

Improved labelling of pesticides - Stage 2

Kevin Bodnaruk AKC Consulting Pty Ltd

Project Number: AH01019

AH01019

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The research contained in this report was funded by Horticulture Australia Ltd with the financial support of all levy paying industries.

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ISBN 0734108079

Published and distributed by: Horticultural Australia Ltd Level 1 50 Carrington Street Sydney NSW 2000

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IMPROVED LABELLING OF PESTICIDES - STAGE 2.

Final Report

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To liaise with the APVMA, Avcare, State government regulatory bodies and industry to improve labelling of pesticides.

AKC Consulting Pty Ltd acknowledges the funding support provided by the Horticultural Australia Limited for this project.

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respect of the matters set out in this publication.

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Media Summary

Horticulture Australia in response to grower concerns has been looking at the issue of pesticide labelling, i.e., their ease of use or lack thereof. Pesticide labels are important as they are meant to communicate, to inform users how to use pesticides safely and efficaciously. If the label is read, understood and its directions followed, the likelihood of agricultural chemicals causing unwanted effects are remote. Coherent labels are therefore a fundamental part of any considered approach to pesticide management.

Unfortunately, what has been found is that pesticide labels are not always easily read or understood. In a previous study a number of areas of concern were identified as needing change. The aim of this project was, using the previous work as a basis, to try and facilitate improvement in pesticide labels via discussions with government and the chemical industry.

While certain elements, identified as being in need of change, have been advanced, progress in the key area of label clarity has been slow. It is believed that there needs to be a greater focus by regulators on the provision of better information to farmers. If farmers are better equipped then issues such as consumer and user safety and environmental protection will be better addressed.

To achieve this it is recommended that government should initiate targeted research to identify those elements on a label in need a greatest change. The results of which could be used to amend labels to ensure that pesticide users are adequately informed in a clear and unambiguous manner.

For more information on the labelling project contact Kevin Bodnaruk on 02 94993833.

TECHNICAL SUMMARY

Horticulture Australia in response to grower concerns has been investigating the issue of pesticide labelling, i.e., their ease of use or lack thereof. Pesticide labels are an important part of farm management as they are meant to communicate too and inform users on how to use pesticides safely and efficaciously. If the label is read, understood and its directions followed, the likelihood of pesticides causing unwanted effects are remote. Coherent labels are therefore a fundamental part of any considered approach to pesticide management. Unfortunately, what has been found is that pesticide labels are not always easily read or understood.

US and European research has identified lack of clarity as a significant problem with regard to user understanding of pesticide labels. A number of factors have been found to contribute to this problem; these included the way in which label statements are worded, i.e., their legalese, their structure and the presentation of information. Current Australian pesticide labels appear to have been written primarily with regard to meeting regulatory requirements rather than the provision of needed information to pesticide users, i.e., that the emphasis appears to be on ensuring that the label text fulfills legislative requirements rather than acting as an effective risk communication document.

No specific Australian research has been carried out in this area and it is proposed that government undertake such work. It is recommended that government should initiate targeted research to identify those elements on a label in need a greatest change. The results of which could be used to amend labels to ensure that pesticide users are adequately informed in a clear and unambiguous manner.

The report also discusses existing APVMA initiatives designed to, *inter alia*, improve the effectiveness of pesticide labels, e.g., the RLC¹ Concept Label. In addition, it touches on some State initiatives related to improved control of use, e.g., SA Agricultural and Veterinary Products (Control of Use) Act 2002 and international developments such as the GHS². While certain elements, identified as being in need of change, have been advanced, progress in the key area of label clarity has been slow. It is believed that there needs to be a greater focus by regulators on the provision of better information to farmers. If farmers are better equipped then issues such as consumer and user safety and environmental protection will be better addressed.

Finally, the report presents a number of recommendations related to enhanced pesticide labelling. These include the undertaking of local research to specifically identify areas of greatest concern and the development, through consultation, of a strategy to initiate improvement.

For more information on the labelling project contact Kevin Bodnaruk on 02 94993833.

¹ Registration Liaison Committee of the APVMA

² The Globally Harmonised System of Classification and Labelling of Chemicals.

1 Introduction

1.1 Background

In 1999, in response to industry concern, Horticulture Australia Ltd (HAL) contracted ChemCert Australia (Vic) Inc to consult with industry groups to quantify issues with pesticide labels. In the final report ChemCert made a number of recommendations for changes that were needed to pesticide labels and outlined possible strategies on how this might be achieved (Jones *et al.* 2000).

