

# CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE

CAC/RCP 61-2005

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# CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE

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CAC/RCP 61-2005

## INTRODUCTION

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This document provides additional guidance for the responsible and prudent use of antimicrobials in food-producing animals, and should be read in conjunction with the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes associated with the Use of Veterinary Drugs in Food-producing Animals* (CAC/GL 71-2009). Its objectives are to minimize the potential adverse impact on public health resulting from the use of antimicrobial agents in food-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry, veterinarians, distributors and producers of food-producing animals.

The marketing authorization procedure has a significant role in establishing the basis for prudent use of veterinary antimicrobial drugs in food-producing animals through clear label indications, directions and warning statements.

A number of codes of practice relating to the use of veterinary antimicrobial drugs and the conditions thereof have been developed by different organisations. These codes were taken into consideration and some elements were included in the elaboration of this *Code of Practice to Minimize and Contain Antimicrobial Resistance*.

In keeping with the Codex mission, this Code focuses on antimicrobial use in food-producing animals. It is recognized that antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.

## AIMS AND OBJECTIVES

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It is imperative that all who are involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in food-producing animals act legally, responsibly and with the utmost care in order to limit the spread of resistant microorganisms among animals so as to protect the health of consumers.

Antimicrobial drugs are powerful tools for the management of infectious diseases in animals and humans. This Code and existing guidelines for the responsible use of antimicrobial drugs in food-producing animals include recommendations intended to prevent or reduce the selection of antimicrobial resistant microorganisms in animals and humans in order to:

- Protect consumer health by ensuring the safety of food of animal origin intended for human consumption.
- Prevent or reduce as far as possible the direct and indirect transfer of resistant microorganisms or resistance determinants within animal populations and from food-producing animals to humans.
- Prevent the contamination of animal derived food with antimicrobial residues which exceed the established MRL.
- Comply with the ethical obligation and economic need to maintain animal health.

This Code does not address environmental issues related to antimicrobial resistance from the use of veterinary antimicrobial drugs but it encourages all those involved to consider the ecological aspects when implementing the Code. Efforts should be made to ensure that environmental reservoirs of veterinary antimicrobial drugs, antimicrobial resistant organisms and resistance determinants are kept to a minimum. In particular:

- Regulatory authorities should assess the impact of proposed veterinary antimicrobial drug use on the environment in accordance with national guidelines or recognized international guidelines<sup>1</sup>.
- Research should be conducted on resistant microorganisms in the environment and the magnitude of resistance determinant transfer among microorganisms in the environment.

The responsible use of veterinary antimicrobial drugs in food-producing animals:

- is controlled by the veterinary profession or other parties with the required expertise.
- is part of good veterinary and good animal husbandry practice and takes into consideration disease prevention practices such as the use of vaccination and improvements in husbandry conditions.
- aims to limit the use of veterinary antimicrobial drugs according to their approved and intended uses, and takes into consideration on-farm sampling and testing of isolates from food-producing animals during their production, where appropriate, and makes adjustments to treatment when problems become evident.
- should be based on the results of resistance surveillance and monitoring (microbial cultures and antimicrobial sensitivity testing), as well as clinical experience.

<sup>1</sup> VICH (2000). *Guidelines on Environmental Impact Assessment for Veterinary Medicinal Products, Phase I*. [http://vich.eudra.org/pdf/2000/G106\\_st7.pdf](http://vich.eudra.org/pdf/2000/G106_st7.pdf)

- does not include the use for growth promotion of veterinary antimicrobial drugs that belong to or are able to cause cross resistance to classes of antimicrobial agents used (or submitted for approval) in humans in the absence of a risk analysis. This risk analysis should:
  - be undertaken by the appropriate national regulatory authority;
  - be based on adequate scientific evidence; and
  - focus on the potential to impact resistance to antimicrobials used in human medicine.
- is aimed at all the relevant parties, such as:
  - regulatory and scientific authorities;
  - the veterinary pharmaceutical industry;
  - distributors and others handling veterinary antimicrobial drugs;
  - veterinarians, pharmacists and producers of food-producing animals.

## **RESPONSIBILITIES OF THE REGULATORY AUTHORITIES**

The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in food-producing animals, have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian through product labelling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in food-producing animals. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of veterinary antimicrobial drug applications. National governments in cooperation with animal and public health professionals should adopt a proactive approach to promote prudent use of antimicrobials in food-producing animals as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, all of which should contribute to reduce the prevalence of animal disease requiring antimicrobial treatment. Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk-analysis, as described in the section “Aims and objectives”.

It is the responsibility of the pharmaceutical company or sponsor<sup>2</sup> to submit the data requested by the regulatory authorities for granting marketing authorisation.

The use of antimicrobial agents in food-producing animals requires a marketing authorisation, granted by the competent authorities when the criteria of safety, quality and efficacy are met.

- The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of antimicrobial agents in food-producing animals. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs.

<sup>2</sup> As defined in the VICH Good Clinical Practice Guideline, [http://vich.eudra.org/pdf/2000/GI09\\_st7.pdf](http://vich.eudra.org/pdf/2000/GI09_st7.pdf)

- The safety evaluation should include consideration of the potential impact of the proposed use in food-producing animals on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals and their environment associated with the use of veterinary antimicrobial drugs.

If dose ranges or different durations of treatment are indicated, the national authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of resistance, when this information is available.

The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (*Terrestrial Animal Health Code*, Appendix 3.9.3).

No veterinary antimicrobial drug should be administered to animals unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance.

Countries without the necessary resources to implement an efficient authorisation procedure for veterinary antimicrobial drugs and whose supply of veterinary antimicrobial drugs mostly depends on imports from foreign countries should:

- ensure the efficacy of their administrative controls on the import of these veterinary antimicrobial drugs,
- seek information on authorizations valid in other countries, and
- develop the necessary technical cooperation with experienced authorities to check the quality of imported veterinary antimicrobial drugs as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of veterinary antimicrobial drugs.

All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of illegal and/or counterfeit bulk active pharmaceutical ingredients and products. Regulatory authorities of importing countries could request the pharmaceutical industry to provide quality certificates or, where feasible, certificates of Good Manufacturing Practices prepared by the exporting country's national regulatory authority.

### Quality control of antimicrobial agents

Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices, in particular:

- to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions.
- to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water.
- to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity.

### Assessment of efficacy

Preclinical data should be generated to establish an appropriate dosage regimen necessary to ensure the efficacy of the veterinary antimicrobial drug and limit the selection of microbial resistant microorganisms. Such preclinical trials should, where applicable, include pharmacokinetic and pharmacodynamic studies to guide the development of the most appropriate dosage regimen.

Important pharmacodynamic information may include:

- mode of action;
- the spectrum of antimicrobial activity of the substance;
- identification of bacterial species that are naturally resistant relevant to the use of the veterinary antimicrobial drugs;
- antimicrobial minimum inhibitory and/or bactericidal concentrations;
- determination of whether the antimicrobial exhibits time or concentration-dependent activity or co-dependency,
- evaluation of activity at the site of infection.

Important pharmacokinetic information may include:

- bio-availability according to the route of administration;
- concentration of the veterinary antimicrobial drug at the site of infection and its distribution in the treated animal;
- metabolism which may lead to the inactivation of veterinary antimicrobial drugs;
- excretion routes.

The use of fixed combinations of veterinary antimicrobial drugs should be justified taking into account:

- pharmacodynamic (additive or synergistic effects towards the target microorganism);
- pharmacokinetics (maintenance of the concentrations of associated antimicrobials responsible for additive or synergistic effects at the site of infection throughout the treatment period).

Clinical data should be generated to confirm the validity of the claimed indications and dosage regimens established during the preclinical phase.

