

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: 610181 FAO I. Cables Foodagri Facsimile: 6799563

ALINORM 91/31

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Nineteenth Session
Rome, 1-10 July 1991

REPORT OF THE FOURTH SESSION OF THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Washington, D.C., 24-27 October 1989

Note: This document incorporates Codex Circular Letter 1989/47-RVDF.

W/25522

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CX 4/60.2

CL 1989/47-RVDF
December 1989

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 Fourth Session of the
Codex Committee on Residues of Veterinary Drugs in Foods
(ALINORM 91/31)

... The report of the Fourth 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 FOURTH
SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

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

1. Draft Maximum Residue Limits for Veterinary Drugs in Foods at Step 8; ALINORM 91/31, paras. 50-60 and Appendix IV.

Governments wishing to propose amendments to the Draft Maximum Residue Limits for Veterinary Drugs, or to comment on the draft maximum residue limits, should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Codex Alimentarius Procedural Manual, Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy, not later than 28 February 1991.

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

1. Progress Report on the Compendium of Veterinary Drugs (United States); see ALINORM 91/31, paras. 61-66.
2. Final Summary Report on the Survey on Intake Studies (United States); see ALINORM 91/31, paras. 67-69.
3. Proposed Draft Glossary of Terms and Definitions (Canada); see ALINORM 91/31, paras. 70-75.
4. Progress Report on the Draft Code of Practice for the Registration and Distribution of Veterinary Drugs (OIE); see ALINORM 91/31, paras. 80-82.
5. Proposals for Additions to the Priority List of Veterinary Drugs Requiring Evaluation (Australia); see ALINORM 91/31, paras. 97-113 and Appendix VIII.

C. REQUEST FOR COMMENTS AND INFORMATION

1. Consideration of the final 34th JECFA Report and Proposed Draft Maximum Residue Limits for Veterinary Drugs at Step 3 - ALINORM 91/31, paras. 40-44 and Appendix III

The Committee agreed to review and solicit comments regarding the 34th JECFA Report (TRS 788 - circulated under separate cover) as well as the recommended MRLVDs at - Step 3 for consideration at the Fifth CCRVDF Session (1990), with a view towards MRLVD submission for adoption at Step 5 at the 19th Session of the Codex Alimentarius Commission in 1991.

2. Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs - ALINORM 91/31, paras. 76-79 and Appendix V

The Committee concluded and agreed to circulate the proposed Code for further evaluation and comment with a view towards the examination of a revised Code prepared by the United Kingdom at the Committee's Fifth Session.

3. Proposed Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods - ALINORM 91/31, paras. 83-87 and Appendix VI

The Committee agreed to circulate the proposed Guidelines for comments with the understanding that a revised version will be prepared by the United States for discussion at the Fifth Session of the Committee.

4. Consideration of Methods of Analysis and Sampling based on Responses to the Information Work Sheet - ALINORM 91/31, paras. 88-96 and Appendix VII

The Committee agreed to circulate the Information Work Sheet concerning Methods of Analysis and Sampling, which details information needed to establish additional methods, for government comments.

Governments and international organizations wishing to submit comments and information on the above subject matter are invited to do so no later than 15 May 1990 and as directed below:

For points C1 and C3 above:

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)

For point C2 above:

Mr. C. Cockbill
Head, Food Standards Division
Ministry of Agriculture, Fisheries and Food
Ergon House, c/o Nobel House
17 Smith Square
London SW1P 2HX
U.K. (Telex No. 21271; Telefax No. 238.6591)

For point C4 above:

Dr. Richard Ellis
Director
Chemistry Division
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 302, Annex Building
300 12th Street, S.W.
Washington, D.C. 20250
U.S.A. (Telex No. 89491; Telefax No. 202.447.2257)

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

Chief
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00100 Rome
Italy (Telex No. 610181 FAO I, Telefax No. 6799563)

Summary and Conclusions

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

- Noted that the Commission had adopted proposed definitions for Maximum Residue Limits for Veterinary Drugs (MRLVD) and Good Practices in the Use of Veterinary Drugs (GPVD), (para. 10).
- Noted that the Commission had adopted procedures for the Elaboration of Codex Maximum Residue Limits for Veterinary Drugs, Elaboration of Codex Maximum Residue Limits for Veterinary Drugs - Introductory Section and Acceptance of Codex Maximum Residue Limits for Veterinary Drugs, (paras. 11-12).
- Requested the Codex Committee on Fish and Fishery Products to keep it informed on the elaboration of a proposed Code of Practice for Aquaculture, especially in regard to the possible formation of a CCRVDF Working Group to elaborate a section on the use of veterinary drugs in aquaculture, (paras. 16-17).
- Agreed to return the proposed draft Maximum Residue Limits for Veterinary Drugs for Albendazole, Sulfadimidine and Trenbolone Acetate to Step 3 in order to allow for additional comments, (para. 44).
- Agreed that several suggestions concerning the deliberations of JECFA would be forwarded to the 36th Session of JECFA for their information and review, (para. 49).
- Agreed to advance the draft Maximum Residue Limits for Veterinary Drugs for Chloramphenicol, Estradiol-17 beta, Progesterone, Testosterone and Zeranol to Step 8 in order to allow for their adoption by the Commission, (para. 60).
- Agreed to have the United States prepare a progress report on the elaboration of a Compendium of Veterinary Drugs for consideration at the Fifth CCRVDF Session, (para. 66).
- Agreed to have the United States prepare a final summary report on the Survey on Intake Studies for consideration at the Fifth CCRVDF Session, (para. 69).
- Agreed to have Canada revise the Proposed Glossary of Terms and Definitions for circulation, comment and discussion at the Fifth CCRVDF Session, (para. 75).
- Agreed to circulate the Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs, as elaborated by the United Kingdom, for further evaluation and comment with a view towards the examination of a revised Code at the Committee's Fifth Session, (para. 79).

Summary and Conclusions (Cont'd)

- Agreed to have the OIE present a progress report on its elaboration of a draft Code of Practice for the Registration and Distribution of Veterinary Drugs to the Fifth CCRVDF Session for information, (para. 82).
- Agreed to circulate the Proposed Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods as prepared by the United States, for further evaluation and comment, with the understanding that a revised version will be examined at the Committee's Fifth Session, (para. 87).
- Agreed to circulate the Information Work Sheet on Methods of Analysis and Sampling, which details information needed for additional methods, for government comment and examination by the Working Group on Methods of Analysis and Sampling, (para. 95).
- Agreed to circulate a questionnaire for the nomination of substances to the Priority List of Veterinary Drugs Requiring Evaluation for examination by the Working Group on Priorities, (para. 113).

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INTRODUCTION

1. The Fourth Session of the Codex Committee on Residues of Veterinary Drugs in Foods was held from 24-27 October 1989 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 38 countries and 6 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 12 (Conference Room Document 8) and Agenda Item 13 (Conference Room Document 9), respectively.

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

OPENING OF THE SESSION (Agenda Item 1)

4. The Session was opened by Dr. Lester M. Crawford, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture. Dr. Crawford highlighted the importance and relevance of the Committee's deliberations in view of international trade issues, and stressed the need for continued cooperation between Codex member governments in the Committee's future activities.

5. Dr. Crawford also addressed the importance of the Committee's deliberations towards strengthening the relationship between Codex and the General Agreement on Tariffs and Trade. The full text of Dr. Crawford's remarks is attached as Appendix II to this Report.

ADOPTION OF THE AGENDA (Agenda Item 2)

6. The Committee had before it the Provisional Agenda for the Session (CX/RVDF 89/1 and Add. 1). The Delegation of Norway noted that Agenda Item 7, "Progress Report on Compendium of Veterinary Drugs for the Americas", was in fact worldwide in scope. The Committee agreed with this observation, and amended the title of this Agenda Item accordingly.

7. The Provisional Agenda was adopted as amended by the Committee.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

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

MATTERS OF INTEREST ARISING FROM THE EIGHTEENTH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Agenda Item 4a)

9. The Committee had before it working paper CX/RVDF 89/2, which summarized the following matters of interest to the Committee arising from the Eighteenth Session of the Codex Alimentarius Commission, (ALINORM 89/40).

Codex Committee on Residues of Veterinary Drugs in Foods

10. The Committee noted that the Commission decided to adopt the proposed definition for "maximum residue level", with the understanding that the name of the definition will

be changed to read "Maximum Residue Limit for Veterinary Drugs", (MRLVD). The Commission also adopted the proposed definition for "Good Practices in the Use of Veterinary Drugs", (paras. 210-214, ALINORM 89/40).

11. The Committee noted that the Commission adopted both procedures for the elaboration of Codex Maximum Residue Limits for Veterinary Drugs, with the understanding that Steps 6 and 7 might be omitted on the basis of a two-thirds majority of votes cast in the Commission, and in view of revisions made regarding the acceptance of standards by regional economic groupings (paras. 215-216, ALINORM 89/40).

12. The Committee also noted that the Commission had adopted procedures for the acceptance of Codex MRLVDs, with the understanding that changes adopted by the Commission regarding the types of acceptance for Codex maximum residue limits for pesticide residues would also be applied to the CCRVDF acceptance procedures, (para. 217, ALINORM 89/40).