One of the major outcomes of the AH99003 report was the establishment of an AusHort Labelling Sub-committee to assist HAL to act on the report. The Labelling Sub-committee with the assistance of a consultant sought to facilitate changes in pesticide labelling. The initial timeframe for the project was 9 months. This was extended by a further 12 months due to the number of ongoing regulatory initiatives occurring at both federal and state levels. These initiatives had the potential to impact on pesticide labelling, e.g., review and potential reform of control of use legislation and reviews of state based pesticide use legislation. To date these initiatives have resulted in only incremental movement towards improvements in pesticide labelling.

1.2 Purpose of labels

The primary function of a pesticide label should be to communicate, to inform users how to use pesticides safely and efficaciously. It general terms it consists of sections providing information on the identity of the product, use patterns, i.e., circumstances in which the product should be used and how the product should be used, e.g., rate, timing, frequency and harvest intervals; otherwise known as good agricultural practise (GAP). It should also provide information on relevant to user and worker safety, e.g., transport, handling, first aid in the event of an accident and re-entry periods; occupational health, and the environment, e.g., storage, disposal of unused product and used containers.

The structure of pesticide labels is a key issue in ensuring that labels provide information which is not ambiguous and which does not impair grower efforts to follow GAP. A number of studies have identified structure and wording can inhibit correct interpretation and are therefore important factors in ensuring unwanted consumer, user or environmental pesticide exposures do not occur (US EPA 1986, Petre 1994 and Venema *et al.* 1997). Farmers want to use pesticides correctly and need to have labels that contain relevant information that is presented in a clear and understandable manner.

1.3 Label requirements (Regulatory framework)

A range of federal and state requirements governs the amount and presentation of information on a pesticide label in Australia. The 'regulatory framework' covering the use of pesticides in Australia is complex and has significant impacts on what is required, the structure and presentation of information on pesticide labels see Table 1. This framework is comprised of Australian state and federal agencies and the enabling legislation. In addition,

there are a number of international organizations and initiatives that potentially impact on aspects of pesticide labelling, e.g., the Globally Harmonized System for Chemical Hazard Classification and Labelling (GHS).

Table 1. Relevant legislation impacting on pesticide use and pesticide labelling in Australia.

Jurisdiction	Act
Commonwealth	The Commonwealth Agricultural and Veterinary Chemicals Code
Commonweath	(Agvet Code) Act 1994.
	Agricultural and Veterinary Chemicals Code Act 1994 and its
	schedule, the
	Agricultural and Veterinary Chemicals Code (the Agvet Code); and
	Agricultural and Veterinary Chemicals Code Regulations (the
	Regulations).
NSW	Pesticides Act 1999
11511	Clean Water Act
	The Environmental Offences and Penalties Act
	The Environmentally Hazardous Chemicals Act
QLD	Agricultural Chemical Distribution Control Act
QLD	Chemical Usage Control Act, 1988
	Environmental Protection Act, 1995
	Transport Operation Act, 1995
	Workplace Health and Safety Act, 1989
SA*	Agricultural and Veterinary Chemicals (South Australia) Act 1994
	Agricultural Chemicals Act (1955) (as amended 1975, 1978, 1986
	& 1987)
	Controlled Substances Act, 1984
	Dangerous Substances Act
	OHS & Welfare Act, 1986
TAS	Agricultural & Vet Chemicals (Control of Use) Act, 1995
	Dangerous Goods Act, 1998
	Environmental Management & Pollution Act, 1994
	Forest Practices Act, 1985
	Public Health Act, 1998
VIC	Agricultural & Veterinary Chemicals Act, 1992
	Dangerous Goods Act, 1985
	Drugs, Poisons & Controlled Substances Act, 1981
	Environmental Protection Act, 1971
	OH&S Act, 1985
WA	Agricultural Produce (Chemical Residues) Act, 1983
	Agricultural & Related Resources Protection Act
	Health Act
	OH&S Act

^{*} New legislation to be enacted either late 2003 or early 2004.

1.4 Current Initiatives

1.4.1 Australia

The management of pesticide labels domestically currently involve four different agencies at the federal level and each of the states. All have significant roles in determining content and structure of chemical labels. This segmentation of responsibility has been identified as a major impediment to significant label reform. While the APVMA is ultimately responsible for labelling the states, Environment Australia (EA), National Occupational Health and Safety Commission (NOHSC) and Therapeutic Goods Authority (TGA) all have considerable input.

The APVMA has a Registration Liaison Committee (RLC) the purpose of which is to ensure an efficient and coordinated approach to the Commonwealth's responsibilities for the supply of agricultural and veterinary chemicals up to and including the point of retail sale . Pesticide labelling has been one area in which the RLC has been active. The committee meets biannually and consists of APVMA, state and other agency regulators, e.g., EA, NOHSC, Department of Agriculture, Fisheries and Forestry (DAFF) and the TGA.

