



CIJIG

COMMONWEALTH INTERDEPARTMENTAL JETACAR IMPLEMENTATION GROUP

FACILITATING THE IMPLEMENTATION OF A NATIONAL ANTIMICROBIAL RESISTANCE MANAGEMENT PROGRAM

PROGRESS REPORT

MARCH 2003

Background

The Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) was established by the Minister for Health and Family Services and the then Minister for Primary Industries and Energy in April 1998. The purpose of the committee was to provide independent expert scientific advice on the threat posed by antibiotic resistant bacteria to human health by the selective effect of agricultural use, and medical over use, of antibiotics. It reported to the Commonwealth Government in October 1999, making 22 recommendations for an antibiotic resistance management program covering regulatory controls; monitoring and surveillance; infection prevention strategies; education; research.

The Commonwealth Government Response to the Report of the JETACAR, released in October 2000 (the Government Response), largely supports the JETACAR's recommendations. It acknowledges the threat posed to human health by antibiotic resistance and supports the development of a national antibiotic resistance management program.

Implementation of the Government Response involves stakeholder consultation and monitoring of the implementation process.

CIJIG Terms of Reference

CIJIG will facilitate:

- the planning;
- development;
- coordination; and
- implementation of;

the antibiotic risk management program proposed by the JETACAR, and as supported by the Commonwealth Government Response to the JETACAR.

(Complete CIJIG Terms of Reference at Appendix 1)

Coordination

Implementation is a shared responsibility of Governments, industries, educators, health and agriculture professionals and the community, and many strategies are being developed by these sectors. At the Commonwealth Government level, two committees were established to help progress the implementation process.

CIJIG

The Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG) was established in November 2000. Its primary responsibility is to oversee and coordinate the continuing Government's response to JETACAR, particularly the implementation of the JETACAR recommendations as described in the Government Response. The CIJIG is composed of technical experts and senior representatives from relevant areas within the Department of Health and Ageing (DoHA) and is jointly chaired by DoHA and the Department of Agriculture, Fisheries and Forestry – Australia (AFFA). The secretariat for the CIJIG is provided through the Population Health Division of DoHA. The respective Chairs of the Australian Health Ministers' Conference (AHMC) JETACAR Taskforce (See Appendix 3), the Primary Industries Standing Committee (PISC) JETACAR Taskforce (See Appendix 3), formerly the Standing Committee on Agriculture and Resource Management (SCARM) JETACAR Taskforce, and the Expert Advisory Group on Antimicrobial Resistance (EAGAR) (See Appendix 2) are also invited to attend CIJIG meetings.

EAGAR

The EAGAR provides independent scientific and policy advice on antibiotic resistance issues, and works closely with the CIJIG to develop and implement the national antibiotic resistance management program. As with its predecessor, the Working Party on Antibiotics (WPA), the EAGAR will provide advice to Commonwealth, State and Territory and Commonwealth Statutory organisations.

The EAGAR was constituted in April 2001 under the Chair of Associate Professor John Turnidge and meets every 3 months. The EAGAR reports through the CIJIG to the Ministers, and for specific policy and guidelines requiring NHMRC endorsement, it will work through HAC to the NHMRC.

Regulatory Controls

(Recommendations 1-9)

Recommendation 1

That Australia adopt a conservative approach to minimise the use of antibiotics in humans and animals and, to further this policy, that infrequently used antibiotics in food-producing animals for growth promotant purposes, or other routine uses where duration and dose level are the same, or very similar, should not be used unless they:

- Are of demonstrable efficacy in livestock production under Australian farming conditions; and
- Are rarely or never used as systematic therapeutic agents in humans or animals, are not considered critical therapy for human use; and
- Are not likely to impair the efficacy of any other prescribed therapeutic antibiotic or antibiotics for animal or human infections through the development of resistant strains of organisms.

Recommendation 2

That the Australian Pesticides and Veterinary Medicines Authority (APVMA – previously NRA) reviews the use of antibiotic growth promotants currently registered in Australia that do not appear to fulfil the criteria listed in Recommendation 1 in terms of their impact on human and animal health, using a risk analysis approach, including a cost-benefit analysis. The priority determined should be consistent with recent international reviews and use the conditions outlined in Recommendations 1 and 4. It is recommended that the priority of the review at this stage be:

- glycopeptides (avoparcin)
- streptogramins (virginiamycin)
- macrolides (tylosin, kitasamycin, oleandomycin)

This review is to be completed and outcomes acted upon within three years (from 2000). Growth promotant claims of such antibiotics that do not pass the review process should be phased out of use within one year subject to consultation with relevant stakeholders.

It is also recommended that the APVMA should review the prophylactic use of avoparcin and virginiamycin in animals and the possible public health impact of this use using the parameters outlined in Recommendation 4. In order that the reviews are performed in a timely manner, it is further recommended that the federal ministers of health and agriculture ensure an adequate allocation of resources to the APVMA to facilitate the rapid completion of the task and implementation of changes.

Actions

- The AVPMA initiated the avoparcin review in 1998, however the manufacturer withdrew this product from the market place in September 1999. There are currently no registered products containing avoparcin in Australia.
- The AVPMA review of virginiamycin has been completed. The draft report of the virginiamycin review was released for public comment in March 2003.
- The review of macrolide antibiotic growth promotants is currently underway.