Criteria to be considered include:

- parameters for qualitatively and quantitatively assessing efficacy;
- diversity of the clinical cases met when carrying out clinical trials;
- compliance of the protocols of clinical trials with good clinical practice, such as VICH guidelines<sup>3</sup>;
- eligibility of the studied clinical cases based on appropriate clinical and microbiological criteria.

### **Assessment of the potential of veterinary antimicrobial drugs to select for resistant microorganisms**

Where applicable, data from preclinical or clinical trials should be used to evaluate the potential for target microorganisms, foodborne and/or commensal microorganisms to develop or acquire resistance.

Appropriate information should be provided to support an adequate assessment of the safety of veterinary antimicrobial drugs being considered for authorisation in food-producing animals. The regulatory authorities should develop criteria for conducting such assessments and interpreting their results. Existing guidelines for antimicrobial resistance risk assessment, such as the OIE Guideline<sup>4</sup> may be used for more comprehensive information. The type of information to be evaluated in these assessments may include, but is not limited to, the following:

- the route and level of human exposure to food-borne or other resistant microorganisms;
- the degree of cross resistance within the class of antimicrobials and between classes of antimicrobials;
- the pre-existing level of resistance, if available, in pathogens causing gastrointestinal infections in humans (baseline determination);
- the concentration of active compound in the gut of the animal at the defined dosage level.

### **Establishment of ADIs (acceptable daily intake), MRLs (maximum residue limit), and withdrawal periods for veterinary antimicrobial drugs**

When setting ADIs and MRLs for veterinary antimicrobial drugs, the safety evaluation is carried out in accordance with international guidelines and should include the determination of microbiological effects (e.g., the potential biological effects on the human intestinal flora) as well as toxicological and pharmacological effects.

An acceptable daily intake (ADI) and a maximum residue limit (MRL) for appropriate food stuffs (i.e., meat, milk, eggs, fish and honey) should be established for each antimicrobial agent. MRLs are necessary in order that officially recognised control laboratories can monitor that the veterinary antimicrobial drugs are being used as

<sup>3</sup> VICH Good Clinical Practice Guideline, [http://vich.eudra.org/pdf/2000/GI09\\_st7.pdf](http://vich.eudra.org/pdf/2000/GI09_st7.pdf)

<sup>4</sup> *Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin*, [http://www.oie.int/eng/publicat/rt/2003a\\_r20314.htm](http://www.oie.int/eng/publicat/rt/2003a_r20314.htm)

approved. Withdrawal periods should be established for each veterinary antimicrobial drug, which make it possible to produce food in compliance with the MRLs.

Withdrawal periods have to be established for each veterinary antimicrobial drug by taking into account:

- the MRLs established for the considered veterinary antimicrobial drug;
- the pharmaceutical form;
- the target animal species;
- the dosage regimen and the duration of treatment;
- the route of administration.

### **Establishment of a summary of product characteristics for each veterinary antimicrobial drug for food-producing animals**

The summary of product characteristics contains the information necessary for the appropriate use of veterinary antimicrobial drugs. It constitutes, for each veterinary antimicrobial drug, the official reference of the content of its labelling and package insert. This summary contains the following items:

- pharmacological properties;
- target animal species;
- indications;
- target microorganisms;
- dosage and administration route;
- withdrawal periods;
- incompatibilities;
- shelf-life;
- operator safety;
- particular precautions before use;
- instructions for the return or proper disposal of un-used or out-of-date products;
- any information on conditions of use relevant to the potential for selection of resistance should be included, for the purpose of guidance on prudent use;
- class and active ingredient of the veterinary antimicrobial drug.

### **Surveillance programmes**

The relevant authorities should develop a structured approach to the investigation and reporting of the incidence and prevalence of antimicrobial resistance. For the purposes of this Code, priority should be given to the evaluation of antimicrobial resistance in foodborne microorganisms.

For reasons of efficiency, the methods used to establish such programmes (laboratory techniques, sampling, choice of veterinary antimicrobial drug(s) and microorganism(s)) should be harmonized as much as possible at the international level (e.g. OIE documents on *Harmonisation of National Antimicrobial Resistance Monitoring and Surveillance Programmes in Animals and Animal Derived Food* [http://www.oie.int/eng/publicat/rt/2003/a\\_r20318.htm](http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm) and *Standardisation and Harmonisation of Laboratory Methodologies Used for the Detection and Quantification of Antimicrobial Resistance* [http://www.oie.int/eng/publicat/rt/2003/a\\_r20317.htm](http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm)).



Preferably, epidemiological surveillance of antimicrobial resistance should be accompanied by data on the amounts of veterinary antimicrobial drugs used by veterinarians and other authorized users in food-producing animals. These data could be collected using one or more of the following sources:

- production data from manufacturers;
- importers and exporters;
- if possible, data on intended and actual usage from manufacturers, wholesale and retail distributors including feed mills, and veterinary prescription records;
- surveys of veterinarians, farmers and producers of food-producing animals.

Regulatory authorities should have in place a pharmacovigilance programme for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance programme should form part of the comprehensive strategy to minimize microbial resistance.

In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavour to achieve this re-evaluation.

### **Distribution of veterinary antimicrobial drugs in veterinary medicine**

The relevant authorities should make sure that all veterinary antimicrobial drugs used in food-producing animals are, to the extent possible:

- prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation;
- supplied only through licensed/authorized distribution systems;
- administered to animals by a veterinarian or, under the supervision of a veterinarian or other suitably trained person authorized in accordance with national legislation; and that
- proper records are kept of their administration (see Responsibilities of Veterinarians: Recording section).

### **Control of advertising**

Advertising of veterinary antimicrobial drugs should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product.

All advertising of veterinary antimicrobial drugs should be controlled by the relevant authorities.

- The authorities should ensure that advertising of veterinary antimicrobial drugs:
  - complies with the marketing authorisation granted, in particular with the content of the summary of product characteristics; and
  - complies with each country's national legislation.

### **Training of users of veterinary antimicrobial drugs**

Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should involve all the relevant professional organisations, regulatory authorities, the pharmaceutical industry, veterinary schools, research institutes, professional associations and other approved users such as farmers and producers of food animals and should focus on:

- information on disease prevention and management strategies to reduce the need to use veterinary antimicrobial drugs;
- relevant pharmacokinetic and pharmacodynamic information to enable the veterinarian to use veterinary antimicrobial drugs prudently;
- the ability of veterinary antimicrobial drugs to select for resistant microorganisms in food- producing animals that may contribute to animal or human health problems; and
- the need to observe responsible use recommendations and using veterinary antimicrobial drugs in animal husbandry in agreement with the provisions of the marketing authorisations and veterinary advice.

### **Development of research**

The relevant authorities should encourage public and private research to:

- improve the knowledge about the mechanisms of action of antimicrobials in order to optimise the dosage regimens and their efficacy;
- improve the knowledge about the mechanisms of selection, emergence and dissemination of resistance determinants;
- develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance;
- further develop protocols to predict, during the authorisation process, the impact of the proposed use of the veterinary antimicrobial drugs on the rate and extent of resistance development; and
- develop and encourage alternative methods to prevent infectious diseases.

### **Collection and destruction of unused veterinary antimicrobial drugs**

The relevant authorities should develop effective procedures for the safe collection and destruction of unused or out-of-date veterinary antimicrobial drugs.

## **RESPONSIBILITIES OF THE VETERINARY PHARMACEUTICAL INDUSTRY**

### **Marketing authorisation of veterinary antimicrobial drugs for food-producing animals**

It is the responsibility of the veterinary pharmaceutical industry:

- to supply all of the information requested by the national regulatory authority in order to establish objectively the quality, safety and efficacy of veterinary antimicrobial drugs; and
- to ensure the quality of this information on the basis of the implementation of procedures, tests and trials in compliance with the provisions of good manufacturing, good laboratory and good clinical practices.

**Marketing and export of veterinary antimicrobial drugs**

Only officially licensed/authorized veterinary antimicrobial drugs should be marketed, and then only through approved distribution systems.

