codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 95/31

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-first Session
Rome, 3 - 12 July 1995

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

Washington, D.C., USA
7 - 10 June 1994

Note: This document incorporates Codex Circular Letter 1994/17-RVDF.

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CX 4/60.2 CL 1994/17-RVDF

TO:
- Codex Contact Points
- Interested International Organizations
- Participants at the Eighth 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 Eighth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 95/31)

The report of the Eighth Session of the Codex Committee on Residues of Veterinary Drugs in Foods is attached. It will be considered by the Twenty-first Session of the Codex Alimentarius Commission which is scheduled to be held in Rome from 3 - 12 July 1995.

PART A. MATTERS FOR ADOPTION BY THE 21ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION

The following matters will be brought to the attention of the 21st Session of the Codex Alimentarius Commission for adoption:

1. **DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 8;** ALINORM 95/31, paras. 44-45, 47-48 and Appendix II

2. **DRAFT REVISED CRITERIA FOR THE INCLUSION IN, OR EXCLUSION FROM, THE PRIORITY LIST;** ALINORM 95/31, paras. 71-72 and Appendix VIII

Governments wishing to propose amendments or to comment on the Draft Maximum Residue Limits and Draft Revised Criteria should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Eighth Edition, pp. 33-35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 30 April 1995**.

3. **PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 5;** ALINORM 95/31, paras. 52, 54, and Appendix IV

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 interest should do so in writing in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Eighth Edition, pp. 28-29) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 30 April 1995**.

PART B.REQUEST FOR COMMENTS

1. RISK ANALYSIS DEFINITIONS; ALINORM 95/31, para. 41 and Appendix IX

When discussing the implementation of risk assessment procedures, the Committee expressed concern at the fact that the use of the various expressions used by Codex in relation to risk analysis had not been harmonized. It considered that further progress would be greatly assisted by having agreed **Definitions** for Codex purposes. It recommended to the Executive Committee that such definitions be elaborated as a matter of priority in accordance with the new Accelerated Procedure with a view to their adoption by the CAC at its 21st Session. The Committee proposed that the definitions contained in Appendix IX to the present report should be sent to governments for comments and also considered by other relevant Codex Committees. It emphasized that any definitions adopted by the Commission should be harmonized to the extent possible with those of other relevant international organizations, for example, the OIE.

Governments are invited to comment on Risk Analysis Definitions, as contained in ALINORM 95/31, Appendix IX. Comments should be sent to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 30 April 1995**.

2. METHODS OF ANALYSIS; ALINORM 95/31, para. 59

The Committee agreed on the recommendations made by the *ad hoc* Working Group on Methods of Analysis and Sampling that member governments continue efforts to provide validated methods to the *ad hoc* Working Group for review for those veterinary drugs with recommended MRLs.

Governments are invited to submit validated methods of analysis to the Chairman of the Working Group, Dr. Richard Ellis, Director, Chemistry Division, USDA, FSIS, Science and Technology, 300 12th Street, SW., Room 603-Annex, Washington, DC 20250, USA, **not later than 31 July 1995**.

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE COMMISSION OR ITS EXECUTIVE COMMITTEE

-Recommended the adoption of the Draft Maximum Residue Limits for sulfadimidine, flubendazole, thiabendazole, isometamidium and bovine somatotropins at Step 8 (paras. 44-45, 47-48);

-Recommended the adoption of the Proposed Draft Maximum Residue Limits for levamisole (muscle, kidney, fat and liver) and diminazene at Step 5 (paras. 52, 54);

-Recommended the adoption of the revised Criteria for the Inclusion in, or Exclusion from, the Priority List to replace the earlier criteria used by the Committee (para. 72);

-Recommended to the Executive Committee that definitions used in risk analysis be elaborated as a matter of priority in accordance with the new Accelerated Procedure with a view to their adoption by the Commission at its 21st Session with the understanding that any definitions adopted by the Commission should be harmonized with those of other relevant international organizations (para. 41); and

-Agreed on a Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation (paras. 69-70).

OTHER MATTERS OF INTEREST TO THE COMMISSION

-Asked for an early resolution of the problem on "Role of Science and other Factors in the Codex Decision-Making Process" by the CCGP so as to allow the Commission to make a clear distinction between the role of science in the adoption of health-related standards by the Commission and the other factors influencing their acceptance by governments at the national or regional level (para. 17);

-Supported the principles of the paper entitled *Risk Assessment Procedures Used by the Codex Alimentarius Commission and its Subsidiary and Advisory Bodies* and the view that the establishment of MRLs for veterinary drugs should continue to be linked to the risk-based ADI (para. 39);

-Agreed that in principle the use of risk analysis procedures should be extended further in the Codex Procedures for the elaboration of standards (para. 40);

-Proposed that Risk Analysis Definitions be sent to governments for comments and also be considered by other relevant Codex Committees (para. 41);

- Retained the MRLs for triclabendazole at Step 7 pending future review by JECFA (para. 46);

-Retained the temporary MRL for levamisole in milk at Step 4 pending future review by JECFA (para. 52);

-Retained the temporary MRLs for spectinomycin and dexamethasone at Step 4 pending future review by JECFA (para. 55);

SUMMARY AND CONCLUSIONS (cont.d)

-Noted that chloramphenicol, flumequine and ronidazole should be added to the "inactive list" (para. 56);

-Agreed on the recommendations made by the *ad hoc* Working Group on Methods of Analysis and Sampling, which included (para. 59):
  -full recommendation of the multiresidue method for febantel, fenbendazole and oxfendazole for all tissues and species, and for sulfadimidine in muscle tissue; and
  -provisional recommendation of the methods for ivermectin in liver and triclabendazole in muscle, liver and kidney;

-Asked Australia to revise the document entitled *Consideration of Greater Harmonization between Setting MRL and Availability of Routine Methods* for the next meeting of the *ad hoc* Working Group on Methods of Analysis and Sampling in the light of the points raised at the Session, in particular, the concern expressed about the recommendation that JECFA should set the MRL within the sensitivity achievable (para. 60);

-Encouraged the use of *ISO Layouts for Standards - Part 2: Standard for Chemical Analysis* (ISO 78/2-1982) and requested that methods be submitted in this format for consideration by the Committee (para. 62);

-Requested the United States to continue the work on Compendium of Veterinary Drugs and to present a progress report at the 9th Session (para. 76);

-Accepted the offer of Australia to prepare a working paper on "Injection Site Residues of Veterinary Drugs" for consideration by the next session and requested liaison with the EC in the preparation of the paper (para. 80)

- Agreed to amend the current status of work by the CCRVDF (para. 80).

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LIST OF APPENDICES

INTRODUCTION

1 The Codex Committee on Residues of Veterinary Drugs in Foods held its Eighth Session from 7 to 10 June 1994 in Washington, D.C., at the kind invitation of the Government of the United States of America. The Session was chaired by Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, United States Food and Drug Administration. The Session was attended by 35 member countries of the Commission, 1 observer country and 7 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. R. 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 8 and 9, respectively.

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

OPENING OF THE SESSION (Agenda Item 1)

4 Ms. Patricia Jensen, Assistant Secretary for Marketing and Inspection Services, US Department of Agriculture, addressed the Committee at the invitation of the Chairman. She emphasized the importance of establishing an international consensus in the setting of standards for foods. This was necessary to avoid international trade disputes and to maintain consumer confidence in the safety of the food supply worldwide.

