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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

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Notice under section 34AC of the Agricultural and Veterinary Chemicals Code: paraquat reconsideration – decisions on reconsideration

1) I, James Deller, Executive Director, Science and Assurance, am a delegate of the Australian Pesticides and Veterinary Medicines Authority (APVMA) for the purpose of reconsidering an approval or registration and making a decision under sections 34, 34A and 34AA of the Agricultural and Veterinary Chemicals Code (scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (**Agvet Code**).

2) This notice is published in the APVMA Gazette pursuant to section 34AC(1)(b) of the Agvet Code and relates to the reconsideration of paraquat active constituent approvals, product registrations and label approvals listed in Attachment A of this notice.

3) The Statement of Reasons for my decisions is included as Attachment B of this notice.

4) The information on which the reasons are based is set out in Attachment C of this notice.

5) Pursuant to section 34A(1) of the Agvet Code, I have decided to:

   a. vary the conditions of paraquat active constituent approvals listed in Attachment A of this notice, in a manner set out in paragraph 24 of the Statement of Reasons, to allow affirmation under section 34(1) of the Agvet Code; and

   b. vary the relevant particulars and conditions of the chemical product registrations listed in Attachment A, in a manner set out in paragraphs 48, 49, 50, 51, 52, 55, 71.9 and 76 of the Statement of Reasons, to allow the approvals to be affirmed under section 34(1) of the Agvet Code; and

   c. vary the relevant particulars of the label approvals listed in Attachment A in the manner set out in paragraph 94 of the Statement of Reasons to allow the approvals to be affirmed under section 34(1) of the Agvet Code.

6) Pursuant to section 34(1) of the Agvet Code, and following my decisions above to vary the relevant particulars and conditions for the active constituent approvals, product registration and label approvals, I have also decided to affirm the active constituent approvals, product registration and label approvals listed in Attachment A as varied.

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Date: 22 June 2026

Attachments:

Note: The below Attachments form part of this Notice.

Attachment A: Active constituent approval(s), product registration(s) and approved label(s) that have been reconsidered.
Attachment B: Statement of Reasons
Attachment C: Information on which the reasons are based.

Attachment A: Active constituent approvals, product registrations and label approvals that have been reconsidered

Table 1: Active constituent approval(s), product registration(s) and associated label approval(s) that have been reconsidered

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
Paraquat	Active	44249	Paraquat Dichloride Manufacturing Concentrate	Syngenta Australia Pty Ltd	N/A	N/A
Paraquat	Active	44387	Paraquat Dichloride Manufacturing Concentrate	Nufarm Australia Limited	N/A	N/A
Paraquat	Active	48272	Paraquat Dichloride Manufacturing Concentrate	Syngenta Australia Pty Ltd	N/A	N/A
Paraquat	Active	51041	Paraquat Dichloride Manufacturing Concentrate	Ronic International Pty Limited	N/A	N/A
Paraquat	Active	54043	Paraquat Dichloride Manufacturing Concentrate	Halley International Enterprise (Australia) Pty Ltd	N/A	N/A
Paraquat	Active	54131	Paraquat Dichloride Manufacturing Concentrate	Capital Commodities (Vic) Pty. Ltd.	N/A	N/A
Paraquat	Active	55327	Paraquat Dichloride Manufacturing Concentrate	ADAMA Australia Pty Limited	N/A	N/A
Paraquat	Active	55682	Paraquat Dichloride Manufacturing Concentrate	Imtrade Australia Pty Ltd	N/A	N/A
Paraquat	Active	55966	Paraquat Dichloride Manufacturing Concentrate	Syngenta Australia Pty Ltd	N/A	N/A
Paraquat	Active	56809	Paraquat Dichloride Manufacturing Concentrate	Conquest Crop Protection Pty Ltd	N/A	N/A
Paraquat	Active	58230	Paraquat Dichloride Manufacturing Concentrate	Sinon Australia Pty Limited	N/A	N/A
Paraquat	Active	59171	Paraquat Dichloride Manufacturing Concentrate	Agrogill Chemicals Pty Ltd	N/A	N/A
Paraquat	Active	64565	Paraquat Dichloride	FMC Australasia Pty Ltd	N/A	N/A

