

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 57971 Telex: 625852-625853 FAO I Cables: Foodagri Rome Facsimile: (6) 57973152-5782610

ALINORM 91/31A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Nineteenth Session

Rome, 1-10 July 1991

REPORT OF THE FIFTH SESSION OF
THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Washington, D.C., 16-19 October 1990

Note: This document incorporates Codex Circular Letter 1990/41-RVDF.

w/z 6802

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CX 4/60.2

CL 1990/41-RVDF
December 1990

TO: - Codex Contact Points
- Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme,
FAO, Via delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the Fifth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 91/31A)

The report of the Fifth Session of the Codex Committee on Residues of Veterinary Drugs in Foods is attached. It will be considered by the 19th Session of the Codex Alimentarius Commission to be held in Rome from 1-10 July 1991.

A. MATTERS OF INTEREST TO THE COMMISSION ARISING FROM THE REPORT OF THE FIFTH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

The following matters will be brought to the attention of the 19th Session of the Codex Alimentarius Commission:

1. Proposed Draft Maximum Residue Limits for Veterinary Drugs at Step 5; paras. 64-76 and Appendix III, ALINORM 91/31A.
2. Proposed Draft Glossary of Terms and Definitions at Step 5; paras. 81-83 and Appendix IV, ALINORM 91/31A.
3. Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs at Step 5; paras. 84-86 and Appendix V, ALINORM 91/31A.
4. Proposed Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods; paras. 87-90 and Appendix VI, ALINORM 91/31A.

Governments wishing to submit comments regarding the implications which the proposed draft maximum residue limits for veterinary drugs, codes of practice or guidelines or any provisions thereof may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Codex Maximum Residue Limits for Veterinary Drugs (at Step 5) (see Codex Alimentarius Procedural Manual, Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy, not later than 31 March 1991.

B. DOCUMENTS OF INTEREST TO BE ELABORATED FOR DISTRIBUTION AND/OR GOVERNMENT COMMENT PRIOR TO THE SIXTH MEETING OF THE CCRVDF

1. Proposed Draft Code of Practice for the Use of Veterinary Drugs in Aquaculture (Canada); see paras. 14-17, ALINORM 91/31A.
2. Progress Report on the Compendium of Veterinary Drugs (United States); see paras. 77-79, ALINORM 91/31A.

3. Final Summary Report on the Survey on Intake Studies (United States); see para. 80, ALINORM 91/31A.
4. Progress Report on the Draft Code of Practice for the Registration of Veterinary Drugs (OIE); see paras. 91-95, ALINORM 91/31A.
5. Consideration of documents elaborated by the *Ad Hoc* Working Group on Methods of Analysis and Sampling concerning Sampling for the Control of Residues of Veterinary Drugs, General Considerations of Analytical Methods for Regulatory Control, Method Performance Attributes and the Analytical Method Data Sheet (United States); see paras. 96-104, ALINORM 91/31A.
6. Consideration of Proposals for Additions to the Priority List of Veterinary Drugs Requiring Evaluation (Australia); see paras. 105-124 and Appendix VII, ALINORM 91/31A.

C. REQUEST FOR COMMENTS AND INFORMATION

1. Consideration of the Report of the 36th Session of the Joint FAO/WHO Expert Committee on Food Additives and Proposed Draft Maximum Residue Limits for Veterinary Drugs at Step 3 (paras. 52-63 and Appendix II, ALINORM 91/31A)

The Committee agreed to review and solicit comments on the 36th JECFA Report (TRS 799 - circulated under separate cover) as well as the proposed draft MRLVDs at Step 3 for consideration at the 6th CCRVDF Session, with a view towards the adoption of the MRLVDs at Steps 5 and 8 at the 20th Session of the Codex Alimentarius Commission in 1993.

Governments and international organizations wishing to submit comments and/or information on the above subject matter are invited to do so no later than 15 May 1991 and as directed below:

Dr. Gerald B. Guest
Director
Center for Veterinary Medicine (HFV-1)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857, U.S.A. (Telex No. 898488 PHS PKLN ROV;
Telefax No. 301.443.3449)

In addition, please forward a copy of the comments to:

Chief
Joint FAO/WHO Food Standards Programme
FAO
Via delle Terme di Caracalla
00100 Rome, Italy

SUMMARY AND CONCLUSIONS

The Fifth Session of the Codex Committee on Residues of Veterinary Drugs in Foods reached the following conclusions during its deliberations:

- Agreed to have Canada prepare a Proposed Draft Code of Practice for the Use of Veterinary Drugs in Aquaculture at Steps 1 and 2, (paras. 14-17);
- Agreed to return the proposed draft Maximum Residue Limits for Closantel, Ivermectin, Levamisole, Benzylpenicillin, Oxytetracycline and Carbadox to Step 3 in order to allow for additional comments, (paras. 52-63);
- Agreed to advance the proposed draft Maximum Residue Limits for Albendazole, Sulfadimidine, and Trenbolone Acetate to Step 5 in order to allow for their adoption by the Commission, (paras. 64-76);
- Agreed to have the United States prepare a progress report on the elaboration of a Compendium of Veterinary Drugs for consideration at the 6th CCRVDF Session, (paras. 77-79);
- Agreed to have the United States prepare a final summary report on the Survey on Intake Studies for consideration at the 6th CCRVDF Session, (para. 80);
- Agreed to advance the Proposed Draft Glossary of Terms and Definitions to Step 5 in order to allow for its adoption by the Commission, (paras. 81-83);
- Agreed to advance the Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs to Step 5 in order to allow for its adoption by the Commission, (paras. 84-86);
- Agreed to advance the Proposed Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods to Step 5 in order to allow for its adoption by the Commission (paras. 87-90);
- Agreed to have the OIE present a progress report on its elaboration of a Draft Code of Practice for the Registration of Veterinary Drugs to the 6th CCRVDF for information, (paras. 91-95);
- Agreed to endorse the continuation of the Ad Hoc Working Group on Methods of Analysis and Sampling under the Chairmanship of the United States, (paras. 96-104), and;
- Agreed to endorse the continuation of the Ad Hoc Working Group on Priorities under the Chairmanship of Australia, (paras. 105-124).

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INTRODUCTION

1. The Fifth Session of the Codex Committee on Residues of Veterinary Drugs in Foods was held from 16-19 October 1990 in Washington, D.C. by courtesy of the Government of the United States of America. The Session was chaired by Dr. Gerald B. Guest, Director, Center for Veterinary Medicine, Food and Drug Administration. Representatives and Observers from 34 countries and 7 international organizations were present.

2. The Session was preceded by meetings of the *Ad Hoc* Working Group on Methods of Analysis and Sampling under the chairmanship of Dr. Richard Ellis (United States) and the *Ad Hoc* Working Group on Priorities under the Chairmanship of Mr. Greg Hooper (Australia). The reports of the Working Group meetings were presented to the Plenary under Agenda Item 13 (Conference Room Document 3) and Agenda Item 14 (Conference Room Document 4), respectively.

3. A list of the participants at the Session, including officers of FAO and WHO, is attached to this report as Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

4. The Session was opened by Mrs. Jo Ann R. Smith, Assistant Secretary for Marketing and Inspection Services, U.S. Department of Agriculture. Mrs. Smith highlighted the importance of science-based, consistent standards for food products to meet the interests of consumers, governments and industry.

5. Mrs. Smith also emphasized the importance of the Committees deliberations towards strengthening the relationship between Codex and the General Agreement on Tariffs and Trade (GATT), especially in view of current deliberations in the GATT Working Group on Sanitary and Phytosanitary Regulations and Barriers within the Uruguay Round of Multilateral Trade Negotiations. Mrs. Smith concluded her remarks by noting the importance of future discussions on these and other issues at the Joint FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in March 1991.

ADOPTION OF THE AGENDA (Agenda Item 2)

6. The Committee had before it the Provisional Agenda for the Session (CX/RVDF 90/1), and agreed to adopt the agenda as presented.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

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

MATTERS OF INTEREST ARISING FROM OTHER CODEX COMMITTEES (Agenda Item 4A)

8. The Committee had before it working paper CX/RVDF 90/2 which, among other issues, summarized the following matters of interest arising from activities of other Codex Committees.

Codex Committee on Pesticide Residues, 22nd Session (ALINORM 91/24)

9. The Committee noted that the CCPR had considered draft maximum residue limits for several substances (paras. 82, 90, 197-199) of interest to the CCRVDF as they may also accommodate veterinary drug uses (endosulfan, flucythrinate, methoprene). The Secretariat agreed to keep the Committee advised of future compounds of interest.

10. The Committee also noted that the "Recommended Method of Sampling for the Determination of Pesticide Residues in Meat and Poultry Products", as elaborated by the CCPR (paras. 313-318), was adopted by the 18th Session of the Commission at Step 5 (paras. 227-228, ALINORM 89/40). The recommended procedure, which was further modified by the CCPR to reflect the effectiveness of residue sampling procedures at the point of export as well as at the point of import, has been circulated for further government comment at Step 6 (CL 1990/20-PR).

Codex Coordinating Committee for North America and the South-West Pacific, 1st Session (ALINORM 91/32)

11. The CCNASWP examined a document related to inspection procedures for fish and shellfish which focused on fishery resource and aquaculture concerns (paras. 84-85). The document considered the consumer safety and health aspects of aquaculture, as well as resource, habitat, environmental and quarantine issues. The Codex Committee on Fish and Fishery Products also discussed this working paper (paras. 151-152, ALINORM 91/18) and agreed that a consultation may need to examine this issue in detail at a future date. The Secretariat agreed to keep the Committee apprised of future activities in this area.

Codex Coordinating Committee for Europe, 17th Session (ALINORM 91/19)

12. The Committee noted that the CCEURO had expressed concern regarding the future work of JECFA (paras. 44-45) and had recommended that FAO and WHO should consider additional JECFA sessions to evaluate food additives, contaminants and residues of veterinary drugs.

13. The Delegation of Australia strongly supported this recommendation, and noted that JECFA should attempt to convene on a twice yearly basis in order to alternately examine food additives and veterinary drugs.

