

Grain Trade Australia Limited PO Box R1829 Royal Exchange NSW 1225 Phone: +61 2 9235 2155 Fax: +61 2 9235 0194

28 February 2018

Agvet Chemicals Branch Sustainable Agriculture, Fisheries & Forestry Division Department of Agriculture and Water Resources GPO Box 858 Canberra ACT 2601

Submitted on-line via email agvetpolicy@agriculture.gov.au

Dear Sir/Madam

RE: Agvet Chemical Task Group (ACTG) Discussion paper: Off-label Use Harmonisation **Proposal**

1. About Grain Trade Australia

Grain Trade Australia (GTA) is the focal point for the commercial grains industry within Australia. It facilitates trade and works to provide an efficient, equitable and open trading environment by providing leadership, advocacy and commercial services to the Australian grain value chain.

GTA members are responsible for over 95% of all grain storage and freight movements made each year in Australia. Over 95% of the grain contracts executed in Australia each year refer to GTA grain standards and/or trade rules.

GTA members are drawn from all sectors of the grain value chain from production to domestic end users and exporters. GTA members are involved in grain trading activities, grain storage, grain for human consumption and stock feed milling. A list of all GTA members is attached.

Within this context, on behalf of its members, GTA provides comment on the Discussion Paper entitled "Agvet Chemical Task Group (ACTG) Discussion paper: Off-label Use Harmonisation Proposal".

2. General Comments on the Document and Costs for Industry

GTA agrees with the intent of the review, being "adoption of a national approach to harmonised offlabel use of agricultural and veterinary (agvet) chemicals". If the project fully achieves its objective various benefits, as outlined in the paper will be realised. However, of significant concern to GTA Members is maintaining customer and marketplace confidence that Australia's regulatory system is world class, supports and facilitates the grain industry meeting customer contract and regulatory requirements for chemical use.

GTA Members trade grain both domestically in Australia and in many overseas countries. While the focus of the paper indicates "international markets", given the large domestic market for Australian grain, it is important that any regulatory reform also considers the views of Australian grain buyers, and ultimately the consumer.

3. Specific Comments

3.1 Off Label Use Definition

The Discussion Paper outlines a definition for off label use, with commentary including "Off-label use relies on a conscious and informed decision to use an agricultural chemical product (either registered or accessible under a permit) to address a specific pest issue. This includes consideration of:

- the rate:
- time and frequency of application;
- the likelihood of residues; and
- the potential for exposure.

This information may come from international practice, professional judgement and consideration of APVMA approved uses (either label or permit)."

GTA questions the required level of knowledge of Australian grain growers to fully comprehend, and be able to access the required information as outlined in the above statement. While Australian grain growers use modern farming practices, are updated continually in best practice management (and arguably are using world best practice) their ability to fully comprehend and understand issues such as outlined in the following points is limited due to the nature of the Australian grain industry supply chain:

3.1.1 Likelihood of Residues

It is questionable whether Australian growers and subsequent buyers of grain, would have the required technical knowledge to determine if use of a chemical as proposed in the Discussion Paper, would result in residues. Additionally, the resulting level of residues arising from chemicals used as outlined in the Discussion Paper may be difficult (and costly) to determine if at the level of detection / quantification.

Different markets (both domestic and export) have differing requirements for chemical residues, being the maximum residue limit (MRL). The only way for a grower, and a subsequent buyer of that grain to truly understand the risks of residues arising from a chemical use would be to perform analysis of that grain in a laboratory.

Depending on the commodity/market/chemical, chemical residue analysis of grain prior to selling from a grower is generally not performed for a variety of reasons including but not limited to:

- Cost of analysis, with many analyses being relatively expensive and in general not required under clauses in many Australian grain industry contracts. These additional costs would need to be absorbed by the grower, thereby reducing profitability.
- Generally short timeframe for marketing of grain based on the price achievable at that time. That is, a market opportunity may arise on any given day and subsequently a grower may sell that grain, not permitting time for collection of a sample and analysis in a laboratory.
- Grower compliance with regulatory requirements for chemical use, with compliance generally indicating residues will be below the applicable Australian MRL.

3.1.2 Market Requirements

If residues arise from the use of an off-label chemical, those residues may, or may not be permitted by the market. Significant education is provided to growers:

- Regulatory such as Control of Use legislation or voluntary commercial training services on chemical application
- Fact Sheets various education material on chemical use and the impacts of misuse on market requirements
- Market requirements MRLs for chemicals via various documents and on-line MRL databases

However, the ability of a grower to directly determine a market requirement for a particular chemical is problematic due to the changing nature of those market requirements. MRL reviews continually occur in markets due to a range of issues. Ensuring all growers have up to date information on those changes would be difficult, if not impossible to achieve.

