codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

ALINORM 93/31A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twentieth Session
Geneva, 28 June - 7 July 1993

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

Washington, D.C., 20-23 October 1992

Note: This report incorporates Codex Circular Letter CL 1992/31-RVDF.

W/Z9726

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CX 4/60.2

CL 1992/31-RVDF
November 1992

TO: - Codex Contact Points
- Interested International Organizations
- Participants at the Seventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods

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

SUBJECT: Distribution of the Report of the Seventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 93/31A)

The report of the Seventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods is attached. It will be considered by the Twentieth Session of the Codex Alimentarius Commission, to be held in Geneva from 28 June - 7 July 1993.

MATTERS FOR ADOPTION BY THE COMMISSION

The following matters will be brought to the attention of the 20th Session of the Codex Alimentarius Commission for adoption:

1. Draft Code of Practice for Control of the Use of Veterinary Drugs at Step 8; paras. 35-39 and Appendix VII, ALINORM 93/31A.

2. Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods at Step 8; paras. 40-43 and Appendix VIII, ALINORM 93/31A.

Governments wishing to propose amendments or to comment on the above draft Code of Practice for Control of the Use of Veterinary Drugs or the draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods should do so in writing in conformity with the Guide to Consideration of Codex Standards at Step 8 (see Codex Alimentarius Procedural Manual, Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, not later than 31 May 1993.

3. Draft Maximum Residue Limits for Veterinary Drugs at Steps 5/8; para. 33 and Appendix II, ALINORM 93/31A.

4. Proposed Draft Maximum Residue Limits for Veterinary Drugs at Step 5; para. 32 and Appendix IV, ALINORM 93/31A.

Governments wishing to propose amendments or to submit comments regarding the implications which the proposed draft Maximum Residue Limits or any provisions thereof may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Codex Standards (at Steps 5 and/or 8) (see Codex Alimentarius Procedural Manual, Seventh Edition) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, not later than 31 May 1993.

SUMMARY AND CONCLUSIONS

The Seventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE COMMISSION

- Recommended the adoption of proposed draft MRLVDs for *flubendazole, thiabendazole, triclahendazole,* the *bovine somatotropins* and *isometamidium* at Step 5 (para. 32);

- Recommended the adoption of revised draft MRLVDs for *closantel* and *ivermectin* at Steps 5/8 (para. 33);

- Recommended the adoption of the draft Code of Practice for Control of the Use of Veterinary Drugs at Step 8 (para. 39);

- Recommended the adoption of the draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods at Step 8 (para. 43);

OTHER MATTERS OF INTEREST TO THE COMMISSION

- Welcomed the initiative in scheduling two JECFA Meetings in 1994, and agreed that future scheduling should allow for the convening of at least one JECFA Meeting devoted to the evaluation of veterinary drugs each year (para. 10);

- Expressed grave reservations about the effects of a proposed COMISA recommendation to its membership to delay submitting data to JECFA pending Commission action on the hormones retained at Step 8 (para. 16);

- Agreed to place *furazolidone, nitrofurazone* and *ractopamine* on an inactive list as maximum residue limits were not established for these compounds (para. 34);

- Decided to maintain the "Inactive List" of Veterinary Drugs for information while requesting a JECFA review (para. 46);

- Congratulated JECFA on the development of a policy concerning the evaluation of veterinary drugs with a long history of use, which should permit an orderly process for JECFA review of such substances (para. 53);

- Agreed to attach the final version of the OIE Code of Practice for the Registration of Veterinary Drugs to the Report for the information of Codex member governments (para. 55);

- Agreed that a progress report on the Compendium of Veterinary Drugs would be presented by the United States at its next session (para. 57);

- Agreed to endorse those methods recommended and the continuation of the *Ad Hoc* Working Group on Methods of Analysis and Sampling under the Chairmanship of the United States (para. 64);

SUMMARY AND CONCLUSIONS (Cont.d)

- Agreed on a Priority List of Veterinary Drugs Requiring Evaluation (para. 69);

- Agreed that a draft proposal for a weighting system for criteria for inclusion of veterinary drugs on the priority list would be prepared (para. 71);

- Recommended the continuation of the *Ad Hoc* Working Group on Priorities under the Chairmanship of Australia (para. 72), and;

- Agreed to advise the Commission of a recommendation to the United States to consider press participation as observers at future Codex meetings (para. 75).

TABLE OF CONTENTS

LIST OF APPENDICES

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods held its Seventh Session in Washington, D.C., at the kind invitation of the Government of the United States of America. The Session was chaired by Dr. Gerald B. Guest, Director, Center of Veterinary Medicine, United States Food and Drug Administration. It was attended by 32 member countries of the Commission and 9 international organizations.

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 Dr. J. Owusu (Australia). The reports of the Working Groups were presented to the Plenary under Agenda Items 12 and 13, respectively.

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

OPENING OF THE SESSION (Agenda Item 1)

4. Dr. Alejandro Thiermann, U.S. Coordinator for Codex Alimentarius, addressed the Committee at the invitation of the Chairman. He referred to the importance of the work of Codex to agricultural trade worldwide and noted that the conclusion of the Uruguay Round will greatly increase the influence of Codex. Dr. Thiermann discussed the changes to Codex procedures proposed by the U.S. that sought to ensure a transparent standard setting process based on sound science. He also noted the efforts made by Codex to increase consumer and industry participation, to streamline the standard setting process, and to establish priorities for the items Codex will consider. He indicated that he believed these changes were important if Codex was to remain a viable organization in the emerging global economy. He concluded by expressing the U.S. Delegation's support for the Codex Secretariat as it faced the formidable task of accomplishing all these changes and improvements.

ADOPTION OF THE AGENDA (Agenda Item 2)

5. The Committee had before it the Provisional Agenda for the Session as contained in document CX/RVDF 92/1. At the suggestion of the Delegation of Canada, the Committee agreed to discuss the process by which drugs were examined by the CCRVDF after JECFA evaluation under Agenda Item 4 (a). At the suggestion of the Chairman, the Committee also agreed to discuss the participation of the press at future Committee meetings under Agenda Item 14 (Other Business and Future Work). The Committee adopted the Provisional Agenda as proposed for its present session.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

6. The Committee appointed Dr. J.M. Rutter (United Kingdom) to serve as Rapporteur for the Session.

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

7. The Committee had before it documents CX/RVDF 92/2 and Conference Room Document 4 when discussing this Agenda Item, which highlighted those matters of interest to the Committee arising from other Codex Committees and the Codex Committee on General Principles, respectively. The Committee focused its discussions on the following matters.

Joint FAO/WHO Expert Committee on Food Additives

8. Several delegations expressed concern that insufficient funds were available for a JECFA meeting on veterinary drugs in 1993. Although it was recognized that the two meetings on veterinary drugs scheduled for 1994 would partially relieve the

backlog of compounds on the priority list, it was felt this arrangement would cause a disruption in the scheduling of future CCRVDF meetings. It was emphasized that a structural long-term solution should be found for the funding of JECFA.

9. The JECFA Secretariat emphasized that the proposed 1993 JECFA meeting on veterinary drugs had been a special case, because it was not in the regular programme budgets of either FAO or WHO. Insufficient funds had been raised for this meeting, and even if funds were found now, it would be impracticable for the meeting to go ahead because of the shortage of time available for the submission and review of the data. It was likely that both organizations would be placing four JECFA meetings in their programme budgets for the 1994-1995 biennium, three of which would be on veterinary drugs (February 1994, late 1994, and mid-1995). While FAO would fund these meetings from their regular programme budget, the WHO regular budget would be able to meet only approximately one-third of the costs. Taking account of the severe financial crisis facing WHO, it was unlikely that more WHO funds would be forthcoming. The Organization was exploring ways of establishing a more stable funding base, but regardless of the procedure used, WHO would be dependent upon Member States for funding a large portion of the costs of these meetings.

10. The Committee, while recognizing that the possibility of scheduling a 1993 JECFA meeting devoted to the evaluation of veterinary drugs was remote, welcomed the initiative of JECFA in scheduling two such meetings in 1994. However, it was agreed that future scheduling should allow for the convening of at least one JECFA meeting devoted to the evaluation of veterinary drugs each year.

Implications for the Codex Committee on Residues of Veterinary Drugs in Foods of the Codex Alimentarius Vote not to Adopt JECFA Recommendations for Growth Promoting Cattle Hormones at Step 8

11. The Committee discussed at considerable length the holding of the hormones *estradiol 17-beta, progesterone, testosterone* and *zeranol* at Step 8 by the 19th Session of the Commission (paras. 154-162, ALINORM 91/40).

12. Subsequent to the Commission decision, the Committee recalled that the 39th Session of the Executive Committee (paras. 56-58, ALINORM 93/3) had referred the United States proposal discussed at the 6th CCRVDF meeting (CX/RVDF 92/1-Add. 1) to the 10th Session of the Codex Committee on General Principles. The U.S. proposal recommended the reform of Commission procedures to ensure that scientific principles would be the only basis for Commission recommendations. The CCGP decided (paras. 70-73, ALINORM 93/33) that a discussion paper should be prepared by the Secretariat, with consultants as necessary, for consideration at the 11th Session of the Codex Committee on General Principles in April 1994.