Recommendation 3

That an appropriate government authority or authorities license, or otherwise control, all importers of antibiotics (for any purpose other than individual human patient use). Licensed importers must provide import returns and distribution, and information based on amounts of active ingredient of agents intended for animal use, to the AVPMA, and to the Therapeutic Goods Administration (TGA) for agents intended for human use.

It is also recommended that a much stronger audit trail for antibiotics from the importer to the end-user be implemented, particularly in the veterinary field, and that the aggregated information on import quantities are made available for scrutiny by relevant authorities and the results are made public.

Actions

Refer also to Recommendation 8 below.

The TGA and APVMA met with representatives of the pharmaceutical and animal production industries, as well as people involved in medical dispensing of antibiotics, in March 2001 to investigate cost-effective options for monitoring and auditing of antibiotic end use. The meeting concluded that more information is needed on the level of end use information required in the antibiotic end use monitoring program. In Australia that there are good records in the early stages of distribution of intended end use, but this becomes patchy later on in the distribution chain.

In human medicine, activities are underway to improve national data on antibiotic prescribing (usage). A pharmacy survey will be recommended to provide estimates of non-subsidised prescriptions dispensed through community pharmacies. This data should be available from March 2002 and will include data from the period that community pharmacy surveys were not conducted. Once estimates of antibiotic dispensing through community pharmacies have been established, the Pharmaceutical Benefits Scheme (PBS) will be in a position to produce annual data on trends on antibiotic use in the community. This data will then be forwarded to the EAGAR and CIJIG.

The Pharmaceutical Benefits Advisory Committee (PBAC) has

instituted a process (with EAGAR collaboration) to ensure that detailed advice on antibiotic resistance and related matters is obtained:

- prior to any new antibiotic proposed for PBS subsidy; and
- for any major change to a current PBS restriction for an antibiotic which is currently subsidised by the PBS. The objective is to ensure that antibiotic resistance and related matters are properly considered in the context of managing PBS.

The TGA and AVPMA have competed a joint proposal to improve the collection of data on antimicrobial use in Australia. The draft document has been circulated for public comment (<http://www.health.gov.au/pubhlth/strateg/jetacar/reports.htm>)

EAGAR has completed a listing of antibiotic imports for the period 1992/1993 to 2000/2001. Imports are classified as Medical, Veterinary or In Feed.

The APVMA recently proposed a mechanism by which data of amounts of antibiotics supplied by veterinary pharmaceutical companies would be collected annually. It is proposed that this data would be collected during 2003 (See <http://www.apvma.gov.au/>).

Actions pending

- EAGAR listing of antibiotic imports to be posted on the EAGAR website.

Recommendation 4

That the APVMA evaluate all new applications, major extensions of use and any reviews of currently registered antibiotics for use in animals by applying the recently redrafted Special Data Requirements (Part 10 of the Vet Requirements Series: Guidelines for Registering Veterinary Chemicals, NRA 1998), which includes a risk analysis of microbial resistance safety.

Actions

- Companies registering new veterinary antibiotics are now required to provide pre-registration information on antibiotic resistance characteristics to the AVPMA as part of the registration process. Australia and the US are the first countries in the world to implement such a process.

Recommendation 5

That a recognised expert authority (the Working Party on Antibiotics or its successor) defines threshold (or trigger) rates of resistance for antibiotics registered for use in animals and circumstances where usage should be investigated and mitigation proceedings instigated where appropriate. In addition, resistance prevalence data should be included in the product information and this information should be updated on a five-yearly basis.

Actions

- This is an area that has been referred to the EAGAR, as it requires specialist expertise. It requires the development of an antibiotic resistance surveillance system and an antibiotic usage surveillance system in order to progress Recommendation 5. See *Recommendations 5,9 and 10*;
- CIJIG has requested EAGAR to monitor developments in the US where this issue is being progressed.

Recommendation 6

That all antibiotics for use in humans and animals (including fish) be classified as S4 (prescription only).

Recommendation 6 allows for exemptions from being scheduled as S4 on a case by case basis. Such exemptions could be considered in cases where the risk of promoting antibiotic resistance was considered minimal, and where third party audited industry codes of practice are established. Ultimately any decisions on this matter will be made by NDPSC.

Actions

- In June 2002, the National Drugs and Poisons Schedule Committee (NDPSC) considered ionophore antimicrobials for inclusion in the S4 schedule. The NDPSC decided not to schedule all ionophores as S4 (some were and continue to be S4).
- The NDPSC has put together a timetable for consideration of all antibiotics not currently scheduled as S4. (<http://www.health.gov.au/tga/docs/html/ndpsc/ndpscgan.htm#2003>) The NDPSC considered a number of antibiotics for S4 scheduling at their February 2003 meeting. The scheduling outcomes can be viewed at <http://www.health.gov.au/tga/docs/html/ndpsc/records.htm> (pages 42-55).
- The scheduling of products containing virginiamycin was also assessed as part of the AVPMA's review.

Recommendation 7

That the Agricultural Resource Management Council of Australia and New Zealand (ARMCANZ) implement a harmonized approach by all States and Territories in Australia (including clarification of responsibilities) to the control of use of veterinary chemicals, including antibiotics.

Actions

See *Recommendation 8 below*.

Recommendation 8

That, following the implementation of Recommendation 7, the relevant State and Territory health agriculture/primary industries legislation is amended to make it an offence to prescribe and/or use a veterinary chemical product contrary to a APVMA label restraint, unless authorised to do so by an APVMA permit.