In March 2003 the APVMA circulated a discussion paper and a concept label for comment. The proposed concept label arose from RLC deliberations, see Appendix I. Input from the labelling sub-committee and industry were sought and relayed to the APVMA. The aim of which is to improve aspects of current labelling for clarity. At this point in time it is uncertain what further progress has occurred on the proposed concept label.

At the state level a number of states are either reviewing or have reviewed their pesticide related legislation. South Australia (SA) is in the process of enacting new legislation, the Agricultural and Veterinary Products (Control of Use) Act 2002. This Act aims to provide a degree of flexibility to farmers in SA with regard to interpretation of certain label statements. For example, pests are not viewed as mandatory, i.e., if crop, rate and frequency are on the label then use of a pesticide against another pest is acceptable.

1.4.2 International

Internationally there is an increasing move towards harmonisation across industries and across jurisdictions. For example, in Europe the Chemicals Policy (COM(2001) 88 final) seeks to harmonise aspects of chemical approval, review and labelling. It covers all chemicals, industrial and agricultural.

Probably of greatest potential impact is the GHS. It is an international effort to harmonize both the criteria for classifying chemicals according to their health, physical and environmental hazards, and approaches for communicating the hazards to workers and consumers via label and Material Safety Data Sheets (MSDS) elements. The GHS has been developed via broad international involvement of governments and non-government organizations (NGOs) from industry, labour and public interest groups. The GHS arose from a 1989 initiative by the International Labour Organization (ILO) concerning the

harmonisation of systems of chemical classification and labelling. The United Nations followed up on the ILO initiative and progressed till the UNCED Rio agreements of 1992.

The aim of the GHS is to harmonise systems for classification and labelling of chemical hazards. The intention is to develop a system that will lead to greater consistency among countries while promoting safer transportation and handling of chemicals in international trade. The stated goal of the GHS is for each country to voluntarily adopt the harmonized recommendations according to their respective needs and circumstances. The scope of the GHS includes all chemicals classified as hazardous. Implementation is expected to take place over the next 3-5 years.

As indicated the GHS is to be adopted voluntarily by each country. In Australia the initial impact of GHS has been in the move by NOHSC to adopt the proposed structure for Safety Data Sheets (SDSs). These will consist of a core set of 16 headings. It is uncertain what impact, if any, the GHS will have on labelling of pesticides in Australia.

2. METHODOLOGY

2.1 Outline

Work in the project has focused on liaising with stakeholders in an attempt to communicate the concerns of horticultural industries with regard to pesticide labels and labelling. Communication activities have centred on ensuring firstly, that horticultural industries perspectives are made known to relevant regulators. Secondly, that the current status of labelling initiatives and their potential implications are made known to horticultural industries; thirdly, ensuring that regulatory agencies are provided with the horticultural industry responses to any issues raised. And lastly, ensuring that chemical manufacturers are contacted and where possible involved in developing solutions to areas identified as problematic.

2.2 Communication

The communication strategy followed was based upon direct contact with stakeholders. This consisted of making contact with stakeholders via face-to-face meetings, telephone contact or participation in meetings and conferences, e.g., participation in GHS Workshop June 2002.

The strategy involved establishing contact with key groups, nominated by the AusHort sub-committee. The purpose of this approach was to raise the awareness of stakeholders of horticultures concerns and establish dialogue between the stakeholders and horticulture.

2.3 Communication activities

2.3.1 Reporting

Regular reports were provided to the responsible HAL Program Manager and the AusHort Labelling Sub-committee. The Sub-committee met three times during the course of the project.

2.3.2 Liaison

Liaised with APVMA, Avcare and individual chemical manufacturers, DAFF, NOHSC, Australian Chamber of Commerce and Industry (ACCI), ChemCert and state departments with regard to current status and potential for labelling reform.

2.3.3 Horticulture Responses

Industry responses were prepared and submitted with regard to the proposed National Code of Practise for the preparation of MSDSs and the APVMA Concept Label discussion paper.

3 RESULTS AND DISCUSSION

3.1 Project Output

Industry responses were prepared and submitted with regard to the proposed National Code of Practise for the preparation of MSDSs and the APVMA Concept Label discussion paper, see Appendix II. The response to proposed National Code of Practice was made via ACCI as NOHSC only recognised ACCI as representing industry, i.e., chemical industry as well as farming industries. The response to the APVMA Concept Label discussion paper was made following consultation with members of the Labelling Sub-committee.