Codex Committee on Pesticide Residues

13. The Committee was informed that the Commission had adopted the Classification of Foods and Animal Feeds as developed by the CCPR, which might be useful to other Codex Committees in dealing with contaminants or residues of veterinary drugs. The Committee agreed with the suggestion of the Delegation of Australia in that definitions proposed in the classification should be considered by CCRVDF in the elaboration of its Glossary of Terms, (paras. 225-226, ALINORM 89/40).

14. The Committee was also informed that the Commission had advanced the Draft Method of Sampling for the Determination of Pesticide Residues in Meat and Poultry Products to Step 6 of the Codex Procedure, and that the sampling plan might also be suitable for other Committees dealing with contaminants and residues in animal products, (paras. 227-228, ALINORM 89/40).

Codex Coordinating Committee for Africa

15. The Committee was informed that the Codex Coordinating Committee for Africa strongly supported the holding of seminars to assist African countries in resolving their problems related to the use of veterinary drugs, especially those of particular interest to the region (e.g. trypanocides).

Codex Committee on Fish and Fishery Products

16. The Committee was informed that the Codex Committee on Fish and Fishery Products was currently undertaking the elaboration of a proposed Code of Practice for Aquaculture, and a questionnaire prepared by the FAO Fisheries Department had been sent to Codex Contact Points and Interested International Organizations for comment, (CL 1989/13-FFP).

17. The Delegation of Canada noted that the Committee may wish to consider the establishment of a Working Group to elaborate a section on the use of veterinary drugs in aquaculture at its Fifth Session. The Committee agreed to request the Codex Committee on Fish and Fishery Products to keep it informed in this regard.

MATTERS ARISING FROM ACTIVITIES OF OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 4b)

Joint FAO/WHO Activities

18. The Committee noted that in view of the steep increase in infections with zoonotic Salmonella and other enteric bacteria, a joint FAO/WHO programme in animal production (in feed and animals during slaughter and storage) had been initiated. This involved good practice in agriculture that entailed training, monitoring, and appropriate services. It would be implemented through national services and both national and international programmes of continuing veterinary education. If success is achieved in reducing major pathogens in food-producing animals, the need for antibiotics and other drugs would be reduced.

WHO Activities

19. The Committee noted that WHO was working on guidelines for the surveillance of antibiotic resistance of pathogens and public health. The document should be issued by late spring 1990 and would facilitate the development of strategies and methods of prevention and control of antimicrobial resistance.

20. The Committee also observed that the 42nd World Health Assembly (May 1989) had passed a resolution relating to food-borne diseases, including those of zoonotic origin. Among its recommendations to the Director-General of WHO was "to continue to assist Member States, in particular through the work of the Codex Alimentarius Commission, in the development of optimum microbiological and hygiene standards for products of animal origin."

Pan-American Health Organization (PAHO)

21. The Observer from PAHO outlined activities of this organization related to the work of CCRVDF including the (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. The Observer acknowledged significant support from the United States Department of Agriculture; (b) initiation in the same Center of a regional programme destined for cooperation in the maintenance and lending of laboratory equipment; (c) continued cooperation with the Unified Laboratory for the Control of Foods and Drugs (LUCAM) in Guatemala City; and (d) various other activities related to food-borne diseases, residues of drugs and pesticides and radioactive contaminants in foods.

European Economic Community (EEC)

22. The Committee noted that on 9 February 1989, the European Commission officially transmitted to the Council a series of three proposals to update and amend directives relating to veterinary medicinal products. This package included a proposal for a regulation which would provide a Community procedure for the establishment of maximum residue levels for veterinary medicines. It was envisaged that MRLs would be established by the Community for all pharmacologically active compounds used in veterinary medicines over a transitional period ending in 1997. Thereafter, it would not be possible to use an active compound in veterinary medicines intended for administration to food producing animals unless an MRL had been established by the Community or unless the compound was included in a positive list of compounds for which it was not necessary to establish an MRL. The EEC Observer noted further that when evaluating these compounds, the results of any prior evaluation which had been undertaken within the Codex system would be taken into consideration.

23. The Committee for Veterinary Medicinal Products, within its working party on the safety of residues, had continued the evaluation of a number of compounds, including the sulfanomides, the nitrofurans, trimethoprim, dapson, dimetridazole, ronidazole, the benzimidazole group, ivermectine, levamisol, the beta lactam antibiotics and other antibiotics. The working party was also preparing guidance for the pharmaceutical industry on the presentation of data required to demonstrate the safety of a veterinary medicinal product.

24. On 27 September 1989, the Commission presented proposals to the Council that there should be an evaluation period for bovine somatotropin up to the end of 1990, during which Member States would not be able to take any unilateral decision to authorize the use of this compound.

25. Finally, work was continuing on the implementation of national residue surveillance programmes and on the development of analytical reference methods for use in any dispute concerning the presence of residues.

Office International des Epizooties (OIE)

26. The head of the Delegation of France informed the Committee of activities of the Office International des Epizooties (OIE).

27. The Committee was reminded that at its Second Session representatives of African countries had expressed a desire for a workshop pertaining to the registration of veterinary drugs. A workshop addressing these concerns was held at Arusha (Tanzania) on 19-20 January 1989. The heads of the veterinary services of 25 countries were represented. The participants formulated a number of recommendations and requested OIE to provide further technical assistance in the development of rules for the registration of veterinary drugs. OIE would respond to this request by developing models for veterinary pharmaceutical legislation and for the registration procedure. A second meeting was planned for 1990.

28. At the 9th Conference of the OIE Regional Commission for the Americas, held in Buenos Aires (Argentina) in June 1989, similar needs were identified. OIE intended to respond with specific proposals.

29. A draft of a simplified form for recording side-effects of veterinary drugs was also developed and circulated for comments. It would be presented to the next International Technical Consultation on Veterinary Drug Registration (ITCVDR), to be held in The Hague, Netherlands, 8-11 October 1990.

30. In response to the comments of the OIE representatives, the Delegation of Australia also informed the Committee of the following recommendations made by the 16th Conference of the OIE Regional Commission for Asia, the Far East and Oceania on 10 October 1989:

- (a) Countries report to the OIE the results of their national residue programmes for animals, poultry, fish and their products and their activities for the control of safe use of pesticides at the farm level.
- (b) The OIE, in collaboration with other international organizations, develops codes of practice for the use of veterinary chemicals and drugs.
- (c) To assist the orderly trade in animals, poultry, fish and their products, countries accept Codex Alimentarius maximum residue limits for veterinary drugs for those chemicals not currently used or registered in their country.

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

31. The representative of COMISA informed the Committee of a signing ceremony which was held on 23 October 1989 which signified the acceptance of a formal constitution for COMISA. The constitution would be incorporated into Belgian law and the organization would be headquartered in Brussels. The organization included animal health manufacturers, national associations from 16 countries, including Australia, Brazil, Canada, Japan, New Zealand and the United States, as well as 10 West European countries.

32. The COMISA representative noted that at the JECFA meeting held in Geneva in January/February 1989 it had acted as a valuable interface between the companies submitting data and the Expert Committee. COMISA continued to hope that the current processes and procedures adopted by JECFA would be improved as JECFA experience with veterinary drugs grew over the years. COMISA also believed it important that every effort be made to enhance the acceptance of standards which JECFA developed by achieving their recognition in countries with major influences on global agricultural trading systems.

33. Another opportunity for COMISA to represent the world-wide industry came in July, when the World Association of Veterinary Food Hygienists invited its participation in a symposium held in Stockholm, Sweden. The theme of the meeting was "Healthy Animals--

Safe Foods--Healthy Man." Although the activities of COMISA thus far had related principally to participation in international meetings, COMISA would not confine itself to these activities. It would serve the industry in other key areas such as the preservation of intellectual property rights, and would provide active support to encourage the adoption of world-wide, objective, science based criteria for the registration of veterinary medicines.

34. Finally, the Observer from COMISA noted its agreement with remarks made at the Third CCRVDF Session by Dr. Lester Crawford (Appendix II, ALINORM 89/31A) in that "A vital mix of regulatory and industry expertise is necessary if international food standards are to be workable in facilitating trade in the real world". The Observer from COMISA applauded this sentiment, and stated that COMISA looked forward with confidence to a continuance, in the years ahead, of a mutually fruitful interaction with inter-governmental bodies such as CCRVDF and JECFA. The world animal health industry supported the goals of Codex and the scientific evaluations undertaken by JECFA. The representative noted that this was an essential activity to assure future consumer confidence and free trade in the global business of animal derived food products.

International Dairy Federation (IDF)

35. The Observer from IDF outlined the work of three expert groups, mainly group A4, dealing with residues and contamination in milk and milk products, group E12 dealing with pesticides, and group E47 concerning antibiotics.

36. Group A4 was preparing a monograph on residues and contamination in milk as an update of IDF monograph 113 (1979). Most of the chapters, including veterinary drugs and pharmacologically active compounds, were now available and had been accepted at the Annual Session of IDF in September 1989 in Copenhagen (antibiotics, sulfanimides, parasiticides, hormones, and teat disinfectants).

37. Group E12 had prepared a provisional IDF Standard entitled "Determination of Organophosphorous Compounds in Milk". This standard would be published in early 1990. It contained background information on the sources of contamination and two categories of analytical methods (A and B) with different degrees of sophistication.