Codex Committee on Fish and Fishery Products, 19th Session (ALINORM 91/18)

14. The Committee noted that the CCFFP had endorsed a FAO Fisheries Department (FII) proposal to hold an expert consultation from 10 to 13 December 1990 in Rome, Italy, to examine a proposed draft Code of Hygienic Practice for Aquaculture (paras. 92-95). The CCFFP had also requested the CCRVDF to examine the possibility of elaborating a proposed draft Code for the Safe Use of Veterinary Drugs in Aquaculture, with the understanding that this request would be endorsed by the Commission.

15. The Committee, while agreeing that the primary responsibility for the development of guidelines concerning the use and control of fish drugs was within its terms of reference, also suggested that this topic be discussed in general terms at the fish consultation with a view towards providing advice.

16. The Delegation of Canada agreed to initiate a working document for discussion at the next CCRVDF session which would examine the types of veterinary drugs used in various countries, with a summary of use controls, recommended levels, restrictions and other pertinent information. The Committee also agreed that the recommendations of the Consultation should be taken into account when elaborating this document, and that it should also include a preliminary proposed draft code on the use of fish drugs as requested by the CCFFP.

17. The Committee concluded that a working group consisting of representatives from Norway, the United Kingdom and the United States would assist Canada in these efforts.

MATTERS OF INTEREST ARISING FROM INTERNATIONAL ORGANIZATIONS (Agenda Item 4B)

World Health Organization (WHO)

18. The Pharmaceutical Unit of WHO reiterated its request made at the Committee's third Session for the submission of information on regulatory matters concerning veterinary drugs. As the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce now includes drugs used in veterinary practice, dissemination of information on the safety and efficacy of these drugs becomes even more important, particularly for importing countries.

19. The WHO Certification Scheme also enables the importing country drug regulatory authority to request a certificate from the exporting country drug regulatory authority confirming that a product is authorized for marketing in the country of export and that the manufacturer had been subject to inspection in accordance with the rules of good manufacturing practice.

20. The WHO representative requested that information should be sent to: Chief, Pharmaceuticals Unit, World Health Organization, 1211 Geneva 27, Switzerland.

Pan American Health Organization (PAHO)

21. The observer from PAHO outlined activities of this organization related to the work of the Codex Committee on Residues of Veterinary Drugs in Foods.

22. Several activities were carried out at regional, sub-regional and national levels with the main objectives to develop food policy, promote projects, elaborate standards, improve training, and disseminate information as follows:

- (a) Strengthening of reference laboratories for residues of chemicals and veterinary drugs in foods situated at the Pan-American Center for Zoonoses in Buenos Aires, Argentina.
- (b) A Caribbean food control laboratory network was set up in December 1989 with responsibility of investigation and analysis of chemical residues of interest to the region.
- (c) Organization of an international course on chemical residues in food held in Cuba in January 1990.
- (d) Organization of a Latin American Congress on Food Technology held in Costa Rica in April 1990.
- (e) Establishing a Latin American network on epidemiologic vigilance on food-borne diseases in September 1989.
- (f) Various other activities related to food control, laboratory maintenance, food inspection and dissemination of information.

European Economic Community (EEC)

23. The Committee noted that in June 1990 the EEC Council of Ministers adopted a new regulation giving the Community powers to adopt legally binding MRLs. The regulation enters into force in January 1992, and after that date, no new active substance may be used in food producing animals unless an MRL has been established by the Community. Moreover, the Community must also establish MRLs for all existing compounds used in

food animals over a five year period, ending in 1997. While adopting this regulation, several amendments were made to harmonize definitions and terminology used in Community legislation with definitions used by Codex. Account will be taken of any existing Codex MRLVDs during the establishment of Community MRLs.

24. The EEC Commission, in close collaboration with the EEC Committee for Veterinary Medicinal Products (CVMP), is in the process of finalizing recommended MRLs for approximately 20 widely used compounds or groups of compounds and it is expected that these will be published shortly.

25. The EEC Commission has presented a proposed regulation to the EEC Council of Ministers to provide legal powers for harmonized MRLs to be accepted on behalf of the Community as a whole.

26. The EEC Council of Ministers has adopted a decision to impose a standstill period on any unilateral decision for the authorization of veterinary medicines containing bovine somatotropin until the end of 1990.

27. In July 1990 the EEC Commission agreed on a series of major new proposals for a future system to guarantee the free movement of veterinary medicines in the Community after 1992. These proposals call for the establishment of a European Medicines Evaluation Agency, and for the creation of new Community drug registration procedures to ensure that a single decision on the authorization of new products is taken which will be binding throughout all 12 Member States.

Office International des Epizooties (OIE)

28. At its previous Session, the CCRVDF was informed by the OIE of the organization of a workshop held at Arusha (Tanzania) in January 1989 devoted to problems encountered by African countries in the registration of veterinary drugs. On that occasion, the OIE agreed to respond to the request of African countries wanting to establish adapted veterinary pharmaceutical legislation. For this objective, the International Group of Experts of the OIE prepared model veterinary pharmaceutical legislation for developing countries, together with guidelines on minimal technical requirements relating to the quality, efficacy, and safety of veterinary drugs which were relevant for the evaluation of registration files. These two documents, together with the form for the reporting of undesirable side effects of veterinary drugs and a report on the distribution of veterinary drugs in Africa, will soon be published in issue 2-90 of the newsletter veterinary drug registration jointly published by the OIE and the International Technical Consultation on Veterinary Drug Registration.

29. However, the group of experts has seen the need to recommend that the OIE continue its work in this field through the implementation of a program aimed at ensuring:

- (a) The training of personnel responsible for the application of veterinary pharmaceutical legislation and registration procedures for these products.
- (b) The transfer of technology to laboratories responsible for the control of pharmaceutical quality of veterinary drugs and of residues of veterinary drugs in food.

30. The group of experts also thought it necessary to create a network of regional reference laboratories in Africa, Latin America, and Asia, with competence in these areas. To achieve this, the OIE programme envisages two preliminary activities:

- (a) Preparation of a list of existing resources, with the aid of an adapted questionnaire aimed at making an inventory of existing laboratories, together with their resources in terms of personnel and scientific equipment, and control methods that are already operational. This questionnaire has already been prepared.
- (b) The creation of an evaluation team that shall examine the laboratory capabilities identified through responses to the questionnaire, and; prepare a list of urgent needs in terms of human, material, and methodological resources.

31. The OIE would like the competent national and regional authorities to be closely associated with this project, including its final formulation. To achieve this, it will take advantage of the upcoming OIE regional conferences scheduled for:

- (a) The countries of the Americas, in Montevideo, Uruguay - beginning of November 1990,
- (b) The countries of Africa, in Abidjan, Cote d'Ivoire - end of January, 1991,
- (c) The countries of Asia, in Iran - 1991.

32. These meetings will facilitate discussions of this program and will assist the countries involved in approaching the appropriate international bodies to request the necessary financial assistance.

33. Moreover, the OIE is continuing to publish semi-annual issues of the newsletter on the registration of veterinary drugs in English, Spanish, and French. During its Fifth meeting at The Hague (8-12 October 1990), the International Technical Consultation on Veterinary Drug Registration, which regularly receives assistance from the OIE, re-affirmed its interest in this newsletter and decided to provide it with greater support by creating a larger network of national correspondents (also see paras. 38-42). This measure is aimed both at improving the dissemination of the newsletter and enriching the contents.

34. The Delegation of Sweden cautioned the organization to focus its work on epizootic diseases, biologicals, vaccines and antibiotics in view of limited resources, its clearly defined tasks, and in consideration of work undertaken by other international bodies.

35. The Delegation of Senegal, supported by the Delegation of Mali, noted that the OIE had provided valuable technical assistance to African countries to improve the examination of veterinary drugs used in the region. Both Delegations, together with the Delegation of Malaysia, also noted that OIE had also provided information to developing countries on the activities of Codex.

36. The Delegation of Malaysia also highlighted the conclusions of a FAO/APHCA/JICA workshop held in September 1990 to address the use of veterinary drugs in developing countries, which referred to the OIE role in the area of veterinary drug registration.

37. The Committee, while noting that the CCRVDF had requested the OIE to conduct the workshop addressing problems of African countries and to prepare the draft code of practice concerning veterinary drug registration, agreed that the activities of the OIE were clearly defined in the area of veterinary drug registration and complemented the work of Codex.

International Technical Consultation on Registration of Veterinary Medicinal Products

38. The Delegation of France informed the Committee that the International Technical Consultation on Veterinary Drugs Registration (ITCVDR) held its Fifth Meeting at The Hague in the Netherlands, 8-12 October, 1990. The Consultation provided an opportunity to bring together some 100 individuals representing 42 countries and 5 international organizations. The extensive participation of 16 African countries was also highlighted.

39. This meeting confirmed the importance of the Consultation, which affords the opportunity, every two years, for a wide-ranging exchange of information and experiences in the rapidly developing field of veterinary drug registration. The topics selected for the Consultation had been grouped into nine sessions which addressed the following topics:

- The activities of international organizations,
- The registration of veterinary drugs in The Netherlands,
- Medicated feeding stuffs,
- Concerns of developing countries,
- Vaccines,
- Efficacy of anti-microbial drugs,
- Societal concerns on veterinary drugs
- The use of drugs in fish farming,
- Pharmacovigilance.

40. At the conclusion of this meeting, the Consultation adopted 17 resolutions, which included the following:

- The program of the International Office of Epizootics (OIE) for developing countries should continue to be strongly encouraged;
- Continuation of the newsletter on the registration of veterinary drugs, published jointly with the OIE, for which the ITCVDR will develop a network of national correspondents;
- Continuation of the list of veterinary drugs essential to developing countries that was requested of the OIE in close cooperation with the World Health Organization;
- Vaccines are regarded as veterinary medicinal products and, therefore, should be evaluated for their registration, with the aid of recognized criteria of quality, efficacy, and safety;
- In regard to social problems associated with the use of veterinary drugs, the Consultation deemed it necessary to increase public confidence in the registration procedures by ensuring their effectiveness and transparency. To achieve this objective, efforts have to be made to understand the consumer concerns and to establish a dialogue with consumer representatives;
- Systems of pharmacovigilance, whose establishment is encouraged by the Consultation in countries that can take advantage, in this area, of existing experience in the human realm;
- Drugs destined for aquatic species.