3.2 Action List

An action list was prepared of key activities to be undertaken, see Appendix III. These actions were to be undertaken by either the consultant and or members of the Labelling Sub-committee. The action list was prepared and prioritised following discussions of the Labelling Sub-committee. The areas of concern used in the prioritisation process were those identified in the final report of project AH99003 (Jones *et al.* 2000). The priority of the issue identified determined the allocation of time and resources, i.e., high priority issues were focused upon. Listed below in Table 2 are those issues given a high priority.

Table 2. High priority labelling issues identified by Labelling sub-committee.

Labelling Issue	Action	Priority	Status
Language used	Identify key individuals within state regulatory bodies that need to be contacted in order to make progress on this issue.	High	Ongoing
Info grouping	Endorse APVMA proposals to group mandatory statements.	High	Completed
Print size	Explore what systems used internationally.	High	Incomplete
Label design	Contact experts in communication on label expression, format etc, with regard to label redesign.	High	Incomplete
Single panel directions	Explore what systems used internationally, i.e., other English speaking countries.	High	Incomplete
Control of Use Regs	Elaborate differences in control of use legislation between states.	High	Incomplete
Control of Use Regs	Contact Control of Use Working Group proposing that control of use be standardised to simplify labels.	High	Completed
Electronic Media	Propose to APVMA that full labels be available on APVMA website.	High	Completed
MSDS	Query NOHSC regarding what can be done to simplify MSDS format for agricultural use.	High	Completed
	If response unsatisfactory approach NFF Chemicals subcommittee.	High	Incomplete
Label changes	Propose to Avcare that coloured sticker be placed in a prominent position on container to flag that significant label change has occurred.	High	Completed
MSDS	Investigate opportunities for simplification and supply of MSDS data.	High	Completed

From the entire action in Appendix III it can be seen that the issues identified can be broadly divided into two categories, i.e., those to improve user education and those improve label clarity. It is noteworthy that of the issues given a high priority all relate to improving label clarity.

From Table 2 it can be noted that a number of issues remain incomplete. This, in part, is due to the slow progress being made at the regulatory level to agree and affect reform, e.g., harmonisation of control of use legislation and the RLC proposed concept label. Due to this relatively protracted process opportunities for horticultures meaningful involvement have been limited.

3.3 Project Outcomes

- Formation of Labelling sub-committee
- Development of an action list based upon the prioritised areas of concern identified in AH99003.
- Horticulture involvement in APVMA discussions with regard to proposed label reforms.
- Contact made with various regulatory and chemical industry stakeholders on issues relevant to labelling.

4 FUTURE CONSIDERATIONS:

4.1 Label clarity

If the label is read, understood and its directions followed, the likelihood of agricultural chemicals causing adverse effects are remote. The reading, understanding, and following directions on pesticide labels are contingent on one another. For a user to understand the information, they must first read the label. In order to follow the instructions, they must be able to understand what was read. Therefore, a fundamental issue that must be addressed in any attempt to improve pesticide labels is their clarity, i.e., comprehensibility. A conclusion drawn from this study is that this aspect of label reform is not being given sufficient consideration by regulators.

The available literature is very clear in identifying comprehension as a significant problem (US EPA 1996, Venema *et al.* 1997 and Smith-Jackson *pers. comm.* 2003). In US research (US EPA 1986) it was found that few people read an entire pesticide label. A number of factors were identified as deterring the reading of a label. These included, the "legalese" used and the crowded format of the label text. This issue was further highlighted by the report of the US EPA Consumer Labeling Initiative (US EPA 1996). While no specific Australian research has been undertaken in this area, from anecdotal evidence gathered as part of this study and Jones *et al.* (2000) it appears a similar situation exists locally. In fact it could be concluded that Australian pesticide labels have been written primarily with the regulatory requirements in mind rather than the needs of the pesticide users, i.e., that the

emphasis appears to be on ensuring that the label text fulfills legislative requirements with user comprehension a very secondary consideration.

The aim should be to provide information on labels in a manner that the intended audience, the user, can easily find and understand. Instructions need to be clear, particularly with regard to mandatory statements, in order to minimise any confusion. Therefore, labels need to be made simple and unambiguous.

A number of examples were cited in discussions with industry representatives where confusion could exist over the interpretation of label statements. On certain labels aerial application guidelines are provided under 'General Instructions', however aerial application is not reflected in the safety directions with regard to PPE³ directions, e.g., "using the prepared spray wear cotton overalls buttoned to the neck and wrist, washable hat, elbow-length PVC gloves, face shield or goggles" which would be impractical for a pilot of a agplane. Another example is where a registrant may refer to a crop group, such as grain legumes, but then also lists individual crops, it is unclear if the list is exhaustive or merely illustrative, i.e., whether the pesticide is approved for all members of a crop group. Further problems were noted for some pesticides where inconsistencies can be found between labels for similar products and even within labels, e.g., on one label two different rates are recorded for the same pest in the same crop in different sections of the Use Instructions. Lastly, a degree of uncertainty was identified over the distinction between advisory and mandatory statements.