- Only veterinary antimicrobial drugs meeting the quality standards of the importing country should be exported from a country in which the products were produced;
- The information necessary to evaluate the amount of veterinary antimicrobial drugs marketed should be provided to the national regulatory authority.

**Advertising**

It is the responsibility of the veterinary pharmaceutical industry to advertise veterinary antimicrobial drugs in accordance with the provisions of the Responsibilities of the Regulatory Authorities, Control of Advertising and to not inappropriately advertise antimicrobials directly to the food animal producer.

**Training**

It is the responsibility of the veterinary pharmaceutical industry to participate in the training of users of veterinary antimicrobial drugs as defined in the section "Training of users of veterinary antimicrobial drugs".

**Research**

It is the responsibility of the veterinary pharmaceutical industry to contribute to the development of research as defined in the section "Development of research".

**RESPONSIBILITIES OF WHOLESALE AND RETAIL DISTRIBUTORS**

Retailers distributing veterinary antimicrobial drugs should only do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.

Distributors should encourage compliance with the national guidelines on the responsible use of veterinary antimicrobial drugs and should keep detailed records of all antimicrobials supplied according to the national regulations including:

- date of supply
- name of prescribing veterinarian
- name of user
- name of medicinal product
- batch number
- quantity supplied

Distributors should participate in the training of users of veterinary antimicrobial drugs as defined in the section "Training of users of veterinary antimicrobial drugs".

## RESPONSIBILITIES OF VETERINARIANS<sup>5</sup>

The veterinarian is responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include changes in husbandry conditions and vaccination programs where vaccines are available.

Veterinary antimicrobial drugs should only be prescribed for animals under his/her care, which means that:

- the veterinarian has been given responsibility for the health of the animal or herd/flock by the producer or the producer's agent;
- that responsibility is real and not merely nominal;
- that the animal(s) or herd/flock have been seen immediately before the prescription and supply, or
- recently enough for the veterinarian to have personal knowledge of the condition of the animal(s) or current health status of the herd or flock to make a diagnosis and prescribe; and
- the veterinarian should maintain clinical records of the animal(s) or the herd/flock.

It is recommended that veterinary professional organizations develop for their members species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs.

Veterinary antimicrobial drugs should only be used when necessary and in an appropriate manner:

- A prescription for veterinary antimicrobial drugs must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period and the amount of antimicrobial to be delivered depending on the dosage, the number, and the weight of the animals to be treated;
- All veterinary antimicrobial drugs should be prescribed and used according to the conditions stipulated in the national legislation.

The appropriate use of veterinary antimicrobial drugs in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.

Determination of the choice of a veterinary antimicrobial drug by:

- The expected efficacy of the treatment based on:

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<sup>5</sup> Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation.

- the clinical experience of the veterinarian;
- the spectrum of the antimicrobial activity towards the pathogens involved;
- the epidemiological history of the rearing unit particularly in regards to the antimicrobial resistance profiles of the pathogens involved. Ideally, the antimicrobial profiles should be established before the commencement of treatment. Should a first antimicrobial treatment fail or should the disease recur, the use of a second veterinary antimicrobial drug should be based on the results of microbiological tests;
- the appropriate route of administration;
- results of initial treatment;
- known pharmacokinetics/tissue distribution to ensure that the selected veterinary antimicrobial drug is active at the site of infection;
- prognosis.
- The need to minimize the adverse health impact from the development of microbial resistance based on:
  - the choice of the activity spectrum of the veterinary antimicrobial drug;
  - the targeting of specific microorganism;
  - known or predictable susceptibilities using antimicrobial susceptibility testing;
  - optimized dosing regimens;
  - the use of effective combinations of veterinary antimicrobial drugs;
  - the importance of the antimicrobial drugs to veterinary and human medicine; and,
  - the route of administration.

If the label conditions allow for some flexibility, the veterinarian should consider a dosage regimen that is long enough to allow an effective recovery of the animal but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.

### Off-label use

The off-label use of a veterinary antimicrobial drug may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of antimicrobial growth promoters should not be permitted.

### Recording

Records on veterinary antimicrobial drugs should be kept in conformity with national legislation. Veterinarians may refer to recording information as covered in the relevant national legislation.<sup>6</sup> In particular, for investigation of antimicrobial resistance, veterinarians should:

<sup>6</sup> Veterinarians can also refer to the *Guidelines for the Design and Implementation of National Regulatory Food Safety Programmes associated with the Use of Veterinary Drugs in Food-Producing Animals* (CAC/GL 71-2009).

- record the antimicrobial susceptibility testing results;
- investigate adverse reactions to veterinary antimicrobial drugs, including lack of expected efficacy due to antimicrobial resistance, and report it, as appropriate, to the regulatory authorities.

Veterinarians should also periodically review farm records on the use of veterinary antimicrobial drugs to ensure compliance with their directions.

### Training

Veterinary professional organizations should participate in the training of users of veterinary antimicrobial drugs as defined in Paragraph 36.

## **RESPONSIBILITIES OF PRODUCERS**

Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They may, as appropriate, call on the assistance of their veterinarian or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals have an important part to play in ensuring the responsible use of veterinary antimicrobial drugs.

Producers of food-producing animals have the following responsibilities:

- to use veterinary antimicrobial drugs only when necessary and not as a replacement for good management and farm hygiene, or other disease prevention methods such as vaccination;
- to implement a health plan in cooperation with the veterinarian in charge of the animals that outlines preventative measures (e.g. mastitis plan, worming and vaccination programmes, etc.);
- to use veterinary antimicrobial drugs in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian familiar with the animals and the production site;
- to isolate sick animals and dispose of dead or dying animals promptly under conditions approved by relevant authorities;
- to comply with the storage conditions of veterinary antimicrobial drugs according to the approved product labelling;
- to address hygienic conditions regarding contacts between people (veterinarians, breeders, owners, children) and the animals treated;
- to comply with the recommended withdrawal periods to ensure that residue levels in animal derived food do not present a risk for the consumer;
- to not use out-of-date veterinary antimicrobial drugs and to dispose of all unused veterinary antimicrobial drugs in accordance with the provisions on the product labels;
- to inform the veterinarian in charge of the unit of recurrent disease problems;
- to maintain all clinical and laboratory records of microbiological and susceptibility tests if required by the national regulatory authority. These data

should be made available to the veterinarian in charge of treating the animals in order to optimize the use of veterinary antimicrobial drugs.

- To keep adequate records of all veterinary antimicrobial drugs used, including the following:
  - name of the veterinary antimicrobial drug/active substance and batch number;
  - name of supplier;
  - date of administration;
  - identification of the animal or group of animals to which the veterinary antimicrobial drug was administered;
  - clinical conditions treated;
  - quantity and duration of the antimicrobial agent administered;
  - withdrawal periods;
  - result of laboratory tests;
  - result of treatment;
  - name of the prescribing veterinarian or other suitably trained person authorized in accordance with national legislation.
- To ensure sound management of animal wastes and other materials to avoid dissemination of antimicrobial agents and resistance determinants into the environment;
- To prevent the unnecessary contact with and transmission of resistant bacteria to all personnel, including farm workers;
- To assist the relevant authorities in surveillance programs related to antimicrobial resistance.

## **CONCLUSIONS**

Veterinary antimicrobial drugs are very important tools for controlling a great number of infectious diseases in both animals and humans. It is vital that all countries put in place the appropriate systems to ensure that veterinary antimicrobial drugs are manufactured, marketed, distributed, prescribed and used responsibly, and that these systems are adequately audited.

This document is designed to provide the framework that countries may implement in accordance with their capabilities but within a reasonable period of time. A stepwise approach may be appropriate for a number of countries to properly implement all of the elements in this document.