41. The Consultation reaffirmed that products destined for aquatic species must be considered as medicinal products and, therefore meet the usual registration requirements of quality, efficacy, and safety. The specific aspects of these medicinal products must, however, be taken into consideration, e.g., the impact of the ambient temperature on the pharmacokinetics of the drugs and their residues. Lastly, it recalled the importance to the protection of human and animal health by ensuring that these medicinal products are distributed through technically competent and officially approved systems.

42. The Consultation concluded by welcoming the proposal of Argentina to organize the Sixth International Technical Consultation on Veterinary Drug Registration.

Consultation Mondiale de l'Industrie de la Santé Animale (COMISA)

43. The representative of COMISA informed the Committee that during the past year COMISA was legally incorporated in Belgium while holding its first Board meeting in April 1990. As a non-profit scientific organization, COMISA encourages conditions for scientific progress in the development of animal health products and effectively communicates the characteristics, intentions and achievements of the industry.

44. During this year COMISA assisted JECFA in coordinating contacts between data submitters and data reviewers and submitted written comments concerning documents under elaboration by the CCRVDF and OIE.

45. At the recent 5th International Technical Consultation on Veterinary Drug Registration COMISA also presented papers on pharmacovigilance and on the need for coordinated action programmes by animal health product manufacturers, food processors and distributors, farmers, veterinarians and others to restore public confidence in the wholesomeness of the food supply.

46. The COMISA representative reiterated their support for proposals within GATT relative to sanitary and phytosanitary measures, and underlined the importance of accepting principles concerning the evaluation of animal health products based on sound, scientific and objective criteria.

International Dairy Federation (IDF)

47. The observer from IDF outlined the work of the following three expert groups, namely A4 (Residues and Contaminants in Milk), E12 (Pesticides) and E47 (Detection of Antibiotics).

48. Group A4 has prepared the final version of the monograph on residues and contaminants in milk and milk products. It was approved at the IDF Annual Meeting in October 1990 (Toronto, Canada), and will be printed within the next few months. The monograph is available from the IDF General Secretariat in Brussels.

49. Group E12 has published a provisional IDF standard on methods for the determination of organophosphorous compounds in milk and milk products. IDF standards concerning "Determination of Organochlorine Pesticide Residues" and "Determination of Polychlorinated Biphenyls (PCBs)" will now be published as final IDF standards.

50. Group E47 has accomplished the following:

- IDF Bulletin No. 220 (1988) on the detection of inhibitors (antibiotics) has been revised. The monograph was approved for publication at the IDF session in October 1990.

- A monograph on "special methods" was prepared and approved in Toronto in October 1990. This monograph describes confirmatory methods for sulfonamides and antibiotics.
- A collaborative trial for comparison of detection limits of microbiological inhibitor-tests was organized. More than 60 laboratories from 23 countries participated. The results will be discussed in March 1991 in Milan, Italy. At that time it will be decided if these trials could be continued in order to fix detection limits for various antibiotics in milk using routinely applied screening and/or confirmation methods.

51. In 1989 a new expert group D46 "Food additives and contaminants" was formed. The work of this group might also be of interest for Codex in the future.

CONSIDERATION OF THE REPORT OF THE 36TH SESSION OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) AND RECOMMENDATIONS FOR MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (Agenda Item 5)

52. The Committee had before it the summary report (CX/RVDF 90/3) and photocopies of the final report of the 36th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (WHO Technical Report Series 799) as well as a comment summary paper concerning this subject (CX/RVDF 90/3-Add.1). The FAO and WHO Joint Secretaries of JECFA summarized the results of the meeting.

53. Three anthelmintic drugs (closantel, ivermectin, and levamisole), two antimicrobial agents (benzylpenicillin and oxytetracycline) and two growth promoters (carbadox and olaquinox) were on the agenda. Acceptable Daily Intakes (ADIs) were established for closantel, ivermectin, benzylpenicillin, and oxytetracycline. A temporary ADI was established for levamisole. For carbadox and olaquinox the Committee concluded that residues resulting from their use were acceptable, provided that the recommended MRL's were not exceeded (carbadox) or under conditions of good practice in the use of veterinary drugs (olaquinox, temporary). Maximum Residue Limits (MRLs) or temporary MRLs were recommended for all of the drugs on the agenda except for olaquinox.

54. A number of items were included in the General Considerations section of the report. Included were the assessment of microbiological risk due to residues of antimicrobial drugs in food and the allergenic potential of residues of veterinary drugs in food. The Committee also included a section on temporary ADIs and MRLVDs that explains their significance as well as procedures by which the veterinary drugs given these designations are brought forward for re-evaluation.

55. The Committee was informed that the 36th JECFA delineated the decision process used to establish recommended MRLs. This involved a decision-tree approach which adjusts the MRL calculated from the ADI value to include consideration of both good practice in the use of veterinary drugs and the adequacy of analytical methodology used to determine the residue. Furthermore, the 36th JECFA described in schematic fashion the approach used by the JECFA to assess the toxicological significance of bound residues.

56. The Committee was further informed that the FAO experts and consultants at the 36th JECFA prepared two procedural documents for use at future JECFA meetings. Both documents were provided to COMISA for circulation and comment among industry representatives. The first document described procedural guidelines and responsibilities in the preparation and review of draft residue monographs. This closely parallels an earlier WHO document on the preparation of toxicological

monographs. The second document lists guidelines for the preparation of residue monographs and was written for use by FAO consultants. Both documents will be given to future data submitters to provide guidance on data needed for residue reviews and monograph preparation.

57. The Delegation of Italy, speaking on behalf of the European Economic Community, stated that detailed consideration of the recommended MRLVDs should be deferred because the summary report did not offer enough information to indicate how the recommended MRLVDs were established. The Delegations of Norway and Finland supported this position. The Delegation of the United States objected to the fact that the full report was not available until the present session, and asked if procedures could be developed that would result in the report being available at least three months before the meeting.

58. The WHO Joint Secretary explained the editing and publication procedures and pointed out that it is unlikely that the time between the meeting and publication can be shortened significantly, considering the need for accuracy. The Delegation of France made two proposals for making draft reports available before the CCRVDF session. The WHO Joint Secretary stated that efforts will be made to implement one of these suggestions, which involved working with the Codex Secretariat to make a draft report available for distribution in advance of the CCRVDF Session following formal editing, but before final publication.

59. The Delegation of Norway, supported by the Delegation of Finland, did not agree with the recommended MRLVDs for the antimicrobials as they were considered to be too high. The Delegation of Norway considered the available analytical procedures to be adequate for measuring residues at lower levels and that the MRLVDs should be 5 to 10 times lower than the Minimum Inhibitory Concentration (MIC). The Delegation of Israel did not believe that it was appropriate to directly relate MRLVDs to MICs. The WHO Joint Secretary briefly explained the scientific basis of the draft MRLVD for oxytetracycline. The Committee noted that it was not possible to discuss scientific issues in great detail and that specific technical comments should be directed to JECFA for consideration.

60. The Delegation of New Zealand expressed concern that the MRLVD for levamisole of 0.01 mg/kg was too low to be reliably detected, while the Delegation of Australia felt that the MRLVD was inconsistent with residue use levels. The Delegation of Australia was also concerned that MRLVDs have been recommended for carbadox, even though a numerical ADI was not established, which runs counter to the procedures that have been established by JECFA. The WHO Joint Secretary responded that this unusual procedure was followed for carbadox because of the nature of the residue (parent drug is not detected) and the difficulty of quantitating the residue.

61. The Delegation of Australia also indicated that several drugs evaluated during the 36th JECFA were given MRLs for "all species" and that this generalization posed problems for national regulatory agencies. The JECFA Secretariat agreed and stated that at future JECFA meetings specific species will be named. The species can be identified from the 36th report for purposes of the present CCRVDF consideration.

62. The Delegation of Poland supported the written comment of the United Kingdom that Footnote 4 of Annex 2 is misleading, where it is stated that "Insufficient information was available to establish an ADI." The section of the report on carbadox did not indicate that this was the reason that an ADI could not be established.

63. Several Delegations requested that the Committee postpone consideration of the JECFA report and the MRLVDs until the next session of the CCRVDF in order to permit

their adequate review and the submission of comments. The Committee agreed to return the proposed draft MRLVDs to Step 3 of the Codex Procedure for comment and for consideration at Step 4 during the Sixth Session of the CCRVDF. At that time, consideration will be given towards advancing these MRLVDs to Step 5 for adoption by the 20th Session of the Commission, with the understanding that the Committee may also strongly recommend the elimination of Steps 6 and 7. The proposed draft MRLVDs are attached as Appendix II to this report.

CONSIDERATION OF THE REPORT OF THE 34TH SESSION OF JECFA AND RECOMMENDATIONS FOR MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (Agenda Item 6)

64. The Committee had for its consideration the report of the 34th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (WHO TRS 788) as well as written comments (CX/RVDF 90/4) received from the European Economic Community in response to CL 1989/47-RVDF.

65. The Delegation of Italy, speaking on behalf of the Member States of the EEC present at the Session, summarized the following comments:

- In view of efforts currently undertaken to promote the use of Codex Standards in international trade, the importance of making the full report of JECFA available to governments at the earliest possible opportunity was stressed in order to avoid any unnecessary delay in the adoption of MRLVDs.
- The choice of safety factors gave rise to concerns within the Community as it was considered necessary to establish MRLVDs for many compounds as soon as possible. It therefore appeared desirable to adopt internationally agreed guidelines on the use of safety factors.
- The residues for which MRLVDs had been established should be set on the basis of a clearly defined chemical entity, such as a marker residue.
- The definitions given in the section on bound residues were considered useful working definitions, which should, however, be kept under review in the light of scientific progress. The Community accepted the approach to bioavailability studies as described in the report but considered that such studies of extractable residues may be of limited value at present.
- The same intake values were used in the Community in respect of muscle tissue, liver, kidney, tissue-fat and eggs. However, it was suggested that JECFA reconsider the figure of 1.5 litre of milk per day as being unnecessarily high. This level could raise practical problems in establishing certain MRLVDs.
- The Community could not accept the recommended MRLVDs for albendazole. Within the Community, a safety factor of 1000 was generally applied to direct selective tetratogens like albendazole instead of the safety factor of 100 used by JECFA. Therefore, the MRLVDs proposed by JECFA would result in a daily consumption in excess of the ADI established by the Community.
- Within the Community it had not been considered appropriate to establish ADI's for dimetridazole and ronidazole. Doubts were expressed as to the use of a safety factor of 200 for ronidazole, as this compound was a recognized carcinogen where the mechanism of carcinogenesis remained unknown.