Pesticide labels are an important element of pesticide management by being the prime medium of risk communication. Therefore, to ensure that pesticide users are adequately informed further effort is needed from both regulators and registrants to firstly ensure that labels are comprehensible and that they are consistent in the information that they provide.

In order to ensure that any reform is relevant it is believed that local research should be undertaken to identify areas of greatest difficulty. It is proposed that government should take responsibility for this research as it has relevance across all agricultural industry sectors, not just horticulture. Such local research could then be coupled with existing international research to facilitate the development of options for improving comprehensibility of labels. All stakeholders could then consider these options with an action plan for change agreed. In particular, what appear to be needed are interagency agreements involving the various federal and state agencies to help improve label structure, eliminate conflicting statements and gaps in coverage.

4.2 User Education

The Labelling Sub-committee did not identify user education as a high priority area. While areas of concern do exist, particularly with regard to understanding technical terms and for people of non-English speaking backgrounds it believed that in the short-term these cam best be dealt with within the current user education framework, i.e., current training

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³ Personal Protective Equipment

requirements such as AgSafe and ChemCert accreditation. APVMA and state based legislative requirements, e.g., NSW Pesticides Amendment (User Training) Regulation 2003 implementing mandatory training requirements with regard to pesticide usage. In addition, APVMA have been discussing with stakeholders the possible development of a prescribed chemical program where users would need higher levels of training certification to access high risk pesticides.

4.3 Control of Use

State Legislation covering the use of pesticides currently differs between states. State and federal negotiations attempting to bring a degree of harmonisation are progressing slowly. Ultimately what is needed is a whole of government approach between all relevant agencies. As an interim a guide is needed elaborating requirements for each state.

5 RECOMMENDATIONS:

- A That APVMA and DAFF are approached to initiate a pesticide user survey investigating comprehensibility, e.g., wording, structure and presentation, of information on current pesticide labels. The aim of which would be to identify and prioritise the areas of greatest concern.
- B That on the basis of the information obtained from a user survey an action plan is developed by APVMA, through consultation, identifying what changes are needed and how these might be implemented.
- C That the activities involved in this project are continued but incorporated within the current HAL project AH01012.
- D That cooperation is sought from other industry groups, e.g., grains and cotton, in order to pursue cross industry pesticide label reform.

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Appendix I. Review of Ag and Vet Labelling Codes – APVMA DISCUSSION PAPER

Background

- Labels on containers of agvet chemical products serve two key functions:
- to provide information on the product to persons who sell, store, transport or use them;
- as an enforcement tool for various Agencies with responsibly for the proper storage, handling, use and disposal of the products and containers.
- Labels are often criticised for not delivering properly in both of these areas. There is a need to balance space limitations and the reluctance of users to read extensive labels with the desire to provide very comprehensive instructions on proper storage, handling, use and disposal of the product and its container.
- Further, marketers often wish to include marketing or advertising type information which further competes for space.
- Layout, print size and the language used on labels are frequently criticised as not being adequate for the range of persons who may need to obtain information from labels.
- Enforcement agencies have encountered difficulties in legal proceedings over the wording and intent of statements on labels.
- It is likely that Australia will implement the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) over the next few years. This labelling review will take into account, as far as possible, likely changes to labels as a result of GHS requirements.
- There is therefore a clear need to examine the current labelling of agricultural and veterinary chemical products.

RLC Review of Labelling

- RLC has established a working group to revise the APVMA's labelling requirements for agricultural and veterinary chemicals.
- As the first stage of its task, the working group has developed a "concept label" for agricultural and veterinary chemicals that it considers reflect the key principles that allow a label to meet the two key functions mentioned above. The latest version of the concept label is attachment 1.
- The end point of the review is that the APVMA is to produce a third edition of the agricultural and veterinary chemical labelling codes, which are currently used to guide registrants in producing labels for chemical products. It is anticipated that the revised labelling codes should be available by July 2004.

Labelling Principles

- The key principles are:
- That the label should be clear on what instructions must be followed by law (mandatory statements), and what statements on labels are warnings of possible adverse outcomes or advice to achieve best results.
- That mandatory statements be prominently shown and be based on information presented to the APVMA which demonstrates that the aspect of use that is to be restricted is either known, or can be reasonably expected, to cause an adverse effect to third parties, ie with respect to trade, public health, or the environment
- That information relating to the key risks be grouped and arranged in a set order.