3.1.3 End Use of Grain

Unless sold directly to a domestic end-user, or specifically sent to a container packer for direct loading to a particular international destination, grain is generally delivered into the Bulk Handling Company (BHC) storage system. In the BHC storage system it is commingled with grain of the same quality with grain from other growers. Thus the grain in any BHC storage may be from various growers and locations, each delivery having a different range of chemicals and level of those residues.

Upon delivery growers are generally required to complete a Commodity Vendor Declaration (CVD) form that requires the grower to outline amongst other things:

- a) Whether the grain was grown and harvested/stored under an officially recognised quality assurance (QA) scheme.
- b) Specifics of each chemical used on that grain for post-harvest stored grain insect control.
- c) Compliance of chemical use with regulations.

Where the grower declares chemical use, a risk assessment of residues arising will determine if that grain is considered suitable for a particular market. However, the true risk can only be assessed via analysis if all chemicals used are declared on the CVD by the grower. As noted above, this analysis is a very costly exercise.

For grain delivered under point c), under the proposed off label harmonisation proposal, it could be considered that off label use fits under relevant "legislation". Hence, the grower would not need to declare which chemicals had been used. In this situation, the marketer of that grain would not only need to fully comprehend which chemicals may have been used on that crop (impractical) but also determine if all such chemicals and resultant residues arising from the grain parcel would be suitable for a particular market. Again, this places significant onus and responsibility on both the grower and marketer to identify a chemical that may or may not be present. Such a process would also be costly and totally impractical to implement.

Given the impracticality of the above, it would be difficult to determine, from an industry or regulatory view point if the chemical residue present would be approved (as per the off label use proposed in the Discussion Paper) or as a result of "Wilful misuse due to the lack of consideration of the risks of using an agricultural chemical product to address a specific pest issue." Under this definition, a grower may fall within the wilful misuse definition via not being able to obtain or comprehend the risks of residues arising on the grain in question.

3.2 The Need for Off Label Use

GTA has no specific comment on the individual grain sector needs for off label use. It is recognised that many "minor crops" require off label use, and are therefore required to comply with the current regulatory process outlined under the minor use permit system.

Given the relatively small economic incentive for chemical registrants to register chemicals in Australia on these minor crops (e.g., given the limited financial return from chemical sales), the Australian regulatory system must be able to support those industries while also ensuring market requirements including regulatory MRLs are met.

It is noted in the Discussion Paper, that "The need for off-label use most commonly arises in response to an immediate need by users where an APVMA registered product or APVMA issued permit is not available, cannot be granted in the time required, or it is too expensive to gather required data for approval. This is particularly an issue in small industries with limited capability and resources to organise or fund permits. The Australian Government has committed \$8 million (2014-2018) to this issue through its Improved Access to Agricultural and Veterinary Chemicals initiative".

This allocation of funding is commended. As is the approach outlined in Table 2 (Approaches to address inconsistencies), being:

The issue	Approaches
Use of a product on a commodity or in a	Prohibit use on a crop or situation that is not listed
situation that is not listed on the APVMA	on the APVMA approved label unless the use
approved label	complies with formal conditions to allow use

It is also noted in the Discussion Paper "It is also important to note that while the APVMA's minor use permit system exists to allow for legal off-label use and assist users in assessing and managing risks, the approaches discussed in this paper are outside of this system".

In practice, it is difficult for industry to separate these two issues.

Where required, various industry organisations apply for minor use permits on behalf of their stakeholders. Depending on the type of permit applied for, these fees are relatively low per application. Once approved, all growers can use that permit under the conditions outlined.

As outlined in the Discussion Paper, "the conditional approach prohibits off-label use that is likely to pose unacceptable risks to food suitability and Australia's trade". As with the minor use permit system, an individual grower may not have the necessary skills to conduct a risk assessment and would rely on a third party such as an industry organisation. In addition, it would seem impractical and inefficient for individual minor crop growers to undertake assessments to comply with the off label use conditions where others may also be seeking to use those same chemical(s) in a given situation leading to unnecessary duplication and additional costs.

3.3 Comments on Specific Conditions

It is recognised that the Conditions listed in the Discussion Paper (Appendix 3) are examples only and not all may be implemented. The following are comments on specific conditions listed in the Discussion Paper.

3.3.1 Limiting Exposure

Purpose	Example Condition
The risk posed by off-label use will be	The commodity is not, or is not likely to be,
lowered by reducing the extent of off-label	exported.
use or excluding higher risk chemicals,	_
commodities or situations.	