- The Community also had reservations about the MRL proposed for sulfadimidine in milk, which would appear unattainable through routine monitoring at present.
- The position of the Community in respect of the use of trenbolone acetate had been stated at previous Sessions of the CCRVDF and remained unchanged.

66. The Delegation of Australia pointed out that the choice of safety factors was a matter of scientific judgement and that it was inappropriate to impose constraints on the rigorous scientific process within JECFA. JECFA was established to advise the Committee on recommended MRLVDs, which included the use of safety factors. The report was considered excellent and clear, and Australia fully accepted the proposed MRL for albendazole at this stage.

67. The Committee had a lengthy and detailed discussion on both general and compound-specific aspects of the selection of safety factors. The Delegations of the Netherlands and Italy discussed the need to establish common rules on the use of safety factors to be applied on certain severe toxic effects, such as carcinogenicity and tetratogenicity. The representative of WHO, supported by the Delegations of Australia and Israel, agreed that too strict rules should be avoided. Each compound should be evaluated individually.

68. The Committee noted that technical questions should be brought back to JECFA by the Chairman and the Secretariat. The JECFA Secretariat stated that certain inputs to JECFA were possible but that JECFA should remain as a totally independent scientific body.

69. The Delegation of Israel, while fully agreeing with the report of the 34th JECFA, requested the Committee to move the draft MRLVDs for albendazole, sulfadimidine, and trenbolone acetate to Step 5. This was supported by the Delegations of Brazil, Finland, Switzerland, Australia, Mozambique, and Poland. The Delegation of Italy stated on behalf of the EEC Member States that they would desire an early consideration by JECFA of all questions raised, but that they were not formally objecting to moving forward the draft MRLVDs to Step 5.

70. The Delegation of the United States also spoke in favour of moving the draft MRLVDs to Step 5. However, in order to clarify the scientific basis on which proposed ADI's and MRLVDs were established, JECFA should elaborate specific criteria. The Delegation also agreed that technical questions from the Committee should be communicated to JECFA through the Chairman of CCRVDF.

71. The Committee agreed to the advancement of the draft MRLVDs for albendazole, sulfadimidine, and trenbolone acetate to Step 5 of the Codex Procedure for adoption by the 19th Session of the Commission. The draft MRLVDs are attached as Appendix III to this report.

72. The Chairman drew the attention of the Committee to the two trypanocides for which JECFA had not established MRLVDs and noted that a request for a significant package of additional data had been made.

73. The Delegation of Belgium suggested that countries which proposed substances for inclusion on the priority list should ensure that data be made available for JECFA evaluation. The Delegation of Senegal questioned whether this requirement could be met by African countries for compounds which are of interest in their regions. The Delegations of Belgium and Israel were concerned about potential discrimination against those drugs which failed to successfully pass a JECFA review, in comparison

to those which could remain on the market because appropriate data for a JECFA evaluation had not been submitted.

74. The WHO Joint Secretary discussed possible ways to gain support for the generation of the minimum data set required for evaluation of the trypanocides. The veterinary pharmaceutical industry should consider pooling resources. Also, the Member States of WHO and FAO and/or other International Organizations should be asked to provide support.

75. The Committee noted that one company had made a commitment to generate data. The Committee concluded that the Joint Secretariat and Chairman of the Committee should send a letter through COMISA to the industry in order to determine the industry position in this matter.

76. The Observer from COMISA, recognizing the responsibility of the industry, indicated that COMISA would examine within its membership what could be done to improve the basis for the continued use of products which were obligatory to maintain animal welfare in tropical regions.

PROGRESS REPORT ON COMPENDIUM OF VETERINARY DRUGS (Agenda Item 7)

77. The Committee had before it working paper CX/RVDF 90/5 when discussing this item (Progress Report On Compendium of Veterinary Drugs), as prepared by the United States.

78. The Delegation of the United States noted that the International Compendium Project had two components. The first involved compiling and making information available on drug approval and animal feed additive registration, including the organizations within each country responsible for these activities. The second part involved compiling approved or registered products from each of the countries. It was noted that both parts had been completed for 21 countries which documented a total of 11,693 officially registered products. Computer software had also been developed for the management of individual registered product information. It was also noted that the software and the data package may be ordered, and computer discs were also available for Codex member governments. The Delegation of Spain also noted the availability of a Spanish Compendium of Veterinary Drugs.

79. The Committee thanked the United States for its efforts, and agreed to continue the elaboration of the Compendium. The Committee also encouraged the submission of additional data by member countries, and noted that a progress report would be presented at its next session by the United States.

FINAL SUMMARY REPORT ON THE SURVEY ON INTAKE STUDIES (Agenda Item 8)

80. The Committee agreed that the Delegation of the United States should prepare a final summary and compilation of dietary intake data for consideration by the CCRVDF at its Sixth Session, as the recent receipt of additional dietary intake data prevented the preparation of the final report (CX/RVDF 90/6) for the current session.

PROPOSED DRAFT GLOSSARY OF TERMS AND DEFINITIONS (Agenda Item 9)

81. The Committee had before it the proposed glossary (CX/RVDF 90/7) as well as government comments summarized in document CX/RVDF 90/7-Add.1. The Delegation of Canada presented a background summary of the documents elaboration and noted changes incorporated since the Committee's last session, including a foreword and definitions elaborated by the Commission, JECFA and other Codex Committees.

82. The Committee agreed to the importance of the glossary and decided it should be forwarded to the 19th Session of the Commission for adoption at Step 5. In taking this decision, the Committee reiterated its position that the Codex Classification of Foods and Animal Foods (CAC/PR 4-1989) should be consulted in the future when revising the glossary in order to prevent duplication of efforts or confusion. In view of time constraints, the Committee also agreed that recent comments from Brazil, Germany and Spain would be taken into consideration at Step 6.

83. The Proposed Draft Glossary of Terms and Definitions is attached to this report as Appendix IV.

PROPOSED DRAFT CODE OF PRACTICE FOR CONTROL OF THE USE OF VETERINARY DRUGS
(Agenda Item 10)

84. The Delegation of the United Kingdom presented the draft Code (CX/RVDF 90/8) as revised in accordance with comments submitted in response to CL 1989/47-RVDF. The Committee also noted comments from Sweden as contained in Conference Room Document 2, as well as other written comments presented to the Secretariat at the present Session.

85. The Committee agreed to the importance of the draft Code and supported forwarding the Code for consideration by the 19th Session of the Commission at Step 5. In view of time constraints, the Committee also agreed that recent comments would be taken into consideration at Step 6.

86. The proposed draft Code of Practice for Control of the Use of Veterinary Drugs is attached to this report as Appendix V.

PROPOSED DRAFT GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR CONTROL OF VETERINARY DRUG RESIDUES IN FOOD (Agenda Item 11)

87. The Committee had before it the proposed draft guidelines (CX/RVDF 90/9) as prepared and revised by the United States based on comments submitted in response to CL 1989/47-RVDF. The Delegation of the United States provided a background summary of the documents elaboration.

88. After considerable discussion, the Committee agreed that those sections of the document addressing screening methods should be removed and forwarded to the Working Group on Methods of Analysis and Sampling for consideration. It was noted that separate annexes addressing screening, sampling and other methods of analysis could be developed by the working group with the understanding that these would be incorporated into the general guidelines after their future adoption by the Commission.

89. The Committee concluded and agreed that the current general introductory aspects of the guidelines should be forwarded to the Commission for adoption at Step 5.

90. The proposed draft general guidelines are attached to this report as Appendix VI.

PROGRESS REPORT BY OIE ON THE DRAFT CODE OF PRACTICE FOR THE REGISTRATION AND DISTRIBUTION OF VETERINARY DRUGS (Agenda Item 12)

91. The head of the Delegation of France, speaking on behalf of the Office International des Epizooties (OIE), presented a background summary of the draft Code (CX/RVDF 90/10) and noted that it was amended to eliminate all parts which were

overlapping with the draft Code of Practice for Control of the Use of Veterinary Drugs prepared by the Delegation of the United Kingdom.

92. It was emphasized that the Code was based on an authorization procedure to manufacture and market veterinary drugs in accordance with good manufacturing practices and to objectively evaluate the technical and scientific data relative to the quality, efficacy and safety of the veterinary drugs.

93. The Committee thanked the OIE for its efforts, and several Delegations directed comments to the representative of the OIE for proposed revisions to the Code.

94. The Committee concluded and agreed that the elaboration of the draft Code, amended to read "Code of Practice for the Registration of Veterinary Drugs", should continue under the direction of the OIE and encouraged the submission of comments directly to the organization.

95. The Committee also agreed that a progress report concerning the proposed Code should be presented by the OIE for information at the Committee's Sixth Session.

CONSIDERATION OF METHODS OF ANALYSIS AND SAMPLING BASED ON RESPONSES TO THE INFORMATION WORK SHEET (Agenda Item 13)

96. The Committee had before it comments submitted in response to the Information Work Sheet (CX/RVDF 90/11), as well as Conference Room Document 3 entitled, "Report to the Plenary Session of the Fourth Meeting of the *Ad Hoc* Working Group on Methods of Analysis and Sampling." The Chairman of the Working Group, Dr. R. Ellis (USA), introduced the report and noted that a total of 56 delegates and observers from Argentina, Australia, Canada, Denmark, Finland, France, Germany, Korea, The Netherlands, New Zealand, Norway, Poland, Spain, Sweden, Swaziland, Switzerland, United Kingdom and the U.S.A. participated. Representatives from the European Economic Community (EEC), COMISA and the Joint FAO/WHO Secretariat were also present.