13. A number of delegations agreed that as the hormones had been retained at Step 8 by the Commission, there was nothing more for CCRVDF to accomplish at this point pending the outcome of CCGP discussions. Other delegations expressed the hope that the Commission would adopt the recommendations for the hormones at Step 8 at its 1993 meeting based solely on scientific grounds.

14. The representative of COMISA felt that the Commission's decision not to adopt the draft standards for hormones at Step 8 in 1991 had a profound impact on the ability of Codex procedures to meet the Commission's objectives within an acceptable timescale. The Commission decision also made it difficult to ensure that production enhancing drugs would have an unbiased and objective review. To reflect these concerns, COMISA asked the Chairman to communicate to the Commission that it would be recommending that its members delay submitting data for the 1994 JECFA meeting until it became clear whether or not the Commission would take any action at its meeting in July 1993 on the hormones retained at Step 8.

15. The Secretariat stressed that JECFA was totally independent of the Commission and the Joint FAO/WHO Food Standards Programme and that it was

unfortunate that COMISA had related a decision taken by Codex member governments to the work of JECFA. It was emphasized that the decisions of JECFA received the full backing of FAO and WHO and as such could be used by any interested party with or without the support of Codex.

16. The Committee acknowledged its understanding of COMISA's concerns, but expressed grave reservations about the effects of COMISA's proposed recommendation to COMISA's membership. The delay in bringing forward data would place not only the 1994 JECFA in jeopardy but could also affect the perceived independence of JECFA. COMISA was urged to consider other ways of achieving its objective.

17. After careful consideration, COMISA indicated that it felt unable to change its position. The Committee regretted this decision, as the COMISA position had serious implications for the work of the Commission, especially in relation to Codex procedures for recommending MRLs for veterinary drugs.

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

18. The Committee was informed that two international meetings concerning antimicrobials in veterinary medicine in relation to microbiological residues had been held: FEDESA Seminar on Antimicrobials in Veterinary Medicine - Public Health Aspects and Good Veterinary Practice (London, December 1991) and another FEDESA Seminar in June 1992 (Washington). The proceedings for both symposia should be published in the spring of 1993.

European Economic Community (EEC)

19. The Observer from the European Community reported that Council Regulation (EEC) 2377/90, had set legally binding MRLs for 24 compounds or groups of compounds in the Community. A copy of the regulation was made available to the Committee as Conference Room Document 7.

20. In addition it was reported that a new Volume had been published describing the procedures used by the Community for the establishment of MRLs and the data package required from the pharmaceutical industry to support such an application. A further publication described the reference methods and materials used within the Community to detect residues in food producing animals. The Observer also reported that evaluation was in hand of applications for MRLs for twelve new active substances and about thirty old substances.

AOAC International

21. The representative of the Association of Official Analytical Chemists International reported that the Association had embarked on validation programmes of new methods including a "Test Kit Performance Testing Program" and a "Peer Verified Programme". The Observer informed the Committee that the AOAC Research Institute had been formed to operate the Test Kit Performance Testing Program, and that the Association continued to be involved in the development of harmonized methods and quality systems protocols. A large number of nutrient labelling methods had been compiled by AOAC. Seventy-two methods were adopted first action and sixty-nine first action methods were elevated to final action during this period.

International Dairy Federation (IDF)

22. The Observer from the IDF informed the Committee on activities being undertaken in the Federation by expert groups on residues and contaminants (A4), detection of pesticides (E12), and detection of antibiotics (E47) in milk and milk products. The Observer reported that the proceedings of the Symposium on the Detection of Inhibitors and Antibiotics, held under the umbrella of IDF in Lund, would be published in the IDF Bulletin. The main conclusion of the Lund Symposium

was that for milk and milk products, an integrated system for the detection of antibiotics and sulfonamides must be developed. New and/or improved detection methods for antibiotics had appeared recently. Moreover, tolerances, safe levels and MRLs were being introduced in different countries. In some cases, the figures differed considerably and this could raise trade problems for milk and milk products.

23. At the 76th IDF Annual Session it had been decided to arrange a workshop on antibiotic residues in milk in late 1993 in Copenhagen. In 1995, a seminar would be arranged in Kiel covering the occurrence and detection of antibiotics and sulfa drugs in milk. An IDF intercomparison test for antibiotics was finalized for publication in the IDF Bulletin during 1992. A new IDF intercomparison study would start October/November 1992, including *oxytetracycline* and *sulfadimidine*.

Office International des Epizooties (OIE)

24. The Observer of the OIE reported on the programmes of the Office with particular attention to pharmaceutical legislation and training. A group of experts on the registration of veterinary drugs had been established and a collaborative Center designated for veterinary drugs with the main functions of providing the OIE with technical assistance on pharmaceutical legislation, transmission of information and training programmes. The OIE was establishing model legislation for the registration of veterinary drugs and recommendations for the marketing of veterinary drugs.

25. The Observer also referred to other activities including the establishment of a model list of essential drugs adapted to different countries and regions, training programmes in Latin America, and collaboration with the International Technical Consultation on Veterinary Drugs Registration (ITCVDR), held in Buenos Aires, Argentina from 22-26 June 1992.

CONSIDERATION OF PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (MRLVDS) AT STEP 4 ARISING FROM THE FORTIETH MEETING OF JECFA (Agenda Item 5)

26. The Committee had before it a summary report of the Fortieth Meeting of the Joint FAO/WHO Expert Committee on Food Additives (CX/RVDF 92/3), an unnumbered draft report of the meeting circulated two months previously, and government comments in Conference Room Document 6 (CX/RVDF 92/3-Add.1). The FAO and WHO Joint Secretaries of JECFA summarized the results regarding the evaluation of particular substances.

27. Several delegations congratulated the JECFA Secretariat for distributing the first draft of the report so soon after the meeting, which had permitted a preliminary review of the recommendations.

28. Five anthelminthic agents (closantel (residues only), *flubendazole*, *ivermectin*, *thiabendazole*, and *triclabendazole*), two antimicrobial agents (*furazolidone* and *nitrofurazone*), two production aids (*bovine somatotropins* and *ractopamine*) and one trypanocide (*isometamidium*) were on the agenda. Numerical acceptable daily intakes (ADIs) and maximum residue limits (MRLS) were allocated to *flubendazole*, *thiabendazole*, *triclabendazole*, and *isometamidium*. The existing ADI for *ivermectin* was increased on the basis of data generated since its previous evaluation, and MRLs in cattle tissues were elaborated. MRLs were elaborated for *closantel*. Neither ADIs nor MRLs were allocated for *furazolidone*, *nitrofurazone*, or *ractopamine*.

29. In discussing the summary report, it was noted that values of recommended MRLs for sheep liver and kidney in Table 1 for *closantel* were reversed. The summary report was amended accordingly. The Delegation of Australia drew attention to the fact that the MRLs for *triclabendazole* in tissues of sheep were not differentiated, while in Australia MRLs of different values had been elaborated in edible tissues.

30. ADIs and MRLs "not specified" were established for the *bovine somatotropins, somagrebove, sometribove, somavibove*, and *somidobove*. JECFA did not wish to imply that these drugs were of "unlimited" safety, but concluded that the margin of safety was so large taking into account proposed use, potential intake of residues and available toxicity data that they represented no hazard to human health and did not require a numerical ADI or MRL to be specified.

31. Concern was expressed about the terminology ADI "not specified" and ADI not allocated. These were similar terms used by JECFA for different situations. ADI not allocated covered data that was insufficient to allocate an ADI as well as data that raised significant health concerns. It was suggested that JECFA add a few words to ADI not allocated and ADI "not specified" to clarify the reasons for these conclusions.

32. The Committee agreed to move the proposed draft MRLVDs for *flubendazole, thiabendazole, triclabendazole*, the *bovine somatotropins* (*somagrebove, sometribove, somavibove*, and *somidobove*), and *isometamidium* to Step 5 for Commission adoption. (See Appendix IV).

33. In view of the previous draft status of *closantel* and *ivermectin* at Steps 5/8 (Appendix IV, ALINORM 93/31), it was agreed that the revised evaluations for these compounds would be included on a revised list of drugs advanced to Steps 5/8 (See Appendix II) for Commission adoption.

34. It was agreed to place *furazolidone, nitrofurazone*, and *ractopamine* on an inactive list (see Appendix VI), as maximum residue limits were not established for these compounds.

DRAFT CODE OF PRACTICE FOR CONTROL OF THE USE OF VETERINARY DRUGS
(Agenda Item 6)

35. The Committee had before it Conference Room Document 3, which contained the comments of the FAO Animal Health Service on the draft code when discussing this Agenda Item.

