# Appendix 1: Terms of Reference

## Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health

### Purpose

In conjunction with the Canadian Food Inspection Agency (CFIA) and other stakeholder groups, Health Canada - Veterinary Drugs Directorate will develop comprehensive overarching policies aimed at identifying and managing the impact on resistance and human health associated with the animal uses of antimicrobial agents.

### Scope

The primary focus of the advisory committee will be to provide information relevant to reducing the potential resistance and human health and safety impacts associated with animal uses of antimicrobial agents. This will include the identification and prioritization of relevant issues surrounding antimicrobial uses and their contribution to resistance as well as the development of strategies to track usage of antimicrobials.

### Role and Mandate of the Advisory Committee

The role of the advisory committee will be to provide advice and assistance to the Director General, Veterinary Drugs Directorate, in the development of policy options related to the animal uses of antimicrobial agents by:

- Identifying and prioritizing issues relevant to a broad range of stakeholders.
- Overseeing, reviewing, commenting on, and providing expertise during the preparation of draft policy documents, based on the issues previously identified.
- Identifying sources of, and facilitating access to, information and expertise relevant to the policy development project.
- Acting as stakeholder representatives to analyze issues, generate options and make recommendations concerning potential solutions.
- Providing feedback to stakeholder groups as appropriate.
- Recommending approaches to communicating risks associated with the animal uses of antimicrobial agents and the strategies identified to mitigate the risks.
- Reviewing, in consultation with the Bureau of Microbial Hazards and the Veterinary Drugs Directorate (Health Canada) and the CFIA, draft policy papers prior to general public consultation and subsequent implementation as policy documents.

Responses to the media regarding committee activity should be handled by the Chairperson (in English) and a designated francophone spokesperson. Individual committee members are free to comment to the media for their organization, but should refer any questions about the committee to committee spokespeople.

As an independent advisory committee, the group can make statements to the media on its own behalf without involvement from Health Canada. However, the committee cannot comment on behalf of the Department. Any communications that attempt to speak for the Department would need to be approved in advance by the Department.

Following each meeting, the committee may wish to write an update that can be used by each member to share information in their organizations or constituencies. This paragraph or letter could be inserted in information letters to members, or sent to media. If possible, Health Canada would appreciate knowing when this information is shared with the media so it can be prepared for follow-up questions.

## Reporting Structure

Provides advice to the Director General, Veterinary Drugs Directorate, Health Products and Food Branch, Health Canada.

## Membership

A small multi-sectoral group of knowledgeable individuals capable of providing advice and assistance to the Veterinary Drugs Directorate. It will incorporate a balanced perspective from a wide range of interested external parties, including representatives from the agriculture and aquaculture industries, the pharmaceutical industry, animal health organizations, animal welfare organizations, the Canadian Veterinary Medical Association, health professionals, academia, consumer groups, provincial governments, etc.

## Term

Members are appointed by the Director General, Veterinary Drugs Directorate, Health Products and Food Branch, Health Canada, for the duration of the project (expected to be approximately three years).

## Meetings

A large portion of the work will be conducted through a variety of communication means, including telephone or video conference interaction with the steering committee and various working groups. It is anticipated that there will be three to four advisory committee meetings per year.

## Management and Administration

The Health Products and Food Branch - Veterinary Drugs Directorate primary contact are the Project Managers, who can be reached as follows:

Dr. Rebecca Irwin
Guelph Laboratory
Health Canada
4th Floor, 1 Stone Road West
Guelph, ON N1G 4Y2

Dr. Lateef Adewoye
Veterinary Drugs Directorate
Holland Cross Complex
Tower A, Ground Floor
11 Holland Avenue
Ottawa, ON K1A 0K9
Address Locator: 3000A

Unfortunately, it will not be possible to pay a per diem for the time spent on work for this committee. Reimbursement of expenditures by committee members related to meeting attendance will be in accordance with Treasury Board guidelines on travel and accommodation.

