GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMME ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS

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INTRODUCTION

1. Food production systems assure that exposure animals to veterinary drugs is not a risk to human health.

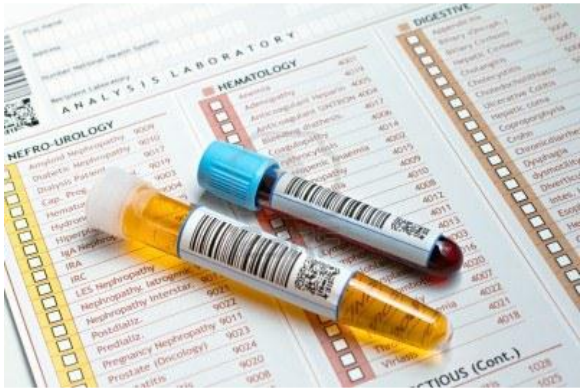
2. Commercial entities in the production and marketing of food have the primary responsibility for food safety.

INTRODUCTION

- Competent authorities:
  - control use of veterinary drugs,
  - verify practices measures veterinary drug distribution and food production systems,
  - effective protection consumer health,
  - fair practice in the food trade,
  - goals of Codex Alimentarius.
  - All parties responsible:
    - consumers information and education
    - sound choice of food products of animal origin.

INTRODUCTION

3. Programme based on risk.



- All food types.
- Controls and verification.
- Risk to consumers.
- Approach based on risk. Resources to real human health protection.

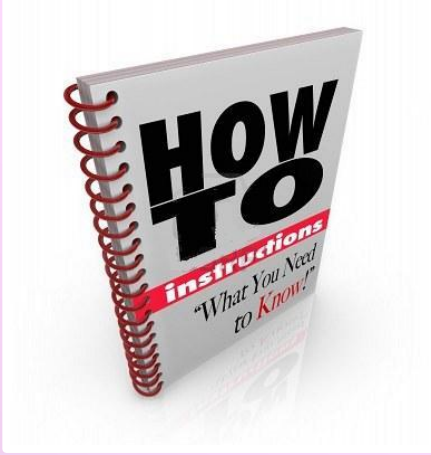
4. Risk profiles vary by country, region, species and/or production system.

INTRODUCTION

- Control and verification assurance programme based on risk.
- Exporting countries certify safety of exported food
- Importing countries confidence to accept consignments.

5. Some developing countries:
   - transition period
   - technical assistance
   - Full implementation of Guidelines.

SCOPE



6. This guide provide principles and guidance for governments.

- design and implementation of national food safety assurance programmes for residues of veterinary drugs.
- Current and future annexes:
  - refinement of guidance for relevant issues
  - Programmes for products of certain species.
  - Annexes in conjunction with this guide.

GENERAL PRINCIPLES

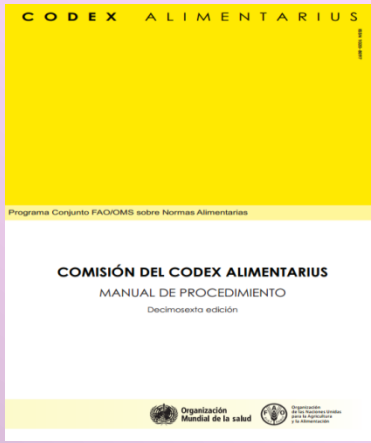
- 7. Programmes:
  - Based on risk. Realistic risk profiles. Reasonably associated with food from the relevant productions systems;
  - Prevention focussed. Realistic risk profiles associated with use of veterinary drugs;
  - Regulatory measures. Relative to human health risk associated with these hazards;

GENERAL PRINCIPLES

- All parties involved in production, marketing and processing systems of animals and food must ensure only safe products to be sold;
- Pre-harvest controls and practices are the primary means for ensuring safe food;
- Role of audits and sampling is to verify implementation and effectiveness of pre-harvest controls and practices;
- System and population based assurances;
- Cost effective and support of stakeholders.

GENERAL PRINCIPLES

8. Veterinary drugs regulated for animal health, animal welfare and protection of the environment.



- Not under the mandate of Codex Alimentarius Commission.
- Identified and justified to form part of residue control programme.

9. The Codex Alimentarius Commission's specific sampling procedures for residues of veterinary drugs in food.

GENERAL PRINCIPLES

- Exempted from *Codex Committee on Methods of Analysis and Sampling*. sampling procedures relevant for the entire control programme.

10. Safety of foods achieved by appropriate rules applied from primary production or import to retail or export.

- All parties involved.
- Competent Authorities verify programmes and actions taken.

GENERAL PRINCIPLES

11. Reliability of laboratory important Competent Authorities.

- Laboratories should use methods validated.
- Internationally accepted (e.g. ISO 17025) quality management principles.

12. Control programmes provides reassurance for importing countries to accept consignments certified as safe by the exporting country.

APPROACH BASED ON RISK

13. Approach **based on risk**.

- Entire production chain.
- All food groups and potential hazards.
- Competent Authorities focus to areas of highest risk.
- Impact on consumer health protection.