36. The Committee was reminded of its previous discussions concerning this issue, where it was decided to circulate the draft Code for an additional round of government comments at Step 6 under CL 1991/26-RVDF, (paras. 54-56 and Appendix VII, ALINORM 93/31).

37. In reviewing the comments submitted by the FAO, the Committee decided not to incorporate the suggestion concerning a revision to paragraph 10 of the Code (Information on Veterinary Drugs), as it was felt to be unnecessary and impractical. Likewise, the FAO comments concerning paragraph 11 (Amounts to be Supplied) were not incorporated as container sizes were felt to be best determined by industry on a case-by-case basis.

38. The Committee agreed to several minor amendments to paragraphs 10, 15 and 20 of the draft Code. The Committee also agreed to add two new paragraphs (21 and 22) concerning the Disposal and Cleaning of Drug Administration Equipment to the Code for completeness.

39. The Committee decided to forward the draft Code of Practice for Control of the Use of Veterinary Drugs to the 20th Session of the Commission for adoption at Step 8. The Code is attached to this report as Appendix VII.

DRAFT GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR CONTROL OF VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 7)

40. The Committee was reminded that the Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods (paras.

57-60 and Appendix VIII, ALINORM 93/31) was circulated for government comment at Step 6 under CL 1991/26-RVDF.

41. In the interest of avoiding duplication of efforts with the Codex Committee on Pesticide Residues (CCPR), the Committee agreed to include the section concerning dairy products from the CCPR Sampling Plans (Appendix VI, ALINORM 93/24) into Appendix B of the RVDF Guidelines.

42. At the suggestion of the Delegation of Australia, the Committee agreed to replace the term "incidence" with "prevalence" throughout the document in the interest of avoiding confusion. The Committee also agreed to several minor amendments to the introduction to the Guidelines.

43. The Committee thanked the United States for its efforts and decided to attach the revisions to the Guidelines to this report as Appendix VIII. This decision was made with the understanding that these revisions, as well as the Guidelines appended to the previous report (Appendix VIII, ALINORM 93/31), would be considered by the Commission for adoption at Step 8.

GOVERNMENT COMMENTS ON VETERINARY DRUGS NOT ASSIGNED AN ACCEPTABLE DAILY INTAKE OR MAXIMUM RESIDUE LIMIT BY JECFA (Agenda Item 8)

44. The Committee had before it document CX/RVDF 92/6 containing government comments from Norway and the United Kingdom on certain veterinary drugs placed on an inactive list (Appendix VI, ALINORM 93/31) because ADIs or MRLs had not been allocated by JECFA. The Delegation of Norway reiterated their written comment (CX/RVDF 92/6) that residues of drugs for which there is inadequate toxicological data on which to set ADIs and MRLs should not be detectable in foods. Other delegations expressed concern that suitable methods would need to be agreed upon if this approach were to be considered.

45. Several delegations noted that the term "inactive list" was inappropriate because work was in progress on some of the substances. Other delegations suggested that the inactive list could be misinterpreted to refer to unsafe substances. The Committee also noted that the inactive list had been prepared to retain evidence of substances for which JECFA had not yet reached conclusions, and the evaluation of these substances was strictly a matter between JECFA an industry.

46. The Committee decided to maintain the inactive list for information only (see Appendix VI). The Committee asked the JECFA Secretariat to review the list and seek information from the manufacturers to ascertain whether additional data would be made available to JECFA and the time scale involved. If there were new information to suggest sufficient public health or trade concerns about any substance on the list it could be assigned a priority category and further data requested.

PROCEDURES FOR THE EVALUATION OF OLDER VETERINARY DRUGS (Agenda Item 9)

47. The Committee had before it document CX/RVDF 92/7, which contained the first draft of the section of the report of the Fortieth Meeting of JECFA concerning the evaluation of veterinary drugs with a long history of use. The Committee also considered Conference Room Document 5, which contained comments submitted by the United States. The Report was introduced by Dr. J. Juskevich, WHO Consultant.

48. At its Fortieth Meeting, JECFA established general principles for the evaluation of older drugs, as well as specific principles in the areas of toxicology and residue chemistry. The general approach taken by JECFA was to provide for flexibility in determining the type of information needed for an evaluation while maintaining the same assurance of safety applied to newer veterinary drugs.

49. Each submission would have to address the main food safety issues in toxicology and residue chemistry, as outlined in document CX/RVDF 92/7. However, it was recognized that for older drugs, data may be available in the scientific literature and from use in man that could provide sufficient information to address specific food safety issues.

50. When evaluating an older veterinary drug, therefore, JECFA would consider all relevant animal studies, an Evaluation Report containing a comprehensive review of the scientific literature, relevant human data, and/or relevant data in the target species. Information on the general class of compounds, as well as on the specific compound, would also be considered.

51. If an adequate assessment of human food safety could be made from the combination of animal studies and alternative sources of information, then an ADI and MRL would be established in the same manner as for newer drugs.

52. The JECFA Secretariat described the process for re-evaluating substances that had been previously reviewed but not assigned ADIs or MRLs. The sponsor would prepare an Evaluation Report that addressed all the critical issues. In some cases, further studies may have to be performed to assess adequately the toxicity of the compound and/or its residues. The manufacturer should discuss with the JECFA Secretariat the status of the Evaluation Report and further studies that may be required so that the feasibility of the re-evaluation of the veterinary drug can be considered.

53. Several delegations congratulated JECFA on the development of a policy that was constructive and pragmatic while maintaining the high standards by which JECFA operates to protect public health. It was noted that the principles outlined in the document were successfully applied at the Fortieth Meeting of JECFA and that they would provide guidance at its future meetings, which should permit an orderly process for the evaluation of older veterinary drugs.

PROGRESS REPORT BY OIE ON THE DRAFT CODE OF PRACTICE FOR THE REGISTRATION OF VETERINARY DRUGS (Agenda Item 10)

54. The Committee had before it Conference Room Document 3, which contained comments of the FAO Animal Health Service on the Draft Code of Practice for the Registration of Veterinary Drugs. The Committee agreed to a minor modification to paragraph 4 as suggested by FAO.

55. The Committee agreed to attach the revised version of the Code of Practice for the Registration of Veterinary Drugs to the Report as Appendix IX for the information of Codex member Governments. The Committee also expressed its sincere appreciation to the OIE for its efforts towards the elaboration and finalization of the Code.

PROGRESS REPORT ON COMPENDIUM OF VETERINARY DRUGS (Agenda Item 11)

56. The Committee noted that the Delegation of the United States had previously agreed (paras. 69-71, ALINORM 93/31) to continue developing the compendium and to present a progress report at the current session. The Delegation of the United States reported that it had collected updated information on the laws and regulations used throughout the world for registration of veterinary products. The third edition of the "Compendium of Regulations and Authorities for Registered Veterinary Products" was made available to all delegates at the session. The Compendium contained information from 73 cooperating countries, including names and addresses of current registration authorities in those countries. The document was also made available in electronic form.

57. The Committee thanked the United States for its efforts. The Committee encouraged the submission of additional data by member countries and by FAO in order to update the Compendium and to continue the development of a data base of

registered veterinary products from each of the countries. The Committee agreed that a progress report would be presented at its next session by the United States.

58. The Delegation of Argentina informed the Committee that its "Compendium of Veterinary Drugs" was now available in print. An electronic version would be available soon.

METHODS OF ANALYSIS AND SAMPLING FOR RESIDUES OF VETERINARY DRUGS IN FOOD (Agenda Item 12)

59. The Committee had before it Conference Room Document 1, "Report To the Plenary Session of the Sixth Meeting of the *Ad Hoc* Working Group on Methods of Analysis and Sampling." A total of 45 delegates and observers from 18 countries attended the meeting. The Chairman, Dr. Richard Ellis (USA), introduced the report.

60. To date, it was noted that eight methods had been adopted and fourteen had been given provisional status. The Working Group discussed different formats for the publication of methods recommended for MRLs and agreed that Codex and Provisional Codex methods should be presented in the ISO format as set out in Appendix 1 of the Working Group Report.

61. The Working Group also discussed procedures for acquiring additional methods for Codex MRLs, and the problems of conducting validation or collaborative studies according to recognized guidelines. The Chairman expressed concern about the availability of sufficient methods and concluded that the Working Group must continue to explore means of identifying them.

62. Rapporteurs for methods for veterinary drug residues for two compounds for which MRLs have been recommended by the 40th meeting of JECFA were appointed, and methods of analysis were discussed for sixteen substances.

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

1. That member government continue efforts to provide validated methods to the *Ad Hoc* Working Group for review for those veterinary drugs with recommended MRLs.

2. That provisional status be given to methods for *chloramphenicol* (method for muscle, milk and eggs), *carazolol* (4 methods) and *sulfadimidine* (milk).

3. That full recommendation status be given to a method for *closantel*.

4. That coordination with the Codex Committee on Pesticide Residues, the Codex Committee on Methods of Analysis and Sampling and this Committee continue in developing valid guidelines for methods of analysis and sampling.

5. That the *Ad Hoc* Working Group on Methods of Analysis and Sampling be continued to serve the Codex Committee on Residues of Veterinary Drugs in Foods.