In practice in most situations, this Condition could not be easily implemented. Unless direct marketed (e.g., ex farm to a container packer for direct loading into a container), grain is generally commingled in bulk storages with grain of a similar quality from various other sources. Frequently the end-use of this grain is not known, nor is the end destination. In these circumstances, grain may be sent to the domestic or export market, or both, depending on a range of commercial factors.

There are no economically practical systems available for industry to meet this Example Condition. Hence this Example Condition could not be implemented for grain.

3.3.2 Limiting Exposure

Purpose	Example Condition
The risk posed by off-label use will be	The use (commodity/product) does not occur any
lowered by reducing the extent of off-label	more frequently than two years in every three (for
use or excluding higher risk chemicals,	seasonal products) or for six continuous months in
commodities or situations.	every 12 for perennial commodities.

It is unclear how such a restriction on use has arisen. Further review of the reasoning for this frequency of use would be required before additional comments could be supplied.

However, as a general rule, where pests arise, use of a chemical in any one season on more than one occasion may be required. Hence label rates should mitigate the risk of residues arising above MRLs, not statements such as those examples in the table.

3.3.3 Limiting Exposure

Purpose	Example Condition
The risk posed by off-label use will be	The use is not on a prescribed major commodity.
lowered by reducing the extent of off-label	For example a prescribed major commodity may be
use or excluding higher risk chemicals,	major crops as listed in Schedule 3A of the 1 July
commodities or situations.	2013 compilation of the Agricultural and Veterinary
	Chemicals Code Regulations 1995.

Minor crops are currently listed on the APVMA website. Also included is a definition of "*Limited use within a major crop*". Schedule 3A of the Agricultural and Veterinary Chemicals Code Regulations 1995 refers to different crops from the Minor crops listed on the APVMA website.

It is reasonably complex for a grower and others in industry to determine the exact criteria applying to the specific instance / commodity where the off label conditions may be enforced. Further consideration of the above Example Condition plus related Conditions would be required prior to receiving industry support.

3.3.4 User Competency & Practices

Purpose	Example Condition
Maximum residue limits (MRLs) ensure	Grower/producer participates in a quality
the food suitability of produce. Monitoring	assurance scheme that involves/includes produce
residues ensures off-label use does not pose	residue monitoring of the treated commodity for
a food suitability threat.	the active constituent in the product used.

Individual grain growers generally do not operate under recognised quality assurance schemes. Growers comply with relevant regulations and voluntary industry management systems, such as the Grain Producers Australia "Growing Australian Grain Guide - Safely managing risks with crop inputs and grain on farm". This is a Guide only, and while most grower groups and their members within Australia comply with that document, it does not involve a formally recognised QA system, nor does it require chemical residue testing. As outlined previously, the cost of such testing would be prohibitive to growers in most situations.

3.3.5 User Competency & Practices

Purpose	Example Condition
Maximum residue limits (MRLs) ensure	The person responsible for the use can demonstrate
the food suitability of produce. Monitoring	that at the time of the product's use their knowledge
residues ensures off-label use does not pose	of:
a food suitability threat.	the MRL (if any) in Australia New Zealand Food
	Standards Code for that commodity
	where the commodity is set out in Table 4 of the
	Agricultural and Veterinary Chemicals Code
	Instrument No. 4 (MRL Standard 2012) and is
	intended (or likely to be) for animal feed, the MRL
	for that commodity the residues in the commodity
	arising from the products use.

Growers are generally not aware of market requirements, specifically where a chemical is not permitted for use on a commodity for a specific market. Frequently, when using a registered chemical (and following approved label instructions) a grower would assume that use is permitted and resulting residues will comply with market MRLs. Growers would not refer to the Food Standards Code and / or Table 4 as listed above prior to applying that chemical.

As stated previously, when sourcing grain from growers, generally a Commodity Vendor Declaration form is required to be completed. Various versions may be used, but each requires either:

- A declaration the grain was grown under a recognised QA system; and / or
- Grain was treated (with a post-harvest chemical that requires specifically referencing) and labels etc. were observed; and/or
- Only for specific markets does all in-crop and post-harvest chemicals used require to be listed. Analysis for post-harvest chemicals may or may not be required.

While implicit that growers are aware of legal obligations for MRLs, the above listed Example Condition would require a modification to all industry CVDs and in practice would add little improvement to the compliance of growers with off-label use or use of any chemical registered in Australia.

