides had been placed on the priority list.

17. The Delegation of Senegal recalled that many delegations to the first session of the Committee had supported the concerns of the African countries. The Delegation suggested that this matter should be followed up with concrete proposals. The Chairman of the Committee confirmed that the future work plans would include reference to these specific problems and drew attention to the list of trypanocides in CX/RVDF 87/3. The Committee decided to examine this issue further under "Other Business". (See paras. 142-147)

Amendments to Terms of Reference

18. The Commission had considered the request of this Committee to amend clause (b) of the terms of reference which meant, in essence, to replace the term "maximum residue levels" with the term "acceptable residue levels", since the MRL concept followed by the Committee on Pesticide Residues was not suitable for veterinary drug residues; in the case of veterinary drugs, health considerations should have a

determining impact on the residue levels. The Commission had decided that the term ARL could lead to confusion, especially with the concept of the ADI and that the Codex residue levels for veterinary drugs should include a notion of a maximum limit. The Commission had not agreed to amend clause (b). The Delegation of the Federal Republic of Germany expressed its disappointment with the above decision, and this view was shared by other delegations. The Committee agreed that a decision on the concept of residue levels for veterinary drugs as well as the appropriate term was of fundamental importance to defining the work of the Committee and that these matters should be fully considered under Items 5 and 8a.

19. The Commission had, however, accepted the wish expressed by this Committee to develop methods of analysis and sampling and amended clause (d) accordingly. In this connection the Commission had also agreed that these methods of analysis and sampling need not be endorsed by the Codex Committee on Methods of Analysis and Sampling. The Committee noted that the above amendments would be included in the Procedural Manual.

20. The Committee was informed of the view of India that this Committee should take into account the WHO recommendations on banning certain drugs in human medicine for public health reasons when evaluating residues of the same drugs for veterinary purposes. The above view was supported by several delegations which requested that this should be done on a case by case basis.

21. The Committee agreed with a suggestion made by the Delegation of the Federal Republic of Germany to consider under "Other Business" the need to establish a list of drugs which should be prohibited on the basis of public health concerns, for use in veterinary medicine.

22. The Committee noted the Commission's recommendations to the Committee on Pesticide Residues, as elaborated by the Committee on General Principles (para. 153), and agreed to apply them in its own activities where appropriate. These recommendations related to the establishment and application of MRLs taking into account good agricultural practices, health considerations and the significance of the food commodities concerned in international trade.

23. The Committee referred to its Ad Hoc Working Group on Methods of Analysis and Sampling a request by Egypt to develop confirmatory methods for simple routine methods. It also noted a request by China to express residues and contaminants on a whole product basis and agreed to take this into account when deciding on the type of recommended residue level for veterinary drugs under Item 5.

Codex Committee on Pesticide Residues - 19th Session (ALINORM 87/24A)

24. The Committee noted that the Codex Committee on Pesticide Residues (CCPR) had asked (a) to be kept informed of work undertaken by this Committee on substances that were also used as pesticides and (b) that the Secretariat should devise measures to avoid overlap of work on multifunctional substances. The Committee agreed, that as a first step, the Secretariat of CCPR should be requested to draw up a list of those pesticides which the CCPR had already considered for use in food producing animals and of any relevant MRLs or other recommended levels for these substances either already established or under consideration. Several delegations strongly supported the exchange of relevant information between the two Committees on a regular basis and requested the Secretariat to take appropriate action.

Recommended Method of Sampling for the Determination of Pesticide Residues in Meat and Poultry Products for Control Purposes

25. The Committee was informed that CCPR was considering the above document with a view to merging the finalized texts with a similar document on plant products already published in Part V of the Pesticide Guidelines. The Committee was informed that the document was being revised in the light of Government comments and would be sent to this Committee as soon as it was available. To avoid further delay due to the timing of sessions of the two Committees, the Chairman of the Ad Hoc Working Group on Methods of Analysis and Sampling was requested to seek comments on the paper by correspondence. The Committee requested to be kept informed of further developments.

Guidelines on Pesticide Residue Trials to Provide Data for the Registration of Pesticides and the Establishment of Maximum Residue Limits

26. The Committee noted that Part II of the above Guideline dealt with food of animal origin. The publication had recently been issued by FAO and was available upon request.

MATTERS OF INTEREST ARISING FROM FAO AND WHO ACTIVITIES (Item 3b)

27. The Committee had before it Working Paper CX/RVDF 87/3 containing brief reports on FAO, WHO and Joint FAO/WHO activities of interest to the work of this Committee.

Joint Activities

(a) Joint FAO/WHO Expert Committee on Food Additives (JECFA)

28. The Committee noted that the 32nd Session of JECFA had been exclusively devoted to the evaluation of residues of veterinary drugs in foods and agreed to discuss this matter further under Agenda Item 4.

(b) Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

29. The WHO Representative reported on the JMPR activities relating to the establishment of Maximum Residue Levels (MRLs) for pesticide residues. MRLs established by JMPR were based upon Good Agricultural Practice (GAP); the toxicological evaluation did not play a role per se in the establishment of MRLs for residues on specific commodities, although the toxicological evaluation did play a role in that MRLs were not established for those pesticides for which ADIs had not been established.

30. Difficult as it was to estimate intake of residues of veterinary drugs in food, it was much more difficult with pesticide residues, because the number of commodities with pesticide residues was much greater than with veterinary drug residues. Despite the difficulties, the need had increasingly been recognized by JMPR to estimate consumer intake of pesticide residues and correlate it with the ADI. Therefore, FAO and WHO had undertaken, at the recommendation of JMPR, a project to do this. A meeting had been held in October 1987 to consider the mechanics of this activity. Briefly, the conclusion was to go through a series of screens, from coarse to fine, to remove pesticides from concern at the earliest stage possible with the least amount of effort. At the coarser levels, the calculations could be made at the international level using composite regional food intake data. At the finest level, the calculations could be made only at the national level. These recommendations could be put into effect, as much as possible, at the 1988 JMPR.

FAO Activities

(a) Animal Production and Health Division (AGA)

31. The FAO Representative provided the following report: "The FAO Trypanosomiasis Control Programme in Africa will continue and it is expected that more than 30 million doses of trypanocides will be annually applied in Africa. Problems with trypanosomes in other continents (Asia and Latin America) are increasingly recognized and trypanocides use in some countries might increase. The Joint FAO/IAEA Division has carried out a study on "Fate of trypanocide drugs in cattle." One of its objectives is to determine the rates of accumulation in organs and length of residual activity. Other veterinary drugs of importance to FAO activities fall into the following major groups:

1. Veterinary vaccines
2. Antibiotics
3. Anthelmintics
4. Insecticides and Acaricides

FAO's major concerns with veterinary vaccines are with efficacy and safety to both animal and man. Some inactivants, adjuvants and antibiotics used to make vaccines may cause some residue problems. An enormous number of antibiotics, anthelmintics, insecticides, and acaricides are being used. If these drugs are used in accordance with the producers' recommendations and under veterinary supervision, risks of residues may be minimal, but most of developing countries are facing problems at the veterinary services' level, and the farmers' level is much worse."

32. The FAO Representative referred to special considerations which should be borne in mind in discussing drug residues:

"New formulations of many drugs are becoming available in forms which may increase residue risks. These formulations include:

- long acting formulations (tetracycline)
- slow release devices for insecticides and anthelmintics, and
- pour-on formulations

The disposal of unused portions of drugs, particularly insecticides, may result in exposure of animals to dangerous levels of these compounds, if not appropriately controlled. This in turn may result in high residues in animal tissues or, in severe cases, in significant mortality. Even water supply sources may face high risks."

33. It was noted that the AGA Division of FAO had been requested to deal with two subjects during next biennium (1988/89):

- "1 To examine safe meat processing techniques to prevent the spreading of major trade diseases such as foot and mouth disease, African swine fever, etc.
2. To examine the use of growth promotants for animal production.

Due to budgetary limitations expected during the next biennium, FAO had decided to hold in 1988 only one Expert Consultation (Meat Processing Techniques to Prevent the Spread of Major Infectious Diseases). It was unfortunate that it would not be possible to hold the consultation on the other important subject which was of more direct relevance to this Committee."

34. The Representative of FAO suggested that, if any other organization would be interested to hold the Expert Consultation on certain selected growth promotants, FAO would support the meeting within the limit of available resources.

(b) Fisheries Industries Division (FII)

35. The Committee was informed that the above Division was preparing a working paper on a Code of Practice for Aquaculture for the next session of the Codex Committee on Fish and Fishery Products (CCFFP). While it was not yet known to what extent the document referred to veterinary drug issues the Committee expressed its great interest in this work and the probable need for very close collaboration. It offered its assistance to CCFFP.

WHO Activities

(a) Information on Veterinary Drugs

36. The Committee expressed its appreciation to Dr. Dunne of the Pharmaceutical Unit of WHO for having included information on veterinary drugs in the WHO information letter on notifications from drug regulatory authorities. It was noted that the WHO Drug Information Bulletin had been upgraded to the status of an official WHO publication.

MATTERS ARISING FROM THE ACTIVITIES OF OTHER INTERNATIONAL ORGANIZATIONS (Item 3c)

37. The Committee had before it document CX/RVDF 87/4, which contained information concerning matters of interest to the Committee from the following International Organizations: International Office of Epizootics (OIE), International Technical Consultation on Veterinary Drug Registration (ITCVDR), International Dairy Federation (IDF), Association of Official Analytical Chemists (AOAC) and the Animal Health Institute International (AHI) (Addendum 1). Other International Organizations were also represented and presented summaries of their activities as outlined below:

International Office of Epizootics (OIE) - International Technical Consultation on Veterinary Drug Registration (ITCVDR)

38. The Observer from OIE reiterated the comments outlined in CX/RVDF 87/4 and outlined the application of Resolution No. XI adopted by the 54th General Session of the International Committee of the OIE in May 1986, in which a working group had prepared an information programme on veterinary drug registration. This programme had been approved by the 55th General Session of the OIE on 22 May 1987.

39. In accordance with this programme, and as presented by the OIE representative, a group of experts had been given the task of drafting minimal guidelines on:

- a) procedures for the approval for use of veterinary drugs;
- b) safety, efficacy and quality controls of veterinary drugs;
- c) forms for the notification of adverse effects of veterinary drugs.

40. It was further stated by the Observer from OIE that the organization was interested in improving veterinary drug registration control, especially in developing countries, and in more effectively coordinating activities in developed countries. The Observer from OIE announced a seminar, on problems related to the use of somatotropic hormones, to be held sometime after the General Seminar of OIE in May 1988 in Paris.

41. The Delegation of Norway referred to OIE activities concerning drug registration as reported to the Committee and stated that this should be taken into account when considering the U.S. proposal for Guidelines on Registration Criteria under Item 13 (Other Business). The Delegation felt that consideration should be given as to whether such guidelines fell within the Committee's terms of reference. The Observer from OIE explained that the OIE was acting as secretariat for the International Technical Consultation on Veterinary Drug Registration (ITCVDR) and was the official organization responsible for disseminating information on these matters.