Actions

The implementation of a harmonised approach by all States and Territories in Australia to the control of use of veterinary chemicals, including antibiotics is currently being progressed. Many jurisdictions already have legislation in place that incorporates the control of use principles agreed by PISC in August 1999. The principles covered:

- Treatment controls which give specific powers to veterinarian and responsibilities to animal carers;
- Supply controls;
- Labelling controls;
- Identification controls;
- Recording controls; and
- General requirements.

Actions pending

- The PISC control of use principles are to be posted on the CIJIG website;
- All States and Territories are expected to incorporate the principles into their legislation by the end of 2003.
- EAGAR recommends that the use of label restraints should be accompanied by an education plan for Veterinarians. EAGAR suggest that longer term legislation should clearly define “food producing animals”.

Recommendation 9

Similar to recommendations made in veterinary medicine, it is recommended that the TGA implement the following:

- inclusion of microbial resistance safety data, including the propensity for promoting resistance and cross-resistance, as a basic requirement of the assessment of all new antibiotics by the TGA, with adoption of similar data requirements to those required in the registration of veterinary antibiotics (Recommendation 4);
- definition by a recognised expert authority (Working Party on Antibiotics or its successor) of the threshold rates of resistance to registered human antibiotics and circumstances where usage should be investigated and mitigation procedures instigated where appropriate; and
- inclusion of national human antibiotic-resistance prevalence data in the product information and updating on a five-yearly basis.

Actions

Refer to Recommendation 3 above.

Monitoring and Surveillance (Recommendations 10-11)

Recommendation 10

That a comprehensive surveillance system be established incorporating passive and active components measuring incidence and prevalence of antibiotic-resistant bacteria and resistance genes, covering all areas of antibiotic use. To achieve this aim, it is further recommended that a multidisciplinary taskforce of relevant experts be formed by the federal ministers of health and agriculture to design, cost and recommend funding mechanisms and management systems for reporting and analysis of antibiotic resistance data in Australia.

The overall surveillance system should include medical (including nosocomial), food-producing animal and veterinary areas, with particular emphasis on the establishment of food-chain (including imported food) and environmental connections, and include molecular studies of resistance genes. The efforts of the taskforce should be directed at adopting a uniform, systematic and synergistic approach across all areas by utilising, enhancing and extending currently available systems and organisational structures.

Actions

- A Strategy for Antimicrobial Resistance Surveillance in Australia is currently being finalised. The strategy and associated action plans encompass surveillance activities in humans (including antibiotic usage and health care acquired infections), animals and animal-derived foods. The strategy has been developed jointly by the Commonwealth Departments of Health and Ageing (DoHA) and Agriculture, Fisheries and Forestry (AFFA).
- The action plans, which include both active and passive components, have been developed by the respective agencies. Input into the food action plan is currently being sought from FSANZ, OzFoodNet and the relevant areas within DoHA and AFFA.
- A Central Coordinating Unit within DoHA has been established for the collation of national surveillance data.
- The strategy and action plans are due to be made available for public consultation in April.
- Aspects of the strategy and action plan for AMR in animals have already begun, with scoping of data for Salmonella resistance in animals currently underway.

Actions pending

- The final draft of the antimicrobial resistance surveillance strategy (and action plans), to go out for public comment.

Recommendation 11

That a comprehensive monitoring and audit system for antibiotic usage be established that covers all areas of antibiotic use. To achieve this aim, it is recommended that the federal ministers of health and agriculture form a multidisciplinary taskforce of medical, veterinary, industry and regulatory experts (including Customs, TGA, Department of Health and Ageing (DoHA), NRA and Department of Agriculture, Fisheries and Forestry – Australia) to refine the current antibiotic import data collection and audit process, and make recommendations to relevant authorities for developing methods of monitoring and audit usage.

Actions

Refer to Recommendation 3 above.

Infection Prevention Strategies and Hygienic Measures

(Recommendation 12)

Recommendation 12

That hazard analysis and critical control points (HACCP)-based food safety procedures be implemented as a means of reducing the contamination of food products with foodborne organisms, including antibiotic-resistant organisms, and that these programs also address on-farm infection control.

Actions

- AFFA in conjunction with FSANZ continues to examine existing procedures, including HACCP to reduce microbial contamination in the production chain (See Appendix 5).
- PIMC Meat Hygiene Standards (underpinned by HACCP) have been developed. The States and Territories are responsible for putting the standards into legislation and their enforcement in the domestic sector. AQIS has this responsibility for the meat export industry.
- In July 2002, FSANZ assumed responsibility for the development of Primary Production and Processing Standards for Australia. These standards are outcome based and focus on food safety in sectors such as seafood, meat, dairy, grains, horticulture, honey, poultry and eggs.
- Industry-based Quality Assurance (QA) Systems continue to be based on HACCP.

Recommendation 13

That where the intensive animal industries (such as meat chicken, pig, feedlot cattle and aquaculture) currently depend on the use of antibiotics to improve feed conversion and prevent and treat disease, cost-effective nonantibiotic methods to increase productivity and prevent disease should be developed by these industries. In relation to this, it is further recommended that the federal ministers of health and agriculture explore additional funding alternatives for this work, taking into account the current efforts of the animal industry research and development organisations.