64. The Committee thanked the Working Group, its Chairman and rapporteur for the report and agreed to endorse the continuation of the *Ad Hoc* Working Group under the Chairmanship of Dr. Richard Ellis (USA).

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

65. The Committee had before it CX/RVDF 92/8, which contained comments and proposals for additions to the priority list of veterinary drugs requiring evaluation by JECFA submitted in response to CL 1992/4-RVDF, and Conference Room

Document 2, the report of the *Ad Hoc* Working Group on Priorities. The Chairman of the Working Group, Dr. J. Owusu (Australia), introduced its report and recommendations.

66. Written comments had been received from Australia, Brazil, Canada, and the United States. Australia and Brazil believed that the current priority list provided a considerable workload for JECFA and proposed no further additions. The United States proposed no additions to the priority list, but confirmed the commitment made by United States-based sponsors to provide data to JECFA. Canada proposed that *ceftiofur sodium* be added to the priority list. New Zealand proposed at the Working Group meeting that *moxidectin* be added to the priority list.

67. The call for data for the Forty-second meeting of JECFA, scheduled for February 1994, had been issued under CL 1992/23-RVDF. Data had been requested by 1 February 1993 on all substances in Category 1 of Appendix X of the report of the Sixth Session of CCRVDF (ALINORM 93/31), except for *apramycin*. However, the Committee was informed that data would not be available on *rafoxanide*, and this substance was removed from the list. *Levamisole* had been evaluated at the Thirty-sixth meeting of JECFA, and it was proposed that it should be brought forward for evaluation at the Forty-second Meeting. The JECFA Secretariat stated that consultations would be held with the industrial sponsor of this substance to consider the feasibility of this action.

68. Most of the veterinary drugs listed in Category 2 of Appendix X of ALINORM 93/31 were provisionally scheduled for evaluation at the Forty-third Meeting of JECFA in late 1994, and the data would be required approximately one year before the meeting. *Chlortetracycline* and *tetracycline* were moved to category 3 because they were considered to be of lower priority than the other veterinary drugs on the list. *Kanamycin* was removed from the list because it was not widely used in food-producing animals and data for its assessment were unlikely to be available. The proposal was made that *ractopamine*, which was evaluated at the Fortieth meeting of JECFA, be added to Category 2 because its residues had the potential to cause trade problems. The manufacturer had provided assurances that the data necessary for a re-evaluation would be available in sufficient time for consideration at the Forty-third meeting and it was added to Category 2 on that basis. *Ceftiofur sodium* and *moxidectin* were added to Category 3 provisionally scheduled for evaluation by JECFA at its Forty-fifth meeting in mid-1995.

69. The Committee agreed on the priority list presented in Appendix X of this report. The Committee also decided to eliminate Categories 4 and 5 (substances of potential interest which may not meet current criteria for evaluation and substances not yet scheduled for evaluation) and delete the substances listed under them in Appendix X of ALINORM 91/31, because it was considered that these categories served no useful purpose.

70. It was pointed out that the proposed dates for the next CCRVDF session and meetings of JECFA would not give the 1994 session of the CCRVDF the opportunity to modify the list of substances in Category 3. It was suggested that changes might be made on an exceptional basis. The JECFA Secretariat reminded the Committee that Member States could request the Secretariat to place veterinary drugs on the JECFA agenda. Such requests would be seriously considered if assurances were made that data would be provided.

71. COMISA had distributed to the Working Group a draft proposal for a weighting system for criteria for inclusion of veterinary drugs on the CCRVDF priority list, which was discussed at the Working Group meeting. The Committee was informed by COMISA that this paper would be revised and submitted to the Codex Secretariat for circulation and discussion at the Working Group on Priorities and at the 8th CCRVDF Plenary Session.

72. The Committee thanked the Working Group, its Chairman, and Rapporteur for the report and decided to endorse the continuation of the *Ad Hoc* Working Group on Priorities under the chairmanship of the Delegation of Australia. The Committee

also agreed that a questionnaire regarding the nomination of veterinary drugs for priority evaluation should be circulated for comment.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

73. The Chairman informed the Committee of previous repeated requests from the press to attend sessions of the CCRVDF, and noted that press admission to the meeting was dependent on the opinion of the Committee and the concurrence of the host country.

74. It was pointed out that the Commission recommended transparency during the elaboration of Codex standards and that meetings were open to internationally recognized organizations.

75. The Committee recommended that the host country consider the participation of press observers at the next session of the CCRVDF on the understanding that such participation would be limited to taking notes of the proceedings. In order to avoid disruption to the Committee's work, no cameras, audio or video recordings would be permitted. The Committee will advise the Commission of this recommendation.

76. The Committee also agreed that its next session would include:

- Consideration of Maximum Residues Limits for Veterinary Drugs at Steps 4 and 7;
- Consideration of the Report of the 42nd Session of JECFA;
- Consideration of Methods of Analysis and Sampling for Veterinary Drug Residues in Foods;
- Consideration of the Priority List of Veterinary Drugs Requiring Evaluation; and
- Progress Report on the Compendium of Veterinary Drugs (U.S.A.);
- Proposal for Ranking the Criteria used for the Prioritization of Compounds for Evaluation by JECFA.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 15)

76. The Committee was informed that its Eighth Session was provisionally scheduled to be held from 7-10 June 1994 in Washington, D.C., with the understanding that the working group meetings would be held on Monday, 6 June.

ALINORM 93/31A
Annex I

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Summary Status of Work

Code/Guideline/Maximum Residue Limit	Step	For Action By:	Document Reference
Draft Maximum Residue Limits for Veterinary Drugs	8	20th CAC	ALINORM 93/31, Appendix II
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5/8	20th CAC	ALINORM 93/31A, Appendix II
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5	20th CAC	ALINORM 93/31A, Appendix IV
Draft Code of Practice for Control of the Use of Veterinary Drugs	8	20th CAC	ALINORM 93/31A, Appendix VII
Draft Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods	8	20th CAC	ALINORM 93/31, Appendix VIII; ALINORM 93/31A, Appendix VIII
Draft Glossary of Terms and Definitions	8	20th CAC	ALINORM 93/31, Appendix IX
Draft Maximum Residue Limits for Veterinary Drugs	7	JECFA CCRVDF	ALINORM 93/31A, Appendix III
Proposed Draft Maximum Residue Limits for Veterinary Drugs	4	JECFA CCRVDF	ALINORM 93/31A, Appendix V
Veterinary Drugs Not Assigned an ADI or MRL	--	Governments 8th CCRVDF	ALINORM 93/31A, Appendix VI
Priority List of Veterinary Drugs Requiring Evaluation	--	20th CAC Governments WG on Priorities 8th CCRVDF	ALINORM 93/31A, Appendix X
Code of Practice for the Registration of Veterinary Drugs	--	None	ALINORM 93/31A, Appendix IX
Process by which MRLVDs are adopted by the Commission	--	Governments 11th CCGP 8th CCRVDF	ALINORM 93/31A, paras. 11-17
Methods of Analysis and Sampling	--	Governments W.G. on Methods of Analysis and Sampling 8th CCRVDF	ALINORM 93/31A, paras. 59-64
Progress Report on Compendium of Veterinary Drugs	--	United States 8th CCRVDF	ALINORM 93/31A, paras. 56-58

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PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Steps 5 and 8 of the Procedure)

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

1.	Substance: Closantel		
2.	Acceptable Daily Intake (ADI) as established by JECFA		0-30 µg/kg body weight
3.1	(a)	Commodity	(a) muscle and liver (sheep)
	(b)	MRL	(b) 1500 µg/kg
	(C)	Definition of residues on which MRL was set	(c) closantel
3.2	(a)	Commodity	(a) kidney (sheep)
	(b)	MRL	(b) 5000 µg/kg
	(c)	Definition of residues on which MRL was set	(c) closantel
3.3	(a)	Commodity	(a) fat (sheep)
	(b)	MRL	(b) 2000 µg/kg
	(c)	Definition of residues on which MRL was set	(c) closantel
3.4	(a)	Commodity	(a) muscle and liver (cattle)
	(b)	MRL	(b) 1000 µg/kg
	(c)	Definition of residues on which MRL was set	(c) closantel
3.5	(a)	Commodity	(a) kidney and fat (cattle)
	(b)	MRL	(b) 3000 µg/kg
	(c)	Definition of residues on which MRL was set	(c) closantel
4.	Reference to recommended methods of analysis		
5.	References to JECFA reports		WHO TRS 799 (1990) WHO TRS 27 (1991) FAO FNP 41/3 (1991) WHO TRS in preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications		Appendix II, ALINORM 91/31A Appendix IV, ALINORM 93/31