97. The Working Group chairman noted that the Group had been provided four papers for review and discussion. The revised document "Sampling for the Control of Residues of Veterinary Drugs in Foods" was discussed at length in the Group. The document content was generally approved but some revisions and amendments were made to emphasize its function as a technical document applicable to the sampling of animal products in general (including fish and honey). The Group also considered the revised document "General Considerations of Analytical Methods for Regulatory Control" and amended it to include coverage of fish and honey. The Working Group recommended that the revised text be circulated to governments for comment on its usefulness to non-specialists as a background document for use in the development of regulatory control systems. The Working Group reviewed the paper "Method Performance Attributes" and was advised that the EEC technical experts generally agreed with the document. The paper will be given to the Joint Secretariat for distribution to member governments for comment. The Group considered the final paper "Analytical Method Data Sheet". Some revisions were made following discussion and the Group concluded that a short note be added to give guidance and describe the terms used in the worksheet to aid completion of the data sheet. The Worksheet will include information on the availability and quality of method standards. The Working Group recommended that the data sheet be supplied to the Joint Secretariat of JECFA to consider its distribution with the call for data for future JECFA Meetings and that the CCRVDF circulate the revised data sheet to member countries with a view to its possible use when assessing suitability of analytical methods for Codex purposes.

98. Methods of analysis were discussed for residues in foods of albendazole, carbadox, chloramphenicol, ivermectin, oxytetracycline, sulfadimidine (sulfamethazine) and zeranol. Methods had been requested but not submitted for benzyl penicillin, closantel, levamisole and trenbolone acetate. In the course of discussion, the Working Group emphasized the need to restrict its recommendation on a method to the residue/tissue combinations for which it had been evaluated and to specify the suitability of the method for screening, routine or confirmatory purposes. After full evaluation, the Group recommended three analytical methods be adopted by the Committee. These methods were for residues of albendazole, carbadox and ivermectin in liver tissue. The other analytical methods reviewed required further validation before a decision for adoption could be made.

99. The Working Group agreed to assemble suitable methods for azaperone, carazolol, chlorpromazine, febantel, fenbendazole, oxfenbendazole, propionylpromazine, spiramycin and tylosin for possible evaluation at a later date. The Working Group also sought to establish improved procedures for ensuring that prior to consideration of a drug by JECFA, suitable methods of analysis had been assessed.

100. The Working Group noted with some concern that with few exceptions inter-laboratory trials of methods of analysis for veterinary drug residues were normally conducted with only a small number of laboratories. They wish to see that situation improved and to that extent, will support the initiatives already being developed (as in EEC and IUPAC) in identifying the availability of suitable materials for study, availability of competent participant laboratories and procedures for transmission of test materials.

101. Other Group deliberations concerned the need for efficient screening methods (particularly in countries with important export trade in animal products), and the use of microbiological inhibition assay methods. The Delegation of Norway pointed out that proper standards and reagents will be difficult to obtain. The Delegation believes that microbiological methods are negatively covered in the Working Group report and that such methods can be used for screening as they are cheap and do not require sophisticated equipment. Dr. Ellis explained that the concerns were related to a specific method with high variability between microbiological and chemical procedures.

102. The Delegation from Spain noted that they had previously requested changes in the definitions used in the Working Group papers to accommodate Spanish translation amendments. The Working Group chairman assured that these comments would be taken into consideration.

103. The Committee agreed to adopt the following Working Group recommendations:

- (a) Subject to final revisions, the documents on Sampling for the Control of Residues of Veterinary Drugs, on General Considerations of Analytical Methods for Regulatory Control, Method Performance Attributes and the Analytical Method Data Sheet be circulated to members of the Committee for comment prior to acceptance at the next meeting of CCRVDF.
- (b) That methods be adopted for albendazole, carbadox and ivermectin for liver tissue as being suitable for the JECFA recommended MRLVDs. Reaffirmation was also made for zeranol methods recommended last year.
- (c) That further validation data be obtained on other promising candidate methods for evaluation by the Working Group. Member governments and drug sponsors are encouraged to provide this data.

- (d) That further consideration be given to the limitations associated with some microbiological and immunochemical methods, to the difficulties associated with development of screening tests and to the international transmission of analytical samples for method assessment/validation.

104. The Committee thanked the Working Group and its chairman for its report and decided to endorse the continuation of the *Ad Hoc* Working Group on Methods of Analysis and Sampling under the chairmanship of Dr. R. Ellis (USA).

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION (Agenda Item 14)

105. The Committee had before it CX/RVDF 90/12 and CX/RVDF 90/12 Addendum 1 (Conference Room Document 1), which contained proposals for additions to the priority list of veterinary drugs requiring evaluation submitted in response to CL 1990/3-RVDF, and Conference Room Document 4, the report of the *Ad Hoc* Working Group on Priorities. The Chairman of the Working Group, Mr. G. Hooper (Australia), introduced the report of the Working Group and its recommendations.

106. Comments were received from Australia, Canada, Cuba, and Poland on the previous priority list while new proposals for the 1993 JECFA were received from the European Economic Community and the United States.

107. The proposals from the European Economic Community and the United States were discussed and considered. Since *porcine somatotropin* was not identified as yet being approved in any country, it was not included on the 1993 list. There was general agreement that the aminoglycosides (*dihydrostreptomycin*, *gentamicin*, *streptomycin*, *neomycin* and *spectinomycin*) proposed by the United States present significant residue problems and review of these compounds might be conducted as a class. The Delegation of the United States agreed to provide an indication of available data by the next session of the CCRVDF. The Delegations of Spain and France proposed that *kanamycin* and *apramycin* be added to the list of aminoglycosides.

108. There was discussion regarding whether it was appropriate to include *lindane* as a veterinary drug. It had been evaluated recently by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). *Lindane* is used as an ectoparasitic agent. Some Delegations stated their contention that it falls within the definition of a residue of a veterinary drug, while others believed that *lindane* is only one of a large number of external animal treatments, and to include it on the priority list would open the way to placing a large number of substances on the priority list that should more properly be considered as pesticides. It was decided to maintain *lindane* on the 1993 priority list. Discussions will be held at the next CCRVDF as to whether or not *lindane* will be placed on the agenda of JECFA or JMPR.

109. For some substances proposed for evaluation in 1993, the data bases may be incomplete. Included in this category was *dexamethasone*, but the Delegation of Germany stated that it was their understanding that the complete data base will be provided by the sponsor. Because the situation was not clear, it was decided to maintain its present status, with a request that more information be provided at the next session of the CCRVDF.

110. The Joint Secretaries of JECFA requested that the 1993 list be prioritized at the next session of the CCRVDF. Mr. Hooper (Australia), at the suggestion of the Delegation of the United States, agreed to ask countries responding to the next questionnaire to prioritize their own lists. On this basis, these substances will be prioritized at the next session of the CCRVDF.

111. The substances proposed at the Committee's Fourth Session for evaluation at the JECFA meeting devoted to veterinary drug residues in 1992 (Appendix VIII, ALINORM 91/31) were also reviewed.

112. A recommendation was made to include the specific benzimidazoles, flubendazole and thiabendazole. *Trimethoprim* and the sulfonamides were moved to the 1993 list because of uncertainty about the nature of the combination data available on them. It was understood that *trimethoprim* is almost exclusively used in combination with sulfonamides and specific information on the available data were requested by the time of the next session of the CCRVDF.

113. It was recommended that *bovine somatotropin* be listed as *bovine somatotropins* because this substance exists in several different forms. The U.S. agreed to provide data on the somatotropins through the joint efforts of four U.S. companies.

114. The observer from COMISA informed the Committee that the sponsors of the *bovine somatotropins* had agreed to submit a common document, presenting an overview of published data. However, the four dossiers containing data pertaining to different pharmaceutical specialities will be presented separately in identical format in order to facilitate their interpretation.

115. The Delegation of France stated that the new information provided by COMISA changed the basis on which the Working Group had discussed the *bovine somatotropins*, because initially a common dossier for the four *bovine somatotropins* had been announced. Although two of the four substances were not yet registered in any country, the Delegation of France noted that it would be possible to evaluate these compounds as a group in view of their analogous structure. However, the Delegation of France emphasized that this decision should not set a precedent for future nominations to the priority list, as substances not registered for use do not qualify for prioritization.

116. The JECFA Joint Secretariat indicated that the proposal made by the sponsors provided a workable procedure. JECFA could decide at the meeting how to handle the data.

117. The Committee was informed by the Working Group report that studies are underway and/or planned on *nitrofurazone* and *furazolidone*. Commitments were made to provide data on *rafoxamide* and *triclabendazole*.

118. At the suggestion of Canada and the United States *ractopamine* was added to the list for 1992. The sponsoring company is committed to providing a complete dossier by mid-1991.

119. The JECFA Secretariat reported that *sulfadimidine* would be included in the 1991 evaluation because the temporary ADI expires in 1991. He also indicated that *ronidazole* and *chloramphenicol* would be included in the 1993 evaluation because the temporary ADI for *ronidazole* expires that year and significant new data on *chloramphenicol* will be available for evaluation at that time. In addition, *olaquinox* will be re-evaluated in 1993 because that is when its temporary acceptance will expire.

120. The Committee noted that the MRL for *chloramphenicol* was scheduled for consideration at the 19th Session of the Commission at Step 8, as decided at the previous CCRVDF Session (paras. 50-60, ALINORM 91/31). Government comments concerning this and other MRLVDs were solicited (CL 1989/47-RVDF) in accordance with the Guide

to the Consideration of Codex Standards at Step 8 (Codex Alimentarius Procedural Manual, Seventh Edition).

121. Considerable discussions took place as to the merits of forwarding or withholding the proposed draft MRLVD for *chloramphenicol*. Several delegations noted that as new data were forthcoming, the Commission should consider withholding final action pending a JECFA re-evaluation. A similar number of Delegations, however, recommended that the MRLVD for *chloramphenicol* should be considered by the Commission as planned.

122. The Chairman reminded the Committee that the decision to adopt the MRLVD for *chloramphenicol* rested with the Commission, and agreed to assist delegations in presenting their divergent viewpoints at that time.

123. The Committee agreed on the priority list as presented in Appendix VII. This list includes those substances that were known to be scheduled for re-evaluation by JECFA at the time of the present session of CCRVDF.