Actions

- An EAGAR workshop was conducted in October 2002 to identify priorities for antimicrobial research in the areas of epidemiology, human health impacts and interventions to limit the emergence and spread of antimicrobial resistance. The workshop was attended by representatives from AFFA, EAGAR, various hospitals and health services providers, animal industry bodies, OzFoodNet and research bodies.

Actions pending

- The EAGAR National Workshop report is posted on the EAGAR Website (<http://www.nhmrc.gov.au/eagar/eagarrrpt.pdf>), and was distributed to all attendees as well as relevant organisations.

Recommendation 14

That DoHA examine current surveillance activities for hospital-acquired (nosocomial) infections, particularly for antibiotic-resistant strains, and that the department work with stakeholders (including the States and Territories) to further develop a comprehensive and standardised national system for monitoring nosocomial infections that will facilitate:

- earlier recognition of a public health problem;
- improvements in infection control and hygiene measures; and
- the timely development of national standards, guidelines and practices for both surveillance and infection control in the health care setting.

Recommendation 15

That prudent use codes of practice for antibiotics be developed and regularly updated by medical and veterinary peak bodies, including learned societies, professional organisations, producer organisations, pharmaceutical companies and State/Territory medical and veterinary registration boards, and promulgated to their members.

Actions

The Australian Veterinary Association and its special interest groups are developing a comprehensive range of general and species-specific professional literature to assist veterinary practitioners on prudent use of antimicrobials.

Recommendation 16

That regularly updated 'antibiotic use guidelines', both human and veterinary, supported and endorsed by the appropriate professional organisations, the pharmaceutical industry and the federal and State and Territory departments of health and agriculture, are widely disseminated and adopted as a 'standard of care' by training institutions, and established as the benchmark for undergraduate and postgraduate teaching. The effectiveness of the 'antibiotic use guidelines' in ensuring prudent prescribing of antibiotics needs to be evaluated every five years.

Actions

In the veterinary field "Antimicrobial Resistance Guidelines for Vets" is available.

Recommendation 17

That, as a priority, learned (medical and veterinary) and professional societies develop continuing educational programs on the issue of antibiotic resistance, including a focus on the prudent use principles, antibiotic use guidelines and alternatives to antibiotic usage.

Actions

Refer to Recommendation 15 above.

Further Research

(Recommendation 18)

Recommendation 18

That all relevant research funding agencies be asked to give priority to research into antibiotic resistance, including:

- alternatives to antibiotics for growth promotion;
- alternatives to antibiotics for prevention and treatment of infections (including vaccines);
- molecular epidemiology and mechanisms of gene transfer;
- population dynamics of antibiotic resistance; resistance epidemiology;
- pharmacoepidemiology;
- efficacy of interventions to reduce antibiotic prescribing and use;
- clinical efficacy studies; and
- rapid diagnostic tests.

Actions

Refer to Recommendation 13 above.

- EAGAR has written to R&D agencies regarding priorities for antibiotic resistance.

Actions pending

- AFFA's report on R&D activities to be posted on the CIJIG website.

Communication

(Recommendations 19-20)

Recommendation 19

That an ongoing funded education strategy be developed by the relevant federal/State/Territory departments with input from stakeholders to provide appropriately targeted information about infection, the role and benefits of prudent antibiotic use and the risks of overuse to the public, relevant professional bodies and stakeholders.

Actions

See Appendix 5

Recommendation 20

That a recognised expert authority (the Working Party on Antibiotics or its successor) assume responsibility for ensuring and coordinating the communication of data on antibiotic usage and prevalence of resistant bacteria to the public and other relevant stakeholders on a regular basis, taking into account the sensitivities of trade and other international implications.

Actions

Refer to Recommendation 21 below.

Coordination of The Resistance Management Program

(Recommendations 21-22)

Recommendation 21

It is recommended to the Ministers of health and agriculture that:

- the current functions and membership of the Working Party on Antibiotics (WPA) be expanded to carry out the antibiotic risk management program outlined in earlier recommendations;
- the administrative and reporting arrangements of the WPA (or its successor) be clarified so it can maintain its independent position and advise the TGA and the NRA and other agencies/statutory bodies as required;
- the coordination of the antibiotic risk management program across government portfolios and industry be provided with secure recurrent funding for the additional tasks outlined in Recommendations 1 to 20;
- the WPA or its successor keep the regulatory framework for the use of antibiotics in human and veterinary medicine and food-producing animals under review and make appropriate recommendations to the regulatory authorities to review the uses of particular antibiotics, taking account of
- the importance of the drug or class of drug in human and veterinary medicine, and
- the potential for human exposure to antibiotic-resistant bacteria acquired from food-producing animals that are human pathogens or that can transfer their antibiotic resistance genes to human pathogens;
- the WPA or its successor, the NRA and the TGA develop appropriate procedures to ensure accountability and transparency of its activities, including established time-frames for reviews;
- the WPA (or its successor) develop a five-year strategic plan and an annual budget for its activities; and
- the operations of the WPA (or its successor) be subject to a five year independent review program.

Actions

EAGAR provides independent scientific and policy advice on antibiotic resistance issues, and works closely with CIJIG to develop and implement the national antibiotic resistance management program. As with its predecessor, the WPA, EAGAR continues to provide advice to the regulatory bodies, AVPMA and TGA, on matters relating to antibiotic resistance, when requested.

EAGAR meets every 3 months.

Refer to the EAGAR website for further information.