38. Group E47 was working on three main subjects: (a) revision of the Bulletin 220 (1987) on the detection of "inhibitors" in milk, including more recently developed screening and confirmatory methods, (b) performance of trials in order to determine detection limits of various antibiotics and sulfa drugs under practical conditions. "Blank" and "fortified" milk powders were prepared and sent to laboratories in member countries of the IDF; (c) a monograph comprising a collection of non-routine methods was under preparation. All available methods were described for the information of the dairy industry and laboratories world-wide.

39. Other topics of work were concerned with sulfa drugs in milk and the pathways of contamination, the selection of more sensitive microorganisms for routine testing purposes and the evaluation of specific tests with special reference to interfering factors.

CONSIDERATION OF THE SUMMARY REPORT OF THE 34TH SESSION OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) INCLUDING RECOMMENDATIONS FOR MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (Agenda Item 5)

40. The Committee had before it the summary report (CX/RVDF 89/3) and the draft final report of the 34th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (Conference Room Document 5). The FAO/WHO Joint Secretaries of JECFA summarized the results of the meeting.

41. The Committee noted that one anthelmintic drug, four nitroimidazoles, two sulfonamides, one growth promoter and two trypanocides were on the agenda. No toxicological data were available on metronidazole, and therefore, it was not evaluated. Acceptable

Daily Intakes (ADI) or temporary ADIs were established for four compounds, including albendazole, ronidazole (temporary), sulfamidine (temporary), and trenbolone acetate. Recommended maximum residue limits for veterinary drugs (MRLVDs) were established for all of these compounds except for ronidazole. Insufficient toxicological information was available to establish ADIs for the other substances which were evaluated.

42. The Committee was informed that chemically-bound residues were a key issue in the evaluation of drug residues during the 34th Meeting. These residues represented drug-related material in animal tissue which had varying toxicological significance and which were difficult to characterize. In those cases where such residues must be evaluated, the 34th JECFA suggested means to determine the bioavailability of the residues. Also, a proposed procedure was devised to calculate the daily intake of residues using bio-availability and residue data as well as food intake factors. An example calculation using trenbolone acetate was presented. Regarding food intake factors, the 34th JECFA used intakes of muscle, liver, kidney and fat rather than the traditional factor of muscle only. This was considered to be a conservative approach to residue evaluation.

43. JECFA also reviewed use of the term "unnecessary" when establishing MRLVDs for endogenous hormones, and decided to retain this term with the understanding that the CCRVDF should continue to use the explanatory footnote as included in Appendix IV to this report. The Committee also noted that JECFA had established definitions for the terms "muscle" and "tissue" as requested by the 3rd CCRVDF Session.

44. In the discussion following the presentation of this report, the Delegation of France, speaking on behalf of the European Economic Community (EEC), stated that the EEC experts had not yet had sufficient opportunity to review the draft report of JECFA or its recommended MRLVDs in detail. The Delegation requested that the Committee postpone consideration of the JECFA report and the MRLVDs until the next meeting of the CCRVDF in order to permit their adequate review and submission of comments. Several other delegations supported this request. The Delegation of France also stressed that the prior review of proposed MRLVDs and the final reports of future JECFA meetings were an integral part of the Committee's work, and the Delegation emphasized the importance of the early circulation of complete JECFA evaluations. The Committee agreed to return the proposed MRLVDs to Step 3 of the Codex Procedure for comment and for consideration at Step 4 during the Fifth Session of the CCRVDF in 1990, with a view towards their submission for adoption at Step 5 to the 19th Session of the Codex Alimentarius in 1991. The proposed draft MRLVDs are attached to this report in Appendix III.

45. The Delegation of the Netherlands expressed concern on the adequacy of analytical methods for residues and their relationship to establishing proper MRLVDs. Other delegations echoed this concern. The Committee was assured that JECFA took adequate analytical methodology into account when establishing MRLVDs. It was pointed out that the CCRVDF Working Group on Methods of Analysis and Sampling was responsible for recommending analytical methods to the Committee. The Chairman of the Working Group informed the Committee that the Group would evaluate methods based on performance criteria, and requested the Member Delegations to submit validated methods.

46. The Delegation of the United States raised a number of general points relating to the processes used by JECFA in evaluating residues of veterinary drugs in foods. The Delegation noted that while JECFA should be commended for the quality of the evaluations performed to date, there was room for improvement, and their suggestions should be considered as constructive comments put forward in the spirit of assuring that the JECFA review process could be carried out with optimal efficiency. The Delegation of the United States proposed that the JECFA Joint Secretariat should consider the following issues:

- (a) Guidelines on Data Preparation - Sponsoring companies should be advised concerning the kinds of data, the degree of detail required, and the format in which data and summaries should be submitted.

- (b) Guidelines on Review of Data - A document similar to WHO Environmental Health Criteria (EHC) 70 ("Principles for the Safety Assessment of Food Additives and Contaminants in Food") on veterinary drugs would be beneficial for the evaluation by JECFA of animal health products to assure uniform application of criteria.
- (c) Expert Committee on Animal Health Products - The characteristics and methods of use of animal health products differed significantly from those of direct food additives. A Committee whose members reflected the expertise and experience unique to veterinary drugs would result in MRLVDs that would be more readily accepted by regulatory agencies and the affected industry.
- (d) Notification and call for data - More lead time should be provided to sponsors of compounds to be evaluated by JECFA to help assure the complete submission of data.

47. The Delegation of France supported the statement made by the Delegation of the United States. In addition, it was stressed that the evaluations must be valid and must be based on stable and constant procedures so that disparities did not arise. The Delegations of Belgium, Costa Rica, the Federal Republic of Germany, the Netherlands, the Republic of Senegal and the United Kingdom supported some or all of the elements outlined by the United States. The Delegation of Costa Rica also stressed the need for residue data from various areas in the world where products were used, because differences in formulations may exist that would change the pharmacokinetic patterns of veterinary drugs. The Delegation of the Netherlands also reminded the Committee that at the First CCRVDF Session a request had been made to establish a separate advisory body.

48. The Joint Secretaries of JECFA thanked the Delegation of the United States for their constructive suggestions and noted the following responses:

- (a) The call for data for the 36th Meeting of JECFA included a list of the types of studies that would ordinarily be included in a dossier submitted to JECFA. It was difficult to be more specific, because special studies that were indicated depended upon the effects that were observed. Sponsors were in the best position to determine which studies were appropriate. All individual animal data should be submitted. WHO had produced guidelines for the preparation of toxicological working papers while FAO intended to produce similar guidelines for the preparation of residue monographs. The preparation of summaries by the data sponsors using the suggested format in these guidelines was encouraged.
- (b) The JECFA Secretariat considered the preparation of a document similar to EHC 70 on veterinary drugs to be premature at this time. Further experience in evaluating residues of veterinary drugs in food must be gained before the preparation of such a document would be feasible.
- (c) There was very little overlap in the membership of JECFA meetings on food additives and veterinary drugs. Most of the members, temporary advisers, and consultants for meetings on veterinary drugs came from agencies and institutes involved with the assessment of veterinary drugs.
- (d) The CCRVDF was moving in the direction of providing longer lead times in that compounds for review by JECFA in both 1991 and 1992 were likely to be recommended at the present Session. Sponsors of drugs could be assured that these compounds would be placed on the agenda of JECFA insofar as possible within established evaluated guidelines.

49. The Committee concluded and agreed that the above suggestions of the Committee would be forwarded to the 36th JECFA Session for review.

CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 7
(Agenda Item 6)

50. The Committee had for its consideration proposed draft MRLVDs as contained in ALINORM 89/31A, Appendix V, which had been circulated to governments for comments (CL 1989/15-RVDF) following their adoption by the Eighteenth Session of the Codex Alimentarius Commission at Step 5, (paras. 249-253, ALINORM 89/40). The proposed draft MRLVDs included chloramphenicol, estradiol 17-beta, progesterone, testosterone and zeranol. Comments in response to the Circular Letter were received from Brazil and Canada (Conference Room Document 3) and France (Conference Room Document 7).

51. The Delegation of France issued a brief statement on behalf of the Member States of the EEC present at the Session. The Delegation expressed concern that the Member States had only a short time to consider the advancement of these draft MRLVDs to Step 8. In view of the increasing significance of Codex standards for international trade, the Delegation requested that every Codex step be considered with due care and therefore, suggested the draft MRLVDs be retained at Step 6 for an additional year, in order to allow their reconsideration at Step 7 at the Fifth Session of the CCRVDF in October, 1990. The Observer from the EEC and the Delegations of Ireland and the Netherlands supported this request. The Delegation of Belgium also stated that there was insufficient time to take a position. So far as the hormones were concerned, the Observer from the EEC reiterated the position of the EEC referred to in paras. 72-73 of ALINORM 89/31A.

52. The Delegation of Australia requested that the MRLVDs be moved forward to Step 8. The Delegations of Canada, the United States, Brazil, Mexico, New Zealand and Poland supported this request, and agreed that sufficient time had been given to consider the draft MRLVDs.

53. The Codex Secretariat and the WHO Representative outlined the elaboration history concerning the draft MRLVDs. They were evaluated by the 32nd Joint Expert Committee on Food Additives (JECFA) in June 1987 and considered by the Second and Third Sessions of the Codex Committee on Residues of Veterinary Drugs in Foods. The Codex Secretariat noted that there had been no changes in the draft MRLVDs since initially reviewed by JECFA in June 1987.