Mandatory statements

- Certain mandatory statements restricting use will appear on the labels of chemical products. These will be based on information presented to the APVMA which demonstrates that the aspect of use that is to be restricted is either known, or can be reasonably expected, to cause an adverse effect to third parties, ie with respect to trade, public health, or the environment.
- These statements will be based on known, product-specific risks within the above categories and not include efficacy or user / animal safety issues. Restricted Chemical Products would be an exception to this general practice if the restriction is based on either human health, training or equipment.
- In general, withholding period statements should not be included in this category because although they will (should) be mandatory under State/Territory control of use legislation they are (usually) dealt with specifically in such legislation
- Identified mandatory statements are to be placed on the front panel of the labels of chemical products. These statements are to be contained within a discrete box on the front panel and repeated in a box (or bold (red) text), at the top of the label panel to which they relate (either Residues and Trade, Health and Safety, or Environmental Protection). State-specific issues may also be required on the front panel.

 1. .
- In the case of a label with such a large number of mandatory statements that it is impractical for them all to appear on the front panel, the statements will appear only at the top of the label section to which they relate. A general statement in a box will be used on the main panel to draw the attention of the purchaser/user to the applicable restrictions. Whenever labels carrying such statements are supplied in sticker/booklet format, an additional mandatory statement requiring the user of the chemical product to read the booklet is to be placed on the main/sticker part of the label.

- Veterinary chemical products will list restrictions that are mandatory for all users, including veterinary surgeons, under a "Restraint/s" heading. The use of a "Restraints" heading to restrict veterinary surgeons using or recommending off-label use when deemed necessary has been nationally promoted for some time now. Treatment of "single" animals only by veterinarians will be permitted contrary to such restraint statements, primarily for animal welfare purposes.
- It may be necessary because of space limitations on many veterinary labels to restrict the mandatory statements to inclusion under such a heading in the Product Use and Information section (certainly for small containers) and not have it repeated on the front panel. In the case of large volume products, such as dips and pour-ons, the statement/s should still appear in a box on the front panel as well.
- "Do not" statements targeted at users (for example "Contraindications") are expected to have force in all jurisdictions, but other statements where the risk is only to users (or their animals) should not have the force of law eg "Do not dip hot or thirsty sheep" should be reworded as advice eg "Warning: hot and thirsty sheep could drink the dip and suffer poisoning".

Information groups

- Information on labels should be grouped under the following general section headings (panels):
- Front panel
- (Human) Health and Safety
- Product Use Instructions and Information
- General Application Advice
- Residues and Trade
- Environmental Protection and Disposal
- Other Information
- The current multi-panel format is recommended for retention. The order in which the information panels appear on labels is recommended to be varied to shift the current emphasis of the panels. These sections relate to the criteria against which the APVMA assesses a chemical product under section 14 of the Agyet Code.
- The names of the sections should be close to those above. In general these sections will include the instructions and information indicated in attached concept labels.

Rationale

• A principal aim to clearly indicate to users of chemical products the mandatory label statements, which will flow from the APVMA's risk assessments in relation to "external" or third party issues, specifically being environment, trade and public health (other than users). This is to be achieved by using a unique format for such mandatory

statements to appear on labels of chemical products.

- At the same time, statements (particularly in relation to efficacy/crop use) that pose no third party risk are to be separated on the label to allow jurisdictions to exempt them totally from use controls if they so desire.
- While the APVMA's risk assessment process considers the outcome of its assessment to provide "mandatory" label statements in all the legislated areas it addresses this may not in fact be the case once a product is registered. Further, states sometimes have their own statements which they require and which the APVMA includes for them.
- The enforcement of the APVMA's "mandatory" statements on labels will vary between jurisdictions and enforcing agencies. For example, while the efficacy assessment depends on use at the registered label rate, most jurisdictions are implementing legislation to allow off-label use at less than label rates. Similarly, although Safety Directions are always provided on labels, in only one jurisdiction is it mandatory that they be followed. In all others these are considered valuable advice statements to be taken into account in formulating a workplace risk assessment involving use of the chemical
- Many companies also use the label in an attempt to reduce their product liability by the
 extensive use of "Restraint" and other "Do not" statements which have not flowed from
 any APVMA risk assessment.
- The Working Group considered that efficacy alone rarely provided any "third party" risk, and so no restraint or "Do not" statements should be used in relation to efficacy. Where such statements may still be required would be the rare situations where it was agreed that use should be limited for other reasons, for example resistance management or use of GMOs.

Comments Sought

• Comments are sought on the format suggested in the concept label and on the general principles outlined above. There will be further opportunity to comment on more specific labelling requirements as the Labelling Codes are being rewritten. However if you have issues of a general nature on labels you may wish to take this opportunity to advise of these.

Appendix II

APVMA Discussion Paper: Review of Ag and Vet Labelling Code.