# Appendix 2: Membership of Advisory Committee and Secretariat

| Committee Member | Affiliation |
|---|---|
| Dr. Scott McEwen (chair) | Department of Population Medicine, University of Guelph |
| Dr. Paul Hasselback (co-chair) | Medical Officer of Health, Chinook Health Region, Lethbridge, Alberta |
| Ms. Brenda Nunns Shoemaker (co-chair) | Consumers' Association of Canada, North Saanich, British Columbia |
| Dr. Rejean Bouchard | Dairy Farmers of Canada, Ottawa, Ontario |
| Ms. Stephanie Brown | Animal Welfare Representative, Toronto, Ontario |
| Dr. Ron Clarke | Canadian Cattlemen's Association, Hague, Saskatchewan |
| Dr. Paul Dick | Canadian Animal Health Institute, Guelph, Ontario |
| Dr. Patricia Dowling | Western College of Veterinary Medicine, Saskatoon, Saskatchewan |
| Dr. Lyn Ferns | Veterinary Pathology Laboratory, Nova Scotia Department of Agriculture and Marketing, Truro, Nova Scotia |
| Dr. S. K. Ho | CARC, c/o Agiculture and Agri-Food Canada, Ottawa, Ontario |
| Dr. Yves Labbé | Chicken Farmers of Canada and CFIA, Ottawa, Ontario |
| Dr. Don Low | Mt. Sinai and Princess Margaret Hospitals, Toronto, Ontario |
| Dr. Keith McMillan | Lilydale Co-operative Ltd. Edmonton, Alberta |
| Mr. Carl Moore | Canadian Pork Council, Ottawa, Ontario |
| Dr. Marie Nadeau | Ministère de l'Agriculture, des Pêcheries et de l'Alimentation, Sainte-Foy, Québec |
| Dr. John Prescott | Department of Pathobiology, University of Guelph |
| Dr. Bill Revington | New-Life Mills Ltd., Cambridge, Ontario |
| Dr. Myron Roth | Salmon Health Consortium, Ottawa, Ontario |
| Dr. Deborah Stark | Canadian Veterinary Medical Association, Ottawa, Ontario |

| Secretariat Member | Affiliation |
|---|---|
| Dr. Lateef Adewoye | Health Canada, Ottawa, Ontario |
| Ms. Estelle Bernier | Health Canada, Ottawa, Ontario |
| Dr. Shiv Chopra | Health Canada, Ottawa, Ontario |
| Dr. Anne Deckert | Health Canada, Guelph, Ontario |
| Dr. Lucye Galand | Health Canada, Ottawa, Ontario |
| Dr. Rebecca Irwin | Health Canada, Guelph, Ontario |
| Ms. Catherine Italiano | CFIA, Ottawa, Ontario |
| Dr. Manisha Mehrotra | Health Canada, Ottawa, Ontario |
| Dr. Richard Reid-Smith | Health Canada, Guelph, Ontario |
| Ms. Annie Savoie | CFIA, Ottawa, Ontario |
| Ms. Linda Webster | CFIA, Ottawa, Ontario |
| Dr. William Yan | Health Canada, Ottawa, Ontario |

# Appendix 3: Extra Tables for Chapter 5

Table A.3.1: Growth promoter claims in the CMIB: (8th edition, 1998)