42. The Delegation of France stated that ITCVDR had implemented the resolutions of the Third Consultation concerning dissemination of information and was issuing, in cooperation with OIE, a periodical newsletter. The Delegation indicated that the Fourth Consultation of ITCVDR was expected to be held in Australia in 1988.

International Dairy Federation (IDF)

43. The Observer from IDF summarized the activities of Group A4 which dealt with residues and contaminants in milk and milk products. It was expected that the first draft monograph on "Residues and Contaminants in Milk and Milk Products" would be available in early 1988. He also informed the Committee that Group E47 had prepared a compendium of detailed descriptions of analytical methods for antibiotics in milk and milk products which was now available.

Association of Official Analytical Chemists (AOAC)

44. The Observer from AOAC referred to the report as contained in CX/RVDF 87/4. In addition, the Observer discussed the protocol for interlaboratory collaborative studies which had been agreed to at a meeting of experts from governmental and international organizations. Further details on this work were contained in the report of the Ad Hoc Working Group on Methods of Analysis and Sampling (See Item 9).

Animal Health Industries (AHI/FEDESA)

45. The Observer from organizations representing the animal health industries referred to the report of the First Session of the Committee and informed the Committee that since that time the European trade associations of veterinary drugs manufacturers had established a new federation (FEDESA) which represented the majority of trade associations within Europe. Through cooperation with other industry associations from the United States, Japan, Canada and Australia industry participation in the work of this Committee and JECFA would in the future be unified. He stated, that industry had been pleased to be able to provide technical information for JECFA to undertake its evaluation of anabolic hormones and chloramphenicol at its 32nd session.

46. The Observer from organizations representing the animal health industries also expressed the following views:

- a) The selection of compounds for priority evaluation should fully reflect the "Criteria for the Selection of Veterinary Drugs for the Establishment of Maximum Residue Levels" agreed to by this Committee. The establishment of a Working Party to examine the Priority List should be considered.
- b) Industry re-affirmed its endorsement of the need to establish a new Joint Expert Committee separate from JECFA (para. 174 of ALINORM 87/31) with scientific input from industry as appropriate.
- c) CC/RVDF should persist in its determination that the regulation of animal

drug residues in food be based solely on the objective expert evaluation of scientific data. Product prohibitions based on ill-defined "consumer demand" or "economic conditions" should be opposed by CC/RVDF.

European Economic Community (EEC)

47. The Observer from the EEC presented the following report on activities of interest to the Committee:

"In accordance with the objectives of the EEC Treaty, the Community has the task of securing the free movement of both veterinary medicinal products and foodstuffs of animal origin within the Community. A considerable volume of legislation has been adopted and this is binding on the Member States of the Community."

Summary of the Legislative Provisions in Force

Veterinary Medicinal Products

"Council Directives 81/851/EEC and 81/852/EEC have extensively harmonized the criteria for authorising the marketing of veterinary medicinal products within the Community. In accordance with the directives, an application for authorisation shall be refused if the use of the veterinary medicinal product may result in residues which may pose a risk to the health of the consumer. Member States are responsible for applying the Community criteria, but there are a number of procedures for coordinating national decisions through the Committee for Veterinary Medicinal Products and its working party on the safety of residues.

Following the entry into force of Directive 87/22/EEC on 1 July 1987, any application to market a veterinary medicinal product derived from biotechnology must be submitted for coordination at the Community level before it is authorised by a Member State. This procedure is also available on a voluntary basis for other high technology medicinal products."

Additives to animal feedingstuffs

"The Community definition of additives to animal feedingstuffs includes a number of medicinal substances used at sub-therapeutic doses for prophylactic or growth promotion purposes, including certain antibiotics and coccidiostatics. In accordance with Directive 70/524/EEC, no additive may be used within the Community unless it has been authorised by the Community and included in a positive list of authorised additives. The authorisation, which specifies detailed conditions of use, will be refused if the use of the additive poses a risk to the health of consumers."

Anabolic Agents

"From 1.1.1988, the use of anabolic hormones for growth promotion purposes will be prohibited within the Community by Directives 81/602/EEC and 85/649/EEC. The use after 1 January 1988 of oestradiol-17B, testosterone and progesterone is permitted for a limited range of therapeutic indications. Detailed provisions for the control of hormone residues are laid down in Directive 85/358/EEC. Commission Decision of 14 July 1987 concerns the methods to be used for detecting residues of substances having a hormonal or thyreostatic action (87/410/EEC)."

Control of Residues

"Directive 86/469/EEC provides for the establishment of a detailed system for the monitoring of residues. In accordance with Directive 83/90/EEC on fresh meat and Directive 85/397/EEC on milk, the Community is required to set specific tolerances for the presence of all therapeutic substances in these products and similar provisions are under consideration for eggs."

"A working party on the safety of residues is providing scientific and technical assistance for the Commission in preparing the necessary proposals. To date, the group has issued recommendations in respect of chloramphenicol, the sulfonamides and the nitrofurans. Work is at an advanced stage on Dapsone, the benzimidazoles, dimetridazole and trimethoprim. Substances chosen for future priority include the other nitroimidazoles, ivermectin, antibiotics and anthelmintics. In addition, the group has completed draft guidelines on the use of veterinary medicines in fish, which will shortly be sent out for consultation."

COMPENDIUM OF VETERINARY DRUGS FOR THE AMERICAS (Item 3d)

48. The Committee had before it the above compendium in CX/RVDF 87/5, Parts I and II and government comments in Addendum I thereto.

49. The First Session of the Committee had discussed briefly the proposal put forward by several Member Countries that a survey of veterinary drugs permitted in the individual countries be carried out. The Committee had recognized that this might be a difficult undertaking because of the enormous number of substances and even larger number of formulations in use in different countries (para. 123 of ALINORM 87/31).

50. The Committee had been informed that a compendium on veterinary drugs was being prepared for the Americas and was near completion. The Committee had expressed its interest in the compendium and had accepted the kind offer of the Delegation of the United States to make copies available for the information of the Committee (para. 125 of ALINORM 87/31).

51. The Delegation of the United States had sent out Part I of the Inter-American Compendium in April 1987 (CX/RVDF 87/5) and had requested comments on the usefulness to the Committee of such a compendium. Replies to the circular letter had been received from Cuba, France, Ghana, Ireland, Poland, United Kingdom, and the United States. The Delegation of the United States had put all comments together into a paper for discussion at the Second Session (Conference Room Document 2; CX/RVDF 87/5 Addendum I) and reported that the comments from the various countries were, in general, very positive; however, many countries had reserved comments until Part II was available.

52. By circular letter (CX/RVDF 87/5 - Part II; September 1987), the Delegation of the United States had sent out an example of Part II of the Inter-American Compendium which covered registered products, covering Bolivia. An additional example of Part II of the compendium covering the United States had been distributed to the delegates at the second session of the CC/RVDF. This was available in English only.

53. The Delegation of the United States supported the development of an international compendium of veterinary drugs and believed that such a compendium would be extremely useful to all member countries of the Codex Alimentarius Commission and to interested international organizations.

54. The Committee congratulated the United States on the excellent work done and considered possibilities to follow-up with additional studies. In view of the need for considerable inputs with regard to time and resources to establish similar national compendia, the Committee recommended that use should be made especially of Part I of the compendium which provided useful information on the services responsible for control of veterinary drugs and facilitated contact with national authorities. The Committee recognized that the establishment of national compendia was outside its terms of reference but encouraged Member Countries to consider developing their own compendia. In this context, the Committee expressed its appreciation to the Delegation of the United States for its willingness to make available the relevant computer software and the data base of its own compendium.

**CONSIDERATION OF THE REPORT OF THE 32ND MEETING OF THE JOINT
FAQ/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Item 4)**

55. The Committee had before it the Summary Report and Conclusions of the 32nd Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as contained in document CX/RVDF 87/6 and comments thereon from Ireland (CRD 5). A copy of the full final draft unedited report was also available to the Committee as Conference Room Document No. 4. The report was introduced by the Joint Secretariat of the 32nd Meeting of JECFA, Drs. J.L. Herrman (WHO) and A.W. Randell (FAO).

56. The Committee noted that the report of JECFA was in two main sections; the first dealing with general principles for the evaluation of veterinary drug residues in food, and the second devoted to the evaluation of six specific substances selected from the priority list established by the First Session of the Committee. With regard to the general considerations, the Committee also noted that JECFA had decided to use the definition for "Veterinary Drug" and "Residue of Veterinary Drug" adopted by the Committee at its first session.

57. The report listed in detail the information required for the evaluation of drugs, covering the following areas: general characteristics; use patterns; pharmacological characteristics; analytical criteria for the detection and quantification of residues; metabolism and pharmacokinetics, toxicological data; and residue depletion studies. It also indicated how these data would be assessed, and how Acceptable Daily Intakes (ADIs) and Acceptable Residue Levels (ARLs) would be estimated. The Committee noted that for the hormonally active substances considered by JECFA, the evaluation was made on the basis of their use as growth-promoting agents only, although JECFA was aware of their use for therapeutic and other purposes. The Committee also noted that the consideration of these substances was based on their use in the bovine species.

58. JECFA had also proposed a working definition of Acceptable Residue Level as follows:

"The Acceptable Residue Level" of a veterinary drug in food is the highest acceptable concentration of residues in food. It is determined from the ADI established by the Joint FAO/WHO Expert Committee on Food Additives and from the estimated intakes of the relevant foods, and is adjusted as necessary to be consistent with good veterinary and agricultural practice and practical analytical methods."

JECFA had agreed that this working definition be reviewed together with alternative approaches to establishing ARLs.

59. In discussing the report of JECFA, the Delegation of the Federal Republic of Germany questioned the implication of the decision regarding chloramphenicol, stating that even though no ADI could be established, the failure to set an ARL left a question as to the recommendations which might be made to governments on how to control residues of veterinary drugs, which, like chloramphenicol, had too few data which could be used to evaluate their safety. The Delegation of France noted that many of the principles and concepts of food toxicology relative to residues were still under development; in many cases there would be no formal conclusions because of this. However, where the data showed an unacceptable gap, there would be a different approach to the evaluation. An understanding of this situation would make it possible to better understand the problems involved and probably to solve them in a proper way.

60. The Delegation of the Netherlands proposed that consideration of the Report of the 32nd meeting of JECFA be postponed until the final document could be widely distributed and opinions of national experts be made available. The Committee agreed to take this into account during its discussion of Item 8a.

61. The Observer from the EEC stated, in reference to the conclusions of JECFA regarding hormones, that the Community had specific legislation regarding the use of hormones and that the European Community and the Member States were bound by this legislation. The European consumer was opposed to the use of hormones for fattening and demanded meat from animals which have not been so treated. The response of the Community to this consumer demand as regards to the food they eat and the enforcement they expect had been to prohibit the use of these hormones as anabolic agents. These included any substances having an oestrogenic, androgenic or gestagenic action and thyreostatic substances. In consequence neither the EEC nor its Member States would be able to accept residue levels for these substances when used for fattening, nor animals or the meat and meat products from animals so treated.