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
			Manufacturing Concentrate			
Paraquat	Active	64765	Paraquat Dichloride Manufacturing Concentrate	Sharda Worldwide Exports Pvt Ltd	N/A	N/A
Paraquat	Active	69493	Paraquat Dichloride Manufacturing Concentrate	Grow Choice Pty Limited	N/A	N/A
Paraquat	Active	87171	Paraquat Dichloride Manufacturing Concentrate	Agrogill Chemicals Pty Ltd	N/A	N/A
Paraquat	Active	89426	Paraquat Dichloride	Hebei Shanli Chemical Company Limited	N/A	N/A
Paraquat	Active	91420	Paraquat dichloride Technical concentrate	Jiangsu Noon Crop Science CO., LTD	N/A	N/A
Paraquat	Product	52141	Kendon Sprayquat 250 Herbicide	Kendon Chemicals & Mnfg Co Pty Ltd	52141/0500, 52141/0999	52141/RV2026
Paraquat	Product	53381	Imtrade Paraquat 250 Herbicide	Imtrade Australia Pty Ltd	53381/1000, 53381/100253, 53381/106312, 53381/51336	53381/RV2026
Paraquat	Product	54520	Halley Paraquat 250 Herbicide	Halley International Enterprise (Australia) Pty Ltd	54520/0801, 54520/1202	54520/RV2026
Paraquat	Product	56102	Kenso Agcare Para-Ken 250 Herbicide	Kenso Corporation (M) Sdn. Bhd.	56102/0610, 56102/0702, 56102/53089, 56102/61702	56102/RV2026
Paraquat	Product	57817	Conquest Explode 250 Herbicide	Conquest Crop Protection Pty Ltd	57817/0307, 57817/0510, 57817/0803	57817/RV2026
Paraquat	Product	58992	Sinmosa 250 Herbicide	Sinon Australia Pty Limited	58992/0105, 58992/50026, 58992/53184, 58992/59400, 58992/101535	58992/RV2026
Paraquat	Product	59419	Inferno Herbicide	Sipcam Pacific Australia Pty Ltd	59419/0505, 59419/102920, 59419/118753	59419/RV2026
Paraquat	Product	61869	Titan Paraquat 250 Herbicide	Titan Ag Pty Ltd	61869/139390, 61869/0510, 61869/0608, 61869/0507	61869/RV2026
Paraquat	Product	61254	Biotis Paraquat 250 Herbicide	Biotis Life Science Pty Ltd	61254/0507, 61254/0510	61254/RV2026
Paraquat	Product	63090	Ozcrop Paraquat 250 Herbicide	Oz Crop Pty Ltd	63090/0708	63090/RV2026