54. The Delegation of France proposed the retention of the MRLVD for chloramphenicol only at Step 6 of the Codex Procedure, since the EEC had doubts concerning the MRLVD "not allocated", particularly in regard to possible impacts on national regulations. While citing the example of the nitrofurans, the Delegation of France also expressed its concern that substances with similar problems could be treated differently. The Delegations of the Federal Republic of Germany and the United Kingdom spoke of work in progress and future additional data on chloramphenicol and supported the request to consider chloramphenicol separately. The Delegations of Belgium, Colombia and the Republic of Senegal also supported the separate consideration of chloramphenicol.

55. The WHO Representative discussed the evaluation of chloramphenicol at the 32nd Meeting of JECFA. The JECFA had concluded that no dose-response relationship could be established for aplastic anaemia. The mechanism for the pathogenesis of this effect was unknown, and no suitable animal model existed. Thus, a no-effect level could not be established and an ADI could not be allocated for chloramphenicol because it was not possible to give an assurance that residues in foods of animal origin would be safe for sensitive subjects. The JECFA had recommended that efforts should be made to replace or prohibit the use of chloramphenicol in food producing animals, particularly in laying birds and lactating animals where high levels of residues in eggs and milk were major problems.

56. The Delegation of Norway, while referring to para. 75 of ALINORM 89/31A, re-confirmed its position that while it did not oppose the advancement of the MRLVDs to Step 8, they opposed the use of hormones as growth promoters. The Delegations of Swaziland, Sweden and Switzerland supported this position.

57. The Delegation of Australia stated that the MRLVD for chloramphenicol should be advanced, especially in view of matters of toxicological concern. The Delegation also stated that failure to advance the MRLVD for chloramphenicol due to the possible availability of future data would set a dangerous precedent.

58. The Delegations of Belgium and France noted that furazolidone and nitrofurazone were removed from immediate JECFA evaluation due to insufficient data. They stated that there was also insufficient data to evaluate chloramphenicol.

59. The Delegations of France and the United Kingdom reiterated that data on chloramphenicol may become available in the near future and they requested clarification as to how data collected prior to the Nineteenth Session of the Codex Alimentarius Commission would be evaluated. The Codex Secretariat indicated that if new data concerning chloramphenicol were presented for JECFA review, procedures existed for the amendment of MRLVDs forwarded to the Commission at Step 8, (Codex Alimentarius Procedural Manual).

60. The Committee agreed to the advancement of the draft MRLVDs to Step 8 of the Codex Procedure for adoption by the Nineteenth Session of the Commission. The draft MRLVDs are attached as Appendix IV to this Report.

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

61. The Committee had before it Conference Room Document 1 (CX/RVDF 89/5) entitled "Progress Report on the Compendium of Regulations and Authorities for Registered Veterinary Products", as prepared by the United States of America.

62. The United States of America, as outlined in CL 1989/9-RVDF, had requested that countries review the data summarized in the draft Compendium with a view towards forwarding corrections and comments. The United States had received comments and corrections concerning this issue from Canada, Cuba, Egypt, France, Japan, the Netherlands, New Zealand, Norway, Sweden and Thailand. Completed questionnaires had also been received from Australia, Austria, Bahamas, Brazil, Burundi, Costa Rica, Haiti, Iceland, Israel, Kuwait, Luxembourg, Malawi, Mali, Malta, Oman, Pakistan, Poland, Surinam, Switzerland, Tanzania, Trinidad and Tobago and Venezuela. The Delegation of the United States thanked all countries which had sent in corrections or responses to the Compendium questionnaire.

63. The Delegation of the United States noted that the Compendium was completed in two parts. The first part reflected world-wide information regarding drug regulation, drug approval and animal feed additive registration, while the second part addressed the availability of veterinary drugs. The Delegation noted further that both parts of the regional compendium were completed, but that only the regulatory section of the international compendium was near completion. The Delegation thanked the Committee for its support in the elaboration of this document.

64. The Delegation of Canada informed the Committee that a comprehensive Compendium listing drugs in Canada would be made available to the U.S.A. The Delegation of the United Kingdom offered to provide the Delegation of the United States with a list of substances used in the United Kingdom and discussed potential difficulties in keeping it up to date in view of its large size.

65. The Delegation of the United States informed the Committee that the Inter-American Compendium was available on computer disc, and expressed appreciation for the support of Canada and the United Kingdom.

66. The Committee decided to have the United States continue the elaboration of the Compendium, especially in regard to the international availability of veterinary drugs, with a view towards its publication and distribution to Codex member governments. The Committee also agreed that the United States should prepare a progress report for consideration at the Committee's Fifth Session.

PROGRESS REPORT ON SURVEY ON INTAKE STUDIES (Agenda Item 8)

67. The Committee had before it Conference Room Document 2 (CX/RVDF 89/6), entitled "Survey of Information on the Dietary Intake of Veterinary Drugs in the Member Countries of the Codex Alimentarius Commission" which contained a background summary and information received in response to the survey, (CL 1989/8-RVDF).

68. The Delegation of the United States introduced the document and recommended to the Committee that the continued elaboration of the survey did not appear to be justified, especially when viewed in context of recent JECFA deliberations concerning this issue, (Section 2.6, Technical Report Series 788). The draft JECFA report stated that "the potential errors in estimating food intake were unlikely to be of great significance; for this reason, no great effort should be devoted to further refining food intake estimates".

69. The Committee agreed that the Delegation of the United States should discontinue the survey and should prepare a summary and compilation of this data for consideration by the CCRVDF at its Fifth Session.

PROPOSED GLOSSARY OF TERMS AND DEFINITIONS (Agenda Item 9)

70. The Committee had before it Working Paper CX/RVDF 89/7 which addressed the Proposed Glossary of Terms and Definitions and Conference Room Document 6 (CX/RVDF 89/7 - Add.1) containing comments from the Spanish Government.

71. The Delegation of Canada presented a background summary of the document's elaboration, and noted that comments were informally solicited from the Governments of Australia, France, Mexico, Spain, Switzerland, the United Kingdom, and the United States of America during its preparation.

72. The Delegations of France, Ireland, Mali, Republic of Senegal, Swaziland, and the United Kingdom suggested that the definition of "bound residue" be amended. The Delegation of the United Kingdom requested that the revised definition take account of soluble macromolecules as well as insoluble macromolecules. The delegations of Ireland and Swaziland also proposed the addition of an explanation concerning the calculation of "bound residues".

73. The Delegation of Norway noted that a preamble should be added to the glossary of terms and definitions in order to emphasize that it was elaborated for the deliberations of CCRVDF only, with a view towards providing information and guidance. The Delegation of the Federal Republic of Germany also suggested a preamble reference to the possibility of future revisions. The Delegations of Colombia, France and Norway also suggested changes to various definitions contained in the proposed glossary.

74. The Delegations of Australia and Poland requested the addition of definitions for terms such as acceptable daily intake, meat, eggs, fish and poultry. The Codex Secretariat noted that these definitions were elaborated in other Codex documents and were therefore eliminated from previous drafts of the proposed glossary of terms. The Delegation of Norway, with support from the Delegations of Australia, Canada and New Zealand, suggested the reinstatement of these definitions.

75. The Committee thanked the Delegation of Canada for its efforts and agreed that the Proposed Glossary of Terms and Definitions should be redrafted by Canada for circulation, comment, and discussion at the 5th CCRVDF Session. The Committee also agreed to include a revised definition for "bound residue", to incorporate other Codex definitions relevant to the deliberations of the Committee, and to add a preamble section reflecting the above discussions.

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

76. The Committee had before it document CX/RVDF 89/8 when discussing this agenda item, as prepared by the Delegation of the United Kingdom.

77. The Delegation of the United Kingdom provided a background summary of the code's elaboration, and indicated that input had been received from the Governments of France and the Netherlands, while some aspects had also been included from a document forwarded by the Delegation of Peru at the Third Session of the Committee.

78. The Delegation of the United States, along with support from the Delegations of ~~the~~ Ireland, the Netherlands, New Zealand, Norway and Spain, commended the United Kingdom for its efforts and recommended that the Code be circulated for solicitation of additional comments. The Delegation of Norway requested that specific terms used in the Code (i.e. medicated feed) might be defined in the CCRVDF glossary, while the Delegation of the Netherlands suggested that the section concerning Information on Veterinary Drugs be expanded to include examples of product information considered essential by national authorities.

79. The Committee concluded and agreed to circulate the proposed Code for further evaluation and comment with a view towards the examination of a revised Code prepared by the United Kingdom at the Committee's Fifth Session. The proposed Code is attached to this Report as Appendix V.

DRAFT CODE OF PRACTICE FOR THE REGISTRATION AND DISTRIBUTION OF VETERINARY DRUGS
(Agenda Item 10a)

80. The Delegation of France, speaking on behalf of the Office International des Epizooties (OIE), presented a background summary of the proposed Code (CX/RVDF 89/8- Part II) and indicated that the document addressed several aspects of veterinary drug registration and distribution. It was noted that the Code recommended general aims and responsibilities only, and that specifics would best be addressed by national regulatory authorities.