62. The Delegation of Sweden referred to a Conference Room Document (CRD 11) which had been distributed and stated that the situation in that country was similar and that it extended to carcinogenic substances as well.

CONSIDERATION OF A WORKING PAPER ON PROCEDURES FOR THE ESTABLISHMENT AND IMPLEMENTATION (ACCEPTANCE) OF RECOMMENDED CODEX RESIDUE LEVELS OF VETERINARY DRUGS IN FOODS (Item 5)

63. The Committee had before it a working paper on the above subject which had been prepared by the Secretariat (CX/RVDF 87/7). The paper provided background information on three items requiring decision by the Committee (1) definition and terms of reference (2) type and nature of recommended residue levels and (3) elaboration and acceptance procedures. It also outlined amendments to the Procedural Manual already adopted by the 17th Session of the Commission which would be included in the current Sixth Edition, and detailed proposals concerning working relationships with other Codex Committees (Annexes 1 and 2), The Committee confirmed these working relationships.

Definitions

64. The Committee confirmed the concept that the establishment of Codex recommendations for residue levels of veterinary drugs in foods should be based primarily on a safety evaluation of toxicological data and should also take into account good practices in the use of veterinary drugs and certain other factors including available methods of analysis. The Committee agreed with the decision of the Commission that the residue levels should include a notion of a maximum.

65. In this light, the Committee examined definitions for a "Maximum Residue Limit" and "Acceptable Residue Level" contained in the discussion paper together with the proposed definitions in the JECFA report and in the Glossary of Terms prepared by the Delegation of Canada (CX/RVDF 87/8).

66. The Committee considered the following points in relation to the definition of Codex recommendations for residue levels of veterinary drugs in foods:

- that toxicologically safe levels were the determining criterion;
- that good practice for the use of veterinary drugs would be used to lower these levels, where appropriate, without discouraging the development of products with lower toxicity;
- that there was a need to consider the availability of practical methods to determine such low levels;
- there was a need to consider the importance of metabolites, and other sources of substances considered as residues within the Codex definition;
- there was a need to consider other aspects such as allergenic and other immunological aspects and resistance problems;
- the implications on the regulatory control of food of animal origin in trade.

67. The Committee agreed on the following definition:

"Maximum Residue Level" (MRL) is the maximum level of residue resulting from the use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any direct or indirect toxicological hazard for human health.

It is established on the basis of an ADI or, where this is not possible because of insufficient scientific knowledge, on the basis of a temporary ADI that utilizes an additional safety factor.

It takes into account factors such as resistance promotion, allergenic potential and other undesirable side effects, whether direct or indirect, for human health.

The MRL may be reduced to accommodate residues that originate in food of plant origin and/or the environment. It may also be reduced to be consistent with good practices in the use of veterinary drugs to the extent that practical analytical methods are available. The concentration is expressed on a fresh weight basis."

68. The Committee recognized that the term "Maximum Residue Level" and the acronym "MRL" were similar to those used in relation to pesticide residues. It agreed that, although this definition was different to the one used to define limits for residues of pesticides in foods, this would not lead to confusion. It was understood that CCPR might be redefining its own definition. (See Appendix III)

69. Because the above definition would need to be included in the Procedural Manual as one of the definitions for the purposes of Codex Alimentarius, it was agreed to refer it to governments for comments in association with the definition for "good practices in the use of veterinary drugs," and to consider both definitions at the next session of the Committee in the light of government comments. These definitions would then be submitted to the 18th Session of the Commission for adoption. The definitions would also be referred to JECFA.

Procedures for the Elaboration of MRLs

70. The Committee considered the proposal for an Elaboration Procedure for Maximum Residue Levels of Veterinary Drugs in Foods contained in the working paper, which was based on the elaboration procedures for maximum residue limits for pesticides (6th Edition Procedural Manual). The Committee noted that, even if this procedure comprised eight steps, it provided for an accelerated procedure under certain conditions whereby Steps 6 and 7 could be omitted, if agreed to by a two-thirds majority of the Commission.

71. The Delegation of Australia expressed concern that the above procedure would not enable the Commission to react expeditiously to recommend MRLs in the case of public health concerns and would require an exceedingly long period of time to cope with the backlog of work. The Delegation therefore submitted proposals for an abbreviated procedure. The Australian view was shared by other delegations and the Committee decided to give further consideration to both proposals.

72. Several delegations favored the Australian proposal. Others expressed the view that the existing procedure provided both for an accelerated procedure and for a more complete examination in cases when this was required. The Secretariat explained that after this Committee had decided on a procedure in the light of government comments, the elaboration procedure selected by the Committee should be submitted through the Committee on General Principles to the Commission for adoption and inclusion in the Procedural Manual. The Committee concluded that governments should be requested to examine carefully the two proposed procedures as contained in Appendix IV and submit their written comments to the next session of this Committee.

Acceptance Procedures

73. The Committee was informed that the acceptance procedures as proposed in the working paper followed the acceptance procedures for pesticide MRLs and that attention should be paid to specific aspects related to the scope of application outlined in the paper.

74. Several delegations wished to be informed on how MRLs could be accepted for cooked or otherwise processed products in view of the fact that the MRLs were, by definition, expressed on a fresh weight basis. The Chairman of the Committee suggested that either individual countries could develop appropriate conversion factors applicable to processed food or that this Committee could consider the elaboration of such factors in the future.

75. The Committee also considered whether the MRLs should apply to home-produced and imported foods, or to imported foods only. This aspect was of particular concern for products which contained residues of veterinary drugs not permitted or required for use in the importing country. The Committee concluded that governments should examine further the proposed acceptance procedures as contained in Appendix V and that following a further review in the light of comments received, the proposed procedure could be submitted to the Commission together with the proposed elaboration procedure.

76. The Committee noted that full acceptance of a Codex MRL meant that it would be equally applied to home-produced and imported products, whereas limited acceptance applied more specifically to imported products. However, it was important to recognize in this context that the Code of Ethics for International Trade specified that

restrictions on imported products should not be greater than those applying to home-produced products.

CONSIDERATION OF PROGRESS REPORT ON THE ELABORATION OF A GLOSSARY OF TERMS AND DEFINITIONS (Item 6)

77. The Committee had before it Working Paper CX/RVDF 87/8 - A Proposed Glossary of Terms for consideration by CC/RVDF prepared by the Delegation of Canada.

78. In introducing the Item the Delegation of Canada recalled that the First Session of the Committee had held the view that agreement on terminology and generally accepted definitions would facilitate the work of the Committee as well as provide guidance to regulatory agencies. The Delegation expressed its appreciation to a number of delegations which had provided constructive comments on a first draft of the glossary. These comments had been incorporated in the present version of the glossary which consisted of four specific sections. The Committee was requested to examine the terms included in the paper.

79. Several delegations held the view that some of the definitions deviated from definitions of the same terms in other Codex texts or were not in line with internationally recognized terminology, and that this should be corrected. The Committee expressed its appreciation to the Delegation of Canada which offered to continue its work on the Proposed Glossary of Terms and encouraged Member Countries to comment on the present text. The Secretariat was requested to assist in the harmonization of these definitions with existing Codex definitions. The Delegation of Canada requested that comments should be forwarded by 1 February 1988 and should contain the following information:

- the complete Codex definition proposed for consideration, including a reference, and,
- a statement on how this alternative definition would better serve the purposes of CC/RVDF.

80. The Committee agreed that consideration of the definitions for "Maximum Residue Levels" and "Good Practices in the Use of Veterinary Drugs" would be considered separately from the glossary of terms (see Items 5 and 7). It was agreed that the revised text of the Proposed Glossary of Terms would be distributed prior to the next session of the Committee.

CONSIDERATION OF "GOOD PRACTICES IN THE USE OF VETERINARY DRUGS" (Item 7)

81. The Committee had for its consideration document CX/RVDF 87/9 on the above subject which had been prepared by the Delegation of The Netherlands in cooperation with WHO and comments thereto from Ireland and the United Kingdom. The paper was introduced by the Delegation of the Netherlands, who stated that the effective control of residues began when the drug was approved for the market, and that the present paper was based on this approach. The paper, however, went beyond a simple definition and contained guidelines for the registration and marketing of veterinary drugs.

82. The Committee expressed its appreciation to the Delegation of the Netherlands and to WHO for the work contained in the paper.

83. Referring to the paper, the Delegation of the United Kingdom drew attention to additional matters of environmental safety and the safety of the product to farm workers

who might be exposed, over long periods, to splashes, spray mist or the fumes of drugs during their application. The Representative of FAO, referring to the problems of registration and marketing of veterinary drugs in developing countries, stated that a guideline along the lines of the present paper would be useful information for veterinary services in these countries, and noted that such information could be incorporated into the manual for the development of veterinary services currently under development by FAO.

84. The Secretariat drew attention to the responsibilities of the Joint FAO/WHO Food Standards Programme which, in principle, did not provide for recommendations concerning safety measures for the handling of chemicals by workers. These matters were the responsibility of the Joint WHO/UNEP/ILO International Programme on Chemical Safety.

85. The Committee followed the proposal made by several delegations to separate the issue contained in the paper and to consider a concise definition for "Good Practices in the Use of Veterinary Drugs" on the basis of the proposed definition in the Glossary of Terms (CX/RVDF 87/8), having regard also to definitions of "Good Animal Husbandry Practices" and "Good Veterinary Practices", where necessary. It agreed that good practices in the use of veterinary drugs constituted only one aspect of the two other definitions and that this Committee would only need to define good practices which were related to residue control.

86. At the request of the Chairman, a small working group (Canada, Federal Republic of Germany, Ireland, Swaziland, United Kingdom, and the United States) was convened to consider the available definitions. The Working Group proposed the following draft which was accepted by the Committee as a basis for further discussions:

"Good Practices in the Use of Veterinary Drugs (GPVD) is the official recommended or authorized usage approved by national authorities, of veterinary drugs under practical conditions in a manner that leaves toxicologically acceptable residues of the smallest amounts practicable."

87. Because this definition was essential to the further work of the Committee, the Committee decided to request government comments, and to consider it at its next session together with the definition for MRL (see paras. 64-69 and Appendix III).

88. Upon the proposal of the Delegation of the Netherlands, the Committee agreed that the title of the paper under discussion would be amended to read "Good Practices for the Registration and Marketing of Veterinary Drugs." The Committee concluded that content of the paper was similar to the matters which had been proposed by the Delegation of the United States for consideration in a code of practice or guideline text (see para. 11). The Committee agreed that such matters were outside its Terms of Reference and, in fact, those of the Food Standards Programme and referred the revised document (see Appendix XII) to the OIE, which had kindly offered to undertake further development of the text in cooperation with the relevant units of FAO and WHO, and taking into account comments made during this meeting. The Committee wished to be kept informed of progress.