| CMIB # | Compound | Species | Level in Feed | Claima[a] |
|---|---|---|---|---|
| 4 | Arsanilic acid | 1. Broilers | 99 mg/kg | growth, f.c. |
| | | 2. Pullets | 99 mg/kg | growth, f.c. |
| | | 3. Layers | 99 mg/kg | growth, f.c. |
| | | 4. Turkeys | 99 mg/kg | growth, f.c. |
| | | 5. Swine | 50–99 mg/kg | growth, f.c. |
| 10.1 | Chlortetracycline HCl | 1. Chickens | 5.5 mg/kg | growth, f.e. |
| | | 2. Turkeys | 5.5 mg/kg | growth, f.e. |
| | | 3. Swine | 5.5 mg/kg | growth, f.e. |
| | | 4. Calves | 11 mg/kg | growth, f.e. |
| | | 5. Lambs | 11 mg/kg | growth, f.e. |
| | | 6. Mink | 27 mg/kg | growth, f.e. |
| 10.2 | Bacitracin (Zn or MD) | 1. Chickens | 4.4 mg/kg | gain, f.e. |
| | | 2. Turkeys | 4.4 mg/kg | gain, f.e. |
| | | 3. Swine | 4.4 mg/kg | gain, f.e. |
| 10.5 | Lincomycin HCl | 1. Broilers | 2.2 mg/kg | growth, f.u. |
| 10.7 | Procaine Penicillin | 1. Chickens | 2.2 mg/kg | growth |
| 10.1 | Tylosin Phosphate | 1. Swine | 44/22/11 mg/kg[b] | growth, f.e. |
| 10.11 | Virginiamycin | 1.Swine | 11 mg/kg | gain |
| | | 2. Chickens | 11 mg/kg | gain, f.e. |
| 10.12 | Bambermycins | 1. Chickens | 2 mg/kg | gain, f.e. |
| | | 2. Turkeys | 2 mg/kg | gain |
| 10.13 | Salinomycin[c] | 1. Swine | 25 mg/kg | gain |
| | | 2. Swine | 25 mg/kg | f.e. |
| 10.14 | Zinc Bacitracin and | 1. Chickens | 3.3/1.1 mg/kg | gain, f.e. |
| | Procaine Penicillin | 2. Turkeys | 3.3/1.1 mg/kg | gain, f.e. |
| | | 3. Swine | 3.3/1.1 mg/kg | gain, f.e. |
| 21 | 3-nitro-4-hydroxy-phenylarsonic acid | 1. Chickens | 50 mg/kg | gain, f.e. |
| | | 2. Chicken-r[d] | 50 mg/kg | gain, f.e. |
| | | 3. Chicken-l[e] | 50 mg/kg | f.e. |
| | | 4. Turkeys | 50 mg/kg | gain, f.e. |
| | | 5. Swine | 25–50 mg/kg | gain, f.e. |
| 34 | Chlortetracycline HCl | Various | See Table 5.6 | |
| 35, A | Oxytetracycline | Various | See Table 5.7 | |

| CMIB # | Compound | Species | Level in Feed | Claim[a] |
|---|---|---|---|---|
| | HCl | | | |
| 38 | CTC, Sulfamethazine & Proc. Penicillin | Swine | See Table 5.8 | |
| 41 | Erythromycin thiocyanate | Breeding Chick. | 220 mg/kg | gain, egg prod'n |
| 49 | CTC & Sulfamethazine | Beef Cattle | 350/350 mg/h/d | gain, f.e. |
| 53 | Carbadox | Swine-w[f] | 55 mg/kg | gain, f.e. |
| 55 | OTC & Neomycin Sulfate | Beef Cattle | 500/500 mg/h/d | gain, f.e. |
| 57 | Monensin sodium | 3. Beef Cattle | 11/33 mg/kg | f.e. |
| | | 5. Cattle[g] | 200 mg/h/d | gain |
| 66 | Lasalocid sodium | 3. Beef Cattle | 36 mg/kg | gain, f.e. |
| | | 4. Cattle[g] | 200mg/h/d | gain |
| 69 | Salinomycin sodium | 2. Beef Cattle | 11,13,16 mg/kg | f.e. |

[a] Growth and increased rate of gain are taken to be synonymous. Feed conversion (f.c.), feed efficiency (f.e.) and feed utilization (f.u.) are taken to be synonymous and are generally defined as feed intake per unit of live weight gain.
[b] 44 mg/kg for use in starters, 22 mg/kg in growers, and 11 mg/kg in finishers.
[c] The efficacy for improvement of feed efficiency in swine has not been established with mash feed;
Claim 2 is for pellet feed only.
[d] Replacement chickens (pullets intended for lay).
[e] Laying (mature) chickens.
[f] Weaner pigs up to 35 kg body weight; carbadox is currently under a federal "stop sale" in Canada.
[g] For cattle on pasture (slaughter, stocker and feeder cattle; beef and dairy replacements).