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
Paraquat	Product	64430	Kenso Agcare Para-Ken 334 Herbicide	Kenso Corporation (M) Sdn. Bhd.	64430/0610, 64430/54874, 64430/61703, 64430/114792	64430/RV2026
Paraquat	Product	64588	Smart Paraquat 250 Herbicide	Crop Smart Pty Ltd	64588/48715, 64588/60109, 64588/118398	64588/RV2026
Paraquat	Product	64651	RC Paraquat 250 Herbicide	Ruralchem Pty Ltd	64651/0410	64651/RV2026
Paraquat	Product	64706	Fosterra Paraquat 250 Herbicide	Fosterra Pty Ltd	64706/49009	64706/RV2026
Paraquat	Product	64731	Agro-Essence Paraquat 250SL	Agro-Alliance (Australia) Pty Ltd	64731/49093, 64731/53446, 64731/54621	64731/RV2026
Paraquat	Product	65148	Trio Paraquat 250 Herbicide	CTS Chemicals Pty Ltd	65148/50279, 65148/135965	65148/RV2026
Paraquat	Product	65537	Sanonda Herbicide Paraquat 250sl	Sanonda (Australia) Pty Ltd	65537/51150	65537/RV2026
Paraquat	Product	65694	Rainbow Paraquat 250 Sl Herbicide	Shandong Rainbow International Co Ltd	65694/51593	65694/RV2026
Paraquat	Product	65713	Pacific Paraquat 250 Herbicide	Pacific Agriscience Pty Ltd	65713/51679	65713/RV2026
Paraquat	Product	66103	Apparent Paraquat 250 Herbicide	Titan Ag Pty Ltd	66103/137280 66103/53597	66103/RV2026
Paraquat	Product	66249	AW Putout 250 Herbicide	Agri West Pty Limited	66249/53075	66249/RV2026
Paraquat	Product	66309	Huilong Paraquat 250 Herbicide	Huilong Agrochemicals Australia Pty Ltd	66309/53355, 66309/107521	66309/RV2026
Paraquat	Product	66531	ACP Paraquat 250 Herbicide	Australis Crop Protection Pty Ltd	66531/53829	66531/RV2026
Paraquat	Product	66548	Echem Paraquat 250 Herbicide	Echem (Aust) Pty Limited	66548/53852	66548/RV2026
Paraquat	Product	67163	Easyfarm Paraquat 250 SL Herbicide	Easyfarm Pty Ltd	67163/55370, 67163/59774, 67163/120285	67163/RV2026
Paraquat	Product	67307	AC Piston 250 Herbicide	Axichem Pty Ltd	67307/55741	67307/RV2026
Paraquat	Product	67437	Agroquat 250 Herbicide	Agrogill Chemicals Pty Ltd	67437/56038	67437/RV2026
Paraquat	Product	67888	Spalding Paraquat 250 Herbicide	DGL Environmental Pty Ltd	67888/57030	67888/RV2026
Paraquat	Product	67977	Ezycrop Paraquat 250 SL Herbicide	Ezycrop Pty Ltd	67977/57214, 67977/59893	67977/RV2026

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
Paraquat	Product	68196	Novaguard Paraquat 250 SL Herbicide	Novaguard Pty Ltd	68196/57751, 68196/59890	68196/RV2026
Paraquat	Product	68477	Agmate Paraquat 250 SL Herbicide	Agcare Pty Ltd	68477/58426	68477/RV2026
Paraquat	Product	68577	Gramoxone 360 Pro Herbicide	Syngenta Australia Pty Ltd	68577/58627, 68577/104881, 68577/127264, 68577/137924	68577/RV2026
Paraquat	Product	69274	Sabakem Paraquat 250SL Herbicide	Sabakem Pty Ltd	69274/60389	69274/RV2026
Paraquat	Product	69502	Cruze 300 Herbicide	DGL Environmental Pty Ltd	69502/60947	69502/RV2026
Paraquat	Product	69712	Paradox 250 Herbicide	Sinon Australia Pty Limited	69712/61482, 69712/105552	69712/RV2026
Paraquat	Product	70143	Farmalinx Powerquat 300 SL Herbicide	Farmalinx Pty Ltd	70143/62602	70143/RV2026
Paraquat	Product	82754	Agritrading Paraquat 250 Herbicide	Agritrading Pty Limited	82754/106654	82754/RV2026
Paraquat	Product	83010	Paraquick Force 350 Herbicide	Nutrien Ag Solutions Limited	83010/107304, 83010/111905	83010/RV2026
Paraquat	Product	83170	Barmac Paraquat 250 Herbicide	Amgrow Pty Ltd	83170/107674	83170/RV2026
Paraquat	Product	83185	Accensi Paraquat 300 Herbicide	Accensi Pty Ltd	83185/107696	83185/RV2026
Paraquat	Product	83835	Rainquat Full Herbicide	Shandong Rainbow International Co Ltd	83835/141205	83835/RV2026
Paraquat	Product	84794	Agmerch Paraquat 250 SL Herbicide	Agmerch Pty Ltd	84794/111440, 84794/132402	84794/RV2026
Paraquat	Product	85110	Kelpie P-Quat 300 SL Herbicide	Sinochem International Australia Pty Ltd	85110/112301	85110/RV2026
Paraquat	Product	85169	Conquest Explode 300 Plus Herbicide	Conquest Crop Protection Pty Ltd	85169/112553	85169/RV2026
Paraquat	Product	85420	Hemani Paraquat 250 SL Herbicide	Hemani Australia Pty Ltd	85420/113232, 85420/129768	85420/RV2026
Paraquat	Product	86364	Genfarm Paraquat 360 Herbicide	Nutrien Ag Solutions Limited	86364/115574	86364/RV2026
Paraquat	Product	86801	Ozcrop Paraquat 360 SL Herbicide	Oz Crop Pty Ltd	86801/116625, 86801/141135	86801/RV2026