SURVEY ON INTAKE STUDIES (Item 8)

89. The Committee recalled that, at its first session, it had discussed briefly the need to consider dietary intake studies in the context of its work and to review already existing international activities related to dietary intake studies (paras. 199-202 of ALINORM 87/31). The Committee had accepted the kind offer of the Delegation of the United States to carry out a survey of the available information in the Member Countries of the Codex Alimentarius Commission on the dietary intake of veterinary drug residues (para. 203 of ALINORM 87/31). The Delegation of the United States had elaborated a questionnaire for the above survey, and by circular letter (CL 1987/3; January 1987) Governments, participants at the First Session of the CC/RVDF, and Interested International Organizations had been asked to submit data as outlined in this questionnaire.

90. Replies to the circular letter were received from the following countries: Australia, Denmark, Egypt, Ireland, Italy, Japan, New Zealand, Norway, Sweden, Thailand, United Kingdom, and the United States. All the information received was assembled into two documents for discussion at the present session (CX/RVDF 87/10 - CRD 8; CX/RVDF 87/10 - CRD 3). The Delegation of the United States thanked all countries which submitted replies.

91. The Delegation of the United States requested further information from the Secretariat about the recommendation from the JMPR that FAO and WHO proceed through appropriate channels with the development of guidelines, to enable governments to make estimations of possible pesticide residue intake that could be compared to the ADI. The Committee was informed that an expert group meeting on this subject had been held in Geneva in October 1987, and that the report and other guidelines would be made available. It was noted that the original questionnaire for the survey might have been somewhat complicated and the Delegation of the United States therefore agreed to simplify it before reissuing it to all countries, to facilitate evaluation of the data.

92. The Committee agreed to continue to conduct the dietary intake survey for an additional year, since the Committee was not in a position yet to actually begin evaluating the data from dietary intake studies, and because additional information from countries which have not yet responded to the survey would be beneficial. The Delegation of the United States expressed its willingness to conduct the survey for an additional year.

CONSIDERATION OF CERTAIN OTHER MATTERS RELATED TO THE ELABORATION OF RECOMMENDED CODEX MRLS (Item 8a)

93. The Committee recalled that it had agreed earlier in the session to introduce this additional Item with the intent to examine the format for expressing Recommended Codex Maximum Residue Levels for Veterinary Drugs in Foods and to consider the recommendations for the six substances evaluated by the 32nd session of JECFA.

94. The Committee considered it important to decide early in its work on the format in which these recommendations should be presented within the elaboration procedure to governments for comments and ultimately be published following their adoption by the Codex Alimentarius Commission.

95. The Committee agreed that the format should include the following details:
1. Name of Veterinary Drug
 2. Acceptable Daily Intake for the Drug (as established by JECFA)
 3. Commodity (for example: beef muscle) - MRL
Commodity (for example: beef liver) - MRL
 4. Definition of the Residue on which the MRL was set
 5. References to Recommended Method(s) of Analysis (when available)
 6. References to JECFA reports
 7. References to Previous Codex Publications
96. The Committee decided that the recommended residue levels for the six substances contained in the Summary Report and Conclusions of the 32nd Meeting of JECFA (CX/RVDF 87/6) should be submitted to governments for comments at Step 3, suitably amended in accordance with the decisions of the Committee regarding terminology. The Committee also agreed that this decision would not prejudice further consideration of the elaboration procedure by this Committee. The proposed draft MRLs are contained in Appendix VI to this report.
97. The Committee noted that this would allow governments to prepare their comments in the light of this report as well as the report of JECFA when published officially in the WHO Technical Report Series.
98. In discussing the footnotes explaining the JECFA recommendations, several delegations wished to have an explanation of the assumed intake of 500 g of meat by a 70 kg person (footnote 4) in the light of comments from the Delegation of the United States that, as a general rule for calculating MRLs, a dietary intake of 500 g of total animal derived products (excluding eggs and milk) should be used. Several delegations questioned whether this amount reflected world-wide dietary habits correctly, since these varied widely. In referring to the footnote, the Secretariat explained that this was a pragmatic but conservative approach, based on a higher than average consumption in the highest meat-consuming countries. The Committee agreed with the approach taken by JECFA in the present situation and recognized that it might have to be modified in the light of further information on dietary intakes and in respect of certain commodities, and, particularly, to take account of extreme intakes.
99. Referring to the draft MRLs proposed by JECFA, the Delegation of Sweden felt it was important to make allowance for metabolites in the MRLs. It was noted that these had been expressed specifically in the MRLs in the case of trenbolone acetate, and that metabolites had been considered during the evaluation of all substances. The Delegation of Sweden was of the opinion that, in addition to the consideration of fresh products, it was necessary to examine metabolites which were formed during the further processing of foods of animal origin.
100. The Representation of WHO informed the Committee that bound residues were a matter for consideration by JECFA. The Chairman added that with certain substances transformation products could be formed already during the process of manufacturing a medicinal product (e.g., formation of isomers from chloro-tetracycline during pelleting).

CONSIDERATION OF METHODS OF ANALYSIS AND SAMPLING: REPORT OF AN AD HOC WORKING GROUP (Item 9)

101. The Chairman of the Ad Hoc Working Group on Methods of Analysis and Sampling, Dr. R. Ellis (U.S.A.), reported on the accomplishment of its first meeting held on 27 November 1987 in conjunction with the Second Session of the CC/RVDF. Delegates and observers from Australia, Canada, People's Republic of China, Cuba, The Federal Republic of Germany, Ireland, The Netherlands, New Zealand, Poland, Sweden, Switzerland, United Kingdom and the United States, Officers of the Joint FAO/WHO Secretariat, and observers of the Association of Official Analytical Chemists (AOAC) had been present. The Chairman and the FAO/WHO Joint Secretariat had informed the Working Group of its status vis-à-vis the Committee and its Terms of Reference. They had emphasized the function and importance of the Working Group for developing criteria, elaborating methods of analysis and sampling for the determination of residues of veterinary drugs in foods, and identifying analytical methods satisfying these criteria for substances of interest to CC/RVDF.

102. The Working Group had reviewed and commented on two working papers prepared under the guidance of the Chairman. Regarding the first paper, "Criteria for Analytical Methods", there was broad acceptance of the paper, developed as a framework for general criteria. It was agreed that three additional points would be elaborated on in the paper - issues related to use of internal standards for analytical methods, more explicitly, comment on commercial test kits for information regarding performance characteristics of such procedures and commercial availability of necessary reagents, and the role of standard reference materials for the validation of analytical methods for compounds of interest to the CC/RVDF and evaluated by JECFA. The Working Group had also emphasized the necessity of characterizing analytical methods by their attributes to give broadest consideration to the scope of analytical methods to be considered by the Working Group for specific substances of interest to CC/RVDF. This paper will be issued as a working paper for the next session of this Committee.

103. Concerning the second working paper, "Sampling for the Control of Veterinary Drug Residues in Foods" (to be issued as a working paper for the next session of this Committee), the Chairman noted that broad acceptance was achieved on the general concepts presented. It was decided that the title should be modified to note that sampling procedures are developed for determining residue levels in foods. Accordingly, the title was amended to "Sampling for the Determination of Residues of Veterinary Drugs in Foods." This emphasized the attitude of the Working Group to harmonize activities with related Codex Committees such as CCPR. The Working Group had agreed to refine certain technical definitions on sampling for the working paper and following agreement by the Working Group, to submit them to the Canadian delegation for inclusion in the Glossary of Terms developed for CC/RVDF (see Item 6). The Working Group had decided to take advantage, where appropriate, of the sampling instructions adopted by CC/MAS and papers being considered by CC/PR, for consistency and to harmonize as much as practical on sampling procedures between the Codex Committees.

104. The Committee agreed that comments on both papers would be sought and these would be incorporated into the respective working papers for consideration by the Working Group and subsequently by the third session of CC/RVDF for adoption.

105. The Committee agreed with the Ad Hoc Working Group that publishing methods of analysis for compounds of interest to CC/RVDF was an important consideration in its

activities. It was agreed that regardless of where and how methods were published, methods should generally be characterized by their performance characteristics rather than their use, to facilitate their selection by national authorities according to their situation and requirements. Consideration would be given to the experiences and mechanisms of the CCPR and other Codex Committees for publishing methods as well as publication in recognized journals to ensure the broadest awareness of such methods. The Committee further agreed with the Working Group that designating reference methods would be an important consideration in such publications for those substances considered important to CC/RVDF.

106. The Working Group had identified as a high priority, the development of criteria for reference methods intended for use in settling international disputes and the Committee assigned the responsibility to draft such criteria, to the delegations of Australia, the Netherlands, and the United States. High priority was also given to specific criteria that may be applied to analyses for chloramphenicol residues.

107. Seven work assignments were agreed to by the Working Group for its consideration. These working papers will become part of the work for its next meeting. The documents are (1) a definition of terms for limit of detection and limit of determination to be prepared by Australia, the Netherlands, United Kingdom, and United States; (2) a summary of general principles for evaluated analytical methods to be prepared by the United States; (3) a paper assigned to the Federal Republic of Germany unifying the criteria for evaluation of analytical methods that have been considered by the 32nd JECFA, or included in the Procedural Manual and the two working papers considered by the Working Group; (4) a document describing procedures and attributes for classifying analytical methods to be prepared by the United States; (5) a paper on considerations of using standard reference materials in the validation of methods, to be prepared by the Netherlands and United States; (6) a draft of definitions of technical terms used in sampling to be prepared by the United States; (7) a draft of specific criteria for reference methods to be prepared by Australia in collaboration with the Netherlands and United States.

108. The Committee agreed with the following recommendation of the Ad Hoc Working Group:

- (1) To seek information on developing statistical sampling plans for residue control programmes of veterinary drugs in foods with the assistance of the Joint FAO/WHO Secretariat (coordinated by the United Kingdom, assisted by the Netherlands and Australia). The Working Group shall consider these data in finalizing its working paper on methods of sampling for the determination of residues of veterinary drugs in foods.
- (2) To request that the Secretariat distribute a paper to be prepared by the delegation of the United States on general principles for the evaluation of analytical methods.
- (3) To seek information from Member Countries on preferred means of publishing the availability of analytical methods for substances of interest to CC/RVDF and evaluated by JECFA. This should be accomplished by Circular Letter through the Secretariat.
- (4) To continue the activities of the Ad Hoc Working Group on Methods of Analysis and Sampling.

REVIEW OP PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION
(Item 10)

109. The Committee had before it working paper CX/RVDF 87/11, which had been issued as a Conference Room Document, concerning the priority list of veterinary drugs requiring evaluation. The Committee recalled its decision to maintain the priority list under review at each session in the light of comments from governments and international organizations. A Circular Letter (CL 1987/12) had been issued which had listed the priority list established by the First Session of the Committee and had drawn attention to the Criteria for the Selection of Veterinary Drugs for the Establishment of Acceptable Residue Levels (para. 150 of ALINORM 87/31).