5 Such harmonization had taken on an even greater importance and visibility with the GATT agreements and she expressed US support for the work of Codex in this area. The Codex Alimentarius Commission is one of three international standard-setting organizations whose health and food safety standards would serve as a key reference point in settling trade disputes. She stated that whilst the Codex system was good, it must be made better to meet the new challenges of responsibility and accountability required by the GATT agreements. The standard-setting process would need to be further streamlined to cope with the rapidly changing world and the procedures made more transparent with greater consumer involvement.

6 Ms. Jensen stressed the need to clarify the role of science in the standard-setting process in order for the Codex Alimentarius Commission to play an effective and credible role in GATT and stated that the CCRVDF deserved special credit in this area. She concluded by emphasizing the importance to the world of harmonization of food standards from both a public health and a trade point of view.

ADOPTION OF THE AGENDA (Agenda Item 2)

7 The Committee adopted the Provisional Agenda as contained in CX/RVDF 94/1.

8 The Committee agreed to the attendance of representatives of the press and that the participation would be limited to taking notes of the proceedings.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

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

MATTERS OF INTEREST TO THE COMMITTEE: (Agenda Item 4)

a)Matters Arising from the Codex Alimentarius Commission and Other Codex Committees

10 The Secretariat introduced document CX/RVDF 94/2, which summarized matters of interest to the CCRVDF arising from the 20th Session of the Codex Alimentarius Commission and other Codex Committees.

Codex Alimentarius Commission (CAC)

11 The Committee noted that the 20th Session of the CAC had adopted the first MRLs for veterinary drugs (albendazole, closantel, ivermectin, benzylpenicillin, oxytetracycline and carbadox) at Step 8. It had retained the MRLs for trenbolone acetate at Step 8 along with those for other growth-promoting hormones. The CAC had also adopted three texts at Step 8: Code of Practice for the Control and Use of Veterinary Drugs; Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods; and Glossary of Terms and Definitions. These adopted MRLs and other texts had been published in *Codex Alimentarius*, Second Edition, Volume 3, which would be sent to governments for acceptance shortly.

Codex Committee on Methods of Analysis and Sampling (CCMAS)

12 The Committee noted that the 19th Session of the CCMAS had recommended two texts for adoption by the 21st Commission: the *Proposed Protocol for the Design, Conduct and Interpretation of Collaborative Studies*; and the *Harmonized Protocol for Proficiency Testing for Laboratory Analysis*. The CCMAS had also discussed *Criteria for Evaluating Acceptable Methods of Analysis* for Codex purposes and had agreed that the impact of the implementation of the proposed approach on the existing Codex methods should be studied.

Codex Committee on Pesticide Residues (CCPR)

13 The Committee noted that the 26th Session of the CCPR had considered a document entitled *Expression and Application of MRLs for Fat-soluble Pesticide in Animal Products* and decided to bring it to the attention of the CCRVDF. The revised section of Proposals had been distributed at the meeting of the Working Group on Methods of Analysis and Sampling of the CCRVDF. The CCPR had also asked the CCRVDF to consider abamectin as the proposed MRLs being elaborated by the CCPR did not cover veterinary uses.

14 The CCPR had decided that the Recommended Method of Sampling for the Determination of Pesticide Residues in Milk, Milk Products and Eggs should be revised. The CCPR had also considered a draft paper on *Pesticides Used Both as Pesticides and Veterinary Drugs* prepared by Australia.

Codex Committee on General Principles (CCGP)

15 The Secretariat reported briefly on the outcome of the 11th Session of the CCGP, a summary of which was contained in document CX/RVDF 94/4 (Conference Room Document 3). The CCGP had discussed a paper prepared by the Secretariat at the request of the 20th Session of the Codex Alimentarius Commission on the *Role of Science and Other Factors in the Codex Decision-Making Process* (CX/GP 94/4). Some of the technical recommendations in the paper had been accepted, including the review of Codex Standards and the need to include relevant factors other than scientific knowledge at various stages of the Codex process. The need for greater transparency in Codex working procedures of expert committees had also been accepted. Other main recommendations in the paper, especially those aimed at separating scientific issues from other issues and those concerned with amendments to the adoption and acceptance procedures were not accepted. The Committee had asked the Secretariat to review in detail all of those elements in the *Procedural Manual* which would potentially need to be amended so as to take into account the manner by which scientific and other factors needed to be considered. A list of the Sections of the *Procedural Manual* potentially affected was contained in Appendix III to the CCGP report (ALINORM 95/33).

16 The CCGP had also expressed the opinion that another Session of the Committee would be required to develop specific proposals for the 21st Session of the CAC. It was reported that the Secretariat would be consulting with the Host Government authorities on this matter in the near future.

17 The CCRVDF **asked** for an early resolution of the problem so as to allow the Commission to make a clear distinction between the role of science in the adoption of health-related standards by the Commission and the other factors influencing their acceptance by governments at the national or regional level. The Chairman stressed that the problem was one of very high priority and that all efforts should be made to resolve the matter so as to allow the adoption in 1995 of the MRLs currently held at Step 8 by the Commission.

Codex Committee on Fish and Fishery Products (CCFFP)

18 The Committee noted that the 21st Session of the CCFFP had considered the Proposed Draft Code of Practice for the Products of Aquaculture and agreed to return it to Step 3 for redrafting. It was noted that the Proposed Draft Code of Practice would contain a Section on the use of veterinary drugs and that this would be submitted to the CCRVDF for consideration at the earliest opportunity.

b)Matters arising from Activities of Other International Organizations

AOAC International (AOAC)

19 The representative of AOAC International provided details of recent work undertaken by the organization. He drew the attention of the Committee to the development of two new programmes for validation of methods of analysis. The AOAC Test Kit Performance Testing Programme certified manufacturer claims regarding the test kit. This involved expert review of performance characteristics developed by the manufacturer and independent performance testing by at least one other laboratory. The AOAC Peer-Verified Methods Programme formed the second new category of validation by the organization. The procedure involved in-house validation followed by validation in at least one other laboratory.

20 The representative also reported that AOAC International had continued its collaboration with ISO and IUPAC on the development of laboratory performance Protocols. AOAC International had adopted 95 methods as first action and 84 as final action during the period of 1992-1993.

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

21 The representative of COMISA stated that COMISA had actively supported the work of the Committee since 1986 by acting as an observer to the CCRVDF and supporting the provision of scientific data to JECFA. Since the last meeting of the Committee, COMISA had welcomed the definition of data requirements for microbiological endpoints and supported the proposed new initiative on harmonization of veterinary drug regulatory requirements adopted at the ITCRVD meeting in Paris in May 1994.

European Community (EC)

22 The representative of the EC presented information on progress in the establishment of MRLs for residues of veterinary medicinal products since Council Regulation (EEC) 2377/90 had entered into force on 1 January 1992. About 50 substances had been reviewed, of which 25 had been assigned final MRLs and the other 25 provisional MRLs. All other substances used in authorized products had to be classified according to the Council Regulation before 1 January 1997 if their continued use in food-producing animals was to be permitted.

23 The Committee was informed of the establishment of the European Agency for the Evaluation of Medicinal Products, which would become operational on 1 January 1995. Through a centralized procedure, Community-wide marketing authorizations would be granted by the European Commission on the scientific advice of the Agency. This procedure would be obligatory for products derived by biotechnology and for performance enhancers and, among other criteria, optional for products derived by high technologies and for veterinary medicinal products containing new active ingredients intended for use in food-producing animals.

