

**COMMUNITY CONSULTATIVE COMMITTEE
MINUTES OF MEETING CCC31**

20 May 2004

John Curtin House, Canberra

MEMBERS PRESENT

Jenni Mack (Chair), Liz Hanna, Jane Fuller, Anne Stanton, Andrew Duncan

APVMA OFFICERS PRESENT

Eva Bennet-Jenkins, Tim Dyke (part), Dennis O'Leary (part), Kathleen Allan, Peter Dagg (part), Ron Hogg (part), Martin Holmes (part), APVMA review evaluators (part).

APOLOGIES

Sid Cowling, Sam Beechey, Alison Brinson

AGENDA ITEM 1 – WELCOME AND APOLOGIES

The Chair welcomed members and APVMA staff.

There was brief discussion about the progress made towards finding a replacement for Ben Cole who resigned from the committee in February. Eva advised that the APVMA had sought nominations from a number of environmental organisations as well as the National Environmental Consultative Forum. Two expressions of interest had been received and the APVMA was awaiting formal their formal submission. In addition Mr Warren Godson (People's Environment Protection Alliance) had approached the APVMA for information about selection to the CCC. Once all submissions had been received the APVMA would prepare a recommendation for a suitable CCC candidate for approval by the Board at its June meeting. Members were advised that the Committee Chair would be involved in the APVMA's consideration and recommendation process. Jenni advised that she had drafted a letter to the APVMA Chair Dr Sheridan that, amongst other things, stressed the importance of the CCC Chair's involvement in the consideration of CCC member nominations. Members approval of the content of the letter was sought.

Letter approved.

Jenni suggested that CCC might consider whether CCC appointments include nomination of alternate members who could attend meetings in a member's absence. Eva reminded the committee that members were appointed as individuals rather than organisations. She added that the issue is worth considering though. Liz Hanna raised the issue that it might be difficult to find a willing and able alternate as occasions where CCC members cannot attend is in some cases only rare. In regards to the meeting process in general, Jane felt that two-day meetings would allow the Committee to better deal with business. The meeting agreed that this could be considered on a needs basis.

AGENDA ITEM 2 – ADOPTION OF AGENDA

The agenda for CCC31, with the addition of the virginiamycin review as a supplementary item, was adopted.

AGENDA ITEM 3 – MINUTES OF CCC30

The minutes of CCC30 were accepted as a true and accurate record of CCC meeting 30(26 February 2004).

AGENDA ITEM 4 – ACTIONS ARISING FROM THE PREVIOUS MEETING

Action 27.5 Eva to arrange for a presentation on 1080 to be given to CCC members at a future meeting.

Eva told members that a presentation on the 1080 review including details of the recommendations could be placed on the August meeting agenda.

DrumMUSTER issues

To be dealt with as part of the Product labelling and container management work plan item.

Liquid fertiliser issues

The meeting noted that a letter outlining CCC concerns regarding the use of liquid fertilisers as a diluent for agricultural chemicals had not yet been prepared. The meeting noted that CCC is seeking advice from the APVMA on whether use of an agricultural chemical product with a liquid fertiliser as a diluent was outside label recommendations and thus a control of use issue. Eva advised that this depended on how precise label instructions with regards to diluents to be used are on individual products and that clearer instructions may be warranted on labels in this regard. The meeting noted that the issues of concern relating to the use of fertilisers as diluents included, compatibility, mixing, efficacy, crop safety and possibly residue and withholding periods. Eva advised members that it is appropriate for the issue to be addressed by the APVMA Registration Liaison Committee (RLC) which consists of representatives of each of the States and Territories, who are responsible for control of use of pesticides and veterinary medicines. Eva agreed to seek input from the APVMA Chemistry and Residue Program about the compatibility and residue issues and from the Pesticide Teams in relation to mixing, efficacy and crop safety issues and prepare an issues paper from the CCC for consideration at a future RLC meeting.

Action 31.1 Eva to prepare a paper, outlining the liquid fertiliser issue, for consideration at a future RLC meeting.

4.1 APVMA Fees Review

Eva provided members with an update on the APVMA fees review. Members were reminded that the fees review was put on hold (Senator Troeth's press release). In the meantime, interim arrangements are being investigated to address the organisations budgetary needs. The proposals are to increase the registration renewal fee for 2004-2005 by 25%.

Tim emphasised that the fundamentals of the fees review was the Australian Government's cost recovery policy.

4.2 Regulatory Science Quality

Eva advised the committee that the project was on hold and that it needed to be reallocated as a result of Tim's promotion to Program Manager, Quality Assurance and Compliance.

AGENDA ITEM 5 – MEMBER REPORTS

5.1 CCC Member Activity

Item deferred

5.2 CCC Member brief

Item deferred.

5.3 Member issues

5.3.1 Update request: GM resistance management committee (Anne Stanton)

Item deferred

5.3.2 Update request: APVMA performance monitoring program (Anne Stanton)

Item deferred.