110. Replies to the Circular Letter had been received from Australia, Canada, Cuba, France, Ireland, Norway, Poland, Sweden, Thailand, United Kindom and the United States. As summarized in the above paper the Chairman of the Committee stated that the comments in general supported the priority list contained in para. 196 of ALINORM 87/31,

111. The Committee decided to retain the classes of drugs contained in the previous list, except for chloramphenicol and growth promoting (anabolic) agents which had been considered by JECFA (see Item 4). However, it decided to indicate in connection with each class those specific substances which it considered should be evaluated by JECFA as soon as possible. The Committee reaffirmed the selection criteria (para. 150 of ALINORM 87/31) and decided to provide information according to these criteria for inclusion in the report. It also agreed that any future proposals for inclusion in the priority list should be accompanied by a summary statement addressing the priority criteria, as applicable.

112. The Delegation of China proposed a large number of substances for inclusion into the list similar to the proposals submitted to the First Session of the Committee.

113. The Delegation of Australia proposed that the benzimidazole class be considered and, in particular, that albendazole be included in the priority list. It offered to provide the supporting data (see Appendix VIII). This was supported by several delegations and agreed by the Committee.

114. The Delegation of Senegal expressed regret that JECFA had to limit the number of compounds for evaluation at its 32nd Session and proposed not to add new compounds to the list. The Committee recalled that more information was now available on the frequently used trypanocides. The Delegation of Senegal, supported by other delegations from the African region, confirmed that two substances, namely diminazene and isometamidium, were of utmost importance. The Committee decided to include these in the priority list.

115. Several delegations proposed inclusion of oxytetracycline in the priority list, mainly because of the occurrence of multiple resistance phenomena. The Delegations of the United States and France informed the Committee that studies on the occurrence of resistance were being carried out currently and proposed that this substance should be included after their results become available. This was supported by the Delegations of Botswana and Senegal.

116. The Delegation of the Netherlands proposed to add ivermectin to the priority list, and this was supported by a number of delegations. The Delegation from Ireland identified ivermectin as a drug requiring future attention for reasons of their wide use,

extreme potency and slow elimination. The Delegation informed the Committee that ivermectin was licensed in most European countries. Other Delegations were of the opinion that drugs containing ivermectin were thoroughly reviewed and that conditions of their safe use had been established. The Committee considered as a general issue whether the priority list should be limited to the number of substances which could probably be evaluated by an expert committee in one session (about 10-12 substances) or whether it should be more extensive. The Committee agreed to the latter provided the selection criteria were complied with.

117. With this in mind the Committee noted the requests by the Delegations of Poland and the People's Republic of China for an evaluation of diethylstilbestrol.

118. The Delegation of Denmark reminded the Committee of the lengthy discussion on β -lactams at its first session. The Delegation informed the Committee that it was considering to propose the evaluation of the β -lactams at the next session, since scientific investigations were now at an advanced stage. The Committee decided to append a supporting statement to the report of this session.

119. The Committee agreed that the revised priority list should be as follows:

- Sulphonamides (sulphamethazine, sulphathiazole)
- Nitrofurans (furazolidone, nitrofurazone)
- Nitroimidazoles (dimetridazole, ipronidazole, ronidazole and metronidazole)
- Quinoxaline-di-N-oxides (carbadox, olaquinox)
- Trypanocides (diminazene, isometamedium)
- Benzimidazoles (albendazole)

120. The Committee reiterated its decision to review and revise, if necessary, at each of its sessions the priority list in the light of comments from governments and international organizations.

CONSIDERATION OF A FIRST DRAFT OF A CODE OF PRACTICE FOR THE USE OF VETERINARY DRUGS (Item 11)

121. The Committee had before it document CX/RVDF 87/12, which contained the text of the above draft Code, prepared by the United Kingdom. The paper was introduced by the Delegation of the United Kingdom who pointed out that the draft was essentially based on a Code already being implemented in the United Kingdom which was directed to farmers. If necessary, a second part of the Code, dealing with advice to veterinarians, would have to be elaborated. At present, a survey was being carried out on the use of the Code to obtain information on its applicability and this may lead in turn to amendments to the Code.

122. The Delegation of the United Kingdom stated that the draft code reflected the situation in its country with regard to the distribution and application of veterinary drugs, a number of which could be handled by the farmer, and noted, however, that other countries might have a more restrictive system. The Delegation of the United Kingdom was of the opinion that sections 3-10 of the draft code could form the basis for a definition of good animal husbandry practice.

123. The Delegation of the Federal Republic of Germany expressed reservations to go along with several aspects of the philosophy underlying the document prepared by the Delegation of the United Kingdom. Points of particular concern were that:

- the impression could arise that unbalanced responsibility for the safe use of animal drugs was given to the farmer, whereas the main responsibility should rather remain on the side of the veterinarian;
- drugs, such as vaccines, hormones, and the majority of the substances listed in the priority lists submitted by the Member Governments should be administered to the animals exclusively after a thoroughly performed diagnosis given by a veterinarian;
- substances such as those mentioned above should only be available on prescription or directly from a veterinarian;
- currently used drugs include a significant number of potentially hazardous substances for which, as in the case of chloramphenicol, future sessions of JECFA might not be able to allocate ADIs and/or MRLs and that these substances should never be in the hands of inadequately educated personnel;
- special risks could arise from the improper diagnosis and treatment of contagious animal diseases.

124. The Delegation of the Federal Republic of Germany expressed its expectations that the Committee would consider any measures:

- to encourage the proper use of drugs (e.g. adequate dosing of efficacious, carefully selected drugs following an expert's diagnosis);
- to limit the use of drugs to the necessary extent in order to prevent residue formation to the largest extent;
- to reduce unavoidable residues to safe and, where appropriate, the lowest possible levels.

125. The Committee noted an error in the French translation and decided that the term "medicament" should be used in lieu of the term "drogue".

126. Several delegations expressed the view that not all of the provisions included in the present draft code were applicable on a world-wide basis and might create difficulties if they were issued to governments in the finalized document.

127. The Delegation of Italy felt that not enough was known about the distribution and administration of veterinary drugs in individual Member Countries and proposed that appropriate information was sought. To facilitate the evaluation of such data, the Delegation of Italy proposed a format of a questionnaire related to registration, source of distribution, storage, prescription requirements, administration and control of withdrawal times.

128. The Committee thanked the Delegation of the United Kingdom for preparing the paper and concluded that the elaboration of this document was an important issue but agreed that it was possibly outside the terms of reference of the Committee. The Committee noted that some aspects of this Code could be related to the proposed draft Code of Practice on the Registration and Marketing of Veterinary Drugs, which the Committee had referred to OIE for further elaboration (see para. 88). It agreed that a Code of Practice on the Control of the Use of Veterinary Drugs to meet the requirements of the MRL's remained an important topic for its own consideration. It requested the Delegation of the United Kingdom to prepare a first draft of such a Code which would

cover all aspects relating to good animal husbandry and veterinary practices, but which would be laid out in general terms so that it would be applicable in all circumstances.

OTHER BUSINESS (Item 12)

129. In view of the considerable number of items raised under the Item, the Committee decided to reverse the order of items and to consider the original Item 12, "Programme of Work and Work Assignments" after "Other Business".

List of Compounds Prohibited for Use in Veterinary Medicine

130. The Delegation of the Federal Republic of Germany proposed that the Committee should consider the establishment of a list of compounds which should not be licensed for use in veterinary medicine. Such a list could include, for example, stilbenes or chlorinated hydrocarbons. It was of importance to arrive at a worldwide agreement especially for substances which had an environmental impact. The Delegation of Sweden wished to extend the list to cover teratogenic and carcinogenic substances.

131. The Delegation of Canada drew attention to the difficulty of establishing a world-wide applicable list since conditions varied in different countries, requiring an accurate risk/benefit analysis in each case. This view as supported by the delegations of Australia and the United Kingdom.

132. The Delegation of Botswana expressed the view that it might be useful to circulate a list of restricted or banned drugs for the information of Member Countries.

133. The Delegation of the Federal Republic of Germany acknowledged the points made by Canada and agreed that these problems might have to be resolved at the national level, and that the Committee could consider it further after having gained more experience.

Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods

134. The Committee recalled that it had agreed earlier in the session to consider a Working Paper containing the above guidelines prepared by the United States. (See para 11).

135. In introducing the document, the Delegation of the United States expressed the opinion that the development of such guidelines was within the Committee's terms of reference and that such guidelines would be beneficial to countries in the process of developing or establishing food control programmes. The Delegation offered to continue to work on this draft, if the Committee decided that these guidelines should be elaborated, and suggested that the paper should be appended to the report.

136. Several delegations requested further explanations to the paper, and, in particular, to the requirement that national control programmes should be able to demonstrate the effectiveness of their food control infrastructure. The Delegation of Kenya was of the opinion that the prerequisites for a control programme, i.e. means for sampling, methods of analysis and interpretation of results of low level residues were not available in many countries, and these residues could therefore not be monitored.

137. The Delegation of Egypt referred to the problems of importing countries which did not have a well developed control system to examine food consignments suspected to be unfit for human consumption. The Delegation drew attention to the need in those countries for equipment, training and standard reference materials.

138. The Delegation of Peru stated that educational aspects were not included in the draft guidelines. The need for training was supported by the Representative of FAO, who referred to the FAO Manual for the Development of Veterinary Services under preparation which could be made available to the author of guidelines. The Committee was also informed of the availability of guidance on quality control of foodstuffs, for example, FAO/WHO/UNEP Guidelines for the Development of Effective National Food Control System.

139. The Committee noted that a regulatory programme for control of veterinary drug residues in foods was implemented in the United States and that its major aspects had been taken into account in the above paper.

140. The Committee thanked the Delegation of the United States for the preparation of the paper and accepted the kind offer of the United States to revise the document in light of the above comments concerning this subject.

141. It was agreed that the revised document would be distributed for comments prior to the next session of the Committee.

Matters of Concern to Countries of the African Region

142. The Delegation of Senegal made the following statement: "During the examination of Item 3 of the agenda the Delegation of Senegal raised a question of particular interest for countries of the African region. This question it recalled referred to paragraph 169 of document CX/RVDF 87/2 entitled Matters Arising from the Seventeenth Session of the Codex Alimentarius Commission and its Committees.

143. "The Delegation noted that the paragraph cited referred to specific problems linked to studies of residues of veterinary drugs encountered in Africa and also to the decisions taken by the Joint FAO/WHO Codex Alimentarius Commission responsible for food standards. These decisions covered the following points:

- a) The recognition of the priority to be accorded to trypanocides and the inclusion of these products on the priority list of veterinary drugs; a satisfying response for the countries most concerned.
- b) The organization of seminars or workshops to assist African countries to resolve problems of their own.

"Concerning the second point, the Delegation requested the Committee to take a concrete decision; in other terms it proposed to the Committee to designate a country which, in collaboration with the Codex Alimentarius Commission, could undertake necessary consultations for the preparation of such seminars or workshops."

144. This statement was supported by the Delegations of other African countries present.

145. The FAO/WHO Secretariat drew attention to the current budgetary difficulties facing the United Nations and its Specialized Agencies, which meant that the organization of such seminars or workshops was now more difficult than in previous years. Nevertheless, it might prove possible to hold a short workshop on this and other related matters in connection with the Sixth Session of the Codex Coordinating Committee for Africa, scheduled to be held in Cairo in the second half of 1988. Prospects for more lengthy seminars or training courses would most likely depend on the availability of resources from external donors.