The continued availability of veterinary antimicrobial drugs, which are essential for animal welfare and animal health and consequently human health, will ultimately depend on the responsible use of these products by all those involved in the authorisation, production, control, distribution and use of antimicrobials in food-producing animals.

## ENDNOTES

- 1 A. Franklin, J. Acar, F. Anthony, R. Gupta †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, D.G. White, H. C. Wegener & M.L. Costarrica. Antimicrobial resistance: harmonisation of national antimicrobial resistance monitoring and surveillance programmes in animals and in animal-derived food. *Rev. sci. tech. Off. Int. Epiz.*, 2001, 20 (3), 859–870. [http://www.oie.int/eng/publicat/rt/2003/a\\_r20318.htm](http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm)
- 2 D.G. White, J. Acar, F. Anthony, A. Franklin, R. Gupta, †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, H. C. Wegener & M.L. Costarrica. Antimicrobial resistance: standardisation and harmonisation of laboratory methodologies for the detection and quantification of antimicrobial resistance. *Rev. sci. tech. Off. Int. Epiz.*, 2001, 20 (3), 849–858. [http://www.oie.int/eng/publicat/rt/2003/a\\_r20317.htm](http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm)

## LIST OF ABBREVIATIONS USED IN THIS CODE

ADI	Acceptable Daily Intake
CAC	Codex Alimentarius Commission
CAC/RCP	Codex Alimentarius Commission/Recommended Code of Practice
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
FAO	Food and Agriculture Organization of the United Nations
MRL	Maximum Residue Limit
OIE	Office International des epizooties/International Office of Epizooties
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization

## GLOSSARY AND DEFINITIONS OF TERMS

### Veterinary antimicrobial drug

Veterinary antimicrobial drug(s) refers to naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity (kill or inhibit the growth of microorganisms). Where anticoccidial products have antibacterial activity, they should be considered as veterinary antimicrobial drugs, except where this is precluded by national legislation.

### Disease treatment/therapeutic use

Treatment/Therapeutic Use refers to use of an antimicrobial(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness.

### Disease prevention/prophylactic use

Prevention/Prophylactic Use refers to use of an antimicrobial(s) in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease. This treatment includes:



- control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and
- prevention of an infectious disease that has not yet been clinically diagnosed.

### **Growth promotion**

Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.

# CODE OF PRACTICE ON GOOD ANIMAL FEEDING

CAC/RCP 54-2004

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# CODE OF PRACTICE ON GOOD ANIMAL FEEDING

CAC/RCP 54-2004

## SECTION 1. INTRODUCTION

This Code is to establish a feed safety system for food producing animals which covers the whole food chain, taking into account relevant aspects of animal health and the environment in order to minimize risks to consumers' health. This Code applies in addition to the principles of food hygiene already established by the Codex Alimentarius Commission<sup>1</sup>, taking into account the special aspects of animal feeding.

## SECTION 2. PURPOSE AND SCOPE

The objective of this Code is to help ensure the safety of food for human consumption through adherence to good animal feeding practice at the farm level and good manufacturing practices (GMPs) during the procurement, handling, storage, processing and distribution of animal feed and feed ingredients for food producing animals.

This Code of Practice applies to the production and use of all materials destined for animal feed and feed ingredients at all levels whether produced industrially or on farm. It also includes grazing or free-range feeding, forage crop production and aquaculture.

Those issues of animal welfare other than food safety related animal health are not covered. Environmental contaminants should be considered where the level of such substances in the feed and feed ingredients could present a risk to consumers' health from the consumption of foods of animal origin.

While recognizing that, in its totality, a feed safety system would address animal health and environmental issues, in addition to consumers' health, this Code of Practice, in fulfilling the Codex mandate of consumer protection, only addresses food safety. Notwithstanding this, best efforts have been made to ensure that the recommendations and practices in this Code of Practice will not be detrimental to the more general animal health and environmental aspects of animal feeding.

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<sup>1</sup> *Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969).*

## SECTION 3. DEFINITIONS

For the purpose of this Code:

**Feed (Feedingstuff):** Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.

**Feed Ingredient:** A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.

**Feed Additive<sup>2</sup>:** Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products.

**Medicated Feed:** Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual.

**Undesirable Substances:** Contaminants and other substances which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.

## SECTION 4. GENERAL PRINCIPLES AND REQUIREMENTS

Feed and feed ingredients should be obtained and maintained in a stable condition so as to protect feed and feed ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during production, handling, storage and transport. Feed should be in good condition and meet generally accepted quality standards. Where appropriate, good agricultural practices, good manufacturing practices (GMPs) and, where applicable, Hazard Analysis and Critical Control Point (HACCP) principles<sup>3</sup> should be followed to control hazards that may occur in food. Potential sources of contamination from the environment should be considered.

Parties that produce feed or feed ingredients, those that rear animals for use as food and those that produce such animal products need to collaborate to identify potential hazards and their levels of risk to consumers' health. Such collaboration will enable the development and maintenance of appropriate risk management options and safe feeding practices.

### 4.1 Feed ingredients

Feed ingredients should be obtained from safe sources and be subject to a risk analysis where the ingredients are derived from processes or technologies not hitherto evaluated from a food safety point of view. The procedure used should be consistent

<sup>2</sup> Micro-organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration.

<sup>3</sup> Hazard Analysis and Critical Control Point, as defined in the Annex to the *Recommended International Code of Practice on General Principles of Food Hygiene* (CAC/RCP 1-1969).

with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.<sup>4</sup> Manufacturers of feed additives in particular should provide clear information to the user to permit correct and safe use. Monitoring of feed ingredients should include inspection and sampling and analysis for undesirable substances using risk-based protocols. Feed ingredients should meet acceptable and, if applicable, statutory standards for levels of pathogens, mycotoxins, pesticides and undesirable substances that may give rise to consumers' health hazards.

## 4.2 Labelling

Labelling should be clear and informative as to how the user should handle, store and use feed and feed ingredients. Labelling should be consistent with any statutory requirements and should describe the feed and provide instructions for use. Labelling or the accompanying documents should contain, where appropriate:

- information about the species or category of animals for which the feed is intended;
- the purpose for which the feed is intended;
- a list of feed ingredients, including appropriate reference to additives, in descending order of proportion;
- contact information of manufacturer or registrant;
- registration number if available;
- directions and precautions for use;
- lot identification;
- manufacturing date; and
- "use before" or expiry date.

This sub-section does not apply to labelling of feed and feed ingredients derived from modern biotechnology.<sup>5</sup>

## 4.3 Traceability/product tracing and record keeping of feed and feed ingredients

Traceability/product tracing of feed and feed ingredients, including additives, should be enabled by proper record keeping for timely and effective withdrawal or recall of products if known or probable adverse effects on consumers' health are identified. Records should be maintained and readily available regarding the production, distribution and use of feed and feed ingredients to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source and trace-forward to the next subsequent recipients if known or probable adverse effects on consumers' health are identified.<sup>6</sup>

<sup>4</sup> Procedural Manual of the Codex Alimentarius Commission.

<sup>5</sup> Whether and how to label animal feed and feed ingredients derived from modern biotechnology awaits developments on food labelling, being considered by the Codex Committee on Food Labelling.

<sup>6</sup> Development of detailed measures on traceability/product tracing should take into the account: *Principles for Traceability/Product Tracing as a tool within a Food Inspection and Certification System* (CAC-GL 60-2006).

#### 4.3.1 **Special conditions applicable to emergency situations**

Operators should, as soon as reasonable, inform the competent authorities in the country if they consider that a feed or feed ingredient does not satisfy the feed safety requirements established in this Code. The information should be as detailed as possible and should at least contain a description of the nature of the problem, a description of the feed or feed ingredients, the species for which it is intended, the lot identifier, the name of the manufacturer and the place of origin. The competent authorities and operators should immediately take effective measures to ensure that those feed or feed ingredients do not pose any danger to consumers' health.