81. The Delegation of Costa Rica indicated that their Government would be forwarding comments concerning the draft code directly to OIE. They also noted that use of the term "waiting time" included in Section 6 should correspond to the CCRVDF glossary of terms, (i.e. withdrawal time/period and withholding time). The Delegation of Spain also suggested changes concerning the use of the term "waiting time". The Delegation of the Federal Republic of Germany noted that Section 5b of the proposed Code should reference the CCRVDF definition for MRLVD.

82. The Committee concluded and agreed that the elaboration of the proposed Code should continue under the direction of the OIE, and encouraged the submission of comments directly to the organization. The Committee also agreed that a progress report concerning the proposed Code should be presented by the OIE for information at the Committee's Fifth Session.

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

83. The Committee had before it Conference Room Document 4 (CX/RVDF 89/9). The Delegation of the United States provided a background summary of the document's elaboration and outlined the guideline steps needed for the establishment of a residue control programme for veterinary drugs. Technical criteria for the selection of appropriate screening tests for the monitoring of residues of veterinary drugs were also outlined.

84. The Delegation of the United States also noted that problems facing developing countries for controlling pesticide and veterinary drug residues were very similar, and that therefore, coordinated efforts with other Codex Committees working on similar problems should be encouraged.

85. The Delegations of France and Swaziland requested that discussion of the draft guidelines be postponed until the next session in order to allow sufficient time to thoroughly review the document. The Delegation of France also suggested that areas dealing with criteria for analytical methods should not conflict with documents prepared by the Ad Hoc Working Group on Methods of Analysis and Sampling in order to avoid duplication of work.

86. The Delegation of Norway stated that considerations should also be given to the effectiveness of regulations pertaining to drug control in various countries, e.g., to the likelihood of drugs being used illegally.

87. The Committee thanked the Delegation of the United States and agreed to circulate the document for comments, with the understanding that a revised version would be prepared by the United States for discussion at the Fifth Session of the Committee. The document is attached to this Report as Appendix VI.

CONSIDERATION OF METHODS OF ANALYSIS AND SAMPLING BASED ON GOVERNMENT COMMENTS AND THE REPORT OF THE AD-HOC WORKING GROUP ON METHODS OF ANALYSIS AND SAMPLING (Agenda Item 12)

88. The Committee had before it Working Paper CX/RVDF 89/10, as prepared by the Working Group Chairman and Conference Room 8 entitled "Report to the Plenary Session of the Third Meeting of the Ad Hoc Working Group on Methods of Analysis and Sampling". The Chairman of the Working Group, Dr. R. Ellis (U.S.A.) introduced the report of the meeting, and noted that delegates and observers from Australia, Belgium, Canada, Costa Rica, Denmark, Finland, France, Federal Republic of Germany, Ireland, the Netherlands, New Zealand, Norway, Poland, People's Republic of China, Spain, Sweden, Switzerland, United Kingdom, United States, European Economic Community and FAO were present.

89. The Working Group Chairman noted that the Group had been provided with a revised draft of the paper, "Sampling for the Control of Residues of Veterinary Drugs in Foods", as prepared by the United States. The major revision to the draft was the use of point-of-origin sampling as the principal point of control for veterinary drug residues in foods. The Chairman requested comments by Working Group members on the proposed paper by 1 February 1990.

90. The Working Group also reviewed and discussed a total of nine analytical methods submitted for the compounds albendazole, sulfadimidine (sulfamethazine), sulfonamides, zeranol, chloramphenicol and carbadox. After their full evaluation, the Group recommended that two methods be considered for adoption by the CCRVDF. These methods concerned residues of zeranol in muscle and liver tissue and sulfadimidine in animal tissue. The other methods reviewed required more analytical or quality assurance data before a decision for adoption could be made.

91. To assist in the future evaluation of analytical methods, the Chairman assigned specific compounds to individual Working Group members who were responsible for the coordination of the submission of various methods. The Chairman further established a strict time schedule during 1990 so that members of the Group would have a consolidated collection of methods of analysis to examine well in advance of the next CCRVDF meeting.

92. Other Group deliberations included international requirements for the shipment of laboratory test samples of animal origin used in analytical method validation studies, differences in internationally recognized statistics procedures, and a reaffirmation that less sophisticated methods be identified for use by countries having limited resources.

93. During the Committee discussions of the Working Group report, the Delegation of Norway noted three concerns, namely:

- (a) the need to consider method criteria elaborated by other Codex Committees,
- (b) the need to contact OIE for possible information on international requirements for shipment of samples of animal origin, and
- (c) the need to expand documentation on sampling to include other parameters (e.g., extent of use, efficiency of control) under "monitoring" in addition to risk profiles.

94. The Group Chairman, Dr. R. Ellis, agreed with all three points. The Delegation of Norway also had further questions concerning "optimum quantitative performance of a method". The Chairman of the Working Group noted that methods should be optimized to provide the analytical support at the recommended MRLVD. He further noted that the literature references for recommended methods have been provided to the Secretariat.

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

- (a) The analytical methods for sulfadimidine residues in animal tissue and for zeranol residues in liver and muscle tissue were suitable for the enforcement of the recommended MRLVDs. The Committee noted that the scientific literature references for these methods were included in Appendix III and Appendix IV of this Report, respectively.
- (b) That additional analytical methods were needed for evaluation by the Working Group to determine their suitability for enforcement of present and future recommended MRLVDs. The Committee noted that the Information Work Sheet concerning methods of analysis and sampling, which detailed information needed for additional methods, was attached to this Report as Appendix VII.

96. The Committee thanked the Working Group and its Chairman for its report and decided to extend the mandate of the Ad Hoc Working Group on Methods of Analysis and Sampling under the chairmanship of Dr. R. Ellis (U.S.A.).

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION (Agenda Item 13)

97. The Committee had before it CX/RVDF 89/11, which contained proposals for additions to the priority list of veterinary drugs requiring evaluation submitted in response to CL 1989/14-RVDF, and Conference Room Document 9, 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.

98. Responses were received from several countries which requested the consideration of twelve substances for priority evaluation. For most of these substances no indication was given whether data would or could be available for JECFA's consideration. There was a firm indication that data could be made available in the near future on three compounds, namely, ractopamine, rafoxanide and triclabendazole.

99. The Working Group had established four categories of priorities:

- (1) Substances proposed to be considered for evaluation at the JECFA meeting devoted to veterinary drug residues in 1991;
- (2) Substances proposed to be considered for evaluation at the JECFA meeting devoted to veterinary drug residues in 1992;
- (3) Substances of potential interest which may not currently meet all selection criteria, and
- (4) Substances not yet scheduled for evaluation

100. Compounds that had been on the earlier priority list (Appendix VII of ALINORM 89/31A) were rearranged into the new categories established by the Working Group, except that avoparcin was deleted because no support had been provided for its inclusion and no indication had been given that data would be made available. Ractopamine, rafoxanide, and triclabendazole were added to the priority list.

101. In the ensuing discussion, the Delegation of the United States noted that bovine somatotropin (BST) and porcine somatotropin (PST) had been placed in Category 3 by the Working Group. In view of the fact that BST had been approved in at least two countries and was under active consideration in a large number of other countries and that PST was under consideration in several countries, these substances would meet the priority selection criteria previously established by CCRVDF. It was noted further that issues unrelated to science were threatening to affect registration of the somatotropins in several countries, which could create trade problems. The Delegation of the United States therefore requested a scientific review by JECFA of these substances as soon as possible, preferably in 1991, at least in 1992. The Delegation of Canada supported this position.

102. In a statement on behalf of the Member States of the EEC, the head of the Delegation of France shared the views expressed by the Delegation of the United States and Canada that the somatotropins were important products. It was noted that they should, however, be assessed on the basis of the criteria established by the Committee and, therefore, products which were not registered should not be considered. He noted that additional information has been requested from several countries on BST during the review process that would not be available in time for consideration before the 1991 JECFA meeting. On the other hand, PST had not been registered in any countries and had not been evaluated to as great an extent as BST, and therefore, the separate consideration of these substances was suggested. Even though no public health problems had been identified so far during the current evaluation and other criteria were also not met, the EEC countries would nevertheless accept the provisional placement of BST on the list of substances proposed for evaluation by JECFA in 1992, subject to confirmation by the Committee at its Fifth Session in 1990, while PST should be left in Category 3. This position was supported by the Delegation of the United Kingdom, even though it was noted that it was not clear that all selection criteria had been met. The Delegation of the United Kingdom also pointed out the problems in identifying the specific products that should be evaluated, since several different bovine somatotropins with differing amino acid sequences were available.

103. The Delegation of the United States suggested reviewing the somatotropins as a class. They also emphasized that candidate veterinary drugs were only required to meet some, but not necessarily all, of the criteria.

104. As a result of these discussions, the Committee agreed to place BST on the tentative agenda of the 1992 JECFA (i.e., Category 2) and to maintain PST in Category 3. This decision would be re-evaluated at the Fifth Session of the CCRVDF.

105. The Delegation of Belgium, with the support of the Delegations of Italy and the EEC, expressed disappointment that the nitrofurans would not be evaluated until 1992. It was pointed out by the Delegation of France that given their toxicological profile, these substances had been on the priority list since the First Session of the CCRVDF.