3.3.6 User Competency & Practices

Purpose	Example Condition
User has demonstrated the necessary skills	The user of the product holds a Certificate III or
and knowledge to that would allow	higher qualification in risk assessment and risk
identification and management of the risks	management.
in handling and using chemicals off-label.	

While GTA has no comment on risk skills and training thereof of growers, in general as outlined in the Grower Guide, growers are required to undertake training and be competent in chemical use. It is impractical for growers to undertake training and have recognised skills in risk assessment and risk management in chemical use in relation to the market risk to the degree inferred in this Example Condition. GTA is currently not aware of any training courses offered in this area.

Other avenues are used by industry to assist increasing market knowledge of growers, without the need to undergo formal training in order to use chemicals per se, not including the off label recommendations outlined in this Discussion Paper.

3.4 Workplace Health & Safety

GTA makes no comment on this section of the Discussion Paper given that compliance for all GTA Members with all WH&S legislation is mandatory.

4. Summary

GTA supports "The Australian, state and territory governments' acknowledge that the APVMA is the best assessor of risk of agricultural chemicals. Long-term access is most effectively delivered through APVMA issued permits. The work of government to harmonise off-label use is focused on addressing the short-term chemical needs of producers".

A key focus of our markets is confidence in the Australian regulatory system, coupled with an effective industry self-management approach to meeting their quality requirements outlined in contracts.

The approach in the Discussion Paper is intended to provide this confidence through harmonisation of the approach to off label chemical use, however there remains various practical issues that need to be considered further before such a result can be fully achieved.

Thank you for your consideration of this response.

Yours faithfully,

Pat O'Shannassy Chief Executive Officer



Membership List as at 26 February 2018

Website /Phone Organisation Contact

Ordinary Member (Trading)

Level A1 (over 7 Million Tonnes)

Co-operative Bulk Handling Limited Mr Jason Craig cbh.com.au Glencore Agriculture Pty Ltd Mr Philip Hughes glencoreagriculture.com.au

Level A2 (5 - 7 Million Tonnes)

Graincorp Operations Ltd Mr Klaus Pamminger graincorp.com.au

Level A3 (3 - 5 Million Tonnes)

ADM Trading Australia Pty Ltd Mr Darryl Borlase adm.com Cargill Australia Limited Ms Penne Kehl cargill.com.au

Level A4 (1.5 - 3 Million Tonnes)

Bunge Agribusiness Australia Pty Ltd Mr Chris Aucote bunge.com/Agribusiness Cofco International Mr Bruce Li cofcoagri.com.au Mr David Johnson **Emerald Grain Pty Limited** emeraldgrain.com Nidera Australia Pty Ltd Mr David Lengren nidera.com Mr Tony Smith Plum Grove Pty Ltd plumgrove.com.au

Level B1 (1.0 - 1.5 Million Tonnes)

Arrow Commodities Pty Ltd Mr Dominic Vanzella arrowcom.com.au Louis Dreyfus Company Australia Pty Ltd Mr Robert Green louisdreyfus.com.au

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Level B2 (500,000 - 1 Million Tonnes)

Mr Hiro Oda Agrex Australia Pty Ltd agrexaustralia.com.au Australian Grain Export Pty Ltd Mr John Thiele 08 8832 2800 CHS Broadbent Pty Ltd Mr Justin Fay broadbentgrain.com.au Centre State Exports Pty Ltd Mr Jeff Voigt centrestateexports.com.au gwf.com.au George Weston Foods Limited Mr Mark O'Brien Mr Michael Reeves agriproducts.com.au Ridley Agriproducts Pty Ltd Riordan Grain Services Mr Bradley Hogan riordangrains.com.au Riverina (Australia) Pty Ltd Mr Jon Mulally riverina.com.au

Level B3 (250,000 - 500,000 Tonnes)

Wilmar Gavilon Pty Ltd

Agfarm Pty Ltd Mr Ron McCalman agfarm.com.au Agracom Pty Ltd Mr Joe Hallman agracom.com.au **AGRIGRAIN** Mr Jeremy Brown agrigrain.com Agrisk Management Pty Ltd Mr Brett Stevenson 02 9499 4199 Allied Pinnacle Pty Ltd Mr Josh Lawrence alliedmills.com.au Mr Lachlan Allen **Elders Grain** elders.com.au Lempriere Grain Pty Ltd Mr Jonathan Holdsworth lemprieregrain.com.au Quadra Commodities Pty Ltd Mr Robin Cassar quadra.com Robinson Grain Trading Co Pty Ltd Mr Gary Robinson robinsongrain.com.au Ms Jaimee Carrigan Special One Grain Accumulator specialonegrain.com.au United World Enterprises Pty Ltd Mr Jimmy Liu uwetypical.com