5.3.3 PSIC NGO workshop report – development of a new framework for the management of agvet chemicals, National Operating Principles and coordinated website (Anne Stanton).

Members NOTED Anne's report.

Members agreed that the CCC should write to DAFF to express interest in involvement in future meetings and workshops relevant to the National Registration Scheme. In the letter, the CCC would also be able to provide suggestions for resourcing community participation in such meetings.

Action 31.2 CCC to write to DAFF expressing interest in being involved in future meetings or workshops relevant to the National Registration Scheme that require community or public input or involvement.

AGENDA ITEM 6 – PROGRESS OF WORK PROGRAM ITEMS

6.1 AERP Ag: Brief update

Jenni welcomed Tim Dyke and Peter Dagg and invited them to provide a brief update on the implementation of the AERP communication strategy.

Peter advised members that the communication strategy for the AERP is in draft form and would be implemented gradually over the coming 12 months. Dennis stated that the APVMA is yet to determine the extent of promotion it will undertake. Liz added that success of AERP to capture the information will depend on how well it has been promoted to and penetrated the relevant areas.

Anne expressed disappointment that there is no scope for radio or television advertising. She asked whether community service type announcements had been considered. Dennis clarified that government policy (with reference to the Government Communications Unit) does not support public service advertising.

6.2 Communication/consultation

Members NOTED the development of the CCC page and links on the APVMA website. Members were pleased that the first e-bulletin had been finalised and distributed.

Members agreed that they needed to encourage members of their networks to subscribe to the list-server to receive e-bulletin and other announcements.

Members felt that it may be a good idea to include links to member's organisation websites.

Action 31.3 Members to provide Kathleen with details of their organisation's website addresses so that hyperlinks can be created.

6.3 Spray drift risk management

No progress to report.

6.4 Product labelling and container management

Members discussed a number of ways to progress this work plan item of product labelling and container management. The aim of the item is to improve both the content of product labels and the safe and effective handling and disposal of containers. The meeting agreed that the CCC will be seeking to improve the APVMA's oversight of the area but also encouraging it to encourage other organisations involved in this area to raise their standards and practices.

The committee noted that the APVMA is currently developing a new concept label for products that will also involve a major revision of the pesticide and veterinary medicine labelling codes. Labelling issues in relation to container management will be an integral part of the labelling project. The meeting noted that there were a

number of activities ongoing relating to container management including the Avcare project looking at container design.

Members agreed, that in the first instance, it is important that the committee gain a detailed understanding of the issues associated with container management including labelling. To do this the meeting agreed to seek input from a range of stakeholders.

Members agreed to investigate some of the practical issues of container management and labelling with their networks. This will be done via the e-bulletin and other mechanisms to increase CCC's understanding of the issues.

The APVMA agreed to prepare a background paper outlining the regulatory requirements associated with container management including labelling for CCC32.

Members agreed that the issues relating to container management related to:

- design including -durability
- chemical transfer
- safe and efficient handling
- suitability eg shape
- operator friendliness eg graduated marking (closed system)
- disposal including DrumMuster
- labelling including adhesiveness of labels, durability of batch number, date of manufacture etc

Eva agreed to write to a number of organisations including Avcare, NFF, RLC, drumMUSTER, Andy Nicholls, Local governments seeking their input on the container management issues listed above. The letter would set out the scope of the project and ask for any input, assistance or feedback.

Action 31.4 APVMA to prepare a background paper about regulatory requirements associated with -containers including labelling.

Action 31.5 Eva to draft a letter to stakeholders, seeking input into the CCC labelling project.

6.5 Revised CCC work plan

Members agreed that the two major work plan items for the next 12 months would be:

1. Product labelling and container management
2. Community involvement in the APVMA Chemical Review process.

6.6 Chemical Review program

Jenni introduced Ron Hogg and invited him to address the meeting, outlining the current APVMA Chemical Review process. Eva and Ron introduced a number of review team evaluators.

Ron provided a detailed overview of the chemical review process. See attached.

Ron asked members to provide comment on how the APVMA could improve community consultation for chemical reviews and specifically, what role the APVMA could play in community consultation.

Jenni thanked Ron and the review evaluators for their attendance and input.

Members agreed that, to progress the review of community input into the chemical review process, the CCC would prepare an issues paper for consideration by the APVMA. Jenni agreed to start the paper. Members were asked to consider the chemical review process, outline any issues with the existing process and identify process improvements. Eva agreed that this was an important issue that could take considerable time. It is therefore appropriate that members are entitled to claim up to an additional 10 hours of work between meetings for consideration of the level and effectiveness of community involvement in the chemical review process.

Action 31.6 Kathleen to circulate a copy of the Chemical review process presentation to members.

Action 31.7 Members to provide feedback regarding the chemical review process to Jenni for inclusion in an issues paper to be considered at CCC32.

7 APVMA Reports

Members discussed the content and appropriateness of the APVMA reports.