14. Good practices and regular control contribute more to food safety than end product testing.

APPROACH BASED ON RISK

15. Residues may exert an adverse effect on consumers in a number of ways, such as:

- Chronic toxicological adverse effects;
- Acute pharmacological effects on consumers and on the microflora of the gastrointestinal tract of consumers;
- Allergic reactions.

16. Controls and monitoring programme: Risk assessment. Human health.

Non-compliant residues: Follow up.

APPROACH BASED ON RISK

17. Animals and production systems exposed veterinary drugs and other chemicals.

- Importance for consumer health protection varies with type and source.

18. Circumstances required for each veterinary drug pose risk to consumers.

- Likelihood of occurring.
- Essential to design of national residue control and verification programmes.

APPROACH BASED ON RISK

19. Application of control and verification programmes based on risk.

- Exporting countries certify safety of exported food.
- Importing countries accept consignments.
- Additional assessment if necessary.

20. Same principles apply to export assurance programmes applied to national assurance programmes.

REGULATORY FRAMEWORK

- Roles

21. Business operators in production, processing and marketing of food: primary responsibility for ensuring food safety.

22. Competent Authorities:

- Regulate veterinary drugs.
- Verify practices veterinary drug distribution and food production system.
  - Consumers protection.
  - Facilitate trade.

REGULATORY FRAMEWORK

23. Competent authority responsible for providing consumer assurances for foods:

- Ensure sufficient knowledge and control over veterinary drugs being sold and used within the production systems.
- Sufficient knowledge of food safety.

REGULATORY FRAMEWORK

- Approval by competent authority
- *Criteria*

24. Official approval criteria established.
    - Criteria may include assessments of other recognised competent authorities

25. Approval systems:

    (a) Evaluation of human safety of residues of the veterinary drug relying on risk analysis and maximum residue limits;

REGULATORY FRAMEWORK

- Approval by competent authority
- *Criteria*

25. Approval systems:

(b) Take into account needs of the producers in order to reduce temptation to use unapproved veterinary drugs or prohibited substances.

26. Approval systems should take into account that risk profiles and management options may vary substantially among production systems and regions.

REGULATORY FRAMEWORK

- Approval by competent authority
- *Approval restrictions*

27. Approval conditions of veterinary drugs specified in the national regulations.

28. Restriction to mitigate potential risk:
  - Formulations;
  - Criteria of use and route of administration;
  - Indications for use; and
  - Withdrawals.

REGULATORY FRAMEWORK

- Approval by competent authority
- *National register*

29. Veterinary drugs approved in a country should be recorded in a national register.

- Information on veterinary drugs

30. Information and education programmes.
  - Effective treatment,
  - Protection of consumers.

REGULATORY FRAMEWORK

- Sale and use

31. National/regional regulations:
  - Veterinary drugs sold domestically.
  - How these may be used.
  - Only formulations in the National Register.
  - Sanctions against non authorised use.

32. Justified by risk profile, Competent Authorities impose additional conditions on the sale and use for appropriate use and prevent misuse or abuse.

REGULATORY FRAMEWORK

- Sale and use

33. Sale and use conditions may include:

- Sales subject to prescription from a veterinarian;
- Restricting administration to individuals with approved competencies;
- Requiring all treated animals/production systems to be identified in specified ways;
- Requiring all uses to be recorded and/or notified to a unified database(s).

REGULATORY FRAMEWORK

- Sale and use

34. Efficacy and use conditions regularly reviewed against the local risk profile.
  - non-availability of treatments encourages use of non-approved or prohibited substances.

35. Competent Authorities may establish:
  - Exception,
  - Use of non-approved veterinary drugs off-label/extra label, veterinary advice and oversight. National and/or international guidance and technical information.

REGULATORY FRAMEWORK

- Sale and use

36. In animals from which milk, eggs or honey, are collected for human consumption:
  - Only veterinary drugs specifically approved for use in lactating animals, laying birds and honey bees should be used.
  - Specific exemptions may be made for off-label/extra label use.

REGULATORY FRAMEWORK

- Responsibilities of business operators (best practice guidance)

37. Producers should only use approved veterinary drugs strictly in accordance with the official instructions.

  - Off-label use of veterinary drugs in accordance with direct and written advice from a veterinarian in accordance with national authorities.
  - National or international guidance documents and technical information on this issue.

REGULATORY FRAMEWORK

- Responsibilities of business operators (best practice guidance)

38. Producers should seek advice of veterinarians on the application of the correct withdrawal time, if label direction not available or may not be clear.

39. Records should be kept of all details of the treatment and the withdrawal time/withholding time before the anima product is harvested for consumption.

REGULATORY FRAMEWORK

- Responsibilities of business operators (best practice guidance)

40. Business operators to communicate food harvesting restrictions (withdrawal/withholding times) at the time of sale to purchasers of the animals.

41. Processors required to ensure that they only purchase or process animals and animal products from suppliers who can attest the safety of the animals.