(<http://www.nhmrc.gov.au/eagar/contents.htm> - See also, Appendix 2 - EAGAR Terms of Reference and Membership List)

Recommendation 22

That DoHA convene a working group to develop a fully coordinated resistance management plan for human antibiotics, incorporating the elements included in Recommendations 9, 10, 11, 14, 15, 16, 17, 18, 19 and 20. The plan so developed should be incorporated into the recommended functions of the WPA or its successor (see Recommendation 21).

Actions

- CIJIG was established in November 2000. CIJIG facilitates the coordination and communication of AMR management actions between the sectors.
- CIJIG has met four times since November 2000 and will normally meet two to three times per year.
- Refer to the CIJIG Website for further information. (<http://www.health.gov.au/pubhlth/strateg/jetacar/index.htm> - See also, Appendix 1 - CIJIG Terms of Reference and Membership List)
- In accord with CIJIG's Terms of Reference, funding options are being explored that will support the advisory activities of the EAGAR. The NHMRC continues to negotiate with the DoHA on this issue.

Supporting Documentation

- The Commonwealth Government Response to the Report of the Joint Expert Technical Advisory on Antibiotic Resistance (JETACAR) (<http://www.health.gov.au/pubhlth/publicat/document/jetacar.pdf>). Commonwealth Department of Health & Aged Care and the Commonwealth Department of Agriculture, Fisheries and Forestry – Australia, August 2000.
- The use of antibiotics in food – producing animals: antibiotic – resistant bacteria in animals and humans (<http://www.health.gov.au/pubs/jetacar.pdf>). Commonwealth Department of Health & Aged Care, Commonwealth Department of Agriculture, Fisheries and Forestry – Australia, September 1999.
- Draft for Consultation, National Surveillance of Healthcare Associated Infection in Australia (<http://www.health.gov.au/pubhlth/strateg/jetacar/pdf/scope.pdf>). Commonwealth Department of Health & Aged Care, Commonwealth Department of Agriculture, Fisheries and Forestry – Australia, April 2001.



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Appendix 1

Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG)

CIJIG Terms of Reference

- (1) CIJIG will facilitate the planning, development, coordination, and implementation of the antibiotic risk management program proposed by the JETACAR, and as supported by the Commonwealth Government Response to the JETACAR.
- (2) To achieve these objectives, the CIJIG will:
 - (a) Consult with industry, State and Territory Governments (in particular through the AHMC JETACAR Taskforce and the SCARM JETACAR Taskforce), professional bodies and other key stakeholders in planning and implementing an effective national response;
 - (b) Liaise with the Expert Advisory Group on Antimicrobial Resistance (EAGAR) to develop a strategic work plan and communication strategy with defined time lines and planned outcomes;
 - (c) Communicate the Government's antibiotic resistant management program to stakeholders and the community;
 - (d) Respond to policy advice and technical advice received from EAGAR to effect a continuing Commonwealth response to the JETACAR;
 - (e) Examine funding options to support the advisory activities of the EAGAR and to facilitate development and implementation of an antibiotic resistance management plan;
 - (f) Establish appropriate working groups and commission work to further investigate or develop the recommendations contained in the Commonwealth Government Response; and
 - (g) Take such other actions as are necessary.
- (3) The Group will also monitor implementation of the recommendations and report progress to:
 - (a) The Minister for Health and Aged Care and the Minister for Agriculture, Fisheries and Forestry;
 - (b) The AHMC JETACAR Taskforce;
 - (c) The SCARM JETACAR Taskforce; and
 - (d) Stakeholders.

CIJIG Membership

(Updated March 2003)

Name	Representation
Prof John Mathews (Joint Chair)	National Centre for Disease Control, Department of Health and Aged Care
Dr Angelo Valois (Joint Chair)	Technical and International Policy, Department of Agriculture, Fisheries and Forestry
Dr Marion Healy	Australia New Zealand Food Authority
Ms Fiona Brooke	Population Health Division, Department of Health and Aged Care
Dr Jonathan Webber	Office of the Chief Veterinary Officer, Department of Agriculture, Fisheries and Forestry
Dr John McEwen	Therapeutic Goods Administration
Mr Peter Raphael	Australian Pesticides and Veterinary Medicines Authority
Dr Peter MacIsaac	Health Services Division, Department of Health and Aged Care
Mrs Cathy Clutton	Office of National Health and Medical Research Council

Appendix 2

EXPERT ADVISORY GROUP ON ANTIMICROBIAL RESISTANCE (EAGAR)

COMMITTEE MEETING 30 APRIL 2001.

The National Health and Medical Research Council (NHMRC) has established an expert advisory group to provide advice to government and regulatory agencies on antibiotic resistance. This follows the release of the Federal Government's response to the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) Report.

Background

In December 1997, the Federal Minister for Health, Dr Michael Wooldridge, and the then Minister for Primary Industries and Energy, John Anderson, set up JETACAR to assess the scientific evidence linking the use of antibiotics in food producing animals and the emergence of antibiotic resistant bacteria.

JETACAR reported that development and transmission of antibiotic resistance is a threat to human health, and established that transfer of antibiotic resistance from food producing animals to humans does occur. JETACAR recommended that the NHMRC establish an Expert Advisory Group to provide advice on measures to reduce the risks of antibiotic resistance in agriculture and human health.

TERMS OF REFERENCE FOR THE EXPERT ADVISORY GROUP ON ANTIMICROBIAL RESISTANCE.