124. The Committee thanked the Working Group and its Chairman for its report and decided to endorse the continuation of the *Ad Hoc* Working Group on Priorities under the Chairmanship of Mr. G. Hooper (Australia). The Committee also agreed that the questionnaire regarding the nomination of veterinary drugs for priority evaluation should be circulated for comment.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 15)

125. The Committee, while noting that there was no other business proposed for discussion, concluded and agreed that the Agenda for its next session should include the following items:

- Consideration of Recommended Maximum Residue Limits for Veterinary Drugs arising from the 34th, 36th and 38th JECFA Sessions;
- Progress Report on Compendium of Veterinary Drugs;
- Final Report on Survey on Intake Studies;
- Draft Glossary of Terms and Definitions;
- Draft Code of Practice for Control of the Use of Veterinary Drugs;
- Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods;
- Proposed Draft Code of Practice for the use of Veterinary Drugs in Aquaculture;
- Progress Report on the Code of Practice for the Registration of Veterinary Drugs;
- Consideration of Methods of Analysis and Sampling;
- Consideration of Priorities.

DATE AND PLACE OF NEXT SESSION (Agenda Item 16)

126. The Committee noted that the Sixth Session of the Codex Committee on Residues of Veterinary Drugs in Foods would be held in Washington, D.C. at a date to be communicated in the near future. It was strongly suggested that the Committee continue to meet on a yearly basis.

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Summary Status of Work

Code/Guideline/Maximum Residue Limit	Step	For Action by:	Document Reference
Draft MRLVDs arising from 32nd JECFA Session	8	19th CAC	ALINORM 91/31, Appendix IV
Proposed Draft MRLVDs arising from 34th JECFA Session	5	19th CAC	ALINORM 91/31A, Appendix III
Proposed Draft MRLVDs arising from 36th JECFA Session	3	Governments 6th CCRVDF	ALINORM 91/31A, Appendix II
Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs	5	19th CAC	ALINORM 91/31A, Appendix V
Proposed Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods	5	19th CAC	ALINORM 91/31A Appendix VI
Proposed Draft Glossary of Terms and Definitions	5	19th CAC	ALINORM 91/31A, Appendix IV
Proposed Draft Code of Practice for the Use of Veterinary Drugs in Aquaculture	1,2	Canada 6th CCRVDF	ALINORM 91/31A, paras. 14-17
Methods of Analysis and Sampling	--	Governments 6th CCRVDF	ALINORM 91/31A, paras. 96-104
Priority List of Veterinary Drugs Requiring Evaluation	--	Governments 6th CCRVDF	ALINORM 91/31A, Appendix VII
Compendium of Veterinary Drugs	--	United States 6th CCRVDF	ALINORM 91/31A, paras. 77-79
Final Summary Report on the Survey on Intake Studies	--	United States 6th CCRVDF	ALINORM 91/31A, para. 80
Draft Code of Practice for the Registration of Veterinary Drugs	--	OIE 6th CCRVDF	ALINORM 91/31A, paras. 91-95

Summary Status of Work (Cont'd)

Code/Guideline/Maximum Residue Limit	Step	For Action by:	Document Reference
Definitions for "Maximum Residue Limit for Veterinary Drugs" and "Good Practice in the Use of Veterinary Drugs"	--	No further action required.	ALINORM 91/31, para. 10
Procedures for the Elaboration of MRLVDs - Introduction	--	No further action required.	ALINORM 91/31, para. 11
Procedure for the Elaboration of MRLVDs	--	No further action required.	ALINORM 91/31, para. 11
Procedure for the Acceptance of MRLVDs	--	No further action required.	ALINORM 91/31, para. 12
Amendment to Terms of Reference (Clause (d) - Methods of Analysis and Sampling)	--	No further action required.	ALINORM 89/31, para. 19
Criteria for the Selection of Veterinary Drugs for the Establishment of Maximum Residue Limits (MRLs)	--	No further action required.	ALINORM 89/31, Appendix VIII - Part I
Format for the Presentation of Codex MRLs for Veterinary Drugs	--	No further action required.	ALINORM 89/31, Appendix IV - Part A
Definition for "Veterinary Drug" and "Residue of Drug"	--	No further action required.	ALINORM 87/31, paras. 93, 101

ALINORM 91/31A
APPENDIX I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

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ALINORM 91/31A
APPENDIX II

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
AT STEP 3

NOTE: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1. Substance: Closantel
2. Acceptable Daily Intake (ADI) as established by JECFA 0 - 0.03 mg/kg body weight
- 3.1 (a) Commodity (a) edible tissues of sheep
(b) MRL (b) 1.5 mg/kg
(c) Definition of residues on which MRL was set (c) closantel
- 3.2 (a) Commodity (a) Bovine tissue: muscle
(b) MRL (b) 0.5 mg/kg (Temporary)
(c) Definition of residues on which MRL was set (c) closantel
- 3.3 (a) Commodity (a) Bovine tissue: kidney
(b) MRL (b) 2 mg/kg (Temporary)
(c) Definition of residues on which MRL was set (c) closantel
- 3.4 (a) Commodity (a) Bovine tissue: liver
(b) MRL (b) 1 mg/kg (Temporary)
(c) Definition of residues on which MRL was set (c) closantel
4. Reference to recommended methods of analysis (To be elaborated)
5. References to JECFA reports WHO TRS 799 (1990)
WHO FAS 27
FAO FNP 41/3
6. References to previous Codex publications None

1. Substance: Ivermectin
2. Acceptable Daily intake (ADI) as established by JECFA 0 - 0.0002 mg/kg body weight
- 3.1 (a) Commodity (a) Liver (all species)
(b) MRL (b) 0.015 mg/kg
(c) Definition of residues on which MRL was set (c) 22,23 dihydroavermectin Bla (H2B1a)
- 3.2 (a) Commodity (a) Fat (all species)
(b) MRL (b) 0.02 mg/kg
(c) Definition of residues on which MRL was set (c) 22,23 dihydroavermectin Bla (H2B1a)
4. Reference to recommended methods of analysis USDA/FSIS Chemistry Laboratory Guidebook Method No. 5.035
5. References to JECFA reports WHO TRS 799 (1990)
WHO FAS 27
FAO FNP 41/3
6. References to previous Codex publications None

1. Substance: Levamisole
2. Acceptable Daily Intake (ADI) as established by JECFA 0 - 0.003 mg/kg body weight (temporary)
- 3.1 (a) Commodity (a) Edible tissues and milk (all species)
(b) MRL (b) 0.01 mg/kg (Temporary)
(c) Definition of Residue on which MRL was set (c) Levamisole
4. Reference to recommended methods of analysis (To be elaborated)
5. Reference to JECFA reports WHO TRS 799 (1990)
WHO FAS 27
FAO FNP 41/3
6. References to previous Codex publications None

1. Substance: Benzylpenicillin

2. Acceptable Daily Intake (ADI) as established by JECFA 0.03 mg/person/day (Daily intake of the parent drug should be kept below this level)
- 3.1 (a) Commodity (a) Liver, kidney and muscle
(b) MRL (all species)
(c) Definition of residues on which MRL was set (b) 0.05 mg/kg
(c) Benzylpenicillin
- 3.2 (a) Commodity (a) Milk
(b) MRL (b) 0.004 mg/kg
(c) Definition of residues on which MRL was set (c) Benzylpenicillin
4. Reference to recommended methods of analysis (To be elaborated)
5. References fo JECFA reports WHO TRS 430 (1969)
FAO NMRS 45 (1969)
WHO TRS 799 (1990)
WHO FAS 27
FAO FNP 41/3
6. References to previous Codex publications None

1. Substance: Oxytetracycline

2. Acceptable Daily Intake (ADI) as established by JECFA 0 - 0.003 mg/kg body weight
- 3.1 (a) Commodity (a) muscle (all species)
(b) MRL (b) 0.1 mg/kg
(c) Definition of Residue on which MRL was set (c) Oxytetracycline
- 3.2 (a) Commodity (a) Liver (all species)
(b) MRL (b) 0.3 mg/kg
(c) Definition of residue on which MRL was set (c) Oxytetracycline
- 3.3 (a) Commodity (a) Kidney (all species)
(b) MRL (b) 0.6 mg/kg
(c) Definition of residue on which MRL was set (c) Oxytetracycline
- 3.4 (a) Commodity (a) Fat (all species)
(b) MRL (b) 0.01 mg/kg
(c) Definition of residue on which MRL was set (c) Oxytetracycline

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|-----|---|--|
| 3.5 | (a) Commodity | (a) Milk (all species) |
| | (b) MRL | (b) 0.1 mg/kg |
| | (c) Definition of residue on which MRL was set | (c) Oxytetracycline |
| 3.6 | (a) Commodity | (a) Eggs (all species) |
| | (b) MRL | (b) 0.2 mg/kg |
| | (c) Definition of residue on which MRL was set | (c) Oxytetracycline |
| 4. | Reference to recommended methods of analysis | (To be elaborated) |
| 5. | References to JECFA reports | WHO TRS 430 (1969)
FAO NMRS 45 (1969)
WHO TRS 799 (1990)
WHO FAS 27
FAO FNP 41/3 |
| 6. | References to previous Codex publications | None |
| 1. | <u>Substance:</u> <u>Carbadox</u> | |
| 2. | Acceptable Daily Intake (ADI) as established by JECFA | Limited acceptance of residues |
| 3.1 | (a) Commodity | (a) swine liver |
| | (b) MRL | (b) 0.03 mg/kg |
| | (c) Definition of Residue on which MRL was set | (c) Quinoxaline-2-carboxylic acid |
| 3.2 | (a) Commodity | (a) Swine muscle |
| | (b) MRL | (b) 0.005 mg/kg |
| | (c) Definition of residues on which MRL was set | (c) Quinoxaline-2-carboxylic acid |
| 4. | Reference to recommended methods of analysis | USDA/FSIS Chemistry Laboratory Guidebook Method No. 5.014 |
| 5. | Reference to JECFA reports | WHO TRS 799 (1990)
WHO FAS 27
FAO FNP 41/3 |
| 6. | References to previous Codex publications | None |