106. The Delegation of Australia stated that the Working Group on Priorities was informed that it was unlikely that adequate bases existed for setting ADIs on the two nitrofurans on the list, furazolidone and nitrofurazone, but that further studies were underway that would be available for review by JECFA in 1992. The COMISA representative confirmed, on behalf of a sponsor company, that a data package could be provided by 1991.

107. The Delegation of France agreed that the two nitrofurans could remain on the priority list for 1992 provided that a specific schedule of work was made available at the next session of the CCRVDF and that the evaluation of these compounds was not delayed again.

DATE AND PLACE OF NEXT SESSION (Agenda Item 15)

116. The Committee was informed that the Government of the United States of America offered to host the Fifth Session of the CCRVDF from 15-19 October 1990, with the understanding that the Working Group sessions (i.e. Methods of Analysis and Sampling, Priorities) would be held on Monday 15 October, and the general Plenary Session would convene on Tuesday 16 October. The Committee agreed with this proposal.

108. The Committee agreed to maintain furazolidone and nitrofurazone in Category 2. COMISA advised, on behalf of a sponsor company, agreement to present a progress report on the status of studies on these substances at the Fifth Session of the CCRVDF.

109. The Committee agreed on the priority list as presented in Appendix VIII.

110. Three compounds that were placed in Category 1, (see Appendix VIII) azaperone, chlorpromazine, and propionylpromazine may not have industrial sponsors, so JECFA would be dependent for their evaluation on studies in the published literature. Studies on these substances should be collected by the sponsoring countries or industrial sponsors and submitted to the JECFA Secretariat to facilitate their evaluation.

111. On a related matter, the Delegation of Costa Rica asked about the status of those substances that had been evaluated by JECFA but had not been given ADIs or MRLs because of a lack of data. Some of these drugs, such as the trypanocides, were used extensively in Costa Rica, and it was not clear how the necessary data to assess their safety could be generated. This concern was also expressed by the Delegations of Colombia, Mali, and the Republic of Senegal.

112. The Chairman agreed that this was a major problem without an easy solution, because these were generic drugs without readily-identifiable sponsors. He encouraged companies to generate the appropriate data.

113. The Committee endorsed the circulation of a questionnaire for the nomination of substances for the priority list before the next meeting and to extend for one year the Working Group under the chairmanship of the Delegation of Australia.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

114. The Observer from COMISA reemphasized the views of this organization regarding improvement of JECFA procedures in regard to the evaluation of veterinary drugs and indicated firm support for the suggestions made by the Delegation of the United States. Written comments on the draft Codes of Practice for the Control of the Use of Veterinary Drugs and for Good Practices in the Registration and Distribution of Veterinary Drugs would be forwarded to the Delegation of the United Kingdom and the Observer from the OIE, respectively.

115. The Committee 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 and 36th JECFA Sessions;
- Progress Report on Compendium of Veterinary Drugs;
- Final Report on Survey on Intake Studies;
- Proposed Glossary of Terms and Definitions;
- Proposed Draft Code of Practice for the Control of the Use of Veterinary Drugs;
- Proposed Guidelines for the Establishment of a Regulatory Control Programme for Veterinary Drug Residues in Foods;
- Progress Report on the Code of Practice for the Registration and Distribution of Veterinary Drugs;
- Consideration of Methods of Analysis and Sampling;
- Consideration of Priorities.

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Summary Status of Work

Code/Guideline/Maximum Residue Level	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	3	Governments 5th CCRVDF	ALINORM 91/31, Appendix III
Proposed Draft Code of Practice for Control of the Use of Veterinary Drugs	3	Governments United Kingdom 5th CCRVDF	ALINORM 91/31, Appendix V
Proposed Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods	3	Governments United States 5th CCRVDF	ALINORM 91/31, Appendix VI
Proposed Draft Glossary of Terms and Definitions	3	Canada Governments 5th CCRVDF	ALINORM 91/31, paras. 70-75
Methods of Analysis and Sampling	--	Governments 5th CCRVDF	ALINORM 91/31, Appendix VII
Priority List of Veterinary Drugs Requiring Evaluation	--	Governments 5th CCRVDF	ALINORM 91/31, Appendix VIII
Compendium of Veterinary Drugs	--	United States 5th CCRVDF	ALINORM 91/31, paras. 61-66
Final Report on the Survey on Intake Studies	--	United States 5th CCRVDF	ALINORM 91/31, paras. 67-69
Draft Code of Practice for the Registration and Distribution of Veterinary Drugs	--	OIE 5th CCRVDF	ALINORM 91/31, paras. 80-82
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

Summary Status of Work (Cont'd)

Code/Guideline/Maximum Residue Level	Step	For Action by:	Document Reference
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
Definitions for "Veterinary Drug" and "Residue of Veterinary Drug"	--	No further action required.	ALINORM 87/31, paras. 93 and 101

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It is a very great personal pleasure to be with you today and to present some views from the Government of the United States as you commence the Fourth Session of the Codex Committee on Residues of Veterinary Drugs in Food. This country is enormously pleased to be your host, and we are grateful for the progress you have made under the able leadership of your Chairman, Dr. Gerald B. Guest. Dr. Guest is better known in his home country as the Director of the Center of Veterinary Medicine, Food and Drug Administration. He is nonetheless known throughout the world as a thoughtful, compassionate leader and one of our country's truly distinguished public servants. Dr. Guest, congratulations and best wishes for a most successful Fourth Session.

Next, may I welcome each and every one of you personally, and individually extend the best wishes of the U.S. Government. I hope that your stay in our country will be enjoyable, informative and productive. Your presence here is enduring testimony to the commitment of your government to a safer, more harmonious world both in the area of public health protection and in international trade. The world does not often mark what you do here but mankind is materially better off for what you have done and what you are continuing to do. Our Government will do everything it can reasonably be expected to do to facilitate the work of the Committee, but in the end, it is you who must step into the breach and solve the vexing problems of 1989 and beyond.

I think as you begin the work of the Committee, you have cause for both optimism and pessimism. I think you should feel optimistic; your accomplishments in setting a reasonable priority list of drugs to be evaluated bodes well for present and future work. This Committee has unrivalled international credibility and is, in a real sense, a model for future deliberative bodies of this type. This means, in my view, that you will continue to merit and receive support both from member governments and from the Codex Alimentarius Commission. I also firmly believe your presence has been a beacon for sound, sensible regulation based on scientific analysis. Your presence has likewise not escaped the notice of the animal drug industry and consumers worldwide. I believe both sectors embrace a wholesome view of your intents and purposes. This gives encouragement to the industry as they continue to develop a safer, more effective generation of animal drugs. It gives assurance to consumers of meat, plant, milk, and eggs that these foods will continue to be free from injurious, inadvertent additives.

There are at least three storm clouds, unfortunately, on the horizon. The first troublesome development has been the fact that there is evidence that at least one animal drug company is reluctant to cooperate with the Committee in the evaluation of one of its products. I trust and hope this is a temporary aberration and not the beginning of strained relations with the animal drug industry. I would respectfully call on both the member nations of the Committee and the various professional and trade industry organizations to address this problem with all due urgency. If, in fact, the Joint Expert Committee on Food Additives (JECFA) cannot regularly count on data from all sources, including sponsoring drug firms, then it will be forced to proceed with whatever science is available in the public domain. This may simply be that which is to be found in the published literature. This could potentially result in an inability to set MRLs for a number of compounds, thus disadvantaging those compounds around the world. These unfortunate events, if allowed to happen, would no doubt adversely affect the public acceptability of veterinary drug usage. This is certainly no time to have that happen. I hereby pledge my help in dealing with this unfortunate situation, and I know I can count on all of you to do the same.

This meeting is coloured, I think, by another disturbance. I speak of the apparent uneasiness of some member states with certain findings of JECFA and perhaps, with the priority setting exercise itself. Let me be the first to say that there are no doubt ways and means to improve the functioning of this Committee and of the Codex Alimentarius Commission itself. To that end, the Commission, as you all know, is planning a comprehensive conference on food safety in 1991 that will address both the needs and the rules of Codex. The U.S. heartily supports this initiative and applauds Professor Denner of the United Kingdom for his seminal paper on this subject. Having said all that, let me at this point urge upon all of you a sense of cooperation and community. We are here to deal with some very sensitive issues, but we must remind ourselves that what renders these issues sensitive is the genuine concern of the world's people. We cannot afford to shroud that concern in politics. The forte of the Committee and of the Commission itself is not global politics but scientific analysis. We must continue to sift through the dissonances of the present and be guardians of the scientific method, of rational decision-making, and of fairness for all concerned. We must set MRLs based on an uncompromising concern for human food safety. But we cannot allow ourselves to over-react by extending ourselves beyond admonishment: stay the course, deal with the facts, and come together in a true spirit of world community.