As soon as it becomes likely that a particular feed or feed ingredient is to be traded internationally and may pose a danger to consumers' health, the competent authorities of the exporting countries should notify, at least, the competent authorities of the relevant importing countries. The notification should be as detailed as possible and should at least contain the particulars indicated in the previous paragraph.

#### 4.4 **Inspection and control procedures**

Feed and feed ingredients manufacturers and other relevant parts of industry should practice self-regulation/auto-control to secure compliance with required standards for production, storage and transport. It will also be necessary for risk-based official regulatory programmes to be established to check that feed and feed ingredients are produced, distributed and used in such a way that foods of animal origin for human consumption are both safe and suitable. Inspection and control procedures should be used to verify that feed and feed ingredients meet requirements in order to protect consumers against food-borne hazards.<sup>7</sup> Inspection systems should be designed and operated on the basis of objective risk assessment appropriate to the circumstances.<sup>8</sup> Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.

Monitoring of feed and feed ingredients, whether by industry or official inspection bodies, should include inspection and sampling and analysis to detect unacceptable levels of undesirable substances.

#### 4.5 **Health hazards associated with animal feed**

All feed and feed ingredients should meet minimum safety standards. It is essential that levels of undesirable substances are sufficiently low in feed and feed ingredients that their concentration in food for human consumption is consistently below the level of concern. Codex Maximum Residue Limits and Extraneous Maximum Residue Levels set for feed should be applied. Maximum residue limits set for food, such as those established by the Codex Alimentarius Commission, may be useful in determining minimum safety standards for feed.

<sup>7</sup> *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

<sup>8</sup> *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

#### 4.5.1 **Feed additives and veterinary drugs used in medicated feed**

Feed additives and veterinary drugs used in medicated feed should be assessed for safety and used under stated conditions of use as pre-approved by the competent authorities.

Veterinary drugs used in medicated feed should comply with the provisions of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes associated with the Use of Veterinary Drugs in Food-producing Animals (CAC/GL 71-2009)*.

Borderlines between feed additives and veterinary drugs used in medicated feed may be set to avoid misuse.

Feed additives should be received, handled and stored to maintain their integrity and to minimise misuse or unsafe contamination. Feed containing them should be used in strict accordance with clearly defined instructions for use.

Antibiotics should not be used in feed for growth promoting purposes in the absence of a public health safety assessment.<sup>9</sup>

#### 4.5.2 **Feed and feed ingredients**

Feed and feed ingredients should only be produced, marketed, stored and used if they are safe and suitable, and, when used as intended, should not represent in any way an unacceptable risk to consumers' health. In particular, feed and feed ingredients contaminated with unacceptable levels of undesirable substances should be clearly identified as unsuitable for animal feed and not be marketed or used.

Feed and feed ingredients should not be presented or marketed in a manner liable to mislead the user.

#### 4.5.3 **Undesirable substances**

The presence in feed and feed ingredients of undesirable substances such as industrial and environmental contaminants, pesticides, radionuclides, persistent organic pollutants, pathogenic agents and toxins such as mycotoxins should be identified, controlled and minimised. Animal products that could be a source of the Bovine Spongiform Encephalopathy (BSE) agent<sup>10</sup> should not be used for feeding directly to, or for feed manufacturing for, ruminants. Control measures applied to reduce unacceptable level of undesirable substances should be assessed in terms of their impact on food safety.

<sup>9</sup> WHO *Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food*, June 2000, Geneva, Switzerland.

<sup>10</sup> Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade, OIE Headquarters, Paris, 11–14 June 2001.



The risks of each undesirable substance to consumers' health should be assessed and such assessment may lead to the setting of maximum limits for feed and feed ingredients or the prohibition of certain materials from animal feeding.

## **SECTION 5. PRODUCTION, PROCESSING, STORAGE, TRANSPORT AND DISTRIBUTION OF FEED AND FEED INGREDIENTS**

The production, processing, storage, transport and distribution of safe and suitable feed and feed ingredients is the responsibility of all participants in the feed chain, including farmers, feed ingredient manufacturers, feed compounders, truckers, etc. Each participant in the feed chain is responsible for all activities that are under their direct control, including compliance with any applicable statutory requirements.

Feed and feed ingredients should not be produced, processed, stored, transported or distributed in facilities or using equipment where incompatible operations may affect their safety and lead to adverse effects on consumers' health. Due to the unique characteristics of aquaculture, the application of these general principles must consider the differences between aquaculture and terrestrial-based production.

Where appropriate, operators should follow GMPs and, where applicable, HACCP principles to control hazards that may affect food safety. The aim is to ensure feed safety and in particular to prevent contamination of animal feed and food of animal origin as far as this is reasonably achievable, recognising that total elimination of hazards is often not possible.

The effective implementation of GMPs and, where applicable, HACCP-based approaches should ensure, in particular, that the following areas are addressed.

### **5.1 Premises**

Buildings and equipment used to process feed and feed ingredients should be constructed in a manner that permits ease of operation, maintenance and cleaning and minimises feed contamination. Process flow within the manufacturing facility should also be designed to minimise feed contamination.

Water used in feed manufacture should meet hygienic standards and be of suitable quality for animals. Tanks, pipes and other equipment used to store and convey water should be of appropriate materials which do not produce unsafe levels of contamination.

Sewage, waste and rain water should be disposed of in a manner which avoids contamination of equipment, feed and feed ingredients.

### **5.2 Receiving, storage and transportation**

Chemical fertilizers, pesticides and other materials not intended for use in feed and feed ingredients should be stored separately from feed and feed ingredients to avoid the potential for manufacturing errors and contamination of feed and feed ingredients.

Processed feed and feed ingredients should be stored separately from unprocessed feed ingredients and appropriate packaging materials should be used. Feed and feed ingredients should be received, stored and transported in such a way so as to minimize the potential for any cross-contamination to occur at a level likely to have a negative impact on food safety.

The presence of undesirable substances in feed and feed ingredients should be monitored and controlled.

Feed and feed ingredients should be delivered and used as soon as possible. All feed and feed ingredients should be stored and transported in a manner which minimizes deterioration and contamination and enables the correct feed to be sent to the right animal group.

Care should be taken to minimize deterioration and spoilage at all stages of handling, storage and transport of feed and feed ingredients. Special precautions should be taken to limit fungal and bacterial growth in moist and semi-moist feed. Condensation should be minimized in feed and feed ingredient manufacturing and processing facilities. Dry feed and feed ingredients should be kept dry in order to limit fungal and bacterial growth.

Waste feed and feed ingredients and other material containing unsafe levels of undesirable substances or any other hazards should not be used as feed, but, should be disposed of in an appropriate manner including compliance with any applicable statutory requirements.

### **5.3 Personnel training**

All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in protecting food safety.

### **5.4 Sanitation and pest control**

Feed and feed ingredients, processing plants, storage facilities and their immediate surroundings should be kept clean and effective pest control programmes should be implemented.

Containers and equipment used for manufacturing, processing, transport, storage, conveying, handling and weighing should be kept clean. Cleaning programmes should be effective and minimise residues of detergents and disinfectants.

Machinery coming into contact with dry feed or feed ingredients should be dried following any wet cleaning process.

Special precautions should be taken when cleaning machinery used for moist and semi-moist feed and feed ingredients to avoid fungal and bacterial growth.

### 5.5 Equipment performance and maintenance

All scales and metering devices used in the manufacture of feed and feed ingredients should be appropriate for the range of weights and volumes to be measured, and be tested regularly for accuracy.

All mixers used in the manufacture of feed and feed ingredients should be appropriate for the range of weights or volumes being mixed and be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions, and be tested regularly to verify their performance.

All other equipment used in the manufacture of feed and feed ingredients should be appropriate for the range of weights or volumes being processed, and be monitored regularly.