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07 3713 8700

Mr Matt Albion

Ordinary Member (Trading) (contd)

Level C (under 250,000 Tonnes)

Mr Brad Waterfield A T Waterfield & Son Ptv Ltd 03 5382 3725 Mr Kim Vater A W Vater and Co vater.com.au Access Grain Pty Ltd Mr Wade Humphreys accessgrain.com.au Adams Australia Pty Ltd Mr Ian Mack adamsaustralia.com.au **Agmark Commodities** Mr Richard Alcorn agmark.com.au Mr Kishore Bulchandani Agri Om Australia Pty Ltd agriom.com.au Agri-Oz Exports Ptv Ltd Mr Francois Darcas 03 9830 7021

Agriex Australia Pty Ltd Mr Joseph Khnessier 02 9232 0690 Agrifoods Australia Mr Rob Anderson agrifoodsaustralia.com.au Agromin Australia Pty Limited Mr Rajni Patel agromin.com.au

AGT Foods Australia Mr Peter Wilson agtfoods.com/australia
AMPS Agribusiness Group Mr Simon McDougall ampsagribusiness.com.au

AMPS Agribusiness Group
Associated Grain
Associated Grain
Mr Todd Jorgensen
O7 4662 1999
Auscott Ltd
Mr Peter Webb
auscott.com.au
AusiCan Commodities
Mr Palwinder Singh
ausican.com

Australian Choice Exports Pty Ltd Mr James Hunt australian choice exports.com.au

Australian Grain Growers Co-operative Limited Mr Bruce McDonald aggcoop.com.au
Australian Grain Storage Mr Matt Bailey sunrice.com.au

Australian Growers Direct Pty Ltd Mr Tom Lucas ausgrowersdirect.com.au

Australian Mungbean Company Pty Ltd Mr Damien White australianmungbean.com.au

Australian Storage Alliance Pty Ltd Mr Jon Bucknall 0447 652 716
AvantAgri Australia Pty Ltd Mr Peter Woods avantagri.com.au
Baker Grain Mr Richard Baker bakergrain.com.au
Berriwillock Grain Storage Co-Operative Ltd Mr Tony Bellinger moulameingrain.com

BFB Pty Ltd Mr Terry Brabin bfb.com.au
Blairs Produce Company Mr Sean Blair 02 6025 4600
Boolah Grains Pty Ltd Mr Stuart Tighe 02 6754 0343
Boort Grain Co-Operative Mr Jon Bucknall 02 9875 3919
Broun and Co Grain Pty Ltd Mr Wal Broun brounandco.com.au

C & S Trading Pty Ltd Mr Craig Scholz scholzbh.com.au
C K Tremlett Pty Ltd Mr Andrew Tremlett 08 8524 9050

Carpendale Commodities Mr Andrew Kluck 0448 761 246
Cameron Pastoral Company Pty Ltd Mr Ken Cameron 07 4671 4144

Castlegate James Australasia Pty Ltd Mr Ross Giovanetti castlegatejames.com.au Cleveland Agriculture Mr Chris Hurwood 02 6756 5004 Coorow Seeds Mr Brian Pover coorowseeds.com.au

COPRICE Ms Kirsty Cutter coprice.com.au
Cremer Australia Pty Ltd Mr Scott Haughton cremer.com.au

DA Hall and Co Mr Bruce Holden 07 4695 5777
Dalby Bio-Refining Limited dbrl.com.au

Dalgrains (Qld) Pty LtdMr Tobin Cherrydalgrains.comDarwalla Milling Co Pty LtdMr Gary Heidenreich07 3822 0527Deacon Seeds CompanyMr Terry Deacon07 4662 3217Deckert Group Pty LtdMr Chris Deckertdeckerts.com.au

Defiance Maize Products Pty Ltd Mr Rodney Walker corson.co.nz Demeter Cormack Pty Ltd Mr David Oates 08 6389 0098 Mr Hamish Robertson directcommodities.com.au Direct Commodities Pty Ltd Donnellons Bulk Haulage Pty Ltd Mr Bill Donnellon 0428 136 483 ED & F Man Grains Australia Mr Oliver White edfman.com East Coast Stockfeed Pty Ltd Mr Stuart Dolden ecsf.com.au

Export Trading Group Australia Pty Ltd Mr Shayne Clark etgworld.com
Feed Central Pty Ltd Mr Tim Ford feedcentral.com.au

Fellows Nominees Mr Paul Fellows fellowsbulk.com.au
FertInvest Pty Ltd Mr Preyesh Barar fertinvest.com
Findlays Barellan Mr Neil Findlay 02 6963 9246

Level C (under 250,000 Tonnes) cont.