REGULATORY FRAMEWORK

- Responsibilities of business operators (best practice guidance)

42. Producers have appropriate food safety assurance measures with respect to the use of veterinary drugs.
    - Workers directly involved with the animals should be familiar with these measures.
43. Producers be able to identify all food-producing animals which have been treated with veterinary drugs and compliance with withdrawal/withholding

REGULATORY FRAMEWORK

- Responsibilities of business operators (best practice guidance)

44. Food safety assurance measures ensure harvesting (e.g. milk, eggs, honey) at appropriate withdrawal/withholding times.

45. Treated or exposed animals kept separate from not treated, or identified.

46. Harvest restrictions products handled not to mix with consumption products.
    - Equipment adequately cleaned prior to being used on other animals.

VERIFICATION PROGRAMMES

- Purpose

47. Audits and Inspection of control points.
    - Point of harvest testing.
    - Reduce reliance on chemical analyses.
    - Higher degree of assurance.

48. Confidence in practices and controls.
    - Adequate and applied to ensure the health of consumers.
    - Ensure that exposure to residues in excess of ADI rarely occurs.

VERIFICATION PROGRAMMES

- Purpose

49. Verification programmes contribute to:

a. Verification of assumptions at registration;
b. Identification of unacceptable chains of advice;
c. Evaluation of effectiveness of veterinary drug label information related to food safety;
d. Evaluation of the effectiveness of education or risk reduction programmes;
e. Evaluation of Quality Management Systems;
f. Verification of corrective actions.

VERIFICATION PROGRAMMES

- General design principles

50. Can cover the entire food chain.
  - Combined system of inspection/audits.
  - Sampling/laboratory analysis.
  - Frequency, point and type of activity based on risk assessment. Most effective control.

51. Classified according to objective:
  - System verification programmes;
  - Risk-targeted verification programmes;
  - Surveys;
  - Port of entry testing programmes.

VERIFICATION PROGRAMMES

- General design principles

52. Verification programmes may focus on assessing:

a. Effectiveness of a control system; and/or

b. Compliance by individuals or groups.

VERIFICATION PROGRAMMES

- System and targeted programme design
  a. Define their purpose;
  b. Identify the population being sampled;
  c. Sampling non-biased or targeted (directed);
     - base the number of samples on statistics;
     - pre-determine targeting criteria of sampling;
  d. Pre-determine the criteria to be applied to the analysis of the results;
  e. Define sampling and identification procedures that allow tracing each sample back to its origin and independent confirmation of the finding in case of dispute.

VERIFICATION PROGRAMMES

- Risk Profiling
- 56. Risk profile considerations include:
  a. The type of hazard presented;
  b. Adverse human health effect associated with the residue (e.g. chronic toxicity, acute pharmacological, allergic reaction, or microbiological disturbance);
  c. Circumstances required to produce residues and likelihood of occurring at concentrations and frequencies of risk to consumer health;
  d. Dietary consumption required for the residue to be a realistic consumer health risk.

VERIFICATION PROGRAMMES

- Risk Profiling
- 57. Competent Authorities estimates types, quantities and use patterns of veterinary drugs in their jurisdiction.
- 58. Following should be considered:
  a. Circumstances required for veterinary drug to cause adverse impact on consumers;
  b. Likelihood of such circumstances occurring.
- 59. Sources and exposure pathways of residues associated to veterinary drugs in production systems should be described.

VERIFICATION PROGRAMMES

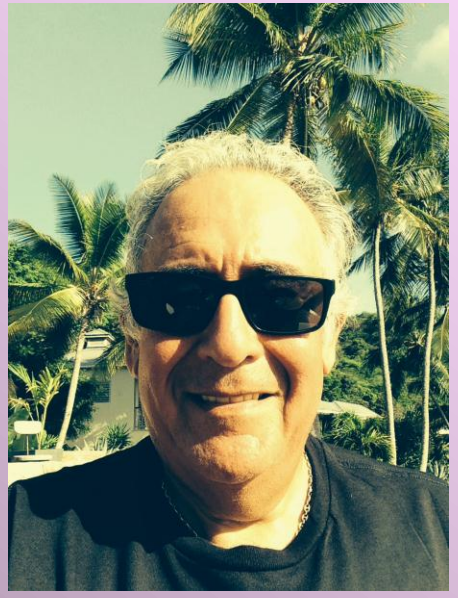
- Risk Profiling
- 60. The following sources of veterinary drug residue should be considered:
  a. Veterinary drugs authorised in the jurisdiction of the Competent Authority;
  b. Veterinary drugs that are known to be, or suspected of being misused.

VERIFICATION PROGRAMMES

- Risk Profiling
- 61. The exposure pathways of veterinary drug residue should be considered:
  a. Intended e.g. direct administration to the animals;
  b. Indirect administration to the animals through addition to feed or water;
  c. Unintended contamination via e.g. feed, water, or the environment.

VERIFICATION PROGRAMMES

- Risk Profiling
- 62. Control points for audit/inspection:
  a. Sellers and purchasers of veterinary drugs. What is sold and how is marketed;
  b. Users of veterinary drugs. How drugs are being used, e.g. according to label, records being kept, animal's identification
  c. Animal and product distributors:
     - Food harvest restrictions communicated?;
  d. Assurance systems used by processors and/or producers ensure suitability of animals or product supplied for the using purposes?



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