### 5.6 Manufacturing controls

Manufacturing procedures should be used to avoid cross-contamination (for example flushing, sequencing and physical clean-out) between batches of feed and feed ingredients containing restricted or otherwise potentially harmful materials (such as certain animal by-product meals, veterinary drugs). These procedures should also be used to minimise cross-contamination between medicated and non-medicated feed and other incompatible feed. In cases where the food safety risk associated with cross-contamination is high and the use of proper flushing and cleaning methods is deemed insufficient, consideration should be given to the use of completely separate production lines, transfer, storage and delivery equipment.

Pathogen control procedures, such as heat treatment or the addition of authorised chemicals, should be used where appropriate, and monitored at the applicable steps in the manufacturing process.

### 5.7 Recalls

Records and other information should be maintained as indicated in sub-section 4.3 of this Code to include the identity and distribution of feed and feed ingredients so that any feed or feed ingredient considered to pose a threat to consumers' health can be rapidly removed from the market and that animals exposed to the relevant feed can be identified.

## SECTION 6. ON-FARM PRODUCTION AND USE OF FEED AND FEED INGREDIENTS

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This section provides guidance on the cultivation, manufacture, management and use of feed and feed ingredients on farms and in aquaculture.

This section should be used in conjunction with the applicable requirements of Sections 4 and 5 of this Code.

To help ensure the safety of food used for human consumption, good agricultural practices<sup>11</sup> should be applied during all stages of on-farm production of pastures, cereal grain and forage crops used as feed or feed ingredients for food producing animals. For aquaculture the same principles should apply, where applicable. Three types of contamination represent hazards at most stages of on-farm production of feed and feed ingredients, namely:

- Biological, such as bacteria, fungi and other microbial pathogens;
- Chemical, such as residues of medication, pesticides, fertilizer or other agricultural substances; and
- Physical, such as broken needles, machinery and other foreign material.

## 6.1 Agricultural production of feed

Adherence to good agricultural practices is encouraged in the production of natural, improved and cultivated pastures and in the production of forage and cereal grain crops used as feed or feed ingredients for food producing animals. Following good agricultural practice standards will minimize the risk of biological, chemical and physical contaminants entering the food chain. If crop residuals and stubbles are grazed after harvest, or otherwise enter the food chain, they should also be considered as livestock feed. Most livestock will consume a portion of their bedding. Crops that produce bedding material or bedding materials such as straw or wood shavings should also be managed in the same manner as animal feed ingredients. Good pasture management practices, such as rotational grazing and dispersion of manure droppings, should be used to reduce cross-contamination between groups of animals.

### 6.1.1 Site selection

Land used for production of animal feed and feed ingredients should not be located in close proximity to industrial operations where industrial pollutants from air, ground water or runoff from adjacent land would be expected to result in the production of foods of animal origin that may present a food safety risk. Contaminants present in runoff from adjacent land and irrigation water should be below levels that present a food safety risk.

### 6.1.2 Fertilizers

Where manure fertilization of crops or pastures is practised, an appropriate handling and storage system should be in place and maintained to minimize environmental contamination, which could negatively impact on the safety of foods of animal origin. There should be adequate time between applying the manure and grazing or forage harvesting (silage and hay making) to allow the manure to decompose and to minimize contamination.

Manure, compost and other plant nutrients should be properly used and applied to minimize biological, chemical and physical contamination of foods of animal origin which could adversely affect food safety.

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<sup>11</sup> Guidelines on this definition are under development by FAO.

Chemical fertilizers should be handled, stored and applied in a manner such that they do not have a negative impact on the safety of foods of animal origin.

### 6.1.3 **Pesticides and other agricultural chemicals**

Pesticides and other agricultural chemicals should be obtained from safe sources. Where a regulatory system is in place, any chemical used must comply with the requirements of that system.

Pesticides should be stored according to the manufacturer's instructions and used in accordance with Good Agricultural Practice in the Use of Pesticides (GAP)<sup>12</sup>. It is important that farmers carefully follow the manufacturer's instructions for use for all agricultural chemicals.

Pesticides and other agricultural chemicals should be disposed of responsibly in a manner that will not lead to contamination of any body of water, soil, feed or feed ingredients that may lead to the contamination of foods of animal origin which could adversely affect food safety.

## 6.2 **Manufacturing of feed on-farm**

### 6.2.1 **Feed ingredients**

On-farm feed manufacturers should follow the applicable guidelines established in sub-section 4.1 of this Code when sourcing feed ingredients off the farm.

Feed ingredients produced on the farm should meet the requirements established for feed ingredients sourced off the farm. For example, seed treated for planting should not be fed.

### 6.2.2 **Mixing**

On-farm feed manufacturers should follow the applicable guidelines established in Section 5 of this Code. Particular attention should be given to sub-section 5.6 of this Code.

In particular, feed should be mixed in a manner that will minimize the potential for cross-contamination between feed or feed ingredients that may have an effect on the safety or withholding period for the feed or feed ingredients.

### 6.2.3 **Monitoring records**

Appropriate records of feed manufacturing procedures followed by on-farm feed manufacturers should be maintained to assist in the investigations of possible feed-related contamination or disease events.

Records should be kept of incoming feed ingredients, date of receipt and batches of feed produced in addition to other applicable records set out in sub-section 4.3 of the Code.

<sup>12</sup> See Definitions for the Purposes of the Codex Alimentarius (Procedural Manual of the Codex Alimentarius Commission).

### 6.3 Good animal feeding practice

Good animal feeding practices include those practices that help to ensure the proper use of feed and feed ingredients on-farm while minimising biological, chemical and physical risks to consumers of foods of animal origin.

#### 6.3.1 Water

Water for drinking or for aquaculture should be of appropriate quality for the animals being produced. Where there is reason to be concerned about contamination of animals from the water, measures should be taken to evaluate and minimise the hazards.

#### 6.3.2 Pasture grazing

The grazing of pastures and crop lands should be managed in a way that minimises the avoidable contamination of foods of animal origin by biological, chemical and physical food safety hazards.

Where appropriate, an adequate period should be observed before allowing livestock to graze on pasture, crops and crop residuals and between grazing rotations to minimise biological cross-contamination from manure.

Where agricultural chemicals are used, operators should ensure that the required withholding periods are observed.

#### 6.3.3 Feeding

It is important that the correct feed is fed to the right animal group and that the directions for use are followed. Contamination should be minimised during feeding. Information should be available of what is fed to animals and when, to ensure that food safety risks are managed.

Animals receiving medicated feed should be identified and managed appropriately until the correct withholding period (if any) has been reached and records of these procedures must be maintained. Procedures to ensure that medicated feed are transported to the correct location and are fed to animals that require the medication should be followed. Feed transport vehicles and feeding equipment used to deliver and distribute medicated feed should be cleaned after use, if a different medicated feed or non-medicated feed or feed ingredient is to be transported next.

### 6.4 Stable feeding and lot/intensive feeding units

The animal production unit should be located in an area that does not result in the production of food of animal origin that poses a risk to food safety. Care should be taken to avoid animal access to contaminated land, and to facilities with potential sources of toxicity.

#### 6.4.1 Hygiene

The animal production unit should be designed so that it can be adequately cleaned. The animal production unit and feeding equipment should be thoroughly cleaned regularly to prevent potential hazards to food safety. Chemicals used should be

appropriate for cleaning and sanitising feed manufacturing equipment and should be used according to instructions. These products should be properly labelled and stored away from feed manufacturing, feed storage and feeding areas.

A pest control system should be put in place to control the access of pests to the animal production unit to minimise potential hazards to food safety.

Operators and employees working in the animal production unit should observe appropriate hygiene requirements to minimise potential hazards to food safety from feed.