Northern Riverina Grains Pty Ltd

Origin Grain Pty Ltd

PB Seeds Pty Ltd

OOMA Enterprises NSW Pty Limited

Five Star Stock Feeds Mr Tim Huggins fssf.com.au Mr Kurt Wilkinson Fletcher International Exports Pty Ltd fletchint.com.au FREE Eyre Grain Pty Ltd Mr Mark Rodda free-eyre.com.au Mr Chandru Hiremath Golden Harvest Grain Exports goldenharvest.net.au Grain Direct Australia Mr Chris Kochanski graindirect.com.au Mr Paul Pearsall Grain Link (NSW) Pty Ltd 02 6962 9500 Grain Link WA Pty Ltd Mr Andrew Goyder grainlink.com.au Grainforce Pty Ltd Mr Derek Larnach 02 6331 4880 **Grainpro Pty Limited** Ms Angela Bonfante grainpro.com.au Mr Sanjiv Dubey GrainTrend Pty Ltd graintrend.com **Greentree Farming** Mr David Brown 02 6751 1228 GV Grain & Fodder Ms Joanne Harry 03 5828 3063 Hanlon Enterprises Grain Mr Peter Gerhardy 02 6924 1781 Harberger's Farm Supplies (Trading) Pty Ltd Mr Reece Harberger harberger.com.au Hassad Australia Operations Company Pty Ltd Ms Terrie Morgan 02 9900 3700 Iloura Resources Pty Ltd Mr Hans Hol iloura-resources.com Independent Grain Handlers Pty Ltd Mr Brad Bryant igh.net.au Irwin Stockfeeds Mr Bryan Irwin irwinstockfeeds.com.au Itochu Australia Ltd www.itochu.com.au Mr Justin Swan J K International Ptv Ltd Mr Sandeep Mohan iki.com.au J W Koek & Company Mr Brian Algate 07 3341 4548 James Stock Feed and Fertilizer Pty Ltd Mr Adrian Moule jamesstockfeed.com.au Mr David Barlow Jerilderie Grain Storage & Handling 03 5886 0344 KB Agri Services Pty Ltd Mr Karl Bliss 07 4634 4320 K M & W M Kelly & Sons Mr Matt Kelly kellygrains.com.au Kangaroo Island Pure Grain Pty Ltd Ms Emma Tonkin kipuregrain.com Mr Andrew Kennett Kennett Rural Services Pty Ltd kennettrural.com.au Lachlan Commodities Pty Ltd Mr Tony Cogswell 02 6851 2077 Laharum Bulk Handling Co Mr Donald Carter 03 5381 2666 lakegrain.com.au Lake Grain Pty Ltd Mr Derek Davis Lane Grain Pty Ltd Mr Garry Lane 02 6887 3309 Laragon Almond Processors Pty Ltd Mr Mark Webber laragon.com.au Laucke Flour Mills P/L Mr Roger Laubsch laucke.com.au Lawson Grains Pty Ltd Mr Angus Blair lawsongrains.com LDC Enterprises Australia Pty Ltd Mr Richard Porter 07 3253 5999 LINX Cargo Care Mr David Simpson linxcc.com.au LPC Trading Pty Ltd Mr Simon Langfield 02 6383 7222 Malteurop Australia Pty Ltd Mr Jack King 03 5277 1950 08 9831 1021 **Matthews Transport and Grain Traders** Mr Neville Matthews Max Grains Pty Ltd Mr Jack Fahy maxgrains.com.au MC Croker Pty Limited Mr Greg Carroll crokergrain.com.au McNaughts Grain & Fertilizer Pty Ltd Mr Daniel McNaught mcnaughts.com Melaluka Trading Pty Ltd Mr Simon Pritchard melalukatrading.com.au Mellco Ptv Ltd Mr Steve Mellington 0419 867 971 Moulamein Grain Co-Operative Ltd Mr Tony Bellinger moulameingrain.com Moxey Farms Pty Limited Ms Jill Smith 02 6344 8462 MSM Milling Pty Ltd Mr Peter MacSmith 02 6364 5999 Murrumbidgee Grains Pty Ltd Mr Peter Hassall 02 6937 9100 Mr Shane McGregor Namoi Cotton Ltd namoicotton.com.au Nandaly Grain Co-Operative Ltd Mr Tony Bellinger 03 5078 1217 Network Grains Pty Ltd Mr Craig Dennis 07 4637 8500 Newcastle Agri Terminal Pty Ltd Mr Jock Carter 02 4962 4006

Mr Jon Bucknall

Mr Peter Brick

Mr Peter Blair

Mr Malcolm Berry

02 9875 3919

03 5720 8500

pbseeds.com.au

oomaenterprises.com.au

Level C (under 250,000 Tonnes) cont.