1.	Substance: Ivermectin	
2.	Acceptable Daily intake ADI as established by JECFA	0-1 µg/kg body wieght
3.1	(a) Commodity	(a) Liver (cattle)
	(b) MRL	(b) 100 µg/kg
	(c) definition of residue which MRL was set	(c) 22,23 dihydroavermectin B1a (H2B1a)
3.2	(a) Commodity	(a) Fat (cattle)
	(b) MRL	(b) 40 µg/kg
	(c) Definition of Residue which MRL was set	(c) 22,23 dihydroavermectin BLa (H2B1a)
3.3	(a) Commodity	(a) Liver (sheep, pigs)
	(b) MRL	(b) 15 µg/kg
	(c) Definition of residues	(c) 22,23 dihydroavermectin B1a (H2B1a)
3.4	(a) Commodity	(a) Fat (sheep, pigs)
	(b) MRL	(b) 20 µg/kg
	(c) Definition of residues which MRL was set	(c) 22,23 dihydroavermectin B1a (H2B1a)
4.	Reference to recommended methods of analysis	USDA/FSIS Chemistry Laboratory Guidebook Method No. 5.035
5.	References to JECFA reports	WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991) WHO TRS In preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications	Appendix II, ALINORM 91/31A Appendix IV, ALINORM 93/31

1.	Substance: Benzylpenicillin	
2.	Acceptable Daily Intake (ADI) as established by JECFA	30 µg/kg/person/day (daily intake of the parent drug should be kept below this level)
3.1	(a) Commodity (b) MRL (c) Definition of residues on which MRL was set	(a) liver, kidney and muscle (cattle and pigs) (b) 50 µg/kg (c) Benzylpenicillin
3.2	(a) Commodity (b) MRL (c) Definition of residues on which MRL was set	(a) milk (cattle (b) 4 µg/kg (c) Benzylpenicillin
4.	Reference to recommended methods of analysis	(To be elaborated)
5.	References of JECFA reports	WHO TRS 430 (1969) FAO NMRS 45 (1969) WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991)
6.	References to previous Codex publications	Appendix II, ALINORM 91/31A Appendix IV, ALINORM 93/31
1.	Substance: Oxytetracycline	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-3 µg/kg body weight
3.1	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) muscle (cattle, sheep, pigs, chickens, turkeys, fish) (b) 100 µg/kg (c) Oxytetracycline
3.2	(a) Commodity (b) MRL (c) Definition of residue on which MRL as set	(a) Liver (cattle, sheep, pigs, chickens, turkeys) (b) 300 µg/kg (c) Oxytetracycline
3.3	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Kidney (cattle, sheep, pigs, chickens, turkeys) (b) 600 µg/kg (c) Oxytetracycline
3.4	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Fat (cattle, sheep, pigs, chickens, turkeys) (b) 10 µg/kg (c) Oxytetracycline
3.5	(a) Commodity (b) MRL (c) Definition of residue on which MRL was set	(a) Milk (cattle) (b) 100 µg/kg (c) Oxytetracycline

3.6	(a) Commodity	(a) Eggs (chickens)
	(b) MRL	(b) 200 µg/kg
	(c) Definition of residue on which MRL was set	(c) Oxytetracycline
4.	Reference to recommended methods of analysis	McWeeney, D.J. et al, Food Science Laboratory, MAFF (to be published) (Provisional)
5.	References to JECFA reports	WHO TRS 430 (1969) FAO NMRS 45 (1969) WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991)
6.	References to previous Codex publications	Appendix II, ALINORM 91/31A Appendix IV, ALINORM 93/31
1.	Substance: Carbadox	
2.	Acceptable Daily Intake (ADI) as established by JECFA	Limited acceptance of residues
3.1	(a) Commodity	(a) liver (pigs)
	(b) MRL	(b) 30 µg/kg
	(c) Definition of Residue o n which MRL was set	(c) Quinoxaline-2-carboxylic acid
3.2	(a) Commodity	(a) Muscle (pigs)
	(b) MRL	(b) 5 µg/kg
	(c) Definition of residues on which MRL was set	(c) Quinoxaline-2-carbosylic acid
4.	References to recommended methods of analysis	USDA/FSIS Chemistry Laboratory Guidebook Method No. 5.014. Lynch, M. and Bartolucci, R.O., J. Association of Analytical Chemists, (1982), 65, 66-70, (Provisional)
5.	References to JECFA reports	WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991)
6.	References to previous Codex publications	Appendix II, ALINORM 91/31A Appendix IV, ALINORM 93/31

ALINORM 93/31A
Appendix III

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Retained at Step 7 of the Procedure)

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

1.	Substance: Sulfadimidine	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-4 µg/kg body weight (Temporary)
3.1	(a) Commodity	(a) Meat, liver, kidney and fat
	(b) MRL	(b) 300 µg/kg (temporary)
	(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) 100 µg/kg (temporary)
	(c) Definition of residue on which MRL was set	(c) sulfadimidine
3.3	(a) Commodity	(a) Milk (cattle)
	(b) MRL	(b) 50 µg/l (temporary)
	(c) Definition of residue on which MRL was set	(c) Total residue
3.4	(a) Commodity	(a) Milk (cattle)
	(b) MRL	(b) 25 µg/l (temporary)
	(c) Definition of residue on which MRL was set	(c) sulfadimidine
4.	References to recommended method(s) of analysis	(a) Journal of the Association of Official Analytical Chemists Vol. 66 (1983) pp. 881, 884 (b) Journal of Agriculture and Food Chemistry May-June 1981, pp. 621-624
5.	Reference to JECFA Reports	WHO TRS 788 (1989) WHO TRS 815 (1991) WHO FAS 25 (1990) FAO FNP 41/2 (1990)
6.	References to previous Codex Publications	Appendix III, ALINORM 91/31 Appendix III, ALINORM 91/31A Appendix III, ALINORM 93/31

ALINORM 93/31A
Appendix IV

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 5 of the Procedure)

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

1.	Substance:	Flubendazole	
2.	Acceptable Daily Intake (AID) as established by JECFA		0-12 µg/kg body weight
3.1	(a)	Commodity	(a) muscle and liver (pigs)
	(b)	MRL	(b) 10 µg/kg
	(c)	Definition of residues on which MRL was set	(c) Flubendazole
3.2	(a)	Commodity	(a) muscle (poultry)
	(b)	MRL	(b) 200 µg/kg
	(c)	Definition of residues on which MRL was set	(c) Flubendazole
3.3	(a)	Commodity	(a) liver (poultry)
	(b)	MRL	(b) 500 µg/kg
	(c)	Definition of residues on which MRL was set	(c) Flubendazole
3.4	(a)	Commodity	(a) eggs
	(b)	MRL	(b) 400 µg/kg
	(c)	Definition of residues on which MRL was set	(c) Flubendazole
4.	Reference to recommended methods of analysis		
5.	References to JECFA reports		WHO TRS In preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications		

1.	Substance: Thiabendazole	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-100 µg/kg body weight
3.1	(a) Commodity	(a) muscle, liver, kidney, fat (cattle, pigs, goats, sheep) milk (cattle, goats)
	(b) MRL	(b) 100 µg/kg
	(c) Definition of Residues on which MRL was set	(c) sum of thiabendazole and 5-hydroxythiabendazole
4.	Reference to recommended methods of analysis	
5.	References to JECFA reports	WHO TRS In preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications	
1.	Substance: Triclabendazole	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-3 µg/kg body weight
3.1	(a) Commodity	(a) muscle (cattle)
	(b) MRL	(b) 200 µg/kg
	(c) Definition of residues on which MRL was set	(c) Triclabendazole
3.2	(a) Commodity	(a) liver, kidney (cattle)
	(b) MRL	(b) 300 µg/kg
	(c) Definition of residues on which MRL was set	(c) Triclabendazole
3.3	(a) Commodity	(a) fat (cattle); muscle, liver, kidney, fat (sheep)
	(b) MRL	(b) 100 µg/kg
	(c) Definition of residues on which MRL was set	(c) Triclabendazole
4.	Reference to recommended methods of analysis	
5.	References to JECFA reports	WHO TRS In preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications	
1.	Substance: Isometamidium	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-100 µg/kg body weight
3.1	(a) Commodity	(a) muscle, fat, milk (cattle)
	(b) MRL	(b) 100 µg/kg
	(c) Definition of residues on which MRL was set	(c) Isometamidium

3.2	(a)	Commodity	(a) liver (cattle)
	(b)	MRL	(b) 500 µg/kg
	(c)	Definition of residues on which MRL was set	(c) Isometamidium
3.2	(a)	Commodity	(a) kidney (cattle)
	(b)	MRL	(b) 1000 µg/kg
	(c)	Definition of residues on which MRL was set	(c) Isometamidium
4.	Reference to recommended methods of analysis		
5.	References to JECFA reports		WHO TRS In preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications		

1. Substance: Bovine Somatotropins

2.	Acceptable Daily Intake (ADI) as established by JECFA		Not specified [1]
3.1	(a)	Commodity	(a) muscle, fat, liver, kidney, milk (cattle)
	(b)	MRL	(b) Not specified [2]
	(c)	Definition of residues on which MRL was set	
4.	Reference to recommended methods of analysis		
5.	References to JECFA reports		WHO TRS In preparation WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	References to previous Codex publications		

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[1] ADI "not specified" is a term applicable to a veterinary drug for which there is a large margin of safety for the consumption of its residues based on available toxicity and margin of safety for the consumption of its residues based on available toxicity and intake data when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the Committee has concluded that use of the veterinary drug does not represent a hazard to human health and that there is no need to specify a numerical acceptable daily intake.