146. The Observer from OIE informed the Committee that the OIE General

Conference for African Countries was held every two years and that it might be possible to hold a workshop or seminar in connection with the conference. He noted, however that delegates to the Conference were not always the same people responsible for the control of residues of veterinary drugs in foods, especially at the technical level. He suggested in this case that other agencies could be invited to sponsor, in cooperation with OIE, such a meeting and participate in its organization.

147. The Committee supported the proposals of the Delegation of Senegal, but recalled that the Codex Alimentarius Commission, under its terms of reference could not sponsor or arrange such meetings. It welcomed the idea put forward by the Observer from OIE and re-affirmed its previous opinion that the responsible organizations should make endeavours to assist the countries of the African region in the control of residues of veterinary drugs in foods.

PROGRAMME OF WORK (Item 13)

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

- Consideration of MRLs arising from the 32nd Session of JECFA, at Step 4
- Format for the Presentation and Publication of MRLs
- Definitions for the purpose of the Codex Alimentarius Commission
 - a) Maximum Residue Level
 - b) Good Practice for the Use of Veterinary Drugs
- Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs to Meet MRLs (United Kingdom)
- Procedures for the Elaboration and Acceptance of Codex MRLs
- Glossary of Terms (Canada)
- Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods
- Priority List of Veterinary Drugs Selected for Evaluation
- Progress report on the survey of intake studies (U.S.A.)
- Progress report on the Compendium of Veterinary Products (U.S.A.)
- Report of the Ad Hoc Working Group on Methods of Analysis and Sampling.

149. The Committee noted the Brazilian proposal to elaborate at a future session:

- i) Development of studies with the purpose of creating a table for animal food additives (dyeing, pigments, growth promoters and others).
- ii) Development of studies for the adoption of a programme to control the amounts of veterinary drugs in general foods that take into due consideration the economic conditions of developing countries.

150. The Committee reiterated its opinion that given the very large number of veterinary drugs that needed to be considered, the establishment of a separate expert committee was desirable, or at least frequent meetings of JECFA should be held and coordinated with the timing of the sessions of this Committee.

DATE AND PLACE OF THE NEXT SESSION (Item 14)

151. The Committee was informed that the Government of the United States offered to host the Third Session of the Committee in late October 1988 in Washington, D.C. Several delegations expressed the view that the next session of this Committee should be scheduled to be held after the next JECFA dealing with the evaluation of veterinary

drugs. The Committee recognized that additional time was required to make the JECFA data available to Governments prior to being considered by this Committee.

152. The Committee agreed with the Chairman that every effort should be made by FAO and WHO to anticipate the date of the next session of JECFA (Veterinary Drugs) but that, in any case, the matters proposed for the next agenda, justified holding the Third Session of this Committee in October 1988; the exact date would be communicated in due course.

SUMMARY STATUS OP WORK

Standard/Code	Step	For Action by	Document Reference
Proposed Draft MRLs for Veterinary Drugs in Foods	3	Governments	ALINORM 89/31, (para. 96) and Appendix VI
Review of Priority List of Veterinary Drugs Requiring Evaluation	-	(a) 33rd JECFA (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 109-120) and Appendix VIII
Compendium of Veterinary Drugs for the Americas (I and II)	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 48-54); CX/RVDF 88/... ¹
Glossary of Terms and Definitions	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 77-80); CX/RVDF 88/... ¹
Methods of Analysis and Sampling for Determination of Veterinary Drug Residues in Foods	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 101-108); CX/RVDF 88/... ¹ (two papers)
Intake Studies on Residues of Veterinary Drugs in Foods	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 89--92); CL 1987/3; CX/RVDF 88/... ¹
Code of Practice for the Use of Veterinary Drugs	-	(a) U.K. (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 121-128); CX/RVDF 88/... ¹
Definition for "Good Practices in the Use of Veterinary Drugs"	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 81-88) and Appendix III
Definition for "Maximum Residue Level"	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 64-69) and Appendix III
Procedures for the Elaboration and Acceptance of Codex MRLs	-	(a) Governments (b) 3rd CC/RVDF	ALINORM 89/31 (paras. 70-76, 93-100) and Appendices IV and V
Good Practices for the Registration and Marketing of Veterinary Drugs	-	(a) OIE (b) FAO/WHO	ALINORM 89/31 (para. 88) and Appendix VII
Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods	-	(a) U.S.A.	ALINORM 89/31 (paras. 134-141); CX/RVDF 88/... ¹

¹ - Working paper to be prepared for discussion at the 3rd CC/RVDF.

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REMARKS BY

FRANK E. YOUNG, M.D., PH.D., COMMISSIONER OF FOOD AND DRUGS

Good morning and welcome to the United States. It is a pleasure for me to open this Second Session of the Codex Committee on Residues of Veterinary Drugs in Foods. The Codex Alimentarius Commission is truly a unique organization which serves two vital functions in the international community -first it facilitates international trade in food by helping to harmonize national differences in import requirements and second, Codex serves as an example of how nations can cooperate, putting political concerns aside and working together objectively to resolve difficult public health issues.

The significance of veterinary drug residues in foods is rapidly becoming an issue of intense international concern and debate. The formation of a new Codex committee to deal specifically with residues of veterinary drugs illustrates the growing importance of this area internationally. This is further highlighted by the great number of countries attending this meeting today and by the caliber of each country's representatives.

The world needs a forum where international disputes can be settled in an impartial, non-political manner. Your Codex Committee is the internationally recognized forum for resolving such important food safety issues and your hard work and dedication over the last year has demonstrated that Codex can be a rapid as well as impartial and effective mechanism for resolving difficult international public health questions. This Committee has accomplished a great deal in a short amount of time and all of you here should be commended for making this possible, and for setting an example of international cooperation.

FDA ROLE IN CODEX

The FDA has been a very active participant in Codex since its inception and in fact Mr. John L. Harvey, FDA Deputy Commissioner, was the Chairman of the First Meeting of the Codex Alimentarius Commission, which was held in July 1963. Since that time Codex has given regulators from all parts of the world the chance to discuss common problems and learn from each other. It has given scientists the opportunity to freely share their findings. And it has given business people from around the world the chance to discuss their trade problems with regulators and to transfer technology in an informal, non-competitive atmosphere.

The FDA strongly supported the formation of this Committee on Residues of Veterinary Drugs in Foods. I was pleased that the United States became the host country under the very able leadership of Dr. Lester Crawford, with whom I have worked very closely, both when he was at FDA and now in his present position at USDA.

WHO SUPPORT

As the United States representative to the Executive Board of the World Health Organization, I have spoken out strongly for a continued commitment on the part of WHO to the work of Codex. I have also taken every opportunity to affirm the United States¹ support for the current level of financial support provided by WHO to the Joint FAO/WHO Food Standards Programme.

I also supported a WHO Executive Board Resolution encouraging countries to make greater use of Codex Standards and Codes of Practice.

In this role, I have had the pleasure of working closely with Dr. Donald Houston, the U.S. Coordinator for Codex activities, and I would like to commend him today on the fine job he has done in this very demanding position.

ANIMAL DRUG RESIDUES

The growing challenge to secure wholesome food of animal origin in quantities sufficient to feed the ever increasing world population leads to the compelling need to search for means of enhancing productivity in animal husbandry. However, such an endeavour often involves the use of physiologically, pharmacologically, and toxicologically potent substances. In countries with large scale animal production, a high percentage of animals are exposed at one time or another during their life-span to various chemicals, such as drugs to prevent or cure diseases and feed additives to increase feed efficiency or to promote growth. As agricultural production is increasingly becoming an industrial operation all over the world, the introduction of new substances into food animals will certainly continue.

In recent years, concern over the presence of drug residues in edible products derived from food-producing animals has rapidly grown and is still growing. This concern is not limited to the scientific community; consumers all over the world have, through various means, expressed their sincere desire for a food supply free from potentially unsafe levels of chemicals. American consumers have certainly not been shy in letting their regulators know how they feel about drug residues in meat.

FDA PLAN OF ACTION

When I became Commissioner in 1984, I was given a mandate to prepare the FDA not just to meet the challenges of today but to be ready to address those of the 21st century. I have done this by identifying important initiatives in the form of an Action Plan. The FDA is about to embark on the implementation of the second phase of this Action Plan. One of the major initiatives in this eleven point plan is veterinary product safety, and the major thrust of this initiative is in the area of residues of veterinary drugs in foods.

As you all may know, a major responsibility of the FDA is to assure that meat, milk, and eggs derived from animals treated with veterinary drugs will be free from potentially harmful or otherwise illegal residues. These responsibilities are fulfilled by FDA's Center for Veterinary Medicine (CVM) under the very excellent leadership of Dr. Gerald Guest. Dr. Guest also serves as the United States delegate to your Codex Committee.

CVM has taken the lead in establishing an interagency regulatory task force to identify and characterize tissue residue problems and to function as a steering group for focused review of prevention and resolution strategies. The task force will define and characterize sources of residues, products most commonly affected, and producer and processor practices that may lead to high risk animals, likely to contain violative residues.

As part of the tissue residue programme, CVM will develop and implement a plan for tissue residue prevention, complementing these efforts will be the development of an extensive, broad-based programme of intramural and extramural research, focused on developing new and/or improved analytical methods for detection, characterization, and quantification of residues of significant animal drugs in meat, milk, and eggs.

Thus, under Action Plan Phase II, CVM will be undertaking major new initiatives in the regulation of animal drugs and feed additives, designed both to serve animal health needs and assure the production of abundant and wholesome animal-derived food products for consumers. I hope that the impact of this major initiative by FDA will be felt both on an international level as well as nationally.

Many other nations have also taken steps to control the use of veterinary drugs, but the rules vary widely from country to country. These differences among nations may present difficulties in international trade: for example, when one country allows the use of a drug or hormone, it may not be able to export its products to a country which prohibits the use of that drug if they contain detectable residues. The use of increasingly more sensitive methods of analysis can inhibit trade to those countries that impose a very low tolerance for certain residues. It is our responsibility to work to ensure that national trade policies reflect the best science, and that unwarranted trade barriers are not erected as a result of our failure to share and reach consensus on important scientific issues related to food safety. We at FDA stand ready to share our expertise and to learn from others in a free and open exchange.

ACCOMPLISHMENTS OF THE COMMITTEE

The Codex Alimentarius Commission is the internationally recognized forum for resolving such food safety issues which become food trade issues. More and more the world will be looking to your Committee for guidance in these international disputes. The safety evaluation of veterinary drug residues share many features with the evaluation of other chemicals, such as food additives and residues of pesticides, and you will certainly be able to build upon the work of other Codex committees in those areas.

Your Committee has accomplished a great deal in the past year. The establishment of criteria for the selection of priority drugs and agreement on a priority list have been the key to your success so far. These steps enabled the Joint Expert Committee to meet in a relatively short amount of time to consider drugs which your Committee identified as a high priority to both public health and to international trade.