24 The Observer further informed the Committee that the Community Reference Laboratories for the Research of Residues, which had been officially approved in 1991, had started their activities in August 1993. In close collaboration with the national reference laboratories within the EC, the improvement and harmonization of the methods of analysis, as well as the coordination of research in new methods had been regarded as urgent priorities.

International Dairy Federation (IDF)

25 The representative of the IDF informed the Committee of activities being undertaken by Group E503 in the IDF. Group E503 considered and validated methods for antibiotics, sulfonamides and inhibitors in raw milk. The Group had organized workshops and symposia on the detection of antibiotics and other antimicrobial inhibitors in milk and milk products (Workshop on Antibiotics and Other Microbial Inhibitors in Raw and Heat-treated Milk, December 1993, Denmark and Symposium on Antimicrobial Drugs, August 1995, Germany). Intercomparison studies were carried out and evaluated as part of a validation programme for detection methods. The representative informed the Committee that the IDF No 528:1991, collection of methods available for the detection of antibiotics and inhibitors, was being continuously revised and updated.

International Organization of Consumers Unions (IOCU)

26 The representative of IOCU welcomed the improved transparency and efforts to increase consumer involvement in Codex procedures. Both initiatives would contribute to the technical quality of Codex standards and to consumer confidence in food produced to meet those standards.

Office Internationale des Epizoöties (OIE)

27 The OIE Representative reported that the OIE had continued to provide programmes of training and information relating to veterinary drugs. The OIE newsletter on veterinary drug registrations was published twice a year in English, French and Spanish. The training programmes included seminars and workshops dedicated to the veterinary drug legislation and regulation at both the national and regional levels. Such seminars had recently been held in Bamako (Mali), Rabat (Morocco), Bogota (Colombia), Bogor (Indonesia) and Harare (Zimbabwe).

28 The OIE had responded to requests from interested countries on the transfer of technologies related to the pharmaceutical quality control of veterinary drugs. Contacts had been made with laboratories potentially capable of undertaking such controls, most notably in Mali, Côte d'Ivoire, Niger, Morocco, Colombia, Thailand, Indonesia and Zimbabwe.

International Technical Consultation on the Registration of Veterinary Drugs (ITCRVD)

29 The 7th ITCRVD was held at the Headquarters of OIE in Paris in May 1994. More than 90 participants representing 43 countries participated. Several recommendations were adopted directed to current important questions related to veterinary drug registration such as: good laboratory practices; inspection of laboratories; distribution; registration agencies; data banks; and environmental hazards. Two workshops were organized to consider the OIE programme relative to veterinary drug legislation and the control of veterinary drug residues in foods. A joint ITCRVD/Industry session was devoted to the international harmonization of scientific requirements for veterinary drug registration. An important recommendation adopted during this session invited the OIE to establish an *ad hoc* group to prepare proposals in this regard.

Pan American Health Organization (PAHO)

30 The representative of PAHO reported its activities concerning food protection conducted within the framework of the Regional Program of Technical Cooperation in Food Protection, approved by the Pan American Sanitary Conference and the Ministers of Health and Agriculture in the region of the Americas. The PAHO programme was administered by the Veterinary Public Health Program. Implementation was accomplished through 14 Veterinary Public Health and Food Protection Consultants, located in several countries. The Pan American Institute for Food Protection and Zoonoses - INPPAZ -provided laboratory support for food protection and zoonoses activities. Under the coordination of the Veterinary Public Health Program, a Regional Advisor acted as the focal point for the activities in food protection. The representative further informed the Committee of specific food protection activities including integrated programmes of food protection, strengthening of laboratory and inspection services, and epidemiological surveillance of foodborne diseases.

-UPDATE ON THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS RELATED TO SANITARY AND PHYTOSANITARY MEASURES AND THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE

31 The Secretariat introduced document CX/RVDF 94/4, which contained a brief reference to the texts of the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement (1994) on Technical Barriers to Trade. The texts of these Agreements as adopted in the Final Act of the Uruguay Round in December 1993 had been circulated by the Codex Secretariat to Contact Points under cover of Circular Letter 1994/3-GEN. It was noted that these texts had been the subject of legal revisions, not affecting the substance of the Agreements, prior to the final signing of the Uruguay Round Final Act in Marrakesh in April 1994. The Committee noted that the implications of the Final Act Agreements in relation to the work of Codex would be the subject of discussions at the Executive Committee's 41st Session.

c) Report of the Forty-Second Session of JECFA

32 The Committee had before it a summary of the report of the Forty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (CX/RVDF 94/7). The FAO and WHO Joint Secretaries of JECFA summarized the results.

33 Nine veterinary drugs were on the agenda for evaluation. Acceptable daily intakes (ADIs) and maximum residues limits (MRLs) were allocated to diminazene, levamisole and sulfadimidine. ADIs and temporary MRLs were allocated to dexamethasone and spectinomycin. Neither ADIs nor MRLs were allocated to chloramphenicol or to flumequine due to insufficient data. Additional data were not available on ronidazole, so the temporary ADI was not extended. The Committee concluded that residues resulting from the use of olaquindox in pigs under conditions of good practice in the use of veterinary drugs were temporarily acceptable, pending the submission of the results of requested residue studies.

34 The assessment of antimicrobial activity was carefully considered. The Expert Committee concluded that such activity should be assessed in all cases when antimicrobial agents are reviewed and that, in some cases, antimicrobial activity may be an appropriate endpoint for establishing an ADI. The Committee was aware that methods for examining microbiological endpoints were under development. Until these methods have been developed further, the Committee decided to remain flexible in its approach to establishing ADIs for residues of antimicrobial drugs.

35 The JECFA, in its report, provided guidance on the need for relevant and timely data for assessing the human food safety of residues of veterinary drugs and discussed risk assessment procedures that it used (see Agenda Item 5).

36 The Chairman of the Forty-second meeting of JECFA, Dr. J. Boisseau, pointed out that this was the first chance to implement the "Old Drug" policy that was developed at the Fortieth meeting. The Expert Committee found that the application of general principles to such drugs was difficult and assessments had to be performed on a case-by-case basis.

37 The Committee (CCRVDF) was informed that FAO and WHO were planning on convening two JECFA meetings per year, one of which would be dedicated to the evaluation of veterinary drugs, as recommended at the 7th Session of the CCRVDF. Future meetings on veterinary drug residues were planned for November 1994 (43rd meeting), June 1995 (45th) and June 1996 (47th). To better coordinate with CCRVDF Sessions, JECFA meetings on veterinary drug residues were planned to be convened each February from the 48th meeting onwards, which was scheduled to be held in February 1997.

IMPLEMENTATION OF RISK ASSESSMENT PROCEDURES (Agenda Item 5)

38 The CAC at its 20th Session, July 1993, had discussed a paper entitled *Risk Assessment Procedures Used by the Codex Alimentarius Commission and its Subsidiary and Advisory Bodies* (ALINORM 93/37) prepared by a consultant, Dr. S. Hathaway (New Zealand). The CAC had welcomed the recommendations contained in this paper and had asked that the paper be sent to all relevant Codex Committees for review and discussion. The Committee had before it the paper cited above, document CX/RVDF 94/5 containing extracts from the

CAC report and the (draft) report of the 42nd Meeting of JECFA, and Conference Room Document 6 (Definitions used in Risk Analysis prepared by New Zealand).