## 6.5 Aquaculture<sup>13</sup>

Aquaculture includes a wide range of species of finfish, molluscs, crustaceans, cephalopods, etc. The complexity of aquaculture is reflected in the wide range of culturing methods ranging from huge cages in open seas to culturing in small freshwater ponds. The diversity is further reflected by the range of stages from larvae to full grown size, requiring different feed as well as different culture methods. Nutritional approaches range from feeding only naturally occurring nutrients in the water to the use of sophisticated equipment and scientifically formulated compound feed.

To ensure food safety, necessary precautions should be taken regarding culturing methods, culturing sites, technologies, materials and feed used to minimize contamination in order to reduce food hazards.

## SECTION 7. METHODS OF SAMPLING AND ANALYSIS

### 7.1. Sampling

Sampling protocols should meet scientifically recognized principles and procedures.

### 7.2. Analysis

Laboratory methods developed and validated using scientifically recognized principles and procedures should be used.<sup>14</sup> When selecting methods, consideration should also be given to practicability, with preference given to those methods which are reliable and applicable for routine use. Laboratories conducting routine analyses of feed and feed ingredients should ensure their analytical competency with each method used and maintain appropriate documentation.<sup>15</sup>

<sup>13</sup> Aquaculture producers should refer to relevant sections of the Code of Practice for Fish and Fishery Products for additional information (CAC/RCP 52-2003).

<sup>14</sup> *General Criteria for the Selection of Methods of Analysis Using the Criteria Approach* (Procedural Manual of the Codex Alimentarius Commission).

<sup>15</sup> For example, through quality assurance systems such as ISO 17025.

# CODE OF PRACTICE FOR THE REDUCTION OF AFLATOXIN B<sub>1</sub> IN RAW MATERIALS AND SUPPLEMENTAL FEEDINGSTUFFS FOR MILK PRODUCING ANIMALS

CAC/RCP 45-1997

## 1. BACKGROUND

- 1.1 Aflatoxin B<sub>1</sub> contamination of animal feedingstuffs can be a very serious problem, occurring in part due to inadequate storage conditions. Contamination may also occur at the preharvest stage and be exacerbated by inadequate storage conditions. Good cropping practices, use of seed varieties bred for resistance to seed-infecting fungi and insect pests as well as the use of appropriate approved pesticides represent reasonable preventive measures to control contamination in the field. Even with application of these practices, conditions created by the environment and/or traditional agricultural procedures may defeat any preventative measures.
- 1.2 Practices that reduce aflatoxin B<sub>1</sub> contamination in the field and after harvest should be an integral part of animal feedingstuff production, particularly for the export market because of the additional handling and transport steps required to get the product to the final destination. The factors most amenable for prevention of fungal infection and aflatoxin B<sub>1</sub> production involve proper drying and storage of the feedingstuff prior to transport. The problems created by too much moisture are magnified greatly by deficient post-harvest crop handling techniques.
- 1.3 Investigations concerning the biological fate of aflatoxin B<sub>1</sub> (AFB<sub>1</sub>) in lactating dairy cattle have demonstrated the transmission of residues into milk, occurring as the metabolite aflatoxin M<sub>1</sub> (AFM<sub>1</sub>). Although AFM<sub>1</sub> is considered to be less carcinogenic than AFB<sub>1</sub> by at least an order of magnitude, its presence in dairy products should be limited to the lowest level practicable. The amount of daily ingested AFB<sub>1</sub> which is transferred into milk is in the range of 0.17 to 3.3%.
- 1.4 To ensure the lowest possible level of AFM<sub>1</sub> in milk, attention should be given to residues of AFB<sub>1</sub> in the lactating dairy animal's daily feed ration.
- 1.5 To date there has been no widespread government acceptance of any decontamination treatment intended to reduce aflatoxin B<sub>1</sub> levels in contaminated animal feedingstuffs. Ammoniation appears to have the most practical application for the decontamination of agricultural commodities, and has received limited regional (state, country) authorization for its use with animal feed under specified conditions (i.e. commodity type, quantity, animal). Also, research suggests that the addition of the anticaking/binding agent "hydrated sodium calcium aluminosilicate" to aflatoxin contaminated



feeds may reduce AFM<sub>1</sub> residues in milk, depending on the initial concentration of AFB<sub>1</sub> in the feed.

## 2. RECOMMENDED PRACTICES

### 2.1 Crop production

- 2.1.1 Prepare seed bed for new crop by destroying or removing the seed heads or fruits (e.g. corn ears, peanuts, etc.) of aflatoxin susceptible crops.
- 2.1.2 Utilize soil tests if possible to determine fertilizer needs and apply fertilizer and soil conditioners to assure adequate soil pH and plant nutrition to avoid plant stress, especially during seed development.
- 2.1.3 When feasible, use seed varieties bred for fungal resistance and field tested for resistance to *Aspergillus flavus*.
- 2.1.4 As far as practicable, sow and harvest crops at times which will avoid high temperature and drought stress during the period of seed development/maturation.
- 2.1.5 Minimize insect damage and fungal infection by the proper use of appropriate approved insecticides and fungicides and other appropriate practices within an integrated pest management program.
- 2.1.6 Use good agronomic practice, including measures which will reduce plant stress. Such measures may include: avoidance of overcrowding of plants by sowing at the recommended row and intra-plant spacings for the species/varieties grown; maintenance of a weed free environment in the growing crop by the use of appropriate approved herbicides and other suitable cultural practices; elimination of fungal vectors in the vicinity of the crop; and crop rotation.
- 2.1.7 Minimize mechanical damage to crops during cultivation.
- 2.1.8 Irrigation is a valuable method of reducing plant stress in some growing situations. If irrigation is used ensure that it is applied evenly and individual plants have an adequate supply of water.

### 2.2 Harvest

- 2.2.1 Harvest crops at full maturity unless allowing the crop to continue to full maturity would subject it to extreme heat, rainfall or drought conditions.
- 2.2.2 As much as possible avoid mechanical damage during harvest.
- 2.2.3 Where applicable dry crops to a minimum moisture content as quickly as possible.
- 2.2.4 If crops are harvested at high moisture levels dry immediately after harvest.

- 2.2.5 Avoid piling or heaping wet freshly harvested commodities for more than a few hours prior to drying or threshing to lessen the risk of fungal growth.
- 2.2.6 Ensure adequate protection from rain during sun drying.

### **2.3 Storage**

- 2.3.1 Practice good sanitation for storage structures, wagons, elevators and other containers to ensure that stored crops will not be contaminated. Proper storage conditions include dry, well ventilated structures that provide protection from rain or seepage of ground water.
- 2.3.2 For bagged commodities, ensure that bags are clean and dry and stack on pallets or incorporate a water impermeable layer between the sacks and the floor.
- 2.3.3 Ensure that crops to be stored are free of mould and insects and are dried to safe moisture levels (ideally crops should be dried to a moisture content in equilibrium with a relative humidity of 70%).
- 2.3.4 Prevent insect infestation by the use of appropriate approved insecticides.
- 2.3.5 Ensure that the storage facilities are free of insects and mould by good housekeeping and/or the use of appropriate approved fumigants.
- 2.3.6 Prevent access by rodents and birds.
- 2.3.7 Store at as low a temperature as possible. Where possible aerate commodities stored in bulk through continuous circulation of air through the storage vessel to maintain proper temperature and moisture.
- 2.3.8 Use of a suitable authorized preservative e.g. an organic acid such as propionic acid, may be beneficial in that such acids are effective in killing moulds and fungi and preventing the production of mycotoxins. If organic acids are used, it is important that the amounts added are sufficient to prevent fungal growth and is consistent with the products end use.

### **2.4 Transport**

- 2.4.1 Make sure that transport containers and vehicles are free of mould, insects and any contaminated material by thoroughly cleaning before use or re-use. Periodic disinfection with appropriate approved fumigants or other pesticides may be useful.
- 2.4.2 Protect shipments from moisture by appropriate means such as airtight containers, covering with tarpaulins, etc. Care must be taken in the use of tarpaulins to avoid sweating of the commodity that could lead to local moisture and heat build up which are prime conditions for fungal growth.