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
Paraquat	Product	87191	4Farmers Paraquat 300 Herbicide	4 Farmers Australia Pty Ltd	87191/117737	87191/RV2026
Paraquat	Product	87259	Conquest Explode 360 Herbicide	Conquest Crop Protection Pty Ltd	87259/117967	87259/RV2026
Paraquat	Product	87271	ACP Paraquat 360 Herbicide	Australis Crop Protection Pty Ltd	87271/118004	87271/RV2026
Paraquat	Product	87370	Kelpie P-Quat 250 SL Herbicide	Sinochem International Australia Pty Ltd	87370/118207, 87370/136519	87370/RV2026
Paraquat	Product	87424	Titan Paraquat 360 Herbicide	Titan Ag Pty Ltd	87424/118325, 87424/139549	87424/RV2026
Paraquat	Product	87665	Spraytop 330 Herbicide	ADAMA Australia Pty Limited	87665/118915	87665/RV2026
Paraquat	Product	88941	Genfarm Paraquat 250 SL Herbicide	Nutrien Ag Solutions Limited	88941/122985	88941/RV2026
Paraquat	Product	89076	F.S.A. Paraquat 250 Herbicide	Four Seasons Agribusiness Pty Ltd	89076/123547	89076/RV2026
Paraquat	Product	89808	Genfarm Para 250 SL Herbicide	Nutrien Ag Solutions Limited	89808/126163	89808/RV2026
Paraquat	Product	89981	Smart Paraquat 300 Herbicide	Crop Smart Pty Ltd	89981/126635	89981/RV2026
Paraquat	Product	90742	Agro-Essence Paraquat 300 Herbicide	Agro-Alliance (Australia) Pty Ltd	90742/129923	90742/RV2026
Paraquat	Product	91705	CropSure Parashot Plus 360 Herbicide	Cropsure Pty Ltd	91705/133194	91705/RV2026
Paraquat	Product	91833	JN PARAQUAT 250 HERBICIDE	JIANGSU NOON CROP SCIENCE CO., LTD	91833/133611	91833/RV2026
Paraquat	Product	91989	Red Dog Paraquat 250 Herbicide	OZ CROP PTY LTD	91989/134100	91989/RV2026
Paraquat	Product	92586	Weed Force Dagger 250 Knockdown Herbicide	WEED FORCE PTY LTD	92586/135970	92586/RV2026
Paraquat	Product	92841	Submarino Paraquat 250 SL Herbicide	SUBMARINO PTY LTD	92841/136885	92841/RV2026
Paraquat	Product	93182	Sabakem Paraquat 360SL Herbicide	SABAKEM PTY LTD	93182/138177	93182/RV2026
Paraquat	Product	93444	eChem Paraquat 360 Herbicide	ECHEM (AUST) PTY LIMITED	93444/139189	93444/RV2026
Paraquat	Product	94216	F.S.A. Paraquat 360 Herbicide	FOUR SEASONS	94216/141841	94216/RV2026