Finally, all of us here are having to deal with an erosion of confidence in the scientific community. Unfortunately, this has translated into a disillusionment with science itself and with scientific regulatory agencies. The reasons for this are illusory, but among those most frequently cited are: 1) a decreased scientific literacy rate, 2) a disenchantment with some of the products of science such as nuclear science and pesticides, and 3) a discontentment with the pace of the technological age. Some symptoms of this phenomenon can be seen in public concerns about irradiated food, bio-engineered products, and the call for a "Fourth Hurdle"* in national products approval schemes. I believe Codex must provide the most sophisticated scientific analysis of the safety of a given compound and that it must steer clear of sociological analyses. That is for individual nations to consider, but these considerations must proceed from a scientific base. That is to say, before socio-political decisions are considered, a national government would want to know whether the product is safe or not safe. I happen to personally believe that the market place and not national governments should govern further discrimination once a product is adjudged safe, but I also believe national sovereignty applies to veterinary product approvals just as it does to other fields of endeavour. I would furthermore hope, however, that when nations conscientiously disagree there could be an effective means of dispute settlement. It is in this regard that I commend for your harmonization the U.S. proposal titled "The Harmonization of Sanitary and Phytosanitary Measures" which will be discussed next week in Geneva during the continuation of the Uruguay Round of the General Agreement on Tariffs and Trade. Codex Alimentarius, Office International des Epizooties, and the International Plant Protection Convention are intended to serve as repositories of scientific judgment and advice in the U.S. proposal. The U.S. recognizes this would be a bold move, but we also are convinced our proposal is both realistic and workable. I hope very much that it is adopted during this round of negotiations.

I would hope one further thing and that is that we as leaders in our individual nations can do something about the crisis in public confidence. I believe that we in the scientific and regulatory communities are at least partly to blame. Therefore, I believe we should attempt to be part of the solution by:

* The Fourth Hurdle refers to socioeconomic criteria. That is, once a product has been, by scientific analysis, proved safe, effective, not dangerous to humans or the environment, it might be further evaluated as to its effects on the social and/or economic order(s).

1. More effective communication -- the major regulatory decisions we make should be accompanied by a clear, unalloyed public statement setting forth the premises upon which the decision was based and the mechanism through which the decision was reached. An example of this is the U.S. Food and Drug Administration's product approval summaries.
2. More and better public hearings -- open hearings on the major regulatory issues of the day can be an efficacious means of listening to what the people want and why they want it. A U.S. example is the four regional hearings on food labelling now being conducted by the FDA and FSIS.
3. More efficient and fairer regulatory schemes -- the public loses respect for and, eventually, confidence in inefficient bureaucracies however well intentioned. We must become models of management and efficiency. The public likewise is confused when various food products are regulated by different ministries (departments) with different levels of intensity. In the U.S., we have an ultra-intensive meat and poultry regulatory system but there is no equivalent scheme for other food groups including fish.
4. Foundations or centers of scientific integrity -- we need independent institutions designed to advance the case for scientific decision-making by:
A) developing programmes for the study of ethical research and responsible reporting of scientific results; B) developing programmes of public education on scientific decision-making; C) developing proactive advocacy programs in which the scientific aspects of major public policy decisions are emphasized; D) developing programmes for the study of proper use of science in public policy decisions; E) analyzing the legal, moral, and social consequences of regulatory decisions not based on science.

In closing, let me thank you very much for affording me the opportunity to speak before you today. I should like to end with a quotation from a truly great American hero which, of course, is our custom in the "colonies". It was the automobile-maker Henry Ford who said, "Don't find fault. Find a remedy". It is my fervent hope that this will be your watchword this week.

..... Until we meet again.

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 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 0-0.5 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 (To be elaborated)
5. References to JECFA reports WHO TRS 788 (1989)
WHO FAS 26
6. References to previous Codex publications None
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 (a) Meat, liver, kidney and fat
(b) MRL (b) 0.1 mg/kg
(c) Definition of residue on which MRL was set (c) sulfadimidine
- 3.3 (a) Commodity (a) Milk
(b) MRL (b) 0.05 mg/kg
(c) Definition of residue on which MRL was set (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 26 |
| 6. | References to previous Codex Publications | None |
| 1. | Substance: <u>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 on which MRL was set | (a) Liver
(b) 10 µg/kg
(c) Alpha-trenbolone |
| 4. | Reference to recommended 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)
WHO FAS 23 (1988)
WHO FAS 26 |
| 6. | References to previous Codex publications | None |

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 8

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

- | | |
|---|--|
| 1. <u>Substance: Chloramphenicol</u> | |
| 2. Acceptable Daily Intake (ADI) as established by JECFA | No ADI Allocated |
| 3. (a) Commodity
(b) MRL
(c) Definition of Residue on which MRL was set | (a) Foods of animal origin
(b) Not allocated
(c) Chloramphenicol |
| 4. References to Recommended Methods of Analysis | (To be elaborated) |
| 5. References to JECFA reports | WHO TRS 430 (1969)
WHO TRS 763 (1988)
FAO FNP 41 (1988)
WHO FAS 23 (1988) |
| 6. References to previous Codex Publications | None |
| 1. <u>Substance: Estradiol - 17B</u> | |
| 2. Acceptable Daily Intake (ADI) | Unnecessary* |
| 3. (a) Commodity
(b) MRL
(c) Definition of Residue on which MRL was set | (a) Foods of bovine origin
(b) Unnecessary*
(c) Estradiol - 17B |
| 4. References to Recommended Method(s) of Analysis | |
| 5. References to JECFA Reports | WHO TRS 669 (1981)
WHO TRS 763 (1988)
FAO FNP 41 (1988) |

* Establishing an ADI and a Maximum Residue Limit for a hormone that is produced endogenously at variable levels in human beings was considered unnecessary by the Committee. Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.

- | | | |
|----|--|--|
| 6. | References to previous Codex Publications | None |
| 1. | <u>Substance: Progesterone</u> | |
| 2. | Acceptable Daily Intake (ADI) as established by JECFA | Unnecessary* |
| 3. | (a) Commodity
(b) MRL
(c) Definition of Residue on which MRL was set | (a) Foods of bovine origin
(b) Unnecessary*
(c) Progesterone |
| 4. | References to Recommended Method(s) of Analysis | |
| 5. | References to JECFA reports | WHO TRS 669 (1981)
WHO TRS 763 (1988)
FAO FNP 41 (1988) |
| 6. | References to previous Codex Publications | None |
| 1. | <u>Substance: Testosterone</u> | |
| 2. | Acceptable Daily Intake (ADI) as established by JECFA | Unnecessary* |
| 3. | (a) Commodity
(b) MRL
(c) Definition of Residue on which MRL was set | (a) Foods of bovine origin
(b) Unnecessary*
(c) Testosterone |
| 4. | References to Recommended Method(s) of Analysis | |
| 5. | References to JECFA Reports | WHO TRS 669 (1981)
WHO TRS 763 (1988)
FAO FNP 41 (1988) |
| 6. | References to previous Codex Publications | None |
| 1. | <u>Substance: Zeranol</u> | |
| 2. | Acceptable Daily Intake (ADI) as established by JECFA | 0-0.5 µg/kg body weight |

* Establishing an ADI and an Maximum Residue Limit for a hormone that is produced endogenously at variable levels in human beings was considered unnecessary by the Committee. Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health.

- | | | |
|-----|---|--|
| 3.1 | (a) Commodity | (a) Bovine liver |
| | (b) MRL | (b) 10 µg/kg |
| | (c) Definition of Residue on which MRL was set | (c) Zeranol |
| 3.2 | (a) Commodity | (a) Bovine muscle |
| | (b) MRL | (b) 2 µg/kg |
| | (c) Definition of Residue on which MRL was set | (c) Zeranol |
| 4. | References to Recommended Method(s) of Analysis | <u>Biomedical and Environmental Mass Spectrometry, Vol. 15</u>
Jan. 1988, pp. 45-56 |
| 5. | References to JECFA reports | WHO TRS 683 (1982)
WHO TRS 696 (1983)
WHO TRS 763 (1988)
FAO FNP 41 (1988)
WHO FAS 23 (1988) |
| 6. | References to previous Codex Publications | None |

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APPENDIX V

PROPOSED DRAFT CODE OF PRACTICE FOR CONTROL
OF THE USE OF VETERINARY DRUGS AT STEP 3

INTRODUCTION

1. This Code sets out guidelines on the prescription, application and control of drugs used to preserve animal health or to improve animal production. The Code is intended to apply so as to contribute to the protection of public health throughout the Member States of the sponsoring organizations.
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.
3. Veterinary products (including medicated feeds) used in food producing animals should be administered (or incorporated into feed) in compliance with the relevant product information approved by national authorities or in accordance with a prescription or direction issued by a qualified veterinarian.

REGISTRATION AND DISTRIBUTION - GENERAL REQUIREMENTS

4. All veterinary therapeutic products and medicated premixes for inclusion in animal feeds should be registered with the national authority. Products should only be distributed through veterinarians, registered wholesalers, pharmacists or other retail outlets nationally approved for this purpose.

RESPONSIBILITY OF THE VETERINARIAN - 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 clear instructions should be provided on methods of use, taking account of the competence of the user to perform 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 and that the continuous use of antimicrobial products will favour the development of resistance. It is the responsibility of the veterinarian 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 treat disease with medicinal products known to be specific.

8. The veterinarian should stress the need for diseased animals to be separated where possible and individually treated.

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.

SOURCES OF VETERINARY DRUGS

10. Veterinary products should be obtained from veterinarians, pharmacists or other outlets authorised in paragraph 4 above.

INFORMATION ON VETERINARY DRUGS

11. 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 recommended withdrawal periods and any other constraints on the use of the product including any precautions regarded as necessary for safeguarding human health and the environment.

AMOUNTS TO BE SUPPLIED

12. 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

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

ADMINISTRATION OF MEDICINES

14. 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.