ALINORM 91/31A
APPENDIX III

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
AT STEP 5

Note: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1. Substance: Albendazole
2. Acceptable Daily Intake (ADI) as established by JECFA 0-0.05 mg/kg body weight
- 3.1 (a) Commodity (a) Muscle, fat and milk
(b) MRL (b) 0.1 mg/kg
(c) Definition of residues on which MRL was set (c) 2-aminosulfone metabolite
- 3.2 (a) Commodity (a) Liver and kidney
(b) MRL (b) 5 mg/kg
(c) Definition of residues on which MRL was set (c) 2-aminosulfone metabolite
4. Reference to recommended methods of analysis USDA/FSIS Chemistry Laboratory Guidebook Method No. 5.034
5. References to JECFA reports WHO TRS 788 (1989)
WHO FAS 25 (1990)
FAO FNP 41/2 (1990)
6. References to previous Codex publications Appendix III, ALINORM 91/31
1. Substance: Sulfadimidine
2. Acceptable Daily Intake (ADI) as established by JECFA 0-0.004 mg/kg body weight (Temporary)
- 3.1 (a) Commodity (a) Meat, liver, kidney and fat
(b) MRL (b) 0.3 mg/kg
(c) Definition of Residue on which MRL was set (c) Total residue

3.2	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Meat, liver, kidney and fat (b) 0.1 mg/kg (c) sulfadimidine
3.3	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Milk (b) 0.05 mg/kg (c) Total residue
3.4	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Milk (b) 0.025 mg/kg (c) sulfadimidine
4.	References to recommended method(s) of analysis	(a) <u>Journal of the Association of Official Analytical Chemists</u> Vol. 66 (1983) pp. 881, 884 (b) <u>Journal of Agriculture and Food Chemistry</u> May-June 1981, pp. 621-624
5.	Reference to JECFA Reports	WHO TRS 788 (1989) WHO FAS 25 (1990) FAS FNP 41/2 (1990)
6.	References to previous Codex Publications	Appendix III, ALINORM 91/31
1.	<u>Substance: Trenbolone acetate</u>	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-0.02 µg/kg body weight
3.1	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Muscle (b) 2 µg/kg (c) Beta-trenbolone
3.2	(a) Commodity (b) MRL (c) Definition of residues on which MRL was set	(a) Liver (b) 10 µg/kg (c) Alpha-trenbolone
4.	Reference to recommend method of analysis	(to be elaborated)
5.	References to JECFA reports	WHO TRS 683 (1982) WHO TRS 696 (1983) WHO TRS 763 (1988) WHO TRS 788 (1989) FAO FNP 41 (1988)

FAO FNP 41/2 (1990)
WHO FAS 23 (1988)
WHO FAS 25 (1990)

6. References to previous Codex
publications

Appendix VI, ALINORM 89/31
Appendix V, ALINORM 89/31A
Appendix III, ALINORM 91/31

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APPENDIX IV

PROPOSED DRAFT GLOSSARY OF TERMS AND DEFINITIONS
AT STEP 5

Foreword

The Glossary of Terms and Definitions has been elaborated by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) with a view towards providing information and guidance to the Committee, and is intended for internal Codex use only.

The Glossary is intended to be an open list which is subject to review by the CCRVDF in order to update, modify or add to the list of terms. Relevant terms elaborated by other Codex committees are included.

1. Acceptable Daily Intake (ADI)^{3/}: An estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg).
2. Bioavailable Residues^{3/}: Those residues that can be shown, by means of an appropriate method (e.g. Gallo-Torres method) to be absorbed into systemic circulation when fed to laboratory animals.
3. Bound Residue: Residues derived from the covalent binding of the parent drug or a metabolite of the drug and a cellular biological soluble or insoluble macromolecule. These residues are not extractable from the macromolecule by exhaustive extraction, denaturation or solubilization techniques. They do not result from the incorporation of metabolized, radiolabelled fragments of the drug into endogenous compounds, or the same macromolecule by normal biosynthetic pathways. Information concerning the calculation of bound residues may be found in Annex 3 of the 34th Report of JECFA (pages 58-61, WHO TRS 788).
4. Egg: Egg (in shell) of domesticated chickens (hens).
5. Extractable Residue^{2/}: Those residues extracted from tissues or biological fluids by means of aqueous acidic or basic media, organic solvents and/or hydrolysis with enzymes (e.g. sulfatase or glucuronidase) to hydrolyse conjugates. The extraction conditions must be such that the compounds of interest are not destroyed.
6. Fish: Means any of the cold-blooded aquatic vertebrate animals commonly known as such. This includes Pisces, Elasmobranchs and Cyclostomes. Aquatic mammals, invertebrate animals and amphibians are not included. It should be noted, however, that this term may also apply to certain invertebrates, particularly Cephalopods.
7. Good Practice in the Use of Veterinary Drugs (GPVD)^{1/}: Is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions.
8. Marker Residue^{3/}: A residue whose concentration decreases in a known relationship to the level of total residues in tissues, eggs, milk or other

animal tissues. A specific quantitative analytical method for measuring the concentration of the residue with the required sensitivity must be available.

9. Maximum Residue Limit for Veterinary Drugs (MRLVD)^{1/} is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) 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 toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

When establishing an MRL, consideration is also given to residues that occur in food of plant origin and-or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

10. Meat: The edible part of any mammal.
11. Milk: Exclusively the normal mammary secretion obtained from one or more milkings without either addition thereto or extraction therefrom. The term may be used for milk treated without altering its composition, or for milk the fat content of which has been standardized under domestic legislation. The term may also be used in association with a word or words to designate the type, grade, origin and/or intended use of such milk or to describe the physical treatment or the modification composition to which it has been subjected, provided that the modification is restricted to an addition and/or withdrawal of natural milk constituents. In international trade, the origin of the milk shall be stated if it is not bovine.
12. Muscle^{2/}: Muscle tissue only.
13. Non-Extractable Residues^{2/}: These residues are obtained by subtracting the extractable residues from the total residues and comprise:
- i) Residues of the drug incorporated through normal metabolic pathways into endogenous compounds (e.g. amino acids, proteins, nucleic acid). These residues are of no toxicological concern.
 - ii) Chemically-bound residues derived by interaction of residues of parent drug or its metabolites with macromolecules. These residues may be of toxicological concern.
14. Poultry: Means any domesticated bird including chickens, turkeys, ducks, geese, guinea-fowls or pigeons.
15. Regulatory Method of Analysis: A method that has been legally enacted and/or validated in a multi-laboratory study and can be applied by trained analysts using commercial laboratory equipment and instrumentation to detect and determine the concentration of a residue of a veterinary drug

in edible animal products for the purpose of determining compliance with the MRL.

16. Residues of Veterinary Drugs^{1/}: Include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned.
17. Screening Method: A rapid, relatively inexpensive, and rugged field method used for testing for a specific substance or closely related group of substances which are sufficiently selective and sensitive to allow at least semi-quantitative detection of residues in contents in accordance with the established maximum limit.
18. Temporary Acceptable Daily Intake (TADI)^{2/}: Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA.
19. Tissue^{2/}: All edible animal tissue, including muscle and by-products.
20. Tissue, Control: Tissue from animals not treated with veterinary drugs of the same species, sex, age and physiological status as the target species.
21. Tissue, Dosed: Tissue from animals of the test species that have been treated with the drug according to its intended use.
22. Tissue, Spiked or Fortified: Tissue containing known concentrations of the analyte added to the sample of control tissue.
23. Total Residue^{2/}: The total residue of a drug in animal derived food consists of the parent drug together with all the metabolites and drug based products that remain in the food after administration of the drug to food producing animals. The amount of total residues is generally determined by means of a study using the radiolabelled drug, and is expressed as the parent drug equivalent in mg/kg of the food.
24. Validated Method: An analytical method which has been subjected to a multi-laboratory study for accuracy, precision, reproducibility performance and ruggedness. Concise written procedures for sample selection, preparation and quantitative analysis are provided for inter-laboratory quality assurance and consistency of results, on which an appropriate regulatory method of analysis can be established.
25. Veterinarian Client-Patient Relationship: The relationship is recognized when the livestock enterprise, premises and husbandry practices are known to the veterinarian as a result of a recent professional visit to the site and the veterinarian is available for emergency on site consultation and is responsible for preventative medicine programs.
26. Veterinary Drug^{1/}: Any substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry,

fish or bees, whether used for therapeutic, prophylactic, or diagnostic purposes, or for modification of physiological functions or behaviour.

27. Withdrawal Time and Withholding Time: This is the period of time between the last administration of a drug and the collection of edible tissue or products from a treated animal that ensures the contents of residues in food comply with the maximum residue limit for this veterinary drug (MRLVD).

Notes:

- 1/ These definitions have been adopted by the Codex Alimentarius Commission, and are included in the Codex Alimentarius Procedural Manual.
- 2/ These definitions have been established and adopted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- 3/ These definitions, as previously established and adopted by the Joint FAO/Expert Committee on Food Additives, have been modified by the Codex Committee on Residues of Veterinary Drugs.

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APPENDIX V

PROPOSED DRAFT CODE OF PRACTICE FOR CONTROL
OF THE USE OF VETERINARY DRUGS AT STEP 5

Introduction

1. This Code sets out guidelines on the prescription, application, distribution, and control of drugs used for treating animals, preserving animal health or improving animal production. The Code is intended to apply to all States which are members of the organizations under whose auspices the project is being developed and to contribute towards the protection of public health.
2. Good practice in the use of veterinary drugs (GPVD), as defined by the CCRVDF, is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions. The maximum residue limit for veterinary drugs (MRLVD) may be reduced to be consistent with good practice in the use of veterinary drugs. The MRLVD is based on the type and amount of residue considered to be without toxicological hazard for human health while taking into account other relevant public health risks as well as food technological aspects.
3. Veterinary products (including premixes for manufacture of medicated feeding stuffs) used in food producing animals should be administered (or incorporated into feed) in compliance with the relevant product information approved by national authorities and/or in accordance with a prescription and/or instruction issued by a qualified veterinarian.

Registration and Distribution - General Requirements

4. All medicinal products (i.e., all veterinary therapeutic products) and medicinal premixes for inclusion in animal feeds should comply with the OIE Code of Practice for the Registration of Veterinary Drugs and be registered with the national authority. Products should only be distributed through veterinarians, registered wholesalers, pharmacists or other retail outlets permitted by national laws and regulations. Storage and transport conditions must conform to the specifications on the label, in particular those concerning temperature, humidity, light, etc.