Mr Shane Wall PeaCo 03 5497 1766 Pearson's Grain Pty Ltd Mr Darren Pearson pearsonsgroup.com.au Peters Commodities Ptv Ltd Mr Michael Oxlev petcom.com.au Mr Jogesh Virk Phoenix Global Australia Pty Ltd phoenixcommodities.com.au

Premium Grain Handlers P/L Mr John Orr pgh.com.au

Mr Andrew Kell **Preston Grain** 02 6977 1733 Pulse Association of the South East (PASE) Inc Ms Leanne Burr 08 9071 3655

Mr Dene Ladmore Quattro Ports quattroports.com.au Quirindi Grain & Produce Mr John Webster 02 6746 1911 Reid Stockfeeds Pty Ltd Mr Ian Reid reidstockfeeds.com.au

Rhodium Resources Australia Pty Ltd Mr Mark Fitzgerald rhodiumresources.com Mr Andrew Philpotts Rivalea (Australia) Pty Ltd - Animal Nutrition rivalea.com.au Riverina Oils & BioEnergy Pty Ltd Mr Lachlan Herbert riverinaoils.com

Roty Grain Store Mr Brian Newman 02 6988 8221 Mr Tim Ruddenklau Ruddenklau Grain Pty Ltd 08 8842 1314

Rural Logic (Aust) Pty Ltd Mr Michael Wood rurallogic.com.au SANWA Pty Ltd Mr Charles Emerson sanwa.com.au Mr Matthew Crane Seedhouse Tasmania seedhouse.com.au Shannon Bros Bulk Haulage Mr Clayton Shannon 03 5390 2264 Silo Bag Grain (NSW QLD) Pty Ltd Ms Lesley Kilby 02 6847 1788

Mr Dia Ram Sharma Societa Cofica Pty Ltd societacofica.com.au 02 69 552 779 Southern Cotton Trading Pty Ltd Mr Chris Veness Mr Campbell Brumby Southern Grain Storage Pty Ltd 03 5267 2351

Southern Stockfeeds (Operations) Pty Ltd Mr David Jemmet 03 5437 8295 Spagricon Australia Pty Limited Mr Jiger Kotecha spagricon.com.au

Standard Commodities Australia Pty Ltd Ms Elizabeth Bozinoska stancom.com.au Summer Hill Grains Mr Barney Hughes 0428 694 363 SunPork Farms Feed Mills Mr Mark Young 08 8532 4434

Tasmanian Agricultural Producers Pty Ltd Mr David Skipper tasagproducers.com.au Thallon Grains Pty Ltd Mr Andrew Earle 02 6756 5004

TSS Grain Mr Trevor Macleod tasstockfeed.com.au Twynam Pastoral Company Ms Lesley Heidtman twynam.com ulusoyflour.com Ulusoy Asia Pacific Mr Mark Madjarevic Unigrain Pty Ltd Mr Ervin Leong unigrain.com.au

Unique Grain Management Pty Ltd Mr Mark Thiele uniquegrain.com.au Universal Commodity Management Mr Tim Dean commoditymanagement.com.au W B Hunter Pty Ltd Mr Stewart Coombes 03 5821 5744

Ward McKenzie Pty Ltd Mr Geoff Hammon mckenziesfoods.com.au Watershed Commodities Mr Jack Vivers 0427 715 543 WHG Oceania Pty Ltd Gesheng Shen 02 8040 3030 Whyalla Beef Pty Ltd whyallabeef.com.au

Wilken Grain Mr Richard Wilken wilkens.com.au Wimpak Pty Ltd Mr James French wimpak.com.au WW Agri Pty Ltd Mr Steve Sloss wwagri.com.au XLD Grain Pty Ltd Mr Lachie Stevens xldgrain.com.au

Yenda Prods Grain Pty Ltd Mr Luke Mancini 0437 512 322

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Transport Operator

Gehrke Grains and Transport Pty Ltd Mr Julian Gehrke 07 5465 6695 Hamilton Contracting (NSW) Pty Ltd Ms Jodie Hamilton hamiltoncontracting.com.au Wakefield Grain Export Services Mr Bikash Ram wakefields.com.au