Response: K Bodnaruk on behalf of the AusHort Project AH01019 – Improved labelling

GENERAL REMARKS

This is the response of the Improved Labelling Project Committee to the discussion paper. The structure of pesticide labels is acknowledged as a key issue in Australian agriculture. Their correct interpretation is an important factor in ensuring unwanted consumer, user or environmental pesticide exposures do not occur. Farmers want to use pesticides correctly and need to have labels that contain relevant information that is presented in a clear and understandable manner.

Regulatory controls have a crucial role to play in ensuring that labels provide information which is not ambiguous and which does not undermine industry efforts to develop and implement good agricultural practices.

We therefore welcome this discussion document on labeling and look forward to participating in further discussion about these issues with the APVMA and other interested stakeholders.

COMMENTS ON THE CONTENTS OF SPECIFIC POINTS

- 1 Pesticide labels should be viewed first and foremost as hazard communication tools with greater emphasis on the provision of clear practical information to end-users. The enforcement element should be secondary. The committee is concerned that if enforcement related issues are emphasised the potential benefits of the review will be diminished.
- 2. Many of the issues relating to storage, handling, use and disposal are being covered through education by industry based training programs such as AgSafe and ChemCert. What linkages are there likely to be between this aspect of labels and the current APVMA project on prescribed products and user accreditation?
- 3. As per the comment to point 1 pesticide labels are risk communication tools and should not be used for product promotion. Therefore, no consideration should be given to their use in this manner.
- 4. Has the APVMA been able to identify the needs of different user groups or sought advice from researchers in the area of information design? In progressing the label review identifying potential barriers to understanding and developing strategies to better deal with them should be a priority.

- 6. It is our understanding that the GHS recommendations are for each country to voluntarily adopt according to their respective needs. How does the APVMA plan to assess the suitability of such GHS requirements as pictograms, signal words, and harmonised hazard and precautionary statements? The possible implementation of GHS for pesticides in Australia raises a number of significant issues that, we believe, would require intense consultation prior to any adoption.
- 8. As per the comments to point 4, has the APVMA sought advice from researchers in the area of label structure and comprehension? Research has shown that many terms used to communicate safety precautions are often not understood. Revising label requirements without reference to how such statements could be better formulated threatens to undermine the current initiative. We would therefore, strongly urge the APVMA to seek expert advice in this area.
- 9. The outline of the "concept label" provided did not provide sufficient detail to allow the committee to assess the value of some of the proposed changes, e.g., the proposed presentation and wording of mandatory and advisory statements. An example or mock label would, we believe, allow use to better comment.

Also, could there be greater flexibility in the expression of the 'Product use Instructions and Information' section? For example, could the instructions be structured to allow the Pest to be used as the key element rather than crop?

- 10. It is not clear from the discussion paper whether the July 2004 end point signifies the completion of the review in its entirety, or is it the completion of the first stage? This needs to be clarified?
- 15. The inclusion of state specific statements is of concern as it could add unnecessarily to a labels complexity and potential confusion.
- 19. This is an area that we believe requires clarification particularly with regard to what is permitted. The APVMA needs to clarify whether a positive or negative list approach is being followed, e.g., only uses listed on the label are allowed anything else is unacceptable or the alternative, a 'negative list' system, where uses not permitted are listed.
- 20. Inclusion of hazard classification would be of benefit to users when undertaking risk assessments when fulfilling OH&S (Workcover) requirements.

The listing of specific export harvest intervals (EHI's) Under Residues and Trade could add to the complexity. Particularly where pesticides have multiple crop uses and those crops have multiple export destinations.

25. As per the comment to point 15 there is concern that the inclusion of specific statements for individual states could add unnecessarily to a labels complexity. Furthermore, it is unclear how this is to be handled, as the "concept label" makes no reference to where else

such statements would or could be placed. Also, has there been consideration of the likely impact in this area of the AFFA initiative on control of use?

No	Labelling Issue	Action	Priorit
			y
	APVMA		
1	Establish IWG	Completed, Implementation Working Group (IWG) established.	Nil
2.1	Hazardous	Issue with regard to current status of hazardous	Med
	substances	substance identification on label needs to be clarified.	
2.2	Batch Numbers	Contact Avcare regarding legibility of Batch Numbers	Low
3.1 & 3.2	Language used	Identify key individuals within state regulatory bodies that need to be contacted in order to make progress on this issue.	High
3.3	Info grouping	Endorse APVMA proposals to group mandatory statements.	High
3.4	Print size	Explore what systems used internationally.	High
		As per 3.1 & 3.2 Contact experts in communication on label expression, format etc, with regard to label redesign.	High
3.5	Single panel directions	Explore what systems used internationally, i.e., other English speaking countries.	High
		Elaborate differences in control of use legislation between states.	High
3.6	Poison schedule	Confirm why poison scheduling was removed from labels.	Med
3.7	Re entry periods	Propose to Avcare/APVMA base recommendation,	Med