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
				AGRIBUSINESS PTY LTD		
Paraquat, amitrole	Product	67344	Imtrade Para-Trooper Herbicide	Imtrade Australia Pty Ltd	67344/55849, 67344/101488, 67344/107531, 67344/115164	67344/RV2026
Paraquat, amitrole	Product	89484	Imtrade Guerrilla Herbicide	Imtrade Australia Pty Ltd	89484/125000, 89484/133061	89484/RV2026
Paraquat, Diquat	Product	58336	Halley Premier 250 Herbicide	Halley International Enterprise (Australia) Pty Ltd	58336/0504, 58336/0805	58336/RV2026
Paraquat, Diquat	Product	58412	Imtrade Spraykill 250 Herbicide	Imtrade Australia Pty Ltd	58412/104038	58412/RV2026
Paraquat, Diquat	Product	58470	Conquest Scorcher 250 Herbicide	Conquest Crop Protection Pty Ltd	58470/0208, 58470/0304, 58470/0904, 58470/54699	58470/RV2026
Paraquat, Diquat	Product	59098	Spray-Plant 250 Herbicide	Sipcam Pacific Australia Pty Ltd	59098/0305, 59098/1208	59098/RV2026
Paraquat, Diquat	Product	59333	Kenso Agcare Speedy 250 Herbicide	Kenso Corporation (M) Sdn. Bhd.	59333/0205, 59333/49612, 59333/53090, 59333/61930	59333/RV2026
Paraquat, Diquat	Product	61460	Alarm Herbicide	Sipcam Pacific Australia Pty Ltd	61460/1006	61460/RV2026
Paraquat, Diquat	Product	61860	Titan Eos Herbicide	Titan Ag Pty Ltd	61860/0607, 61860/0808	61860/RV2026
Paraquat, Diquat	Product	62495	Sanonda Paraquat/Diquat Herbicide	Sanonda (Australia) Pty Ltd	62495/0308	62495/RV2026
Paraquat, Diquat	Product	64325	Farmalinx Paradat Herbicide	Farmalinx Pty Ltd	64325/0809	64325/RV2026
Paraquat, Diquat	Product	64704	Fosterra Paraquat / Diquat Herbicide	Fosterra Pty Ltd	64704/49007	64704/RV2026
Paraquat, Diquat	Product	64802	Kwicknock 250 Herbicide	Grow Choice Pty Limited	64802/0310, 64802/60104	64802/RV2026
Paraquat, Diquat	Product	65295	Rainbow Diqu-Para 250 Herbicide	Shandong Rainbow International Co Ltd	65295/51629, 65295/61985	65295/RV2026
Paraquat, Diquat	Product	65708	Pacific Diquat/Paraquat 250 Herbicide	Pacific Agriscience Pty Ltd	65708/51671	65708/RV2026
Paraquat, Diquat	Product	66327	AW Dismantle Herbicide	Agri West Pty Limited	66327/53393	66327/RV2026
Paraquat, Diquat	Product	66788	Agro-Essence Paraquat+Diquat 250 Herbicide	Agro-Alliance (Australia) Pty Ltd	66788/54406	66788/RV2026
Paraquat, Diquat	Product	67399	Easyfarm Paraquat-Diquat 250 Herbicide	Easyfarm Pty Ltd	67399/55961, 67399/59778	67399/RV2026

Active Constituent(s)	Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
Paraquat, Diquat	Product	67627	Apparent Weedy Seedy 250 Herbicide	Titan Ag Pty Ltd	67627/56500, 67627/102353	67627/RV2026
Paraquat, Diquat	Product	67707	Smart Combination 250 Herbicide	Crop Smart Pty Ltd	67707/56672, 67707/60106, 67707/118522	67707/RV2026
Paraquat, Diquat	Product	67891	Spalding Exocet 250 Herbicide	DGL Environmental Pty Ltd	67891/57038	67891/RV2026
Paraquat, Diquat	Product	68075	Ezycrop Paraquat-Diquat 250 Herbicide	Ezycrop Pty Ltd	68075/57436, 68075/59891	68075/RV2026
Paraquat, Diquat	Product	68202	Novaguard Paraquat-Diquat 250 Herbicide	Novaguard Pty Ltd	68202/57760	68202/RV2026
Paraquat, Diquat	Product	68280	Agro Burner 250 Herbicide	Agrogill Chemicals Pty Ltd	68280/57926	68280/RV2026
Paraquat, Diquat	Product	68479	Agmate Paraquat & Diquat 250 SL Herbicide	Agcare Pty Ltd	68479/58428	68479/RV2026
Paraquat, Diquat	Product	83169	Barmac Paraquat/Diquat 250 Herbicide	Amgrow Pty Ltd	83169/107673	83169/RV2026
Paraquat, Diquat	Product	83923	Accensi Paraquat / Diquat Prime 250 Herbicide	Accensi Pty Ltd	83923/109251	83923/RV2026
Paraquat, Diquat	Product	85112	Raystar Paraquat Diquat SL Herbicide	Raystar Cropprotection Pty Ltd	85112/112304	85112/RV2026
Paraquat, Diquat	Product	89832	Genfarm Di-Par 250 SC Herbicide	Nutrien Ag Solutions Limited	89832/126207	89832/RV2026
Paraquat, Diquat	Product	89918	Trio Paraquat Diquat 250 SL Herbicide	CTS Chemicals Pty Ltd	89918/126340, 89918/135188	89918/RV2026
Paraquat, Diquat	Product	90172	Cropsure Squadron 250 Herbicide	Cropsure Pty Ltd	90172/127840	90172/RV2026
Paraquat, Diquat	Product	91135	Agmerch Paraquat 135 & Diquat 115 Herbicide	Agmerch Pty Ltd	91135/131016	91135/RV2026