39 The Committee **supported** the principles of the Hathaway paper and the view that the establishment of MRLs for residues of veterinary drugs should continue to be linked to the risk-based ADI (Acceptable Daily Intake). In this regard the Committee noted that its procedures and those of JECFA were in general consistent with the principles enunciated in the paper.

40 The Committee also **agreed** in principle that the use of risk analysis procedures should be extended further in the Codex Procedures for the elaboration of standards. Some delegations were of the opinion that the roles of the expert committees and the Codex committees in regard to risk assessment and risk management respectively should be clarified. However, it was noted that overall Codex procedures had to take into account those Committees such as Food Hygiene and Meat Hygiene which did not receive independent external expert advice on a regular basis.

41 The Committee expressed concern at the fact that the use of the various expressions used by Codex in relation to risk analysis had not been harmonized. It considered that further progress would be greatly assisted by having agreed **Definitions** for Codex purposes. It **recommended** to the Executive Committee that such definitions be elaborated as a matter of priority in accordance with the new Accelerated ("Fast-Track") Procedure with a view to their adoption by the CAC at its 21st Session[1]. The Committee **proposed** that the definitions contained in Appendix IX to the present report should be sent to governments for comments and also considered by other relevant Codex Committees. It emphasized that any definitions adopted by the Commission should be harmonized to the extent possible with those of other relevant international organizations, for example, the OIE.

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

42 The Committee had before it the following documents: ALINORM 93/31A Appendix III, containing Draft MRLs held at Step 7; ALINORM 93/31A Appendix IV, containing Draft MRLs advanced from Step 5 to Step 6 by the 20th Session of the CAC; CX/RVDF 94/7 to which was attached the summary and conclusions of the 42nd meeting of JECFA; CX/RVDF 94/6, containing the comments of Norway, Spain and Thailand in response to Codex CL 1993/24-RVDF; and Conference Room Document 5, containing the comments of the European Community. It was agreed to discuss the Draft MRLs substance by substance.

Sulfadimidine

43 It was noted that MRLs for sulfadimidine had been held at Step 7 by the Sixth Session of the Committee pending re-evaluation by JECFA (ALINORM 93/31, paragraph 31). The Committee noted that the 42nd meeting of JECFA had allocated a full ADI of 0-50 µg/kg body weight and had confirmed the previously established MRLs for sulfadimidine in meat, liver, kidney, fat and milk when expressed as the parent drug. The Chairman of the 42nd JECFA noted that the MRLs had been confirmed at these levels in order to take account of possible allergenic responses even though the ADI had been raised.

44 The Committee **advanced** the MRLs for sulfadimidine as presented in Appendix II of this report to Step 8 of the Procedure for consideration by the Commission. The draft MRLs based on total residue of the drug were deleted.

Flubendazole and Thiabendazole

45 The Committee **advanced** the MRLs for these substances as presented in Appendix II of this report to Step 8 of the Procedure for consideration by the Commission. It was noted that the EC, while not opposing the

[1] *Procedural Manual of the Codex Alimentarius Commission*, 8th Edition, pages 30-31.

advancement of the MRLs to Step 8, would review the conclusions of JECFA to determine whether to implement them within the EC.

Triclabendazole

46 The Committee noted that further data related to toxicity and total residues distribution and depletion were likely to become available in the near future. Pending the review of these data by JECFA, the Committee **retained** the MRLs for triclabendazole, as contained in Appendix III of this report, at Step 7 of the Procedure.

Isometamidium

47 The Committee **advanced** the MRLs for isometamidium as presented in Appendix II of this report to Step 8 of the Procedure for consideration by the Commission. The Committee was informed that use of this substance was not foreseen in the European Community and that it was therefore not subject to Council Regulation (EEC) 2377/90. The establishment of MRLs by the EC for this substance was not foreseen.

Bovine Somatotropins (BST)

48 The Committee **advanced** the MRLs for the bovine somatotropins as contained in Appendix II of this report to Step 8 of the Procedure for consideration by the Commission.

49 The Committee was informed that there was a moratorium on the licensing of BST in the EC until the end of 1994. While not objecting to advancing the MRLs for BST to Step 8, the EC could not take a formal position at the present time in regard to the adoption of these MRLs.

CONSIDERATION OF PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 4 ARISING FROM THE 42ND JECFA (Agenda Item 7)

50 The Committee had before it document CX/RVDF 94/7 which contained Summary and Conclusions of the 42nd JECFA. In response to CX/RVDF 94/7, only Poland had sent a comment stating that the Polish food legislation provided zero tolerance for residues of veterinary drugs in food.

Levamisole

51 The MRLs for levamisole had been retained at Step 4 by the 7th Session of the CCRVDF because the ADI and the MRLs had been temporary. The 42nd JECFA had recommended a full ADI and full MRLs for muscle, kidney, fat and liver in cattle, sheep, pigs and poultry (see Appendix IV). However, the 42nd JECFA had not considered the temporary MRL for milk (cattle) (see Appendix V) and had been unable to recommend an MRL for eggs.

52 The Delegation of Germany, speaking on behalf of the EC, stated that the EC had set provisional MRLs of 10 µg/kg for levamisole for muscle, kidney, liver, fat and milk for all food producing animals. These would expire on 1 January 1995 and the EC would be reviewing its MRLs in the light of the JECFA recommendations. In the meantime, the EC would not oppose the advancement of the recommended MRLs for levamisole to Step 5. The Committee **agreed** to advance the Proposed Draft MRLs recommended by the 42nd JECFA for muscle, kidney, fat and liver for cattle, sheep, pigs and poultry to Step 5 and to retain the temporary MRL for milk (cattle) at Step 4 pending future review by JECFA.

Diminazene

53 The 42nd JECFA had allocated a full ADI and full MRLs for muscle, liver, kidney and milk for cattle (see Appendix IV). The Committee noted that although some of the MRLs appeared to be relatively high, the bioavailability of diminazene in man was very low. The Committee was informed that diminazene was not foreseen to be used in the EC and was not subject to Council Regulation (EEC) 2377/90.

54 The Committee **agreed** to advance the Proposed Draft MRLs for muscle, liver, kidney and milk of cattle to Step 5.

Spectinomycin and Dexamethasone

55 The Committee noted that the 42nd JECFA had recommended temporary MRLs for spectinomycin and dexamethasone (see Appendix V) and **agreed** to retain these MRLs at Step 4.

Chloramphenicol, Flumequine and Ronidazole

56 The Committee noted that chloramphenicol, flumequine and ronidazole should be added to the "inactive list" (see Appendix VI). It also noted that in the event of trade disputes over compounds in the "inactive list", no Codex MRL was available. However, if appropriate data became available for any of these compounds, manufacturers and/or countries should contact the JECFA Secretariat to seek its evaluation. The Committee further noted that human exposure to medical or veterinary uses of chloramphenicol could be quite different. For example, short-term exposure for medical reasons might be desirable in certain cases, whereas involuntary exposure via residues in food was likely to cause concern.

METHODS OF ANALYSIS AND SAMPLING FOR RESIDUES OF VETERINARY DRUGS IN FOOD (Agenda Item 8)

57 The Committee had before it Conference Room Document 1, *Report to the Plenary Session of the Seventh Meeting of the Ad Hoc Working Group on Methods of Analysis and Sampling*. A total of 57 delegates and observers from 20 countries attended the meeting. The Chairman, Dr. Richard Ellis (USA), introduced the report.

58 Rapporteurs were appointed to evaluate methods of analysis for residues of three veterinary drugs for which MRLs had been recommended by the 42nd meeting of JECFA and methods of analysis were discussed for 17 substances.