Table A.3.2: Summary of CMIB 34 chlortetracycline HCl

| Species | Total Claims | GP Claims[a] | GP Plus...[b] | Prophylactic[c] | Rates[d] | Notes |
|---|---|---|---|---|---|---|
| Broilers | 8 | 7 | 5 | 1 | 220 (2) | 5 |
| | | | | | 110 (5) | |
| | | | | | 55 (1) | |
| Layers | 6 | 6 | 4 | 1 | 110 (5) | |
| | | | | | 55 (1) | |
| Pullets | 7 | 6 | 4 | 1 | 220 (1) | 5 |
| | | | | | 110 (5) | |
| | | | | | 55(1) | |
| Turkeys | 12 | 7 | 5 | 2 | 220 (3) | 5 |
| | | | | | 110 (7) | |
| | | | | | 55 (2) | |
| Lambs | 1 | 0 | 0 | 0 | 22(1) | |
| Swine | 4 | 2 | 1 | 1 | 110 (2) | |
| | | | | | 55(2) | |
| Beef and NL Dairy[e] | 1 | 0 | 0 | 1 | 0.22mg/kg BW[f] | |
| Calves | 2 | 0 | 0 | 2 | 55 (2) | |

[a] growth promoter claims are claims that refer to growth and/or feed efficiency, but not a recognized disease condition. Typically, these claims refer to "stress due to..." or similar phrasing.

[b] growth promoter plus... refers to growth and/or feed efficiency but also mentions another recognized disease condition such as chronic respiratory disease, atrophic rhinitis, synovitis, non-specific enteritis. These are a subset of the growth promoter claims.

[c] Prophylactic claims are claims that refer to the expected exposure of target species to a named disease condition. This is the 55 mg/kg level except for one claim in turkeys (110 mg/kg for synovitis/infectious sinusitis) and for beef and non-lactating dairy cows.

[d] Rates given as mg/kg of diet unless otherwise indicated; the number of claims at that rate are given in brackets.

[e] Non-lactating dairy animals.

[f] BW = body weight; claim also allows 70 mg/head/day.

Table A.3.3: Summary of CMIB 35 oxytetracycline HCl

| Species | Total Claims | GP Claims[a] | GP Plus...[b] | Prophylactic[c] | Rates[d] | Notes |
|---|---|---|---|---|---|---|
| Broilers | 8 | 7 | 5 | 1 | 220 (2) | 5 |
| | | | | | 110 (5) | |
| | | | | | 55 (1) | |
| Layers | 6 | 6 | 5 | 1 | 220 (1) | |
| | | | | | 110 (4) | |
| | | | | | 55 (1) | |
| Pullets | 7 | 6 | 5 | 1 | 220 (2) | 5 |
| | | | | | 110 (4) | |
| | | | | | 55(1) | |
| Turkeys | 9 | 7 | 6 | 2 | 220 (2) | |
| | | | | | 110 (6) | |
| | | | | | 55 (1) | |
| Lambs | 2 | 0 | 0 | 0 | 110(1) | |
| | | | | | 22 (1) | |
| Swine | 5 | 2 | 2 | 1 | 550 (1) | |
| | | | | | 110(2) | |
| | | | | | 55(2) | |
| Beef | 1 | 0 | 0 | 1 | 75mg/hd/d[e] | |
| Calves | 2 | 0 | 0 | 2 | 55 (2) | |

[a] growth promoter claims are claims that refer to growth and/or feed efficiency, but not a recognized disease condition. Typically, these claims refer to "stress due to..." or similar phrasing.

[b] growth promoter plus... refers to growth and/or feed efficiency but also mentions another recognized disease condition such as chronic respiratory disease, atrophic rhinitis, synovitis, non-specific enteritis. These are a subset of the growth promoter claims.

[c] Prophylactic claims are claims that refer to the expected exposure of target species to a named disease condition. This is the 55 mg/kg level except for one claim in turkeys (110 mg/kg for synovitis/infectious sinusitis) and for beef and non-lactating dairy cows.

[d] Rates given as mg/kg of diet unless otherwise indicated; the number of claims at that rate are given in brackets.

[e] 75 mg/head/day for prevention of bloat.