Attachment B: Statement of Reasons

Contents

Material findings of fact and reasons for my decisions

1. Subsection 34(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (**Agvet Code**) provides that I must affirm the approval or registration if, and only if, I am satified:

    a. for an active constituent—that the constituent meets the safety criteria; and

    b. for a chemical product—that the product meets the safety criteria, the trade criteria and the efficacy criteria; and

    c. for a label—that the label meets the labelling criteria; and

    d. that the constituent, product or label complies with any requirement prescribed by the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth) (**Agvet Code Regulations**).

2. Subsection 34(2) of the Agvet Code provides that section 34(1) applies only to the extent that I decide to reconsider matters covered by that subsection.

3. For the purposes of making a decision on the reconsideration of the approval or registration, section 34(3) of the Agvet Code provides that I must:

    a. have regard to:

        - any information given, or submissions made, to the APVMA in response to a notice given under subsection 32(1); and
        - any submissions made to the APVMA in response to an invitation under paragraph 32(2A)(b) or 34AB(2)(f); and
        - any information given by the holder in response to an invitation given by the APVMA (whether or not under this Code) in relation to the constituent, product or label; and
        - any information, report, results or sample given to the APVMA in response to a notice given under section 33; and
        - any information given to the APVMA as required by section 161 in relation to the constituent, product or label; and
        - any other information that I consider necessary to enable me to make a decision on the reconsideration; but

    b. not take into account any submission, information, report, results or sample not covered by the above.

4. I have outlined at Attachment C, the information covered by subsection 34(3)(a) that I have had regard to in making the reconsideration decisions.

5. Subsection 34A(1) of the Agvet Code provides that, if I:

    a. am not satisfied as mentioned in subsection 34(1); but

    b. am satisfied that the relevant particulars or conditions of the approval or registration can be varied in such a way as to allow the approval or registration to be affirmed;

    I must vary the relevant particulars or conditions.

6. In considering whether the relevant particulars or conditions of the approval or registration can be varied in such a way as to allow the approval or registration to be affirmed, subsection 34A(2) provides that I may only have regard to the following:

a. submissions, information, reports, results or samples that I had regard to under section 34; and

b. submissions made to the APVMA in response to the invitation under subsection 34AB(2)(f) (notice of proposed decision).

7. I have reconsidered paraquat active constituent approvals, registrations of chemical products containing paraquat as the active constituent and associated label approvals under Part 2, Division 4 of the Agvet Code to determine whether:

7.1. the active constituents meet the safety criteria (section 5A of the Agvet Code);

7.2. the chemical products meet the safety criteria (section 5A of the Agvet Code), the trade criteria (section 5C of the Agvet Code), and the efficacy criteria (section 5B of the Agvet Code);

7.3. the labels meet the labelling criteria (section 5D of the Agvet Code); and

7.4. the active constituents, chemical products and labels comply with any requirements prescribed by the Agvet Regulations.