59 The Committee **agreed** to adopt the following Working Group recommendations:

1. that the *ad hoc* Working Group should be allowed to continue its work for the CCRVDF;

2. that member governments continue efforts to provide validated methods to the *ad hoc* Working Group for review for those veterinary drugs with recommended MRLs;

3. that sponsors are encouraged to make available analytical methods for compounds on the present and future JECFA agendas;

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

5. that provisional status be given for methods for ivermectin in liver and triclabendazole in muscle, liver and kidney; and

6. that full recommendation status be given to the multiresidue method for febantel, fenbendazole and oxfendazole for all tissues and species, and for sulfadimidine in muscle tissue.

60 The Committee discussed the Conference Room Document 4 on the *Consideration of Greater Harmonization between Setting MRL and Availability of Routine Methods*, prepared by Australia. It asked Australia to revise the document in the light of the points raised, in particular the concern expressed about the recommendation that JECFA should set the MRL within the sensitivity achievable. The Committee asked the Working Group to consider the revised document at its next meeting so that the paper could be considered with the Working Group recommendations at the next Plenary Session of the CCRVDF.

61 The Committee noted the concerns of the Working Group regarding the recommendations of the Codex Committee on Methods of Analysis and Sampling that two documents related to methods evaluation be adopted by the Commission for Codex purposes (see para. 12 above and ALINORM 95/23, paras. 34-43 and Appendix V). The Working Group had expressed concern at the possibility of finding a sufficient number of laboratories to comply with the recommended criteria foreseen in the CCMAS protocol.

62 On a related matter, the Working Group had also expressed concern at the problems of making the methods of analysis endorsed by the Committee available to the scientific community and especially to regulatory control laboratories. The Committee **encouraged** the use of the *ISO Layouts for Standards - Part 2: Standard for Chemical Analysis* (ISO 78/2-1982), and requested that methods be submitted in this format for consideration by the Committee.

63 The Committee thanked the Working Group, its Chairman and the rapporteur for the report and **agreed** that Dr. Richard Ellis (USA) should continue as Chairman of the *ad hoc* Working Group.

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION (Agenda Item 9)

64 The Committee had before it Conference Room Document 2, the report of the *Ad Hoc* Working Group on Priorities, and CX/RVDF 94/9, a paper prepared by COMISA (Consultation Mondiale de l'Industrie de la Santé Animale) which included proposed revised criteria for the inclusion of veterinary drugs in the priority list. The Chairman of the Working Group, Dr. J. Owusu (Australia), introduced the report and recommendations.

65 Formal nominations for substances to be placed on the priority list were received from Australia, Belgium, and Brazil. Australia recommended porcine somatotropin, cypermethrin, and α-cypermethrin, Belgium recommended diclazuril, and Brazil recommended nicarbazin. Thailand requested that oxytetracycline and oxolinic acid be placed on the priority list for consideration of maximum residue limits (MRLs) for the giant prawn (*Penaeus monodon*). Commitments had been made for provision of relevant data on these veterinary drugs.

66 Nominations were made at the Working Group meeting for clenbuterol (United Kingdom), doramectin (United States of America and European Community), and abamectin, thiamphenicol, tilmicosin, and xylazine (European Community). Although it was believed that data would be made available on all of these substances, there was a need to follow up on these substances to ensure that this would be the case. COMISA made the commitment to assist in this effort.

67 A list had been sent by Egypt to the Chairman of the Working Group requesting that certain drugs be placed on the priority list. However, little information on availability of data was provided, and most of the drugs had already been considered by JECFA, so none of these drugs was added to the priority list.

68 Of the drugs listed above, abamectin, cypermethrin, and α-cypermethrin have pesticidal as well as veterinary drug uses. Both abamectin and cypermethrin had been evaluated by JMPR (Joint FAO/WHO Meeting on Pesticide Residues). The Codex definition of *pesticide* includes ectoparasiticides, so the definition might have to be changed if substances used for this purpose were to be considered veterinary drugs. While theoretically it should not make much difference whether the toxicological evaluation of such substances is performed by JECFA or JMPR, the Committee believed that it was appropriate that JECFA, rather than JMPR, reviewed the residue data for veterinary uses.

69 On the basis of the above considerations, the Committee **agreed** that the following substances should be added to the priority list:

abamectin
clenbuterol
cypermethrin
α-cypermethrin
diclazuril
doramectin
nicarbazin
oxolinic acid
oxytetracycline (giant prawns -residue)
porcine somatotropin
thiamphenicol
tilmicosin
xylazine

70 The tentative agendas for the forty-third (November 1994), forty-fifth (June 1995), and forty-seventh (June 1996) meetings of JECFA are listed in Appendix VII. The agendas include substances that require re-evaluation for a number of reasons, including requests made at the present session of the CCRVDF and drugs scheduled for re-evaluation by JECFA. Abamectin, diclazuril, and doramectin, three drugs listed above, were placed on the agenda of the forty-fifth meeting of JECFA because the manufacturers indicated that data could be submitted in a timely fashion and because it would be more efficient to evaluate abamectin and doramectin along with moxidectin, which had been already on the agenda. The Delegation of Italy, after asking for clarification on the priority-setting process, requested that thiamphenicol be reviewed at the forty-fifth meeting. The proposal was not accepted because no clear indication was presented by the EC that data could be made available in time. Dexamethasone was on the agenda of the forty-third meeting for consideration of residues in horses and of the forty-seventh meeting to consider methods of analysis. The Secretariat emphasized the fact that the final agendas of JECFA were the responsibility of the Directors-General of FAO and WHO.

Criteria for the Inclusion of Substances in the Priority List

71 The Committee noted a COMISA proposal to change the criteria for placing veterinary drugs on the priority list and a proposal for introducing a weighting system for the criteria. The COMISA proposal to introduce a weighting system was not considered further as a backlog of substances to be reviewed by JECFA no longer existed. The Working Group had proposed some changes in the criteria outlined by COMISA, and additional changes were made by the Committee. The Committee considered whether specific reference should be made to the presence of residues arising from the use of the drugs when these residues could result in trade problems or public health problems, but concluded that such specific reference was not necessary. The Committee **agreed** to include a specific reference to public health. The Committee also noted that the obligation to provide a complete dossier conforming with the present criteria on either toxicological or residues studies could create difficulties for developing countries when proposing substances for inclusion in the priority list.

72 The revised criteria as contained in Appendix VIII were **adopted** by the Committee and would be **submitted** to the Commission for adoption to replace the earlier criteria used by the Committee (ALINORM 87/31, paras. 148-162).

73 The Committee thanked the Working Group, the Chairman, and the 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.

PROGRESS REPORT ON COMPENDIUM OF VETERINARY DRUGS (Agenda Item 10)

74 The Committee noted that at its 7th Session (ALINORM 93/31A, paras. 56-58), it had been agreed that the United States would present a progress report at the 8th Session of the CCRVDF. The Delegation of the United States reported that with the collaboration of 77 countries and international organizations the revised 4th edition of *Compendium of Regulations and Authorities for Registered Veterinary Products* had been prepared and published both in electronic form and hard copy. Both documents were made available to all delegations at the Session. The Delegation of the United States expressed its willingness to continue this work and to expand the availability of the Compendium through computer network such as Internet.