Responsibility of the Veterinarian and of Others Authorized to Handle or Administer Medicines - General Provisions

5. Whenever veterinary drugs are handled or administered it is important to recognize that potentially hazardous effects may occur in animals or in human operators. When the administration of a medicine is not under direct veterinary supervision, it is therefore essential that, after the diagnosis, clear instructions should be provided on dose and methods of use, taking account of the competence of the user performing the work and ensuring that the correct calculation of, and the importance of adhering to, withdrawal periods is fully understood. It is similarly important to ensure that the farm facilities and management systems employed enable the withdrawal periods to be observed.

6. In determining treatments, veterinarians should ensure that an accurate diagnosis is obtained and be guided by the principles of maximum effectiveness combined with minimum risk. Specific treatments should be presented using as few products as possible and avoiding the use of combination products, unless pharmacological advantages have been demonstrated.
7. Veterinarians should keep in mind that uncontrolled and unlimited use of medicinal products may lead to the accumulation of undesirable residues in the animals treated and in the environment, and that the continuous use of anticoccidial, antibacterial or anthelmintic products may favour the development of resistance. It is the responsibility of the veterinarian or other authorized persons to draw up programmes of preventive medicine for the farmer and to stress the importance of sound management and good husbandry procedures in order to reduce the likelihood of animal diseases. Every effort should be made to use only those drugs known to be effective in treating the specific disease.
8. The veterinarian should stress the need for diseased animals to be segregated from healthy animals and treated individually where possible.
9. Beyond his responsibility for advice on measures that will reduce the incidence of disease and for controlling it when it arises, the veterinarian is also responsible for taking the welfare of livestock fully into account.

Information of Veterinary Drugs

10. Product information considered essential by the national authority to ensure the safe and effective use of veterinary medicinal products must be made available in the form of labelling and nationally approved data sheets or leaflets. Information on dosage schedules should be complemented by instructions on dose-related recommended withdrawal periods, contra-indications and any other constraints on the use of the product including any precautions regarded as necessary.

Amounts to be Supplied

11. Medicines should not be supplied in excess of immediate requirements as this may lead to incorrect use or to deterioration of the products.

Preparation of Medicines

12. The preparation of medicines and medicated feeds should be undertaken by suitably trained personnel, using appropriate techniques and equipment.

Administration of Medicines

13. Special attention should be paid to using the correct dosage, site and route of administration. Note should be taken of all warning statements and contra-indications for use (in particular any incompatibility with other medicinal products). It is important not to use the product once the expiry date has passed.
14. In disease circumstances where no authorized product exists or certain indications or target species are not provided for in the product

literature, the veterinarian can on his own responsibility or with advice from the manufacturer have recourse to other licensed products or off label use. Administration of products in this manner, however, may have unpredictable side effects and give rise to unacceptable residue levels. Veterinarians should therefore only embark on such uses, especially in food-producing animals, after the most careful consideration of the needs of the disease situation. Under these circumstances, a significantly extended withdrawal time should be assigned for drug withdrawal prior to marketing milk, meat or eggs. The veterinarian is responsible for providing written instructions on the use and withdrawal times for all medicines used off label. Off label use by persons other than veterinarians must not be permitted except when such use is conducted or permitted under the supervision or prescription of the veterinarian.

15. To avoid the presence of unacceptable residues in meat or other by-products of animal origin it is essential that the livestock owner adheres to the withdrawal period laid down for each product and dose regime or to a suitably lengthy withdrawal period where none is specified. Full instructions should be given as to how this period is to be calculated including the use of on site residue detection methods where applicable and on the disposal of any animals slaughtered during treatment or before the end of the withdrawal period. If animals are sold before the end of the withdrawal period, the buyer must be informed.

Record Keeping Requirements

16. The veterinarian and/or the livestock owner or other authorized persons should keep a record of the products used, including the quantity, the date of administration, and the identity of animals on which the medicines were used. Each record should be kept for at least two years, and presented when required by the competent authorities.

Withdrawal of Veterinary Drugs

17. Where the veterinarian or other authorized person suspects that unexpected adverse reactions involving illness, abnormal clinical signs, or death in animals, or any harmful effects in persons administering veterinary medicines have been associated with a veterinary product they should be reported to the appropriate national authority. Regular feed-back or information to veterinarians and manufacturers on suspected adverse reactions should be encouraged.

Storage of Veterinary Drugs

18. Veterinary products should be correctly stored in accordance with label instructions. It should be kept in mind that storage temperatures are critical for some medicines, while exposure to light or to moisture can damage others. Prescription medicines should be separated from non-prescription medicines.
19. All veterinary products should be stored in secure premises and kept under lock and key where practicable and out of reach of children and animals.

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APPENDIX VI

PROPOSED DRAFT GUIDELINES FOR THE ESTABLISHMENT
OF A REGULATORY PROGRAM
FOR CONTROL OF VETERINARY DRUG RESIDUES IN FOODS
AT STEP 5

Nations need control programs to protect the health of their citizens from hazards which may come from the food supply. The overall goal of such control programs is to ensure a safe and wholesome food supply for a nation's citizens. The specifications of a control program are determined by the importance of the various health risks that could be incurred by consumers of animal food products.

One type of risk would occur if meat were consumed from animals that were infected with microorganisms or toxins that may affect the health of the consumer. This type of health risk can be minimized by meat inspection programs that emphasize sanitary conditions in slaughtering establishments and provide specific procedures on how to recognize the signs of disease in food animals.

Another kind of danger can occur if food animals have been raised using veterinary drugs or pesticides. The use of drugs or pesticides can result in residues of these chemicals in food derived from the treated animals. The safety of the human food requires a full scientific evaluation of the relative hazard as well as quantity of a drug residue remaining in the tissues of treated livestock and poultry and a systematic set of procedures that will assure effective control of such residues in human food

In addition to health protection benefits in having an effective residue control program, a country with such a program has the capability to participate in the community of food trading nations with confidence. This is because an effective residue control program can also serve as the foundation for certifications about the food safety of the country's exported products, as well as provide assurance of safety of products imported into the country.

In establishing an effective residue control program, a country should first provide a system for determining the safety of veterinary drugs. Procedures should also be developed for controlling the manufacture, distribution and use of veterinary drugs within the country. It also is essential that a food inspection program be established by the laws or other authority to deal with products which contain violative residues of veterinary drugs.

The second step in developing a residue control program is determining what veterinary drugs are being used in the country. The determination of the veterinary drugs used should identify those drugs that are manufactured in the country and those drugs that are imported for use.

The third step often takes the form of establishing maximum permitted residue limits of veterinary drugs in food products. The maximum permitted residue limit allows the assessment of animal drug use in terms of compliance with goals established by the residue control program. Only after decisions have been made about permitted residue limits is it sensible to conduct analytical testing for compliance assessment purposes. However, countries may need to conduct drug residue testing for purposes other than keeping adulterated food out of commerce. This testing may be part of investigations into the kinds of drug residues being found in human food. This type of information is essential in the continuing

Disposal of Veterinary Drugs

20. Veterinary drugs remaining after treatment has been completed must be disposed of safely. Partially used containers should not be retained for future use. Unused drugs beyond their expiry date may however be returned to the vendor if there is an agreement to that effect. Where administration of medicines is not under direct veterinary supervision, users should be advised about correct disposal measures, e.g., to reduce potential contamination of the environment.

developing of a residue control program. For countries that do not have technical expertise in making these residue control decisions, the work of JECFA/Codex would be a useful and beneficial resource.

In the implementation of this program, the country needs to establish a sampling plan for animal products. This includes making decisions on the number of samples to be taken, and which products will be sampled. The country needs to designate which laboratories will analyze the samples. The country also needs a quality control program for assuring uniformity in the methods of sampling and analysis.

Initially, a country could establish a residue control program using screening methods to monitor animal products. The use of these methods would not require investment in complex laboratory equipment and associated training costs, and would allow samples to be rapidly analyzed. The major emphasis in the training of personnel should be in the use and interpretation of screening test results.

A screening test can be defined as a qualitative or semi-quantitative analytical method that will reliably determine the presence of substance above a defined level in the test sample. By using this definition a negative test result indicates that the food from test sample is safe for consumption and no further testing is required. A positive result indicates that a residue violation may exist and further action is required. Follow-up action would be determined by the objectives of residue control program of the country performing the tests. In certain cases, additional analytical testing may be required to verify or confirm the results of the screening test.

In the implementation of a residue program that includes the use of screening tests, a quality assurance program needs to be established that will assure that screening methods used for the testing of animal products will reliably perform at the Codex MRL or limit set under national regulations.

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APPENDIX VII

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION
OR RE-EVALUATION

1. Substances proposed for consideration and evaluation at the 1992 JECFA meeting devoted to veterinary drugs residues:

Bovine Somatotropins
Clostantel
Flubendazole
Furazolidone
Nitrofurazone
Ractopamine
Rafoxanide
Thiabendazole
Triclabendazole

2. Substances proposed for consideration and evaluation at the 1993 JECFA meeting devoted to veterinary drug residues:

Apramycin ^{d/}
Chloramphenicol
Chlortetracycline
Dexamethasone ^{a/}
Dihydrostreptomycin ^{d/}
Enrofloxacin
Flumequine ^{a/}
Gentamicin ^{d/}
Imidocarb
Kanamycin ^{d/}
Lindane ^{b/}
Neomycin ^{d/}
Olaquinox
Oxolinic acid ^{a/}
Ronidazole
Spectinomycin ^{d/}
Streptomycin ^{d/}
Sulfonamides ^{a/}
Tetracycline
Trimethoprim

3. Substances scheduled for evaluation at the 1994 JECFA meeting devoted to veterinary drug residues:

Levamisole

4. Substances of potential interest which may not currently meet all selection criteria:

Porcine Somatotropin

5. Substances not yet scheduled for evaluation:

Phenothiazines (acetylpromazine, promazine)

NOTES

- a/ Data base may be incomplete.
- b/ Recently evaluated by JMPR.
- c/ Specific compounds to be identified.
- d/ Individual countries to provide data.