Table A.3.4: Summary of CMIB 38 chlortetracycline/sulfamethazine/procaine penicillin

| Species | Total Claims | GP Claims[a] | GP Plus...[b] | Prophylactic[c] | Rates[d] |
|---|---|---|---|---|---|
| Swine | 6 | 4 | 2 | 0 | 110/110/55 (6) |

[a] growth promoter claims are claims that refer to growth and/or feed efficiency, but not a recognized disease condition. Typically, these claims refer to "stress due to..." or similar phrasing.
[b] growth promoter plus... refers to growth and/or feed efficiency but also mentions another recognized disease condition such as chronic respiratory disease, atrophic rhinitis, synovitis, non-specific enteritis. These are a subset of the growth promoter claims.
[c] Prophylactic claims are claims that refer to the expected exposure of target species to a named disease condition. This is the 55 mg/kg level except for one claim in turkeys (110 mg/kg for synovitis/infectious sinusitis) and for beef and non-lactating dairy cows.
[d] Rates given as mg/kg of diet unless otherwise indicated; the number of claims at that rate are given in brackets.

# Appendix 4: Presentations Made to Committee

| Presenter | Date | Topic |
|---|---|---|
| Diane Kirkpatrick, Health Canada | December 13, 1999 | Background on the Policy Development Process |
| Jean Breton, Kelly Butler, Health Canada | March 20, 2000 | Veterinary Drug Regulation and Approval Process in Canada |
| Don Low, Mt Sinai Hospital | March 20, 2000 | Antibiotics Important in Human Medicine |
| Richard Reid-Smith, Health Canada | March 20, 2000 | Antimicrobial Use Surveillance |
| Anne Deckert, Health Canada | March 20, 2000 | Antimicrobial Resistance Surveillance |
| Scott McEwen, University of Guelph | March 20, 2000 | Risk Assessment |
| Ian Alexander, Health Canada | June 19, 2000 | Extra Label Drug Use |
| Bruce Wozny, Health Canada | June 19, 2000 | Sale of Active Pharmaceutic Ingredients as Drugs for Veterinary Use |
| Mansen Yong, Health Canada | June 19, 2000 | Human Health Safety Assessment of Veterinary Drugs |
| Myron Roth, Aqua Health Ltd | June 19, 2000 | Antimicrobial Use in Canadian Aquaculture |
| Bill Revington, New Life Feeds | January 15, 2001 | Use of Antimicrobials – Feed Producer's Perspective |
| Stephen Sundlof, U.S. Food and Drug Administration, Rockville MD, U.S.A. | June 7, 2001 | The United States Perspective on Agricultural Antimicrobial Resistance Issues |
| John Turnidge, Women and Children's Hospital, Adelaide, Australia | June 7, 2001 | The Australian Perspective on Agricultural Antimicrobial Resistance Issues |
| Paula Fedorka-Cray U.S.D.A., Athens, GA, U.S.A. | June 7, 2001 | National Antimicrobial Resistance Monitoring System and Related Research Activities in the United States |

# Appendix 5: List of Abbreviations

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|---|---|
| AAFC | Agriculture and Agri-Food Canada |
| AASP | American Association of Swine Practitioners |
| AHI | Animal Health Institute |
| AIDS | acquired immunodeficiency syndrome |
| AMDUCA | *Animal Medicinal Drug Use Clarification Act* |
| AMR | antimicrobial resistance |
| API | active pharmaceutical ingredients |
| ARET | Accelerated/Reduction of Toxics |
| ARS | Agricultural Research Service |
| ARO | antibiotic resistant organisms |
| ATC vet | Anatomical Therapeutic Chemical Veterinary Classification |
| AVMA | American Veterinary Medical Association |
| BCMAFF | British Columbia Minister of Agriculture, Fisheries and Food |
| BSE | bovine spongiform encephalopathy |
| BVD | Bureau of Veterinary Drugs |
| CAHI | Canadian Animal Health Institute |
| CAIA | Canadian Aquaculture Industry Alliance |
| CARC | Canadian Agri-Food Research Council |
| CARD | Canadian Adaptation and Rural Development Fund |
| CBA | Canadian Bison Association |
| CBHEPA | Canadian Broiler Hatching Egg Producers Association |
| CCA | Canadian Cattleman's Association |
| CCAR | Canadian Committee on Antimicrobial Resistance |
| CCC | Canadian Cervid Council |
| CCP | critical control point |
| CDC | Centers for Disease Control and Prevention |
| CEMA | Canadian Egg Marketing Agency |
| CIDPC | Centre for Infectious Disease Prevention and Control |
| CFA | Canadian Federation of Agriculture |
| CFC | Chicken Farmers of Canada |
| CFIA | Canadian Food Inspection Agency |
| CHEQ | Canadian Hatching Egg Quality |
| CHF | Canadian Hatchery Federation |
| CMIB | Compendium of Medicated Ingredients Brochure |
| CNISP | Canadian Nosocomial Infection Surveillance Program |
| COFFSP | Canadian On-Farm Food Safety Program |
| CPC | Canadian Pork Council |
| CSF | Canadian Sheep Federation |