75 The Delegation of Malaysia thanked the United States for preparing the Compendium and reported that Malaysia was using this document regularly. The Delegation, however, noted that there were certain

differences in regulatory responsibilities in Malaysia compared with other countries. The Delegation of the United States informed the Committee that consideration could be given, if necessary, to changes in the format of the Compendium if the necessary information was provided.

76 The Committee thanked the United States and unanimously requested the United States to continue this work.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

77 The Delegation of Israel raised concerns about the principle of the EC reserving its position within the CCRVDF or slowing the advancement of MRLs recommended by JECFA when different MRLs were adopted by the EC. Israel requested that the scientific criteria underlying the EC's position be made available in advance of future meetings.

Medium-Term Programme of Work

78 The Committee had before it CX/RVDF 94/2, which contained Medium-Term Objectives by Programme Area as Appendix I and the Committee's current status of work as Annex 1 of Appendix I.

79 The Secretariat informed the Committee that as indicated in CX/RVDF 94/2, all Codex Committees had been requested by the Commission to consider their medium-term objectives as a standing agenda item. A report on the current status of the work of the CCRVDF should be made to the Executive Committee to be reviewed in the light of the medium-term objectives. The Secretariat highlighted those medium-term objectives relevant to the CCRVDF, namely, contaminants (including residues of veterinary drugs) and risk assessment. The Committee was asked to consider these objectives and future work relevant to the objectives.

80 The Committee noted that the subject 187 "Process by Which MRLVDs are Adopted by the Commission" had been incorporated into and superseded by the subject 126 assigned for the CCGP, "Role of Science in Codex Decision-Making Process", and, therefore, the subject 187 should be deleted from the list. The Delegation of Australia, supported by several countries, proposed that the Committee should discuss "Injection Site Residues of Veterinary Drugs" and offered to prepare a working paper for consideration by the next session of the Committee. The EC reported that it was considering the same topic and the Committee requested that Australia should liaise with the EC in the preparation of a paper for the next Plenary Session of the CCRVDF. The Committee was also informed that the Working Group on Methods of Analysis and Sampling would discuss "Availability of Standards" and "Consideration of Greater Harmonization between Setting MRL and Availability of Routine Methods" at its next meeting.

DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

81 The Committee was informed that its Ninth Session was tentatively scheduled for 24-27 October 1995 held in Washington, D.C., with the working group meetings held on Monday, 23 October.

82 Noting the high priority given by the CCRVDF to the clarification of "Role of Science" in Codex Procedures, the Secretariat was requested to consider all possible options to schedule a meeting of the CCGP before the 21st Session of the Commission in July 1995. If it was found necessary, the next session of the CCRVDF should be postponed to accommodate the CCGP Session in early 1995. The Committee hoped that this would be unnecessary in the light of concerns expressed by some delegations about the delays in advancing MRLs for compounds already in the system and arising from the two forthcoming JECFA meetings. If it was inevitable, however, the date of the next CCRVDF Session would be determined after the consultation between the United States and the Secretariat.

Annex I

SUMMARY STATUS OF WORK

Subject	Step	For Action by	Document Reference
Draft Maximum Residue Limits for Veterinary Drugs	8	21st CAC	ALINORM 95/31, Appendix II
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5	21st CAC	ALINORM 95/31, Appendix IV
Draft Maximum Residue Limits for Veterinary Drugs	7	JECFA CCRVDF	ALINORM 95/31, Appendix III
Proposed Draft Maximum Residue Limits for Veterinary Drugs	4	JECFA CCRVDF	ALINORM 95/31, Appendix V
Priority List of Veterinary Drugs Requiring Evaluation	1	41st Executive Committee Governments JECFA CCRVDF	ALINORM 95/31, Appendix VII
Risk Analysis Definitions	1	41st Executive Committee Governments Relevant Codex Committees	ALINORM 95/31, para. 41 and Appendix IX
Draft Criteria for the Inclusion in, or Exclusion from, the Priority List	-	21st CAC	ALINORM 95/31, paras. 71-72 and Appendix VIII
Methods of Analysis and Sampling	-	Governments CCRVDF	ALINORM 95/31, paras. 57-62, 80
List of Veterinary Drugs Evaluated by JECFA on Which No Action Has Been Taken by the Committee	-	Governments	ALINORM 95/31, Appendix VI
Injection Site Residues of Veterinary Drugs	-	Australia, EC 9th CCRVDF	ALINORM 95/31, para. 80
Consideration of Greater Harmonization between Setting MRL and Availability of Routine Methods	-	Australia WG on Methods of Analysis and Sampling	ALINORM 95/31, para. 60
Progress Report on Compendium of Veterinary Drugs	-	United States	ALINORM 95/31, paras. 74-76

Appendix I

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DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 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 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	0-50 µg/kg body weight
3.1(a) Commodity	(a)Muscle, liver, kidney and fat
(b)MRL	(b) 100 µg/kg
(c)Definition of residue on which MRL was set	(c)sulfadimidine
3.2(a) Commodity	(a)Milk (cattle)
(b)MRL	(b) 25 µg/l
(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* **66** (1983) 881, 884 (b)*Journal of Agricultural and Food Chemistry* **29** (1981) 621-624
5.Reference to JECFA Reports	WHO TRS 788 (1989) WHO TRS 815 (1991) WHO FAS 25 (1990) FAO FNP 41/2 (1990) WHO TRS (to be published) WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.Reference to previous Codex reports	Appendix III, ALINORM 91/31 Appendix III, ALINORM 91/31A Appendix III, ALINORM 93/31 Appendix III, ALINORM 93/31A

1. ***Substance: Flubendazole***	
2.Acceptable Daily Intake (ADI) 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 residue on which MRL was set	(c)flubendazole
3.2(a) Commodity	(a)Muscle (poultry)
(b)MRL	(b) 200 µg/kg
(c)Definition of residue on which MRL was set	(c)flubendazole
3.3(a) Commodity	(a)Liver (poultry)
(b)MRL	(b) 500 µg/kg
(c)Definition of residue on which MRL was set	(c)flubendazole
3.4(a) Commodity	(a)Eggs
(b)MRL	(b) 400 µg/kg
(c)Definition of residue on which MRL was set	(c)flubendazole
4.References to recommended method(s) of analysis	**Marti, A.M., Mooser, A.E., and Koch, H.** Determination of Benzimidazole Antihelmintics in Meat Samples *J. Chromatography* **498** (1990) 145-147
5.Reference to JECFA Reports	WHO TRS 832 (1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.Reference to previous Codex reports	Appendix IV, ALINORM 91/31A

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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 residue on which MRL was set	(c)sum of thiabendazole and 5-hydroxythiabendazole
4.References to recommended method(s) of analysis	**Ellis, R.L.**, USDA, Food Safety and Inspection Service, Analytical Chemistry Laboratory Guidebook: Method BNZ, July 1991
5.Reference to JECFA Reports	WHO TRS 832 (1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.Reference to previous Codex reports	Appendix IV, ALINORM 91/31A

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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 residue on which MRL was set	(c)isometamidium
3.2(a) Commodity	(a)Liver (cattle)
(b)MRL	(b) 500 µg/kg
(c)Definition of residue on which MRL was set	(c)isometamidium
3.3(a) Commodity	(a)Kidney (cattle)
(b)MRL	(b) 1000 µg/kg
(c)Definition of residue on which MRL was set	(c)isometamidium
4.References to recommended method(s) of analysis	**Mignot, A., Lefebvre, M., and Vidal, R.** Determination of isometamidium concentration in plasma and tissue samples of young bulls after intramuscular administration of trypamidium at a level of 1 mg.kg-1. Unpublished report submitted to FAO by Rhone Merieux, Toulouse Cedex, France (1991)
5.Reference to JECFA Reports	WHO TRS 832 (1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.Reference to previous Codex reports	Appendix IV, ALINORM 91/31A

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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 residue on which MRL was set	(c)Not applicable
4.References to recommended method(s) of analysis	Torkelson, A.R., Dwyer, K.A., and Rogan, G.J. Radioimmunoassay of somatotropin in milk from cows administered recombinant bovine somatotropin Abstract, *J. Dairy Sci*., **70** (Suppl. 1) (1987), 146
5.Reference to JECFA Reports	WHO TRS 832 (1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.Reference to previous Codex reports	Appendix IV, ALINORM 91/31A

[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.