15. 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 after the most careful consideration of the needs of the disease situation.

16. To avoid the presence of harmful residues in meat or other livestock by-products it is essential that the livestock owner adheres to the withdrawal period laid down for each product. Full instructions should be given as to how this period is to be calculated and on the disposal of any animals slaughtered during treatment or before the expiry of the withdrawal period. If animals are sold before the end of the withdrawal period, the buyer must be informed.

RECORD KEEPING REQUIREMENTS

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

18. Where the veterinarian suspects that 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 with responsibility for recalling such products. Regular feed-back of information to veterinarians and manufacturers on suspected adverse reactions should be encouraged.

STORAGE OF VETERINARY DRUGS

19. 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.

20. 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.

DISPOSAL OF VETERINARY DRUGS

21. 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.

**PROPOSED DRAFT GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY
PROGRAMME FOR CONTROL OF VETERINARY DRUG RESIDUES IN FOODS AT STEP 3**

Nations need a full spectrum of control programmes to protect the health of their citizens from hazards which may come from the food supply. One type of danger would occur if citizens were eating meat from animals which had diseases that could affect people. Meat inspection programmes, with their requirements for sanitary conditions in slaughtering establishments and detailed procedures to search for signs of disease in animals, provide protection against the hazards of disease. Another kind of danger can occur if food animals have been produced using veterinary drugs or pesticides without considering what happens to these compounds in the bodies of livestock. A residue control programme should provide protection against this kind of hazard.

There are other benefits to having an effective residue control programme. An important benefit to a country with such a programme is the capability to participate in the community of food-trading nations with confidence. This is because an effective residue control programme can also be the basis of a quality assurance programme for imported products and the foundation for certifications about the safety of exported products.

In setting up an effective residue control programme, a country needs (in addition to or as an adjunct to an inspection programme) a system for controlling the manufacture, use and distribution of veterinary drugs within the country, and the authority to recognize and deal with residue violative products in a manner comparable to what is done about other types of adulteration in meat products.

The first step in developing a control programme is information gathering and establishing of routine systems for knowing what veterinary drugs are entering the country, being manufactured in the country, and being used in the country. The second step involves decision-making about what type of controls need to be placed upon these activities. The final expression of these controls often takes the form of establishing permitted residue levels of veterinary drugs in food products. For countries who do not have scientists to assist them in making these decisions, the work of JECFA/Codex would be of immense benefit. Only after decisions have been made about permitted levels is it sensible to commence analytical testing for veterinary drug residues.

As a first step, the developing country could establish a residue control programme which utilizes screening methods (especially multiresidue methods) to monitor animal products. This would not require investment in esoteric and complex laboratory instrumentation and associated training costs. Equipment routinely available in most residue laboratories should be directly applicable to screening methods. A major emphasis should be given to the training of personnel in the use and interpretation of screening tests.

A screening test is defined as a qualitative analytical method that will indicate when a test analyte is either not present in the target sample or is below the level of concern. The purpose of a screening test is to give a quick result that has a high probability of accurately indicating that a problem exists. Unless the screening test is accompanied by a confirmatory assay of some sort, the results are not intended to be used a part of a regulatory action against the product's owner.

In the implementation of this programme, 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 programme for assuring uniformity in the methods of sampling and analysis.

In selecting the appropriate screening methods for use in a residue control programme, the analyst should make sure that the following test performance information is available.

1. The method should be sensitive at the level of concern (tolerance or MRL) for that particular compound.
2. If the test is for a biological fluid, there is correlation between the results and the levels of the analyte in tissue (this is probably not a major issue in an import residue programme).
3. There is an adequate description of the technical principles of the method including a list of the critical reagents and instruments needed.
4. There is a demonstration that the biological reagents can be consistently produced on a batch-to-batch basis. Ideally this should be supplemented with information on quality assurance tests that the user can apply to assure test performance.
5. The stability of all reagents should be shown, including data on the reagents in their manufactured or storage form and at analytical dilution.
6. In certain biochemically based test methods, the detector or indicating instrument is the analyst himself. Many rapid tests depend on a visual colour interpretation by the analyst. The method should demonstrate that it is minimally sensitive to variations in the analyst's interpretation.
7. The long term availability of reagents should be determined.
8. Stability data on the critical reagents should be included so as to preclude test malfunction due to degraded products. Properly dried biochemical reagents are usually quite stable for extended periods of time. However, when reagents are prepared for use, the useful lifetime of the reagents can be drastically reduced. The user of the test should also determine that the test materials are stable under the conditions of use at his location.
9. Stability data on the analyte should also be provided. These data are especially important in drugs and chemicals occurring in biological matrices. Metabolism of the test analyte can continue at the cellular level or in the homogenate.
10. Data should be provided to show that components from drug free matrix do not interfere with the determination of the test analyte or its metabolites.
11. Data should be presented showing the number or percentage of true negative results obtained by testing samples from animals that have not been exposed to the drug or chemical.
12. A determination of the assay specificity should be given including the complete array of chemicals tested for cross-reactivity and a rationale for their selection.
13. A list of potential interfering substances from the environment should be given. These are specific compounds or conditions that might adversely affect the optimum performance of the method.
14. The developer of the screening method should provide information that:
 - (a) the test has been optimized.
 - (b) critical steps in the method have been identified.
 - (c) interfering substances have been identified and controlled.
 - (d) the method has been shown to work using authentic samples (from animals having incurred residues).
 - (e) the test results have been confirmed with alternative methods when appropriate.
 - (f) information on performance of the test relative to existing techniques is available.

INFORMATION SHEET ON METHODS OF ANALYSIS AND SAMPLING

A. DESCRIPTIVE INFORMATION

1. Name of compound
2. Chemical Class
3. Veterinary Use
4. Analyte(s) measured
If other than parent drug, specify
5. Test Matrix
Use separate worksheet for each matrix
6. Measurement System
 - 6a. Chemical
 - 6a1. Instrumental Technology
 - 6a2. Detector System
 - 6b. Immunochemical/Ligand Assay
 - 6b1. Technique
 - 6b2. Detector System
 - 6c. Microbiological
 - 6c1. Technique
 - 6c2. Organism
 - 6c3. Media
7. Sample Preparation and Extraction Procedure
.....
.....
8. Procedure used for Recovery Estimate
9. Sample/Analyte Stability
Warning (if any)
10. Intended use of method
 - a. Screening
 - b. Routine
 - c. Reference
 - d. Confirmatory
11. Reference(s)
.....

12. Contact for Information

- 12a. Name
- 12b. Country
- 12c. Affiliation
- 12d. Address
- 12e. Phone
- 12f. Fax

B. METHOD PERFORMANCE

- 1. Limit of Detection ($\mu\text{g}/\text{kg}$)
How was limit of detection determined?
- 2. JECFA MRL
- 3. Accuracy (recovery from fortified blank tissue)
 - a. Concentration(s) tested ($\mu\text{g}/\text{kg}$)
 - b. Recovery (percent)
- 4. Precision (fortified blank tissue)
 - a. Concentration(s) tested ($\mu\text{g}/\text{kg}$)
 - b. Within laboratory coefficient of variation (percent)
 - c. Between laboratory coefficient of variation (percent)
- 5. Precision (incurred residue tissue)
 - a. Mean concentration(s) ($\mu\text{g}/\text{kg}$)
 - b. Within laboratory coefficient of variation (percent)
 - c. Between laboratory coefficient of variation (percent)
- 6. Statistics AOAC ISO Other (Specify)
- 7. Method validation data
 - a. Number of laboratories
 - b. Number of analysts
- 8. Specificity/Interferences
 - a. Compounds tested for specificity
- 9. Analytical Range ($\mu\text{g}/\text{kg}$)

C. QUALITY ASSURANCE

- 1. Training and experience required to perform method
 - a. Analysts with little or no residue experience
 - b. Analysts with residue experience

2. Reagent stability measurements
 - a. Linear range of method ($\mu\text{g}/\text{kg}$)
 - b. Stability of standard curve overtime
3. Ruggedness Testing
 - Yes
 - No
 - Critical steps in method (specify)
4. Safety considerations
5. Method versatility
 - a. Can method detect and or quantitate other analytes?
 - Yes
 - No
 - b. If yes, please specify
6. Reagent and Equipment considerations
 - a. Are all reagents and equipment commercially available?
 - Yes
 - No
 - b. If no, please identify a reliable source
7. Other comments

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APPENDIX VIII

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION

1. Substances proposed to be considered for evaluation at the JECFA meeting devoted to veterinary drug residues in 1991:

Febantel
Fenbendazole
Oxfendazole
Carazolol
Spiramycin
Tylosin
Azaperone*
Chlorpromazine*
Propionylpromazine*

* Evaluation is subject to data submission.

2. Substances proposed to be considered for evaluation at the JECFA meeting devoted to veterinary drug residues in 1992:

Triclabendazole
Rafoxanide
Sulfonamides*
Trimethoprim
Furazolidone
Nitrofurazone
Benzimidazoles (those not included in 1991)
Bovine Somatotropin

* Including but not limited to sulfaquinoxaline and sulfadimethoxine.

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

Ractopamine
Porcine Somatotropin

4. Substances not yet scheduled for evaluation:

Tetracycline
Chlortetracycline
Phenothiazines (acetylpromazine, promazine)