Eva introduced the Balanced Scorecard (BSC) approach that is being adopted by the APVMA for all planning and reporting activities. Eva showed a copy of the Dashboard report that is given to the Board that provides a brief overview of how the APVMA is performing in key areas. Eva advised members that the APVMA could tailor a BSC and Dashboard type report for the CCC that could replace the existing reports. Members were enthusiastic about this.

Action 31.8 APVMA to develop a BSC and Dashboard report for the CCC.

7.1 Registration

Members NOTED the Registration Programs' Report.

Eva discussed the timeframe issue with members. Timeframes have been affected by a 200% increase in applications over the last two years that has resulted in a backlog of applications that need to be progressed. The new label approval process has also impacted on timeframe compliance. Eva advised members that the situation has improved over recent months.

Liz Hanna asked how the APVMA dealt with applications where the chemical is under review. . Eva clarified that applications received during a review were identified and the applicant informed about the review. Applications are assessed and registered/approved against the standards and criteria but are subject to the outcomes

of the review. The requirements to comply with the outcomes of the review are applied via specific conditions of registration.

7.2 Chemical Review

Members NOTED the Chemical Review Report.

7.2.1 Update request: CCA (Anne Stanton)

Members NOTED Anne's request for additional information on the CCA review.

Anne asked whether the APVMA has conducted any testing of material treated with CCA. Eva confirmed that the APVMA had not and that the organisation seeks data from registrants. Anne remains concerned that the APVMA relies on companies to supply supporting data and that independent testing in Australia should be conducted. She questioned whether this was an issue of regulatory science quality.

Andrew advised members that when he recently purchased treated timber; there was no label warnings or information for consumers. Eva stated that an important aspect of the consultation part of the review is the industries ability to demonstrate that retailers are able to supply consumers with appropriate information about the treatments used on different types of timbers. There is however, no legal requirement that this is the case at this stage.

Members sought clarification at what stage in a review should action (eg. recall) be taken. Eva stated that when the APVMA has credible scientific evidence that continued use presents an unacceptable risk, the APVMA can and will act immediately. If however, the APVMA receives new information that merely casts doubt on whether the continued use may present a risk this information first needs to be assessed. If, during or at the end of the assessment it becomes apparent that the new information demonstrates an unacceptable risk the APVMA can and will take action. In order to take regulatory action the APVMA must first determine whether it can or cannot be satisfied that the continued use is unlikely to cause harm.

7.2.2 Virginiamycin Review (Martin Holmes)

Jenni introduced Martin Holmes, Program Manager Veterinary Medicines.

Jenni advised members that she was concerned that the virginiamycin review report had not proceeded through the Board as quickly as hoped. Jenni supported the report prepared by the APVMA and suggested if the delay persisted that the CCC consider sending a letter to the Board outlining its support for the draft report.

Martin was asked to outline the Virginiamycin review process and draft report recommendations.

Martin gave a detailed presentation about the virginiamycin review (see attached).

Martin confirmed that residues are not a problem for virginiamycin. The issue is concerned with the potential for the development of resistance and transfer to humans. Martin explained the concept of antibiotic resistance.

Action 31.9 Kathleen to provide members with an electronic copy of the virginiamycin review presentation.

7.3 Quality Assurance and Compliance Report

Members NOTED the Quality Assurance and Compliance Report.

Members sought clarification why the APVMA has completed its investigation into the insect repellent AERP. Tim advised that the investigation was from a product compliance point of view – that is to see whether there was anything untoward from a compliance perspective. This is separate to the completion of the AERP investigation. The AERP investigation has also been completed with the irritation being classified as ‘possible’. The details have been logged on to the database and will be included in any trend information.

Jenni welcomed Peter Dagg to discuss the AERP report.

Jenni asked about the format of AERP reporting. Peter stated that the reporting is usually done by active constituent so from a regulatory point of view, trends about actives are more easily seen. Reports can be presented however based on whether the report is a human health, environment or efficacy report. Peter also advised that that the CCC would be provided with the annual report that goes into a lot of detail (reporting situations, presenting signs, geographical area etc). If members were interested they could look at the formats of the annual AERP Vet reports that are on the website.

Peter informed members that the quality of reports received to date has been good. Quite a few reports have included supporting medical documentation. Anne asked whether the medical advisory panel had been utilised. Peter stated that up until now, all medical advice has been received from the Office of Chemical Safety within the Australian Government Department of Health and Ageing.

7.4 Board meeting – 22-23 April

Due to time constraints, Eva was only able to provide a list of items discussed at the Board meeting held in Moree on 22-23 April 2004.

Items included:

- 04-05 budget
- 04-05 Operational Plan(BSC approach)
- Minor use initiatives and the appointment of a Minor Use Coordinator
- Development of a quality assurance scheme for agricultural active constituents
- Pool chemicals (specifically the recall action and AAT involvement since)

CLOSE

The Chair thanked members and staff for their attendance.

Meeting closed at 4pm.

Signed

Jenni Mack (Chair)

Kathleen Allan (Secretariat)