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: 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 residue on which MRL was set	(c)5-chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
3.2(a) Commodity	(a)Liver, kidney (cattle)
(b)MRL	(b) 300 µg/kg
(c)Definition of residue on which MRL was set	(c)5-chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
3.3(a) Commodity	(a)Fat (cattle); Muscle, liver, kidney, fat (sheep)
(b)MRL	(b) 100 µg/kg
(c)Definition of residue on which MRL was set	(c)5-chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
4.References to recommended method(s) of analysis	(a)**Marti, A.M., Mooser, A.E., and Koch. H.** Determination of Benzimidazole Antihelmintics in Meat Samples, *J. Chromatog.*, **498** (1990), 145-157
5.Reference to JECFA Reports	WHO TRS 832 (1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.Reference to previous Codex reports	Appendix IV, ALINORM 93/31A

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: Levamisole***

2.Acceptable Daily Intake (ADI) as established by JECFA	0-6 µg/kg body weight
3.1(a) Commodity	(a)Muscle, kidney, fat (cattle, sheep, pigs, poultry)
(b)MRL	(b) 10 µg/kg
(c)Definition of residue on which MRL was set	(c)levamisole
3.2(a) Commodity	(a)Liver (cattle, sheep, pigs, poultry)
(b)MRL	(b) 100 µg/kg
(c)Definition of residue on which MRL was set	(c)levamisole
4.References to recommended method(s) of analysis	(To be elaborated)
5.Reference to JECFA Reports	WHO TRS 799 (1990) WHO TRS In preparation WHO FAS 27 (1991) WHO FAS 33 (1994) FAO FNP 41/3 (1990) FAO FNP 41/6 (1994)
6.Reference to previous Codex reports	Appendix II, ALINORM 91/31A Appendix V, ALINORM 93/31A

1. ***Substance: Diminazene***

2.Acceptable Daily Intake (ADI) as established by JECFA	0-100 µg/kg body weight
3.1(a) Commodity	(a)Muscle (cattle)
(b)MRL	(b) 500 µg/kg
(c)Definition of residue on which MRL was set	(c)diminazene
3.2(a) Commodity	(a)Liver (cattle)
(b)MRL	(b) 12 000 µg/kg
(c)Definition of residue on which MRL was set	(c)diminazene
3.3(a) Commodity	(a)Kidney (cattle)
(b)MRL	(b) 6 000 µg/kg
(c)Definition of residue on which MRL was set	(c)diminazene
3.4(a) Commodity	(a)Milk (cattle)
(b)MRL	(b) 150 µg/l[1]
(c)Definition of residue on which MRL was set	(c)diminazene
4.References to recommended method(s) of analysis	(to be elaborated)
5.Reference to JECFA Reports	WHO TRS In preparation WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.Reference to previous Codex reports	None

[1] Limit of quantitation of the analytical method.

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	0-6 µg/kg body weight
3.1(a) Commodity	(a)Milk (cattle)
(b)MRL	(b) 10 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)levamisole
4.References to recommended method(s) of analysis	(To be elaborated)
5.Reference to JECFA Reports	WHO TRS 799 (1990) WHO TRS In preparation WHO FAS 27 (1991) WHO FAS 33 (1994) FAO FNP 41/3 (1990) FAO FNP 41/6 (1994)
6.Reference to previous Codex reports	Appendix II, ALINORM 91/31A Appendix V, ALINORM 93/31A

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1. ***Substance: Carazolol***

2.Acceptable Daily Intake (ADI) as established by JECFA	0-0.1 µg/kg body weight (Temporary)
3.1(a) Commodity	(a)Muscle and fat (cattle and pigs)
(b)MRL	(b) 5 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)carazolol

3.2(a) Commodity	(a)Liver and kidney (cattle and pigs)
(b)MRL	(b) 30 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)carazolol
4.References to recommended method(s) of analysis	**Keuken, H.J., and Aerts, M.M.L.** *J. Chromatography* **464** (1989) 149-161 (Kidney) **Vogelgesang, J.** *Dtsch. Lebensmittelrudnsch.,* **85** (1989) 251-258 (Liver) **"Steinhart Method"** *Untersuchung von Lebensmitteln - Bestimmung von Carazolol in Gewesen, Amtliche Sammlung von Untersuchungsverfahren* nach §35 LMBG, No. 06, 15-4 (Muscle, Liver and Kidney) **Rose, M.D. and Shearer, G.** *J. Chromatography* **624** (1992) 471-477 (Liver and Kidney)
5.Reference to JECFA Reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.Reference to previous Codex reports	Appendix V, ALINORM 93/31A

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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 residue 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 residue 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 residue on which MRL was set	(c)spiramycin

3.4(a) Commodity	(a)Milk (cattle)
(b)MRL	(b) 150 µg/l (Temporary)
(c)Definition of residue on which MRL was set	(c)spiramycin
4.References to recommended method(s) 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 reports	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A

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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, kidney, (cattle, pigs, sheep)
(b)MRL	(b) 100 µg/kg (Temporary) (Group MRL)[1]
(c)Definition of residue on which MRL was set	(c)oxfendazole sulfone
3.2(a) Commodity	(a)Liver (cattle, pigs, sheep)
(b)MRL	(b) 500 µg/kg (Temporary) (Group MRL)[1]
(c)Definition of residue 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 residue on which MRL was set	(c)oxfendazole sulfone
4.References to recommended method(s) of analysis	See Thiabendazole, Appendix II
5.Reference to JECFA Reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.Reference to previous Codex reports	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A

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, kidney, (cattle, pigs, sheep)
(b)MRL	(b) 100 µg/kg (Temporary) (Group MRL)[1]
(c)Definition of residue on which MRL was set	(c)oxfendazole sulfone
3.2(a) Commodity	(a)Liver (cattle, pigs, sheep)
(b)MRL	(b) 500 µg/kg (Temporary) (Group MRL)[1]
(c)Definition of residue 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 residue on which MRL was set	(c)oxfendazole sulfone
4.References to recommended method(s) of analysis	See Thiabendazole, Appendix II
5.Reference to JECFA Reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.Reference to previous Codex reports	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A

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, kidney, (cattle, pigs, sheep)
(b)MRL	(b) 100 µg/kg (Temporary) (Group MRL)[1]
(c)Definition of residue on which MRL was set	(c)oxfendazole sulfone
3.2(a) Commodity	(a)Liver (cattle, pigs, sheep)
(b)MRL	(b) 500 µg/kg (Temporary) (Group MRL)[1]

(c)Definition of residue 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 residue on which MRL was set	(c)oxfendazole sulfone
4.References to recommended method(s) of analysis	See Thiabendazole, Appendix II
5.Reference to JECFA Reports	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991)
6.Reference to previous Codex reports	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A