1. The Expert Advisory Group on Antimicrobial Resistance (EAGAR) shall provide expert advice to Commonwealth, State and Territory Governments and Commonwealth Statutory Organisations on:
 - Measures to reduce the risks of antibiotic resistance
 - Assessment of the risk of developing resistance to new and marketed antibiotics
 - Public health implications of antibiotic resistance
 - The monitoring of antibiotic use
 - Surveillance and monitoring of antibiotic resistance
 - Antibiotic use in medical and veterinary practice and food production
 - Relevant research and evaluation needs
 - Educational strategies and
 - Other matters relating to the control of antibiotic resistance in Australia.
2. The advice of EAGAR shall be based on an ongoing review of the relevant scientific literature, other available relevant scientific data, surveillance information and measures already adopted to minimise the risks of antibiotic resistance.

Membership of EAGAR

(Updated March 2003)

Name	Primary area of expertise
Associate Professor John Turnidge (Chair)	Public health, Women's & Children's Hospital - Adelaide
Dr Mary Barton	Veterinary science, University of South Australia
Professor Richard Benn	Microbiology, Royal Prince Alfred Hospital
Dr Keryn Christiansen	Microbiology (Australian Drug Evaluation Committee member), Royal Perth Hospital

Dr Grahame Dickson	Medicine, Therapeutic Goods Administration
Associate Professor Peter Collignon	Infectious diseases, Canberra Hospital
Professor Julian Rood	Molecular biology of antibiotic resistance, veterinary medicine, Monash University
Dr Gary Lum	Pathologist, microbiologist, Territory Health Services
Dr Jonathan Webber	Veterinary Science, Department of Agriculture, Fisheries and Forestry
Dr David Jordan	Veterinary Science, Epidemiology
Dr Tim Dyke	Australian Pesticides and Veterinary Medicines Authority
Dr Tom Grimes	Veterinary science, Poultry Industry
Associate Professor John Tapsall	Molecular microbiology, epidemiology and surveillance, Prince of Wales Hospital



Appendix 3

Monitoring implementation – AHMC and PISC

In August 2000 the Australian Health Ministers Conference (AHMC) appointed the AHMC JETACAR Taskforce to monitor and report to the Minister for Health and Ageing on the implementation of the Government Response. This group submitted its Final Report to the AHMC as Out-of-Session Item No 19 (ie OOS Item No:19) in November 2002. This concludes the role of the Taskforce.

Membership of the AHMC JETACAR Taskforce

Name	Representation
Dr John Camie (Chair)	Victoria, Dept of Human Services
Dr Rod Givney	South Australia, Dept of Human Services
Dr Alistair McGregor	Tasmania, Royal Hobart Hospital
Dr Gary Lum	Northern Territory, Royal Darwin Hospital
Dr Paul Dougdale	Australian Capital Territory, ACT Health
Dr Michael Whitby	Queensland, Prince Alexander Hospital
Dr Dorothy Jones	Western Australia, Health Dept of WA
Dr Marion Healy	Food Standards Australia New Zealand
Dr Alex Proudfoot	National Health and Medical Research Council
Prof. John Mathews or Ms Fiona Brooke	Commonwealth Department of Health and Ageing

AHMC JETACAR Taskforce terms of reference

- (1) To facilitate implementation of the recommendations of the JETACAR report in cooperation with the Commonwealth and having regard to the Commonwealth Government response to the JETACAR report.
- (2) To monitor progress towards implementation of the recommendations of the JETACAR report and to consult with the Commonwealth and other key stakeholders in preparation of a progress report.
- (3) To report to AHMC by 1 July 2001.

The Primary Industries Ministerial Council (PIMC), formerly the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ), appointed the PISC Taskforce on JETACAR to monitor the JETACAR implementation from the animal industry perspective.

Membership of the PISC Taskforce on JETACAR

Name	Representation
Dr Robin Vandegraaff (Chair)	Primary Industries and Resources South Australia
Mr David Skerman	Meat and Livestock Australia
Mr John McQueen	Australian Dairy Farmers Federation Ltd
Dr Angelo Valois	Co-chair CIJIG, AFFA
Dr Kevin Doyle	Australian Veterinary Association
Dr Jonathan Webber	Department of Agriculture, Fisheries and Forestry
Mr Chris Etherton	Primary Industries and Resources South Australia
Dr Sarah Plant	Agriculture Western Australia
Mr Hugh Miller	Victorian Dept Natural Resources and Environment

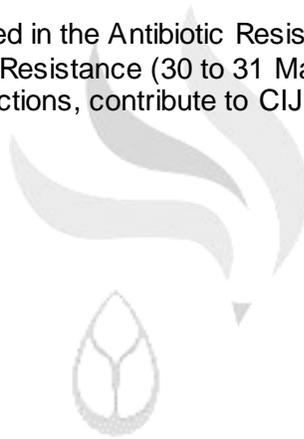
Dr Tom Grimes	Australian Poultry Industry Association
Dr Paul Higgins	Pork Council of Australia Ltd
Mr Lee Cook	New South Wales Agriculture
Mr Rick Webster	Queensland Dept of Primary Industries
Dr Leigh Nind	Australian Pesticides and Veterinary Medicines Authority

PISC Taskforce on JETACAR terms of reference

- (1) To facilitate implementation of the JETACAR recommendations, as modified in the Government Response.
- (2) To provide progress reports to PISC, initially in March 2002.