Broker

0 Large

Medium

Grain Brokers Australia Mr Jeff Winspear grainbrokers.com.au Horizon Grain Brokers Pty Ltd Mr Ash Munro horizongb.com.au INTL FCStone Pty Ltd Mr Brett Cooper intlfcstone.com McDonald Pelz Australia Mr Peter Geary mcdonaldpelz.com Perkins Commodity Brokers Mr Craig Perkins 03 9645 6846 Southern Aurora Markets Mr Pat Cogswell samarkets.com.au Teague Australia Pty Ltd Mr Tim Teague teague.com.au

Sole Operator

A C Grain Mr Adam Clarke 0400 065 763 **ACCB** Australia Mr Andy Cunliffe 0455 105 300 Allied Grain Pty Ltd Mr Angus Wettenhall alliedgrain.com.au Cereal Milling Services Pty Ltd Mr Michael Moss 02 4323 9339 Cogeser (Australia) Pty Ltd Mr Robert Luetolf cogeser.com.au Farm Tender Mr Matt Henke farmtender.com.au Link Brokering Mr Dion Costigan linkbrokering.com.au Mr Todd Lees lotema.com.au Lotema Pty Ltd Mallon Commodity Brokering Mr Ian Mallon

Quest Commodities Pty Ltd Ms Jayne Barker questcommodities.com.au Wimmera Mallee Grain Services Mr Rodney Edgerton egrainservices.com.au Woodside Commodities Pty Ltd Mr Hamish Steele-Park woodcomm.com.au

Corporate

Large

Mr Kristen Hopkins **ASX Limited** asx.com.au/grainfutures Australia And New Zealand Banking Group Mr Ian Hanrahan anz.com.au Australian Grain Technologies Pty Ltd Mr Tristan Coram agtbreeding.com.au Commonwealth Bank of Australia Mr Tom Barraket commbank.com.au

Medium

Agrifood Technology Pty Ltd Ms Doreen Fernandez 03 9742 0589 **AMSPEC** Mr Lee Shilvock amspecgroup.com Australian Superintendence Company Mr Andrew Parry 07 3391 8640 Commodity Inspection Services (Australia) Pty Ltd Mr Mathew Conoulty commodityinspection.com.au Foss Pacific Pty Ltd Mr Simon Kirkman foss.com.au Holding Redlich Mr Geoff Farnsworth holdingredlich.com Holman Fenwick Willan Mr Stephen Thompson hfw.com Mr Ben Jones Intertek intertek.com Merricks Capital Pty Limited Mr Adam Davis merrickscapital.com Mr Jeremy Rosenthal sbalaw.com

Mr Scot Paterson

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Corporate (cont.)

Small

EP Integrated Commodities Pty Ltd Farmanco Marketing Pty Ltd FarMarCo Australia Ptv Ltd Finesse Solutions Pty Limited

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Hay Plains Grain Storage Pty Ltd **IKON Commodities Pty Ltd Lachstock Consulting** MarketAg Pty Ltd

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TE Storage & Logistics Pty Ltd

SGA Solutions Pty Ltd

Ten Tigers

International Affiliate

CCIC Australia Pty Ltd CIS - Commodity Inspection Services

Industry Association

Grain Growers Limited Grain Industry Association of WA Grain Producers Australia Ltd **NSW Farmers Association**

Australia Export Grain Innovation Centre

Victorian Farmers Federation

Merchant Association

Grain Industry Association of SA Grain Industry Association Of Victoria

Grain NSW Inc

Queensland Agricultural Merchants Inc.

Life Members

Mr Mervyn May Mr Christopher Kelly

Mr Geoff Honey (Posthumously awarded)

Ms Tracey Lehmann Mr Donald McTaggart Mr Robert Imrav Mr Malcolm Finlayson

Mr Geoff Webb Mr Chris Hood

Mr Jarrod Tonkin

Mr Stephen Schumacher Mr Ron Harris Mr Simon Clancy

Mr Lachie Stevens Mr Mark Martin Mr Gerard McMullen Mr Scott Still

Mr Mark Murphy Mr Gerard Murphy Ms Hannah Janson Mr Yasuhide Okumura

Mr Raul Ovelar Mr Rod Buckle

Mr Jerome Critch Mr Mark Sloan Mr Peter Longhurst Mr Ian Dalgliesh

Mr Chris Heinjus Mr David Hudson Mr Tom Hage Mr Chris Tonkin

Mr Isherwood Feng

Mr Paul Schweitzer

Mr Richard Simonaitis D. McKeon/M. Southan Ms Larissa Taylor Mr Andrew Weidemann

Mr Robert Hardie Mr Stephen Sheridan

Ms Rebecca Freeman

Mr Colin Peace Ms Joanne Ware Mr John Francis

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Former GTA CEO

Retired