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1. ***Substance: Spectinomycin***

2.Acceptable Daily Intake (ADI) as established by JECFA	0-40 µg/kg body weight
3.1(a) Commodity	(a)Muscle (cattle, pigs, chickens)
(b)MRL	(b) 300 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)spectinomycin
3.2(a) Commodity	(a)Liver (cattle, pigs, chickens)
(b)MRL	(b) 2 000 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)spectinomycin
3.3(a) Commodity	(a)Kidney (cattle, pigs, chickens)
(b)MRL	(b) 5 000 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)spectinomycin
3.4(a) Commodity	(a)Fat (cattle, pigs, chickens)
(b)MRL	(b) 500 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)spectinomycin

3.5(a) Commodity	(a)Milk (cattle)
(b)MRL	(b) 200 µg/l (Temporary)
(c)Definition of residue on which MRL was set	(c)spectinomycin
4.References to recommended method(s) of analysis	**Myers, H.N. and Rindler, J.V.** *J. Chromatography* **176** (1979) 103-108
5.Reference to JECFA Reports	WHO TRS In preparation WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.Reference to previous Codex reports	None

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1. ***Substance: Dexamethasone***

2.Acceptable Daily Intake (ADI) as established by JECFA	0-0.015 µg/kg body weight
3.1(a) Commodity	(a)Muscle, kidney (cattle, pigs)
(b)MRL	(b) 0.5 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)dexamethasone
3.2(a) Commodity	(a)Liver (cattle, pigs)
(b)MRL	(b) 2.5 µg/kg (Temporary)
(c)Definition of residue on which MRL was set	(c)dexamethasone
3.3(a) Commodity	(a)Milk (cattle)
(b)MRL	(b) 0.3 µg/l (Temporary)
(c)Definition of residue on which MRL was set	(c)dexamethasone
4.References to recommended method(s) of analysis	(to be elaborated)
5.Reference to JECFA Reports	WHO TRS In preparation WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.Reference to previous Codex reports	None

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[1]Group MRL for febantal, fendendazole 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.

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
Azaperone	38th Session, TRS 815 (1991)
Chloramphenicol	42nd Session, TRS In Preparation
Chlorpromazine	38th Session, TRS 815 (1991)
Dimetridazole	34th Session, TRS 788 (1989)
Flumequine	42nd Session, TRS In Preparation
Furazolidone	40th Session, TRS 832 (1993)
Ipronidazole	34th Session, TRS 788 (1989)
Metronidazole	34th Session, TRS 788 (1989)
Nitrofurazone	40th Session, TRS 832 (1993)
Propionylpromazine	38th Session, TRS 815 (1991)
Ractopamine	40th Session, TRS 832 (1993)
Ronidazole	42nd Session, TRS In Preparation
Sulfathiazole	34th Session, TRS 788 (1989)
Tylosin	38th Session, TRS 815 (1991)

**PRIORITY LIST OF VETERINARY DRUGS
REQUIRING EVALUATION OR REEVALUATION**

1.Substances scheduled for consideration at the 43rd meeting of JECFA in November 1994

Azaperone *
Carazolol *
Dexamethasone (residues) *
Dihydrostreptomycin
Enrofloxacin
Gentamicin
Neomycin
Oxolinic acid
Spiramycin *
Streptomycin

2.Substances scheduled for consideration at the 45th meeting of JECFA in June 1995

Abamectin
Ceftiofur Sodium
Chlortetracycline
Diclazuril
Doramectin
Febantel *
Fenbendazole *
Levamisole (residues) *
Moxidectin
Oxfendazole *
Oxytetracycline (giant prawns - residues)
Tetracycline
Triclabendazole *

3.Substances proposed for consideration at the 47th meeting of JECFA in June 1996

Alpha cypermethrin
Cypermethrin (residues)
Clenbuterol
Dexamethasone (methodology)*
Imidocarb
Nicarbazin
Olaquindox (residues)*
Porcine Somatotropin
Spectinomycin (residues)*
Thiamphenicol
Thiabendazole (toxicology)*
Tilmicosin
Xylazine

* reevaluation

Note: Of all the substances on the CCRVDF Priority List, only apramycin is not scheduled for review by JECFA.

**DRAFT CRITERIA FOR THE INCLUSION IN,
OR EXCLUSION FROM, THE PRIORITY LIST**
(Submitted to the Commission for adoption)

In order to be placed on the CCRVDF's priority list for the development of a maximum residue limit, the candidate veterinary drug, when used in accordance with good veterinary practices, should meet some, but not necessarily all, of the following criteria:

1.Use of the drug will have potential to cause public health and/or trade problems;

2.Drug available as commercial product; and

3.Commitment that a dossier will be available.

RISK ANALYSIS DEFINITIONS
(Submitted to the Executive Committee at Step 1
of the Accelerated Procedure)

HAZARD: A biological, chemical or physical agent or property that may cause a food to be unsafe for human consumption, or a defect[3] generally considered objectionable.

RISK: A function of the probability of an adverse event and the magnitude of that event, consequential to a hazard(s) in food.

RISK ANALYSIS: A process consisting of three components: risk assessment, risk management and risk communication.

RISK ASSESSMENT: A scientific process of identifying hazards, and estimating risk in quantitative or qualitative terms. This involves four analytical steps:

1. HAZARD IDENTIFICATION - The qualitative indication that a hazard(s) could be present in a particular food;

2. HAZARD CHARACTERIZATION - The quantitative and/or qualitative evaluation of the nature of the adverse effects, and may include a dose-response assessment[4];

3. EXPOSURE CHARACTERIZATION - The quantitative and/or qualitative evaluation of the degree of human exposure likely to occur;

4. RISK CHARACTERIZATION - Integration of the above steps into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainty.

RISK ASSESSMENT POLICY: Pre-determined guidelines for scientific judgements and policy frameworks which may be applied at specific decision points in the risk assessment process.

QUANTITATIVE RISK ASSESSMENT: The estimation of risks as numerical representations including point estimates and/or distributions.

QUALITATIVE RISK ASSESSMENT: The estimation of risks as categorical representations including ordinal rankings, descriptive classifications, etc.

RISK MANAGEMENT: The process of weighing policy alternatives, selecting an appropriate regulatory option, and implementing that option.

RISK COMMUNICATION: An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and stakeholders.

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[3]Defect: A pathological change or other abnormality.

[4]Dose-response assessment: The determination of the relationship between the magnitude of exposure and adverse effects.

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-first Session
Rome, 3 - 8 July 1995

REPORT OF THE EIGHTH SESSION OF THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Washington, D.C., USA
7 - 10 June 1994

Appendix II of ALINORM 95/31, page 27:

The reference to the recommended methods of analysis for ***sulfadimidine**** should read as follows**:**

4.	Reference to recommended method(s) of analysis	(a) *Journal of the Association of Official Analytical Chemists* **66** (1983) 881, 884 (b) *Journal of Agricultural and Food Chemistry* **29** (1981) 621-624 (c) **Malisch, R., Bourgeois, B. and Lippold R.** Multiresidue Analysis of Selected Chemotherapeutics and Antiparasitics *Dtsch. Lebensmittel Rundsch.* **88** (1992) 205-216

* The Eighth Session of the Codex Committee on Residues of Veterinary Drugs in Foods advanced the Maximum Residue Limits for sulfadimidine to Step 8 of the Codex procedure.