[2] MRL "not specified" is a term applicable to a veterinary drug for which there is a large margin of safety for the consumption of its residues based on available data on the identity and concentration of the residues in animal tissues when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the Committee has concluded that the presence of drug residues in the indicated animal product does not present a health concern and that there is no need to specify a numerical maximum residue limit.

ALINORM 93/31A
Appendix V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Retained at Step 4 of the Procedure)

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

1.	Substance: Levamisole	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-3 µg/kg body weight (Temporary)
3.1	(a) Commodity (b) MRL (c) Definition of Residue on which MRL was set	(a) muscle, liver, kidney, fat (cattle, sheep, pigs) milk (cattle) (b) 10 µ/kg (Temporary) (c) Levamisole
4.	Reference to recommended methods of analysis	(To be elaborated)
5.	Reference to JECFA reports	WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991)
6.	References to previous Codex publications	Appendix II, ALINORM 91/31A Appendix V, ALINORM 93/31
1.	Substance: Carazolol	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-0.1 µg/kg body weight (Temporary)
3.1	(a) Commodity (b) MRL (c) Definition of residues on which MRL was set	(a) muscle and fat (cattle (and pigs) (b) 5 µg/kg (Temporary) (c) Carazolol
3.2	(a) Commodity (b) MRL (c) Definition of residues on which MRL was set	(a) liver and kidney (cattle and pigs) (b) 30 µg/kg (Temporary) (c) Carazolol
4.	Reference to recommended methods of analysis	(To be elaborated)
5.	Reference to JECFA reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.	Reference to previous Codex publications	Appendix V, ALINORM 93/31

1.	Substance: Spiramycin		
2.	Acceptable Daily Intake (ADI) as established by JECFA		0-5 µg/kg body weight (Temporary)
3.1	(a)	Commodity	(a) muscle (cattle and pigs)
	(b)	MRL	(b) 50 µg/kg (Temporary)
	(c)	Definition of residues on which MRL was set	(c) Spiramycin
3.2	(a)	Commodity	(a) liver (cattle and pigs)
	(b)	MRL	(b) 300 µg/kg (Temporary)
	(c)	Definition of residues on which MRL was set	(c) Spiramycin
3.3	(a)	Commodity	(a) kidney (cattle and pigs)
	(b)	MRL	(b) 200 µg/kg (Temporary)
	(c)	Definition of residues on which MRL was set	(c) Spiramycin
3.4	(a)	Commodity	(a) milk (cattle)
	(b)	MRL	(b) 150 µg/l (Temporary)
	(c)	Definition of residues on which MRL was set	(c) Spiramycin
4.	Reference to recommended methods of analysis		(To be elaborated)
5.	References to JECFA reports		WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.	References to previous Codex publications		Appendix V, ALINORM 93/31
1.	Substance: Febantel		
2.	Acceptable Daily Intake (ADI) as established by JECFA		0-10 µg/kg body weight (Temporary)
3.1	(a)	Commodity	(a) muscle, fat and kidney (cattle, sheep and pigs)
	(b)	MRL	(b) 100 µg/kg (Temporary) (group MRL)[1]
	(c)	Definition of residues on which MRL was set	(c) Oxfendazole sulfone
3.2	(a)	Commodity	(a) liver (cattle, sheep and pigs)
	(b)	MRL	(b) 500 µg/kg (Temporary) (group MRL)[1]
	(c)	Definition of residues on which MRL was set	(c) Oxfendazole sulfone
3.3	(a)	Commodity	(a) milk (cattle)
	(b)	MRL	(b) 100 µg/l (Temporary) (group MRL)[1]
	(c)	Definition of residues on which MRL was set	(c) Oxfendazole sulfone
4.	References to recommended methods of analysis		(To be elaborated)

5.	References to JECFA reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.	References to previous Codex publications	Appendix V, ALINORM 93/31
1.	Substance: Fenbendazole	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-25 µg/kg body weight (Temporary)
3.1	(a) Commodity	(a) muscle, fat and kidney (cattle, sheep and pigs)
	(b) MRL	(b) 100 µg/kg (Temporary) (group MRL)[1]
	(c) Definition of residues on which MRL was set	(c) Oxfendazole sulfone
3.2	(a) Commodity	(a) liver (cattle, sheep and pigs)
	(b) MRL	(b) 500 µg/kg (Temporary) (group MRL)[1]
	(c) Definition of residues on which MRL was set	(c) Oxfendazole sulfone
3.3	(a) Commodity	(a) milk (cattle)
	(b) MRL	(b) 100 µg/l (Temporary) (group MRL)[1]
	(c) Definitions of residues on which MRL was set	(c) Oxfendazole sulfone
4.	References to recommended methods of analysis	(To be elaborated)
5.	References to JECFA reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.	References to previous Codex publications	Appendix V, ALINORM 93/31
1.	Substance: Oxfendazole	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-4 µg/kg body weight (Temporary)
3.1	(a) Commodity	(a) muscle, fat and kidney (cattle, sheep and pigs)
	(b) MRL	(b) 100 µg/kg (Temporary) (group MRL)[1]
	(c) Definition of residues on which MRL was set	(c) Oxfendazole sulfone
3.2	(a) Commodity	(a) liver (cattle, sheep and pigs)
	(b) MRL	(b) 500 µg/kg (Temporary) (group MRL)[1]
	(c) Definition of residues on which MRL was set	(c) Oxfendazole sulfone

3.3	(a)	Commodity	(a) milk (cattle)
	(b)	MRL	(b) 100 µg/l (Temporary) (group MRL)[1]
	(c)	Definitions of residues on which MRL was set	(c) Oxfendazole sulfone
4.		References to recommended methods of analysis	(To be elaborated)
5.		References to JECFA reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.		References to previous Codex publications	Appendix V, ALINORM 93/31

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[1] Group MRL for febantel, fenbendazole, and oxfendazole individually or in combination. The MRL value is the sum of the residues of fenbendazole, oxfendazole, and oxfendazole sulfone, calculated as oxfendazole sulfone.

ALINORM 93/31A
Appendix VI

LIST OF VETERINARY DRUGS EVALUATED BY JECFA ON WHICH NO ACTION HAS BEEN TAKEN BY THE COMMITTEE

NOTE: The current list indicates those substances evaluated by JECFA for which no maximum residue level could be recommended by the Expert Committee. The most usual reason for not establishing an MRL was the inadequacy of data provided to JECFA for evaluation. However, it is essential to consult the Expert Committee report for a full understanding of the status of the substance concerned.

Substance	JECFA Reference
Dimetridazole	34th Session, TRS 788 (1989)
Ipronidazole	34th Session, TRS 788 (1989)
Metronidazole	34th Session, TRS 788 (1989)
Ronidazole	34th Session, TRS 788 (1989)
Sulfathiazole	34th Session, TRS 788 (1989)
Diminazene	34th Session, TRS 788 (1989)
Isometamidium	34th Session, TRS 788 (1989)
Olaquindox	36th Session, TRS 799 (1990)
Tylosin	38th Session, TRS 815 (1991)
Azaperone	38th Session, TRS 815 (1991)
Chlorpromazine	38th Session, TRS 815 (1991)
Propionylpromazine	38th Session, TRS 815 (1991)
Furazolidon	40th Session, TRS In preparation
Nitrofurazone	40th Session, TRS In preparation
Ractopamine	40th Session, TRS In preparation

ALINORM 93/31A
Appendix VII

DRAFT CODE OF PRACTICE FOR CONTROL OF THE USE OF VETERINARY DRUGS AT STEP 8

INTRODUCTION

1. This Code sets out guidelines on the prescription, application, distribution, and control of drugs used for treating animals, preserving animal health or improving animal production. The Code is intended to apply to all States which are members of the organizations under whose auspices the project is being developed and to contribute towards the protection of public health.

2. Good practice in the use of veterinary drugs (GPVD), as defined by the CCRVDF, is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions. The maximum residue limit for veterinary drugs (MRLVD) may be reduced to be consistent with good practice in the use of veterinary drugs. The MRLVD is based on the type and amount of residue considered to be without toxicological hazard for human health while taking into account other relevant public health risks as well as food technological aspects.

3. Veterinary products (including premixes for manufacture of medicated feeding stuffs) used in food producing animals should be administered (or incorporated into feed) in compliance with the relevant product information approved by national authorities and/or in accordance with a prescription and/or instruction issued by a qualified veterinarian.