In this regard I would like to commend the Joint Expert Committee on Food Additives which met in June 1987 to evaluate anabolic agents and chloramphenicol. The very thorough evaluation of these compounds by this Committee and the very rapid publication of a summary of their findings demonstrates that this Committee can be a very effective, impartial mechanism in which disputes over the public health significance of veterinary drug residues can be worked out in.

COMMITTEE PLANS

To develop and maintain a sound regulatory system requires considerable scientific expertise and financial resources. Many countries are not in a position to establish a comprehensive system to evaluate and regulate veterinary drugs. In such countries neither the public health nor animal production are adequately served. In addition to public health concerns within their own boundaries, countries without adequate regulatory controls also face commercial disadvantages, since the significance of residues in international trade in food of animal origin is rapidly increasing.

An international organization such as the Codex Committee is in a unique position to help resolve these problems by identifying minimal requirements which veterinary drugs have to fulfill before they can be admitted to the marketplace. In looking at your very ambitious agenda for the week, I am pleased to see that you have targeted

the important issue of establishing standards of practice for the proper use of veterinary drugs. Within the framework of a solid national regulatory system, codes of practice for users of veterinary drugs can be very helpful in deterring unintentional misuse. By focusing on procedures to achieve the lowest residue content possible and on appropriate measures to control residues, this effort may prove to be one of your Committee's most significant contributions to food safety.

Another important task of your Committee will be to establish procedures for the selection of analytical methods and sampling for veterinary drugs. As I mentioned previously, this is a high priority here in the United States and I look forward to the report of your Ad Hoc Working Group on Methods of Analysis and Sampling.

Additionally, it is essential to undertake studies to measure the actual exposure of the consumer to veterinary drugs. Your Committee has taken a tremendous step forward in this area by conducting a survey on dietary intake of veterinary drug residues. I understand that several of you participated in this survey, submitting large amounts of information. This survey will form the basis for the Committee's dietary intake studies and will give assurances to all nations that the levels which you set for residues of veterinary drugs are safe.

Another important task for all of you this week will be agreement on procedures for the establishment and implementation of recommended Codex residue levels of veterinary drugs in foods. By establishing a solid framework of procedures, your Committee will be able to work more effectively in the coming years on your important goals.

CONCLUSION

In summary, 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 food trade issues that are also food safety issues. In the future, much of the most important work of Codex will be accomplished by committees such as this and by all of you here today. There is a great deal of expertise gathered here today and it is to everyone's advantage to work together to review veterinary drug use, set guidelines for appropriate use, and establish internationally acceptable limits on residues of veterinary drugs in foods. Good luck to all of you as you proceed to meet these challenges.

Thank you.

DRAFT DEFINITIONS OF "MAXIMUM RESIDUE LEVEL" AND "GOOD PRACTICE
IN THE USE OF VETERINARY DRUGS"

For the purpose of the Codex Alimentarius:

"Maximum Residue Level (MRL) is the maximum level of residue resulting from the use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any direct or indirect toxicological hazard for human health.

It is established on the basis of an ADI or, where this is not possible because of insufficient scientific knowledge, on the basis of a temporary ADI that utilizes an additional safety factor.

It takes into account factors such as resistance promotion, allergenic potential and other undesirable side effects, whether direct or indirect, for human health.

The MRL may be reduced to accommodate residues that originate in food of plant origin and/or the environment. It may also be reduced to be consistent with good practices in the use of veterinary drugs to the extent that practical analytical methods are available. The concentration is expressed on a fresh weight basis".

"Good Practices in the Use of Veterinary Drugs (GPVD) is the official recommended or authorized usage approved by national authorities, of veterinary drugs under practical conditions in a manner that leaves toxicologically acceptable residues of the smallest amounts practicable. "

PROPOSED PROCEDURES FOR THE ELABORATION OF CODEX
RECOMMENDATIONS FOR
MRLS OF VETERINARY DRUGS

A. **PROPOSED PROCEDURE FOR THE ELABORATION OF CODEX**
RECOMMENDATIONS FOR MRLS OF VETERINARY DRUGS (EXTRACT
FROM CX/RVDF 87/7)

STEPS 1, 2 and 3:

The Secretariat distributes the draft recommendations for MRLs for veterinary drug residues, based on JECFA evaluations, and requests comments from governments and interested international organizations on all aspects, including possible implications of the draft recommendations for maximum limits on veterinary drug residues on their economic interests.

STEP 4:

The CC/RVDF examines the recommendations for MRLs for veterinary drug residues, in the light of comments. The Codex Committee, when formulating its recommendations for proposed draft Codex MRLs, takes all appropriate matters into consideration including the need for urgency, the government comments at Step 3 and the likelihood of new evidence becoming available in the immediate future and, on the

basis of such considerations, indicates to the Commission those proposed draft MRLs which, in its view, need to be passed through the full Procedure and those for which there might be an omission of Steps 6 and 7, it being understood that any MRL at Step 5, for which it has been recommended that Steps 6 and 7 could be omitted or any MRL at Step 8 shall be dealt with by the Commission in accordance with the Guide to Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards.

STEPS 5-8:

As for the Procedure for the Elaboration of World-wide Codex Standards, Codex Alimentarius Procedural Manual, Sixth Edition, (pages 39 to 41).

MRLs should be presented to Governments for comments and/or acceptance in the following format:

1. Name of Veterinary Drug
2. Acceptable Daily Intake for the Drug (as established by JECFA)
3. Commodity (for example: beef muscle) - MRL
Commodity (for example: beef liver) - MRL
4. Definition of the Residue on which the MRL was set
5. References to Recommended Method(s) of Analysis (when available)
6. References to JECFA reports
7. References to Previous Codex Publications.

B. PROPOSED PROCEDURE FOR THE ELABORATION OF RECOMMENDED CODEX MAXIMUM RESIDUE LEVELS OF VETERINARY DRUGS IN FOODS (AUSTRALIAN PROPOSAL)

STEP 1"

The Secretariat distributes the draft recommendations for maximum residue levels for veterinary drug residues, based on JECFA evaluations, and requests comments from Governments and interested International Organizations on all aspects, including possible implications of the draft recommendations for maximum levels on veterinary drug residues on their economic interests.

STEP 2:

The JECFA recommendations and written country comments are considered by CC/RVDF. If there is general agreement, the recommendations are forwarded to the Commission for adoption. If there are unresolved technical arguments then these are returned to JECFA (Step 1) for resolution during which the recommendations are held at Step 2 pending further consideration.

STEP 3:

Recommended Codex MRLs are published and sent to all member countries. Countries notify their acceptance and when a sufficient number of acceptances have been received, the Commission has them printed as international standards.

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APPENDIX V

PROPOSED PROCEDURE FOR THE ACCEPTANCE OF RECOMMENDED CODEX
MRLS FOR VETERINARY DRUGS IN FOODS
(Extract from CX/RVDF 87/7)

The following acceptance procedure is proposed:

1. A Codex maximum level for veterinary drug residues may be accepted by a country in accordance with its established legal and administrative procedures in respect of the distribution within its territorial jurisdiction of (a) home-produced and imported food or (b) imported food only, to which the Codex maximum level applies in the ways set forth below. In addition, where a Codex maximum level for veterinary drug residues applies to a group of foods not individually named, a country accepting such Codex maximum level in respect of other than the group of foods, shall specify the foods in respect of which the Codex maximum level is accepted.

(i) Full acceptance

Full acceptance of a Codex maximum level for veterinary drug residues means that the country concerned will ensure, within its territorial jurisdiction, that a food, whether home-produced or imported, to which the Codex maximum level applies, will comply with that limit. It also means that the distribution of a food conforming with the Codex maximum level will not be hindered by any legal or administrative provisions in the country concerned which relate to matters covered by the Codex maximum level for veterinary drug residues.

(ii) Limited acceptance

Limited acceptance of a Codex maximum level for veterinary drug residues means that the country concerned undertakes not to hinder the importation of a food which complies with the Codex maximum level for veterinary drug residues on that food by any legal or administrative provisions in the country concerned which relate to matters covered by the Codex maximum level for veterinary drug residues, it being understood that in so undertaking the country concerned does not impose by the Codex maximum level a more stringent maximum limit than is applied domestically.

(iii) Target acceptance

Target acceptance means that the country concerned indicates its intention to give Full Acceptance or Limited Acceptance to the Codex maximum level for a veterinary drug residue after a stated number of years.

2. A country which considers that it cannot accept the Codex maximum level for veterinary drug residues in any of the ways mentioned above should indicate:

i) in what ways its present or proposed requirements differ from the Codex maximum level for a veterinary drug residue, and, if possible, the reasons for these differences;

ii) whether products conforming to the Codex maximum level may be distributed freely, or may be distributed under certain specified conditions, within its territorial jurisdiction insofar as matters covered by the Codex maximum level are concerned.

3. A country which accepts a Codex maximum level for veterinary drug residues according to one of the provisions of paragraph 1 should be prepared to offer advice and guidance to exporters and processors of food for export to promote understanding of and compliance with the requirements of importing countries which have accepted a Codex maximum level according to one of the provisions of paragraph 1.

4. Where, in an importing country, a food claimed to be in compliance with a Codex maximum level for veterinary drug residues, is found not to be in compliance with the Codex maximum level the importing country should inform the competent authorities in the exporting country of all the relevant facts and, in particular, the details of the origin of the food in question (name and address of the exporter), if it is thought that a person in the exporting country is responsible for such non-compliance.

C. Withdrawal or Amendment of Acceptance

The withdrawal or amendment of acceptance of a Codex standard or a Codex maximum level for veterinary drug residues by a country shall be notified in writing to the Codex Alimentarius Commission's Secretariat who will inform all Member States and Associate Members of FAO and WHO of the notification and its date of receipt. The country concerned should provide the information required under the previous paragraphs, whichever is appropriate. It should also give as long a notice of the withdrawal or amendment as is practicable.

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APPENDIX VI

PROPOSED DRAFT MRLS AT STEP 3 OF THE PROCEDURE

Note: Section 5 - Reference to JECFA reports - contains reference to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series. Relevant toxicological monographs are published in the WHO Food Additives Series and specifications of the substances concerned, are published in the FAO Food and Nutrition Paper Series.