The PISC Taskforce on JETACAR met on 14 February 2002 to discuss the progress in implementing the agricultural aspects of the JETACAR recommendations. The taskforce reported to PISC in March 2002. The taskforce plans to meet with stakeholders later in 2002 to discuss the proposed antimicrobial resistance monitoring and surveillance plan.

Members from both Taskforces were actively involved in the Antibiotic Resistance Surveillance Workshop (4 May 2001) and the National Summit on Antibiotic Resistance (30 to 31 May, 2001). The two groups, with their industry and State/Territory Government connections, contribute to CIJIG activities and provide advice in their specific areas of expertise.



Appendix 4

Communication and consultation

In December 2000, the Chairs of CIJIG, AHMC JETACAR Taskforce, and the SCARM JETACAR Taskforce (now the PISC Taskforce on JETACAR) wrote jointly to key stakeholders informing them of the implementation process, the roles of the respective committees, and asking them for their support. Responses have been circulated to the members of CIJIG, AHMC JETACAR Taskforce, PISC Taskforce on JETACAR and EAGAR, and will be considered by the CIJIG and EAGAR in the context of developing future strategies to control antibiotic resistance.

The CIJIG and EAGAR are working collaboratively to develop a strategic work plan. The planning process will involve stakeholder consultation, and the plan will be accessible on the *Implementing JETACAR* web site.

To keep stakeholders informed of progress, the *Implementing JETACAR* web site was launched in March 2001. The site contains progress reports, information on the implementation process, and key dates for coming events:

<http://www.health.gov.au/pubhlth/strateg/jetacar/index.htm>.

An important event in May 2001 was the National Summit on Antibiotic Resistance. This was the first main public forum for communicating the messages of JETACAR to the broader community, in particular to the veterinary and medical communities and various associated industries. It also provided participants, including the public, with the opportunity to raise concerns, identify gaps, and to suggest ways of implementing the JETACAR recommendations in a coordinated way throughout the various sectors. A communique of the National Summit on Antibiotic Resistance is available on the *Implementing JETACAR* web site together with the individual presentations from the speakers.

The National Summit provided a forum for exchanging vital information and fostered multi-sectoral support for a national antibiotic resistance management program. It also provided opportunity for different agencies and individuals to meet and establish networks. An important component of the national antibiotic resistance management program will be the development of a communications and education strategy in 2002. The EAGAR will take an advisory role in the development of this strategy, together with the CIJIG through its various member agencies, the National Prescribing Service (NPS), the Pharmaceutical Health and Rational Use of Medicines (PHARM) committee and consumer groups.

Scoping and development of a national antibiotic resistance surveillance system is also underway. The antibiotic resistance surveillance workshop, held in Melbourne on 4 May 2001, was the first step in this consultation process.

Between June and September 2001 the Commonwealth hosted an extensive consultation process, consisting of focus groups and individual submissions to seek further input into the development of an antibiotic resistance surveillance plan. The consultation team consisted of an independent contractor, officers from the Commonwealth Departments of Health and Ageing, and Agriculture, Fisheries and Forestry – Australia. It is anticipated that an antibiotic resistance strategy will be available for public comment in second half of 2002.

Appendix 5

Recommendation 12 – Hazard Analysis Critical Control Point *(Updated by FZANZ March 2003)*

Considerable work is already under way by Food Standards Australia New Zealand (FSANZ) and AFFA to investigate and document the Hazard Analysis and Critical Control Point (HACCP) procedures that are already in place to reduce microbial contamination in the food production chain to assist in implementing this recommendation. AFFA (including the Australian Quarantine and Inspection Service, (AQIS) and FSANZ met in mid-June 2001 to finalise the following joint report on relevant HACCP procedures currently in place.

The Departments work program assessing the costs, benefits, and efficacy of HACCP-based food safety programs is drawing to a close. The Department will provide a formal draft report to FRSC in August 2002. A final report will be presented to ANZFRMC in November.

Joint AFFA/FSANZ report on recommendation 12

The Commonwealth, State and Territory Governments and industry share responsibility for food safety. This includes the development, implementation and enforcement of policies and regulations.

Activities/Strategies: Government

Food Safety Regulatory Measures: The Commonwealth and the States and Territories share joint responsibility for the development of food safety regulation and policy. States and Territories have responsibility for the implementation and enforcement of these regulations by enactment through State and Territory legislation, including the Food Acts, Meat Acts and Dairy Acts. The State and Territory Food Acts include the requirement for the production of safe food for all food businesses, including primary producers. The food safety standards were developed by FSANZ at the request of Health Ministers as the means to ensure that this requirement is met. Primary food producers are able to use mechanisms, other than the food safety standards, to meet their obligation to produce safe food. These include industry-driven, market-driven or alternative regulatory arrangements.

(1) The Australia New Zealand Food Standards Code: FSANZ, in close consultation with State and Territory health departments, developed four food safety standards that introduce national food safety requirements for all Australian food businesses, other than primary producers. These standards represent a new, preventive approach to regulating food safety, with the onus resting with the food business to adopt and implement preventive safety measures.

Three of these standards have been accepted: interpretation and application; food safety practices and general requirements; and food premises and equipment. These standards applied from 24 February 2001 and come fully into force as each State and Territory makes the changes needed to enact the standards under their own laws and regulations.