REGISTRATION AND DISTRIBUTION - GENERAL REQUIREMENTS

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

RESPONSIBILITY OF THE VETERINARIAN AND OF OTHERS AUTHORIZED TO HANDLE OR ADMINISTER MEDICINES - GENERAL PROVISIONS

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

6. In determining treatments, it is necessary to ensure that an accurate diagnosis is obtained and be guided by the principles of maximum effectiveness combined with minimum risk. Specific treatments should be presented using as few products as possible and avoiding the use of combination products, unless pharmacological advantages have been demonstrated.

7. Veterinarians should keep in mind that uncontrolled and unlimited use of medicinal products may lead to the accumulation of undesirable residues in the animals treated and in the environment, and that the continuous use of anticoccidial, antibacterial or anthelmintic products may favour the development of resistance. It is the responsibility of the veterinarian or other authorized persons to draw up programmes of preventive medicine for the farmer and to stress the importance of sound management and good husbandry procedures in order to reduce the likelihood of animal diseases. Every effort should be made to use only those drugs known to be effective in treating the specific disease.

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

9. Beyond his responsibility for advice on measures that will reduce the incidence of disease and for controlling it when it arises, the veterinarian is also responsible for taking the welfare of livestock fully into account.

INFORMATION OF VETERINARY DRUGS

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

AMOUNTS TO BE SUPPLIED

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

PREPARATION OF MEDICINES

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

ADMINISTRATION OF MEDICINES

13. Special attention should be paid to the prescription and to using the correct dosage, site and route of administration. Note should be taken of all warning statements, interactions and contra-indications for use (in particular any incompatibility with other medicinal products). It is important not to use the product once the expiry date has passed.

14. In disease circumstances where no authorized product exists or certain indications or target species are not provided for in the product literature, the veterinarian can on his own responsibility or with advice from the manufacturer have recourse to other licensed products or off label use. Administration of products in this manner, however, may have unpredictable side effects and give rise to unacceptable residue levels. Veterinarians should therefore only embark on such uses, especially in food-producing animals, after the most careful consideration of the needs of the disease situation. Under these circumstances, a significantly extended withdrawal time should be assigned for drug withdrawal prior to marketing milk, meat or eggs. The veterinarian is responsible for providing written instructions on the use and withdrawal times for all medicines used off label. Off label use by persons other than veterinarians must not be permitted except when such use is conducted or permitted under the supervision or prescription of the veterinarian.

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

RECORD KEEPING REQUIREMENTS

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

WITHDRAWAL OF VETERINARY DRUGS

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

STORAGE OF VETERINARY DRUGS

18. Veterinary products should be correctly stored in accordance with label instructions. It should be kept in mind that storage temperatures are critical for some medicines, while exposure to light or to moisture can damage others. Prescription medicines should be separated from non-prescription medicines.

19. All veterinary products should be stored in secure premises and kept under lock and key where practicable and out of reach of children and animals.

DISPOSAL OF VETERINARY DRUGS

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

DISPOSAL AND CLEANING OF DRUG ADMINISTRATION EQUIPMENT

21. Disposable equipment used for administration of veterinary drugs must be disposed of safely and in accordance with correct disposal procedures. Where drugs are not administered under veterinary supervision, disposable syringes, needles, catheters and other drug administration equipment should, where ever practicable, be returned to the supplying veterinary practice to ensure correct disposal procedures.

22. Cleaning of equipment used for the administration of veterinary drugs must be carried out in a manner that ensures the safety of human health and the environment. After cleaning, any material containing residues of the veterinary drug should be disposed of using the same procedures that apply to disposal of the drug itself.

ALINORM 93/31A
Appendix VIII

REVISIONS TO THE DRAFT GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR CONTROL OF VETERINARY DRUG RESIDUES IN FOODS

(Advanced to Step 8)

The Committee agreed to the following revisions to the Guidelines previously elaborated at the 6th CCRVDF Session (Appendix VIII, ALINORM 93/31):

1. Replace the term "incidence" with the term "prevalence" throughout the text of the Guidelines.

2. Page 47, Item 9, para.2 was modified to read:

   For determining maximum residue limits, the FAO/WHO Joint Expert Committee on Food Additives (for veterinary drugs) may constitute a useful resource for obtaining these data.

3. (Page 45, para. 3) Revise the first sentence to read:

   Another kind of risk can occur if food animals have been raised using veterinary drugs or pesticides in an inappropriate manner.

4. Incorporate the relevant sections of the Codex Committee on Pesticide Residues Recommended Method of Sampling applicable to dairy products (Appendix VI, ALINORM 93/24), into the appropriate (i.e., Appendix B, Part 1, pages 65-67), section of the Guidelines, as follows:

APPENDIX B

MILK, EGGS, DAIRY PRODUCTS AND AQUATIC ANIMAL PRODUCTS

COMMODITY	INSTRUCTIONS FOR COLLECTION	MINIMUM QUANTITY REQUIRED FOR LABORATORY SAMPLE
I. Group 033 Milks		
Whole Liquid Milk raw, pasteurized, UHT & sterilised	In bulk. Mix thoroughly and immediately take a sample by means of a dipper. In retail containers. Take sufficient units to meet laboratory sample size requirements.	500 ml
II. Group 082 Secondary Milk Products		
A. Skimmed Milk skimmed and semi-skimmed milk;	As for whole liquid milk.	500 ml
B. Evaporated Milk Evaporated full cream & skimmed milk;	Bulk containers (barrels, drums). Mix the contents carefully and scrape adhering material from the sides and bottom of the container. Remove 2 to 3 litres, repeat the stirring and take a 500 ml sample. Small retail containers. Take sufficient units to meet laboratory sample size requirements.	500 ml
C. Milk Powders		
1. Whole;	Bulk containers. Pass a dry borer tube steadily through the powder at an even rate of penetration. Remove sufficient bores to make up a sample of 500 g. Small retail containers. Take sufficient units to meet laboratory sample size requirements.	500 g
2. Low Fat;	As for whole milk powders.	500 g

COMMODITY	INSTRUCTIONS FOR TAKING A PRIMARY SAMPLE	MINIMUM QUANTITY REQUIRED FOR LABORATORY SAMPLE
III. Group 087 **Derived Milk Products**		
A. Cream Fresh, frozen & UHT Single, whipping, whipped, double & clotted;	Bulk containers. Plunge to ensure thorough mixing moving the plunger from place to place avoiding foaming, whipping and churning. Take a 200 ml sample by means of a dipper. Small containers. Take sufficient units to meet laboratory sample size requirements.	200 ml
B. Butter including whey butter and low fat spreads containing butterfat;	In bulk. Take two cores or more of butter so that the minimum total sample weight is not less than 200 g. In pats or rolls. For units weighing over 250 g divide into four and take opposite quarters. For units weighing less than 250 g take one unit as sample.	200 g
C. Butteroil including anhydrous butteroil and anhydrous milkfat;	Mix thoroughly and take a 200 g sample.	200 g
IV. Group 090 **Manufactured Milk** Products (single ingredient)		
A. Yoghurt Natural, low fat through to full cream;	Select number of units sufficient to meet laboratory requirements.	500 g

COMMODITY	INSTRUCTIONS FOR TAKING A PRIMARY SAMPLE	MINIMUM QUANTITY REQUIRED FOR LABORATORY SAMPLE
B. Cheeses All varieties;	Make two cuts radiating from the centre of the cheese if the cheese has a circular base, or parallel to the sides if the base is rectangular. The piece removed should meet the laboratory sample size requirements. For small cheeses and wrapped portions of cheese take sufficient units to meet laboratory sample requirements.	200 g
V. Group 092 **Manufactured Milk Products (multi-ingredient)**		
A. Dairy Ice Cream Only ice cream containing 5% or greater of milk fat.	Select block or units sufficient to meet laboratory sample size requirements.	500 ml
B. Processed Cheese Preparations	Select units sufficient to meet laboratory sample size requirements.	200 g
C. Flavoured Yoghurt	As for natural yoghurt.	500 g
D. Sweetened Condensed Milk	As for evaporated milk.	500 ml
VI. Group 039 (Eggs and Egg Products)		
A. Liquid and frozen eggs	Use sample schedule. Subsample size will be 0.25 liter liquid or 0.5 liter packed shavings from aseptic drillings into containers.	0.5 kg
B. Dried egg products	Use sample schedule. Use same subsample sizes as 1.b. Dried milk products. Collect with aseptic technique.	0.5 kg
C. Shell eggs		
1. Retail packages	Use sample schedule. Subsample size is 1 dozen.	0.5 kg or 10 whole eggs

COMMODITY	INSTRUCTIONS FOR TAKING A PRIMARY SAMPLE	MINIMUM QUANTITY REQUIRED FOR LABORATORY SAMPLE
2. Commercial cases	For 15 cases or less collect 1 dozen from each case, minimum of 2 dozen eggs. For 16 or more cases collect 1 dozen from 15 random cases.	0.5 kg or 10 whole eggs
VII. Class B - Type 08 **(Aquatic Animal Products)**		
A. Packaged fish, fresh, frozen, smoked, Cured, or shellfish (except oysters)	Collect 12 subsamples randomly. Minimum subsample size is 1 kg.	1.0 kg
B. Bulk fish 0.5 - 1.5 kg.	Collect 12 subsamples randomly. Each subsample should total 0.5 kg of edible fish.	1.0 kg
C. Bulk shellfish (except oysters)	Collect 12 subsamples randomly.	1.0 kg
D. Other fish and shellfish products (including oysters)	Collect 12 - 0.25 liter subsamples.	1.0 kg
VIII. Class E - Type 17 **(Derived Edible Products of Aquatic Animal Origin)**		
A. Canned fish and shellfish products (except oysters)	Collect 12 subsamples of 5 cans per subsample.	1.0 kg
B. Other fish and shellfish products - fish flour and meal	Use sample schedule. Collect 1 kg per subsample.	1.0 kg

ALINORM 93/31A
Appendix IX

CODE OF PRACTICE FOR THE REGISTRATION OF VETERINARY DRUGS

(Prepared by the International Office of Epizootics)

1. INTRODUCTION

During the Second Session of the Codex Committee on Residues of Veterinary Drugs in Foods, in October 1987, it was decided that it would be useful to establish a Code of Practice for the approval of veterinary drugs for the purpose of guaranteeing, in particular, that the established maximum residue levels not be exceeded.