1. Substance: **Chloramphenicol**

2.	Acceptable Daily Intake (ADI) as established by JECFA	No ADI allocated
3.	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Foods of animal origin (b) Not allocated (c) Chloramphenicol
4.	References to Recommended Method(s) of Analysis	(To be elaborated)
5.	References to JECFA reports	WHO TRS ... (1988)
6.	References to previous Codex Publications	None

1. Substance: **Estradiol-17 β**

2.	Acceptable Daily Intake (ADI) as established by JECFA	Unnecessary
3.	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Foods of bovine origin (b) Unnecessary (c) Estradiol-17 β
4.	References to Recommended Method(s) of Analysis	
5.	References to JECFA reports	WHO TRS 669 (1981) WHO TRS ... (1988)
6.	References to previous Codex Publications	None

1. Substance: **Progesterone**

2.	Acceptable Daily Intake (ADI) as established by JECFA	Unnecessary
3.	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Foods of bovine origin (b) Unnecessary (c) Progesterone
4.	References to Recommended Method(s) of	

	Analysis	
5.	References to JECFA reports	WHO TRS 669 (1981) WHO TRS ... (1988)
6.	References to previous Codex Publications	None

1. Substance: **Testosterone**

2.	Acceptable Daily Intake (ADI) as established by JECFA	Unnecessary
3.	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Foods of bovine origin (b) Unnecessary (c) Testosterone
4.	References to Recommended Method(s) of Analysis	
5.	References to JECFA reports	WHO TRS 669 (1981) WHO TRS ... (1988)
6.	References to previous Codex Publications	None

1. Substance: **Trenbolone acetate**

2.	Acceptable Daily Intake (ADI) as established by JECFA	0 - 0.01 µg/kg body weight
3.1	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Bovine tissue (b) 1.4 µg/kg (c) β -trenbolone
3.2	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Bovine liver and kidney (b) 14 µg/kg (c) α-trenbolone
4.	References to Recommended Method(s) of Analysis	(To be elaborated)
5.	References to JECFA reports	WHO TRS 683 (1982) WHO TRS 696 (1983) WHO TRS ... (1988)
6.	References to previous Codex Publications	None

1. Substance: **Zeranol**

2.	Acceptable Daily Intake (ADI) as established by JECFA	0-0.5 µg/kg body weight
3.1	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Bovine liver (b) 10 µg/kg (c) Zeranol
3.2	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) Bovine muscle (b) 2 µg/kg (c) Zeranol
4.	References to Recommended Method(s) of Analysis	(To be elaborated)
5.	References to JECFA reports	WHO TRS 683 (1982) WHO TRS 696 (1983) WHO TRS ... (1988)
6.	References to previous Codex Publications	None

**PROPOSAL FOR A CODE OF PRACTICE FOR THE REGISTRATION AND
MARKETING OF VETERINARY DRUGS**

1. **DESCRIPTION**

To assure adequate safeguard of the public health, Good Practice in the use of veterinary drugs requires that veterinary drug products, including biological products and medicated feeds administered to food-producing animals, should always be administered in compliance with the relevant product information as approved by competent control authorities (e.g. in accordance with a prescription issued by a qualified veterinarian).

- (For a definition of the term "Good practice in the use of veterinary drugs" see the Draft-Glossary of Terms of the CC/RVDF).

2. **PRODUCT REGISTRATION**

This implies that, save in exceptional and precisely defined circumstances in which exemption from prevailing registration requirements has been formally accorded by competent authorities to enable a named prescriber to administer an unapproved product for the purpose of testing its effect in accordance with an agreed protocol, all such products should be formally registered for marketing in the country of sale, and that the process of registration should be based upon evidence that assures:

- the quality of the product;
- its safety and efficacy in the target animal species; and
- the safety of food products derived from animals to which the product has been administered.

2.1 **Quality Assurance**

Assessment of the quality of a pharmaceutical product embraces consideration, not only of the composition and purity of the final dosage form, but also of its stability and its pharmaceutical availability in vivo. It should be based on evidence that:

- The product is prepared in conformity with the requirements for "Good Practices in the Manufacture and Quality Control of Drugs" as recommended by the World Health Organization and as required in WHO'S Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce (1);
- the finished dosage form complies with specifications contained in the registration document and, when applicable, with the published pharmacopoeial specification declared on the label.

- (1) Official Records of the World Health Organization. No. 226, 1975, Annex 12.

2.2 **Assurance of Efficacy and Safety**

Assessment of efficacy and safety involves consideration not only of the consequences of administration of the product to the target animal species but also of the possible consequences of the ingestion by consumers of residues of its ingredients, or their metabolites, contained in food products derived from the treated animals. This requires:

- Information relating to the pharmacodynamics, pharmacokinetics and metabolism of the drug and its biological effects in terms of potential adverse effects (e.g., toxic, immunogenic or resistance-inducing properties) as well as evidence from controlled studies that demonstrates the physiological or therapeutic response in each target population of animals;
- consideration of the possible biological consequence to consumers of ingestion of derivative foods and the determination of dosage regimens, and withdrawal periods that, on the basis of dosage determinations or risk analyses, will assure the safety of derivative products to consumers; and
- continued surveillance of the performance of the products in each of its approved indications subsequent to its release for marketing and, particularly, the reporting of any suspected adverse reactions arising from the use of these products, whether in exposed animals or consumers.

3. INFORMATION TO USERS

Such aspects of the above approved information, as are deemed by competent authorities to be necessary to assure the safe and effective use of the product, must be made available to all potential users in the labelling and in any other system of dissemination of information required by the competent authorities.

Information on dosage schedules should always be complemented by instructions on minimum recommended withdrawal periods and any other constraints on the use of the product, in terms of contraindications and precautions, that are regarded as necessary in order to safeguard human health.

4. DISTRIBUTION CHANNELS

In order to prevent a potential hazard to human health all veterinary drugs and medicated premixes for animal feeds that are sold or offered for sale should be:

- Registered for marketing by competent regulatory authorities;
- distributed only through registered wholesalers, pharmacies and other retail outlets specifically approved for this purpose by competent authorities;
- administered to the animal or incorporated in feed mixes in accordance with prescriptions of competent control authorities, which specifies the particular animal or specified group of animals to be treated. All manufacturers, distributors and end-users of these products must ensure that:
 - * All supplies are stored in secure premises;
 - * adequate records of sale or use are maintained; and
 - * these premises and records are open to inspection by competent regulatory authorities.

The responsible veterinarian must assume responsibility for ensuring that:

- The preparation of all medicines and medicated feeds prior to their administration is undertaken by suitably trained personnel using appropriate techniques and equipment;
- adequate records are maintained of:
 - (i) The amounts administered to individual animals on a daily basis;
 - (ii) any suspected drug-related reactions; and
 - (iii) any samples obtained from these animals that may be required for estimation of drug concentrations in derivative foods.

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION

PART I - CRITERIA FOR THE SELECTION OF VETERINARY DRUGS FOR THE ESTABLISHMENT OF MAXIMUM RESIDUE LEVELS (MRLS)

In order to be placed on the CC/RVDF's priority list for the development of a maximum 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.

PART II - PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION ESTABLISHED BY THE SECOND SESSION OF THE CC/RVDF

The Committee agreed that the revised priority list should be as follows:

Sulphonamides (sulphamethazine, sulphathiazole)
Nitrofurans (furazolidone, nitrofurazone)
Nitroimidazoles (dimetridazole, ipronidazole, ronidazole and metronidazole)
Quinoxaline-di-N-oxides (carbadox, olaquinox)
Trypanocides (diminazene, isometamedium)
Benzimidazoles (albendazole)

PART III - SUMMARY OF INFORMATION ON CERTAIN DRUGS RELATED TO THE SELECTION CRITERIA FOR THE SAFETY EVALUATION OF VETERINARY DRUGS

1. The following information was submitted on: (A) albendazole, (B) sulphathiazole, (C) certain nitroimidazoles, and (D) beta-lactam compounds in relation to the criteria for the selection of veterinary drugs for the establishment of maximum residue levels (para. 150 of ALINORM 87/31):

A. Albendazole (Prepared by Australia)

Albendazole is a benzimidazole anthelmintic which controls gastrointestinal roundworms (mature and immature), lungworm, tapeworm and adult liver-fluke in cattle, goats and sheep.

Albendazole has been used in Australia since the late 1970's and has achieved considerable market penetration.

Australia considers that albendazole meets the selection criteria for inclusion on the CC/RVDF's priority list for the development of maximum residue levels. In particular, it is noted that:

(1) The use of the drug may give rise to residues in meat and offal. Australian MRLs are set at 0.1 mg/kg (limit of determination) for meat of cattle, sheep and goats.

(2) Concern has been expressed by some countries about the toxicological evaluation of the drug and, therefore, international evaluation would seem desirable. Australian health authorities do not share these concerns.

(3) The above mentioned reservations about the compound's toxicology has led some countries to support a Codex review. International trade and commerce could be affected.

(4) The drug is available as a commercial product and is registered for use in several countries.

(5) The manufacturer, Smith Kline Animal Health Products, has indicated their full cooperation in providing immediately to JECFA an extensive package of toxicology and residue data.

It is considered that albendazole clearly meets all the selection criteria. Australian authorities can provide further information if necessary.

B. Sulphathiazole (Prepared by Canada)

Sulphathiazole (STZ) is employed in the treatment and prevention of disease in food producing animals including bees. Although the latter application may be considered to be relatively small when compared to other uses of STZ in food producing animals, the characteristics of STZ use in bees are believed to satisfy the criteria for the addition of a drug to the priority list.

The use of STZ in the treatment of American Foul Brood in bees results in residue in honey. This residue is of public health concern. The STZ residue affects trade to a significant degree and causes commercial problems. The drug is commercially available. Canada is aware of the availability of a 90-day study in 2 species (rat and dog). Canada can provide these data and also honey consumption and residue information.

Canada recommends that STZ be added to the priority list of drugs for consideration by JECFA.

C. Certain Nitroimidazoles (Prepared by the United States)

The delegation of the United States believes that the nitroimidazoles, dimetridazole, metronidazole and ronidazole, meet the criteria established by the First Session of the CC/RVDF for the selection of veterinary drugs to be placed on the priority list.

- These drugs result in residues in meat from treated animals.
- The drugs are a matter of public health concern because studies indicate

that they are mutagens and tumorigens.

- The residues of these drugs affect international trade to a significant degree. Major trading countries of the Codex system have significant differences in their approvals of these drugs as far as the species in which they are used and the levels and withdrawal times employed. These differences are causing and will continue to cause major trade problems.
- Ronidazole, ipronidazole and dimetridazole are available as commercial veterinary products in many countries of the Codex Alimentarius. Metronidazole is used in animals in some countries, often as topically applied products. It is also widely used in human medicine. As such, there are extensive toxicological data available in the literature on this compound. It is the belief of the United States that data on this compound should be evaluated by the JECFA because of the extensive similarities in mechanism of action and toxicological effects between members of this class of compounds. Therefore data on metronidazole would have great bearing on an evaluation of dimetridazole, ipronidazole and ronidazole.

Additionally, relevant data on these compounds could be made available for evaluation by the JECFA and work on these compounds has not been undertaken by other Codex Committees.

D. Beta-Lactam Compounds (Prepared by Denmark)

The beta-lactam group of antibiotics was proposed for inclusion in the priority list of compounds at the Codex meeting in October 1986 in Washington. The reasons advanced for inclusion were concerned with the belief that low concentrations of residues in food of compounds from this group may give rise to immuno-pathological problems in man. It is suggested that compounds which may be selected as examples for consideration could include procaine penicillin G., ampicillin, and possibly an appropriate cephalosporin such as cephalonium. In view of additional data currently being generated by industry, it is proposed that these compounds should be considered for inclusion at the next meeting of this Committee.