		e.g., "Wait till crop has dried", in the absence of data.	
3.8	First Aid	None required. Meeting informed that directions have been revised. Labels to be updated in 2002.	Nil
3.9	Directions for Use	Recommend to Avcare that format be standardised.	Med
3.10	Control of Use Regs	Contact Control of Use Working Group proposing that control of use be standardised to simplify labels.	High
3.11	APVMA labelling Consultative Group	Raise possibility with APVMA. Long-term goal.	Low
	AVCARE		
4.1	Training	Request to Avcare re: acceptance of Tree & Vine label changes.	Med
4.2	Extension campaign	Contact ChemCert regarding the inclusion of new model Tree & Vine label in training courses.	Med
4.3	Web addresses re: MSDS's	Being done by companies. No action required.	Nil
4.4	DrumMuster contact	Contact APVMA proposing that a standard statement be placed on labels, e.g., "Users should rinse and return containers via drumMUSTER as part of their environmental responsibility."	Med
4.5	Electronic Media	Really an APVMA issue. Therefore, propose to APVMA that full labels be available on APVMA website. Further to the above, I believe that we should request that the website should be interactive, i.e., provide growers with an opportunity to interrogate the database, e.g., search for products to control specific problems, rather than just a list of labels.	High
5.1	Additional information	Recommend to Avcare that members ensure information is available.	Med

5.2	Compatibility	Nil action in short term.	Low
5.3	Label integrity	Propose to Avcare that Avcare members guarantee label integrity at point of use.	Med
5.4	MSDS	Query NOHSC regarding what can be done to simplify MSDS format for agricultural use.	High
		If response unsatisfactory approach NFF Chemicals subcommittee.	High
5.5	ChemClear	Nil action as contact number will be a company number.	Nil
5.6	Manufacturer contact details	Nil action. Already being done	Nil
5.7	Support data	Encourage manufacturers to provide technical material via manuals etc.	Low
5.8	Label changes	Propose to Avcare that coloured sticker be placed in a prominent position on container to flag that significant label change has occurred.	High
5.9	Resistance mgt	Nil action. Statements already appear on labels.	Nil
5.10	IPM	Nil action. IPM data by its nature very crop and situation specific. Unrealistic to expect such information could be included on label.	Nil
	CHEMCERT		
6.1	Training	Contact ChemCert and other state based training organizations to confirm that model label (Tree & Vine) is included in training programs and definition of terms covered.	Med
6.2	Training	Nil action. Linked to above	Nil
6.3	Formulations & packaging	Nil action. Beyond scope of project. Codes of Practise within each state exist with regard to the issue.	Nil
6.4	Communication of outcomes	Will be ongoing	Med

6.5	Education resources	Nil action. Beyond scope of project.	Nil
6.6	Definition of terms	Linked to 6.1	Nil
	Equipment Manufacturers		
7.1	Training	Contact manufacturers re: information they are making available regarding application of pesticides.	Low
	AusHort		<u> </u>
8.1	Compatibility	Contact commodity groups with regard compatibility issues.	Low
8.2	Training	As per 6.1	Nil
8.3	Minor Use	Beyond scope of project	Nil
8.4	IPM strategies	Beyond scope of project	Nil
	RLC	<u> </u>	
9.1	WHP's	Request that APVMA ensure WHP for same active is consistent across all labels for same uses.	Med
9.2	Control of use by state	Currently this would very difficult. Linked to 3.10.	Nil
9.3	Harmonisation of control of use.	See 3.10	Nil
	NOHSC	1	1
10.1	MSDS	Investigate opportunities for simplification and supply of MSDS data, as per 5.4. Report back to IWG.	High

APPENDIX IV GLOSSARY OF ABBREVIATIONS

ACCI Australian Chamber of Commerce and Industry

APVMA Australian Pesticide and Veterinary Medicines Authority

DAFF Department of Agriculture, Fisheries and Forestry

EA Environment Australia
GAP Good Agricultural Practices

GHS Globally Harmonised System of classification and labelling of chemicals.

HAL Horticulture Australia Limited ILO International Labour Organization

MSDS Material Safety Data Sheets NGO Non Government Organization

NOHSC National Occupational Health and Safety Commission

OH&S Occupational Health and Safety RLC Registration Liaison Committee

UNCED United Nations Conference on Environment and Development

US EPA United States Environmental Protection Agency

WHP Withholding Period