| | |
|---|---|
| CTMA | Canadian Turkey Marketing Association |
| CVM | Center for Veterinary Medicine |
| CVMA | Canadian Veterinary Medical Association |
| DANMAP | Danish Integrated Antimicrobial Resistance Monitoring and Research Programme |
| DFC | Dairy Farmers of Canada |
| DIN | Drug Identification Number |
| DNA | deoxyribonucleic acid |
| DT | definitive phage type |
| E.C. | European Community |
| e.g. | exempli gratia |
| E.U. | European Union |
| EAGAR | Expert Advisory Group on Antibiotic Resistance |
| EDR | emergency drug release |
| EMEA | European Medicines Evaluation Agency |
| EPA | Environmental Protection Agency |
| et al. | et alii |
| FAO | Food and Agriculture Organization |
| FDA | Food and Drug Administration |
| GATT | General Agreement on Tariffs and Trade |
| GMP | good management practices |
| GPP | good production practices |
| HACCP | Hazard Analysis Critical Control Point |
| HCl | hydrochloric acid |
| HIV | human immunodeficiency virus |
| HUS | haemolytic uremic syndrome |
| i.e. | id est |
| IOM | Institute of Medicine |
| JETACAR | Joint Expert Technical Advisory Committee on Antimicrobial Resistance |
| MDR | multidrug-resistant |
| MDRP | multidrug-resistant *Streptococcus pneumoniae* |
| MDRTB | multidrug-resistant *Mycobacterium tuberculosis* |
| MIC | minimum inhibitory concentration |
| MOS | mannan oligosaccharide |
| MRL | maximum residual levels |
| MRSA | methicillin-resistant *Staphylococcus aureus* |
| MT | metric tonne |
| NAFTA | North American Free Trade Agreement |
| NAHMS | National Animal Health Monitoring System |
| NARMS | National Antimicrobial Resistance Monitoring System |
| NAS | National Academy of Sciences |
| NCID | National Center for Infectious Disease |
| NIH | National Institutes of Health |
| NIPA | National Information Program on Antibiotics |

| | |
|---|---|
| NNIS | National Nosocomial Infections Surveillance |
| NRC | National Research Council |
| OFFSP | On-Farm Food Safety Program |
| OIE | Office International des Epizooties |
| OMAF | Ontario Ministry of Agriculture and Food |
| OTC | over-the-counter |
| PAAB | Pharmaceutical Advertising Board |
| PT | phage type |
| QREC | quinolone-resistant *Escherichia coli* |
| QSH | Quality Starts Here |
| R factors | resistance factors |
| R plasmids | resistance plasmids |
| RSPCA | Royal Society for the Prevention of Cruelty to Animals |
| SAGE | Science Advice for Government Effectiveness |
| SHC | Salmon Health Consortium |
| SOP | standard operating procedure |
| SRA | Society of Risk Analysis |
| SVA | Swedish National Veterinary Institute |
| TB | Tuberculosis |
| TDD | Therapeutic Drugs Directorate |
| TGA | Therapeutic Goods Administration |
| TMP/SXT | trimethoprim/sulfamethoxazole |
| TPD | Therapeutic Products Directorate |
| TPP | Therapeutic Products Program |
| UCS | Union of Concerned Scientists |
| U.K. | United Kingdom |
| U.S. | United States |
| USDA | United States Department of Agriculture |
| VCPR | veterinarian-patient-client-relationship |
| VDD | Veterinary Drugs Directorate |
| VICH | International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medical Products |
| VMAC | Veterinary Medical Advisory Committee |
| VMD | Veterinary Medicines Directorate |
| VRE | vancomycin-resistant enterococci |
| WHO | World Health Organization |