2.4.3 Avoid insect and rodent infestation during transport by the use of insect resistant containers or insect and rodent repellent chemical treatments.

## **2.5 Feed production and disposition of AFB<sub>1</sub> contaminated animal feeds**

2.5.1 Ensure that milling equipment is kept clean, free of dust and feed accumulation.

2.5.2 Use an appropriate sampling and testing program to monitor outbound and inbound shipments for the presence of AFB<sub>1</sub>. Because AFB<sub>1</sub> concentration in shipments may be extremely heterogeneous refer to FAO recommendations for sampling plans. Adjust frequency of sampling and testing to take into account conditions conducive to aflatoxin B<sub>1</sub> formation, the regional source of the commodity and prior experience within the growing season.

2.5.3 If aflatoxin B<sub>1</sub> is detected, consider one or more of the following options. In all cases ensure that the aflatoxin B<sub>1</sub> level of the finished feed is appropriate for its intended use (i.e. maturity and species of animal being fed) and is consistent with national codes and guidelines or qualified veterinary advice.

2.5.3.1 Consider the restriction of AFB<sub>1</sub> contaminated feed to a percentage of the daily ration such that the daily amount of AFB<sub>1</sub> ingested would not result in significant residues of AFM<sub>1</sub> in milk.

2.5.3.2 If feed restriction is not practical, divert the use of highly contaminated feedingstuffs to non-lactating animals only.

# GLOSSARY OF TERMS AND DEFINITIONS

## (Residues of veterinary drugs in foods)

CAC/MISC 5-1993

### FOREWORD

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

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

1. **Acceptable Daily Intake (ADI):** An estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg) (See Note 3).
2. **Bioavailable Residues:** Those residues that can be shown, by means of an appropriate method (e.g. Gallo-Torres method) to be absorbed into systemic circulation when fed to laboratory animals (See Note 3).
3. **Bound Residue:** Residues derived from the covalent binding of the parent drug or a metabolite of the drug and a cellular biological soluble or insoluble macromolecule. These residues are not extractable from the macromolecule by exhaustive extraction, denaturation or solubilization techniques. They do not result from the incorporation of metabolized, radiolabelled fragments of the drug into endogenous compounds, or the same macromolecule by normal biosynthetic pathways. Information concerning the calculation of bound residues may be found in Annex 3 of the 34th Report of JECFA (pages 58–61, WHO TRS 788).
4. **Egg:** The fresh edible portion of the spheroid body produced by female birds, especially domestic fowl.  
*Portion of the commodity to which the MRL applies:* The edible portion of the egg including the yolk and egg white after removal of the shell
5. **Extractable Residue:** Those residues extracted from tissues or biological fluids by means of aqueous acidic or basic media, organic solvents and/or hydrolysis with enzymes (e.g. sulfatase or glucuronidase) to hydrolyze conjugates. The extraction conditions must be such that the compounds of interest are not destroyed (See Note 2).
6. **Fat:** The lipid-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental or perirenal

fat. It does not include interstitial or intramuscular carcass fat or milk fat. *Portion of the commodity to which the MRL applies:* The whole commodity. For fat-soluble compounds the fat is analysed and MRLs apply to the fat. For those compounds where the trimmable fat is insufficient to provide a suitable test sample, the whole commodity (muscle and fat but without bone) is analysed and the MRL applies to the whole commodity (e.g., rabbit meat).

7. **Fish:** Means any of the cold-blooded aquatic vertebrate animals commonly known as such. This includes Pisces, Elasmobranchs and Cyclostomes. Aquatic mammals, invertebrate animals and amphibians are not included. It should be noted, however, that this term may also apply to certain invertebrates, particularly Cephalopods.
8. **Good Practice in the Use of Veterinary Drugs (GPVD):** Is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions (See Note 1).
9. **Marker Residue:** A residue whose concentration decreases in a known relationship to the level of total residues in tissues, eggs, milk or other animal tissues. A specific quantitative analytical method for measuring the concentration of the residue with the required sensitivity must be available (See Note 3).
10. **Maximum Residue Limit for Veterinary Drugs (MRLVD):** Is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or  $\mu\text{g}/\text{kg}$  on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food (See Note 1). It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.
11. **Meat:** The edible part of any mammal.
12. **Milk:** Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.  
*Portion of the commodity to which the MRL applies:*—Codex MRLs for fat-soluble compounds in milk are expressed on a whole commodity basis.
13. **Muscle:** Muscle is the skeletal tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat.

*Portion of the commodity to which the MRL applies:* The whole commodity without bones.

14. **Non-Extractable Residues** (See Note 2): These residues are obtained by subtracting the extractable residues from the total residues and comprise:
  - i) Residues of the drug incorporated through normal metabolic pathways into endogenous compounds (e.g. amino acids, proteins, nucleic acid). These residues are of no toxicological concern.
  - ii) Chemically-bound residues derived by interaction of residues of parent drug or its metabolites with macromolecules. These residues may be of toxicological concern.
15. **Poultry:** Means any domesticated bird including chickens, turkeys, ducks, geese, guinea-fowls or pigeons.
16. **Regulatory Method of Analysis:** A method that has been legally enacted and/or validated in a multi-laboratory study and can be applied by trained analysts using commercial laboratory equipment and instrumentation to detect and determine the concentration of a residue of a veterinary drug in edible animal products for the purpose of determining compliance with the MRL.
17. **Residues of Veterinary Drugs:** Include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned (See Note 1).
18. **Screening Method:** A rapid, relatively inexpensive, and rugged field method used for testing for a specific substance or closely related group of substances which are sufficiently selective and sensitive to allow at least semi-quantitative detection of residues in contents in accordance with the established maximum limit.
19. **Temporary Acceptable Daily Intake (TADI):** Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA (See Note 2).
20. **Tissue:** All edible animal tissue, including muscle and by-products (See Note 2).
21. **Tissue, Control:** Tissue from animals not treated with veterinary drugs of the same species, sex, age and physiological status as the target species.

22. **Tissue, Dosed:** Tissue from animals of the test species that have been treated with the drug according to its intended use.
23. **Tissue, Spiked or Fortified:** Tissue containing known concentrations of the analyte added to the sample of control tissue.
24. **Total Residue:** The total residue of a drug in animal derived food consists of the parent drug together with all the metabolites and drug based products that remain in the food after administration of the drug to food producing animals. The amount of total residues is generally determined by means of a study using the radiolabelled drug, and is expressed as the parent drug equivalent in mg/kg of the food (See Note 2).
25. **Validated Method:** An analytical method which has been subjected to a multi-laboratory study for accuracy, precision, reproducibility performance and ruggedness. Concise written procedures for sample selection, preparation and quantitative analysis are provided for inter-laboratory quality assurance and consistency of results, on which an appropriate regulatory method of analysis can be established.
26. **Veterinarian Client-Patient Relationship:** The relationship is recognized when the livestock enterprise, premises and husbandry practices are known to the veterinarian as a result of a recent professional visit to the site and the veterinarian is available for emergency on site consultation and is responsible for preventative medicine programmes.
27. **Veterinary Drug:** Any substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic, or diagnostic purposes, or for modification of physiological functions or behaviour (See Note 1).
28. **Withdrawal Time and Withholding Time:** This is the period of time between the last administration of a drug and the collection of edible tissue or products from a treated animal that ensures the contents of residues in food comply with the maximum residue limit for this veterinary drug (MRLVD).

### Notes

1. Definitions adopted by the Codex Alimentarius Commission as **Definitions for the Purpose of the Codex Alimentarius**. See *Procedural Manual*.
2. Definitions established and adopted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
3. Definitions previously established and adopted by the JECFA, which have been modified by the Codex Committee on Residues of Veterinary Drugs in Foods.

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