The following report was prepared by the International Office of Epizootics at the request of the Codex Committee on Residues of Veterinary Drugs in Foods who considered this organization to be competent in the area of the approval of veterinary drugs.

The preparation of this code of practice is based on:

- a procedure of approval of veterinary drugs intended to evaluate objectively the technical and scientific data relative to the quality, efficacy, and safety of the veterinary drug. Likewise, it should allow the determination of the maximum residue levels that should be respected at the time of the authorized use of veterinary drugs.

- a procedure for authorization of manufacturing that ensures that manufacturing is carried out according to the rules of good manufacturing practices.

No veterinary drug may be marketed in a country before having received the approval of the competent national authority. However, specific and exceptional circumstances may lead the competent national authority to authorize the use of an unregistered drug, especially in the case of clinical tests aimed to demonstrate the efficacy of the drug and performed according to a protocol determined in advance.

The authorities responsible for animal health should be involved with the competent national authority in granting the approval for the veterinary drugs.

No veterinary drug may benefit from an approval unless its pharmaceutical quality, therapeutic efficacy and safety for animals and eventually the consumer has first been demonstrated in the file for approval.

The evaluation of a file for approval is a technical procedure aimed to study, in a critical and objective way, the available scientific data.

2. MANUFACTURING, IMPORT AND EXPORT

a) Manufacturing

If the quality of the veterinary drug is to be controlled, this must be, above all, a manufacturing requirement. All drugs must be manufactured in accordance with the regulations for good practice in manufacturing (WHO, EEC...).

b) Import

The experience acquired in this field shows the importance of controlling veterinary drug imports, which should be limited to authorized products or products that should be used under strictly controlled conditions in clinical experimentations necessary to obtain the approval. The difficulty of establishing adequate customs codifications for veterinary drugs makes it necessary to turn to the veterinary authority for the control of these imports.

c) Export

The quality of the exported veterinary drugs, officially authorized by the exporting country, should be in agreement with the specifications of approval.

The quality of exported veterinary drugs, which have not been authorized by the exporting country, should be guaranteed by the enforcement of good manufacturing practices.

3. PHARMACEUTICAL QUALITY OF THE VETERINARY DRUG

The pharmaceutical quality of the veterinary drug is an essential requirement because it determines the efficacy and safety of the veterinary drug.

To achieve this quality, the company should conceive and implement a system of quality assurance that covers all the stages of development, manufacture and control.

At the conception level, it should especially see to:

- the enforcement of Good Practices in Manufacturing
- the validity of analytical control methods used to verify the compliance of subsequent production lots.
- the stability of the finished product. This requirement is particularly important for countries with a non-temperate climate.
- the quality of the package which, to avoid any type of fraud, should be guaranteed to be tamper proof or should make apparent any eventual violation.

The quality control should especially concern:

- the quality of the raw materials used.
- the composition and galenical quality of the finished product.

4. THERAPEUTIC EFFICACY OF THE VETERINARY DRUG

The evaluation of the efficacy of a veterinary drug should be based on the consideration of the following information:

- pharmacology of the active element or elements contained in the drug which indicate the potential efficacy with regard to the pathological entities to be controlled or the physio-logical mechanisms to be restored and/or modified.
- pharmacokinetics of the active principle in the treated animal, indicating the modes of treatment, galenical formulation, dosage, route

of administration...) which may generate the effective concentrations in the organism of this animal.

- clinical tests performed in accordance with the modes of treatment described in the file for approval, and taking into consideration, if necessary, the characteristics of the breeding and disease profile within the country from which registration is being sought. Proven extrapolations from clinical tests performed in other countries may be accepted.

5. SAFETY OF THE VETERINARY DRUG

The safety of the veterinary drug should be demonstrated for:

- the animal for which the drug is intended.
- the users of veterinary drugs.
- the environment.
- the consumers likely to be exposed to residues of veterinary drugs in food of animal origin.
- the industrial processing of the food.

a) Safety for the treated animal

Thorough tests, which may be performed on the occasion of clinical tests, should allow the accurate assessment of the safety of the veterinary drugs concerning the treated animals. These tolerance studies should take into consideration all the physiopathological and zootechnical effects.

Since the clinical tests performed to put together a file for approval remain necessarily limited, it is essential to continue to control the safety of the registered veterinary drug by means of an appropriate system of pharmacovigilance.

b) Safety for the users of veterinary drugs

When necessary, the precautions that should be taken so the users may handle the drugs without risk will be indicated, as well as the procedures to follow in case of an accident.

c) Safety for the environment

Where necessary, adequate information should be furnished to prove the absence of any undesirable effect of the veterinary drugs on the environment or to prevent them by providing the appropriate instructions for their use.

d) Safety for the consumer

The administration of a veterinary drug to an animal intended to produce food for human consumption might produce, in those foods, residues which are possibly dangerous for the consumer.

The protection of the public health should be insured by the following set of provisions:

- determination of an acceptable daily intake and of a maximum residue level as defined by the Codex Alimentarius.

- determination, for each galenical formulation, of the appropriate withholding time from a study of the kinetics of residues in meat, milk, fish, eggs and honey.

- development of reliable and practicable methods of analysis that allow, particularly from the perspective of screening, the detection, in food, of residue contents at least equal to the established maximum residue level.

- implementation of a plan to monitor the hygienic quality of foods of animal origin that allows to verify the compliance with the Maximum Residue Levels for drug residues considered as having priority.

e) Safety for industrial food processing

Where necessary, adequate information should be furnished to prove that the food coming from treated animals possesses a quality compatible with the requirements of the agroalimentary industry.

6. INFORMATION FOR THE USER

The information, recognized as necessary by the competent national authority, pertaining to quality, efficacy and safety of the veterinary drug will be brought to the user's attention by the appropriate means.

The labelling, determined by the space available, should nevertheless include the following: name, essential elements of the composition, laboratory responsible, registration number, number of the manufacture lot, withholding time if necessary, expiration date, storage conditions if necessary, and, if possible, indications and contraindications.

The instructions of the label should provide information necessary for the proper use of the veterinary drug, in accordance with the terms of the approval.

In particular, it will specify:

- the modes of administration.

- the indications, contraindications and, if the case arises, the side effects.

- the possible precautions for its use, concerning the person handling it, the treated animal, and the environment.

- the storage conditions for the drug, particularly if cold storage is necessary.

- the withdrawal times that should be observed for each food commodity, according to the recommended modes of treatment.

- general information on pharmacology.

It would be desirable that the directions also be written in the everyday language of the country from which registration is sought.

Advertising may be regulated according to the nature of the veterinary drug. It will be limited to only those veterinary drugs authorized by the competent national authority.

ALINORM 93/31A
Appendix X

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REVALUATION

1. SUBSTANCES SCHEDULED FOR CONSIDERATION AT THE FORTY SECOND MEETING OF JECFA IN FEBRUARY 1994

Chloramphenicol*
Dexamethasone
Enrofloxacin
Flumequine
Levamisole*
Olaquindox*
Ronidazole*
Spectinomycin
Sulfadimidine*

2. SUBSTANCES PROPOSED FOR CONSIDERATION AT THE FORTY THIRD MEETING OF JECFA IN LATE 1994

Apramycin
Carazolol*
Dihydrostreptomycin
Gentamicin
Imidocarb
Neomycin
Oxolinic acid
Ractopamine*
Spiramycin*
Streptomycin

3. SUBSTANCES PROPOSED FOR CONSIDERATION AT THE FORTY FIFTH MEETING OF JECFA IN MID-1995

Ceftiofur sodium
Chlortetracycline
Febantel*
Fenbendazole*
Moxidectin
Oxfendazole*
Tetracycline

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* *These substances were placed on the agenda on the basis of reevaluations scheduled by JECFA, not on the basis of CCRVDF priorities.*