The fourth standard requires food businesses to develop and implement a food safety program based on HACCP principles. In October 1999, a decision on the national mandatory adoption of food safety programs was deferred pending more research into the efficacy and costs of food safety programs and the incidence of food borne illness in Australia. The Commonwealth Department of Health and Ageing is funding this work over a three-year period (2000-2003). Such data would enable better-informed decisions about whether food safety programs should be mandated and, if so, what form they should take. However, in the interests of national consistency, the food safety programs standard was adopted as a 'model' standard in November 2000. Under this arrangement, jurisdictions may adopt the standard according to their own timeframes and apply it to the types of businesses considered appropriate in their jurisdictions.

One State (Victoria) has already enacted legislation to require food businesses, with the exception of retailers of low risk pre-packaged food, to develop and implement food safety programs (effective from 1 January 2003).

The Commonwealth, through the Population Health Division within the Department of Health and Ageing, initiated 15 projects in six key areas designed to complement each other and meet the expectations of Health Ministers. The key areas are:

- determining the incidence and causes of foodborne illness (OzFoodNet);
- assessing the costs, benefits and justification for food safety programs;
- developing resources to assist local, state and territory governments implement, interpret and enforce the national food safety standards consistently;
- developing resources to assist charities, not-for-profit groups and volunteer organisations make safe food;
- developing resources to assist industry implement food safety programs and meet the national food safety standards; and
- providing information to consumers on good food safety practices.

The initial program of work on food safety is drawing to an end and a body of evidence has been developed to help Australia consider options for the regulation of food safety management.

At its meeting on 28 August 2002, the Food Regulation Standing Committee (FRSC) agreed that a FRSC policy working group be established to develop options for food safety management in Australia based on the national three year program of work. It was also agreed that this working group report back at the next FRSC meeting in June 2003 with policy options for Ministers.

The working group is currently working on two tasks. Task 1 looks at highest risk food sections and the possible implementation of Food Safety Programs. Task 2 is to identify a process for the risk profiling of food businesses to allow for the identification of all industry sectors into risk categories as part of a process to identify the most appropriate form of food safety management they should undertake.

FSANZ has also undertaken several projects to assist in the implementation of food safety programs. These include:

- Audit system to provide a nationally consistent approach to the enforcement of food safety programs;
- Priority classification for all food businesses, based on risk. The priority assigned to a given food business will influence if, and by when, a food safety program is required as well as the initial audit frequency; and
- A document *Framework for the Development of Food Safety Program Tools* to guide industry bodies and other organisations in the development of simple, practical and cost effective tools to assist individual food businesses to develop a food safety program.

Primary Production and Processing Standards: Under new food regulatory arrangements that came into effect on July 1 2002, FSANZ now has the sole responsibility for developing Primary Production and Processing Standards. In the past this responsibility has resided with various bodies in the agriculture portfolios at Commonwealth and/or State levels. The transfer of responsibility for primary product standards to FSANZ will ensure that, for the first time in Australia, all domestic food standards are integrated and that food regulatory decisions are considered through a whole of chain 'paddock to plate' approach. This is also consistent with international approaches to managing food safety where it has been identified that in order to ensure safe food, responsibility must be taken at all points across the food chain. The new nationally enforceable Standards will form a new Chapter 4 of the *Food Standards Code* and will apply to Australia only. The primary industry sectors that the standards are expected to apply to include but are not limited to Seafood, Meat, Dairy, Horticulture, Honey, Poultry and egg production. The first primary production and processing standard currently under development is for the seafood sector. An Issues Paper, raising a number of issues for consideration in the development of the seafood standard, was released for public comment during December 2002 and February 2003. The Standards will be developed using the best available science and technical expertise, an articulated risk assessment and risk management approach, and wide public consultation. The emphasis will be on food safety not food quality, and consideration may be given to the mitigation of food safety hazards using a food safety plan approach. The new Primary Production and Processing Standards will deliver outcome based, rather than prescriptive requirements and be consistent with Chapter 3 of the *Food Standards Code*. In keeping with FSANZ's statutory requirements, the standards development process will involve extensive consultation with all primary industry sectors, stakeholders and interested parties and will also take into account commodity areas where primary production codes of practice currently exist.

(2) The ARMCANZ Meat Hygiene Standards: A number of standards for the hygienic production of meat, poultry and game meat have been developed through the Meat Standards Committee of ARMCANZ (now PIMC). The States are responsible for putting the standards into legislation and providing administrative arrangements for their enforcement in the domestic sector. The Commonwealth, through AQIS, has this responsibility for the export meat industry. HACCP underpins all the standards. It is envisaged the standards will eventually be reviewed as part of the development of Primary Production and Processing Standards under FSANZ.

Activities/Strategies: Industry

Industry-based Quality Assurance (QA) Systems: Risk based quality assurance systems, incorporating HACCP principles, form the basis of control of food borne hazards across food produced in Australia. Microbial hazards are addressed in company HACCP programs where such hazards are identified as being reasonably likely to occur in that food. Government and industry in Australia continue to evolve food safety controls based on contemporary understandings of HACCP and risk analysis as elaborated in international fora, particularly the Codex Alimentarius Commission.

Many primary industry sectors have made considerable headway in introducing quality assurance systems, including HACCP components, on farms. Examples include CATTLECARE, Flockcare, Graincare, Freshcare, and SQF 2000 SeaQual. Additionally, all of the major supermarket chains in Australia require all of their suppliers to implement HACCP based quality assurance systems as a prerequisite for doing business.