8. Where I was not satisfied of the relevant matters in subsection 34(1) of the Agvet Code in relation to the active constituent approvals, registrations of chemical products containing paraquat as the active constituent and associated label approvals as discussed in my reasons below, I considered whether the relevant particulars or conditions of the approval or registration could be varied in such a way as to allow the approval or registration to be affirmed in accordance with section 34A of the Agvet Code.

Active constituents

9. Subsection 34(1) of the Agvet Code provides that I must affirm the approval of an active constituent if, and only if, I am satisfied that the constituent:

9.1. meets the safety criteria (section 5A); and

9.2. complies with any requirement prescribed by the Agvet Regulations.

10. I have considered all matters covered by subsection 34(1) in relation to the reconsideration of paraquat active constituent approvals specified at Attachment A.

Consideration of whether active constituents meet the safety criteria

11. Subsection 5A(1) of the Agvet Code provides that an active constituent meets the safety criteria if use of the active constituent, in accordance with any instructions approved or to be approved by the APVMA for the constituent or contained in an established standard:

a. is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (subsection 5A(1)(a));

b. is not, or would not be, likely to have an effect that is harmful to human beings (subsection 5A(1)(b)); and

c. is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (subsection 5A(1)(c)).

12. For the purpose of being satisfied as to whether the active constituents meet the safety criteria, I must have regard to the matters specified under subsection 5A(2)(a), and I may also have regard to such other matters as I think are relevant (subsection 5A(2)(b)).

13. For the purposes of considering whether the active constituents specified at Attachment A meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, I have had regard to the matters set out in subsection 5A(2)(a) of the Agvet Code as follows.

14. Section 5A(2)(a)(i) of the Agvet Code – the toxicity of the constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.

14.1. I have considered assessment reports by the APVMA's relevant expert staff regarding the following information in respect of the toxicity of paraquat and its residues as summarised in the *Paraquat Final Review Technical Report*:

a. studies examining the absorption, metabolism and excretion of paraquat in animal models and humans exposed through occupational, accidental or intentional exposure as described in section 3 (Toxicology) of the *Paraquat Final Review Technical Report*;

b. studies on the toxicological effects of paraquat, including the toxicological mode of action, acute and chronic toxicity, genotoxicity, reproductive and developmental toxicity in animal models and humans exposed through occupational, accidental or intentional exposure as described in section 3 (Toxicology) of the *Paraquat Final Review Technical Report*;

c. studies on the potential for paraquat to cause neurotoxicity as described in section 3.1.6.1 of the *Paraquat Final Review Technical Report*;

d. studies on the metabolism and degradation of paraquat on treated crops and the residues and metabolites that are present in commodities following harvest as described in section 5 (Residues and Trade) of the *Paraquat Final Review Technical Report*;

e. studies on the environmental fate and behaviour of paraquat in the environment including degradation and environmental toxicity studies as detailed in section 6 (Environmental Safety) of the *Paraquat Final Review Technical Report*;

f. the APVMA's Record of Approved Active Constituents for paraquat active constituents for use in agricultural chemical products.

g. I note that submissions related to the toxicity of paraquat, and particularly the neurotoxicity of paraquat, which were received following publication of the proposed regulatory decisions on 30 July 2024 have been considered. Details of these considerations have been published separately in the document *Final Regulatory Decisions on Paraquat – Consideration of Neurotoxicity Submissions*. I have had regard to the recommendations in that report and in the Paraquat Final Review Technical Report and I agree with the conclusion that "⋯ *the evidence available to date does not convincingly demonstrate a direct causal association between exposure to paraquat occupationally and/or through residential exposure to pesticides used on nearby land, and an increased risk of developing Parkinson's disease.*"

h. I also note that no changes to the paraquat health-based guidance values are recommended.

14.2. I am satisfied that the following health-based guidance values are applicable for paraquat as described in section 3.2 (Health-based guidance values) of the *Paraquat Final Review Technical Report*.

a. The acceptable daily intake[1](ADI) for paraquat is 0.004 milligram per kilogram body weight per day (mg/kg bw/day) based on a no observed adverse effect level (NOAEL) of 0.45 mg/kg bw/day in a one-year dog dietary study, which observed pulmonary lesions at the next higher dose. The ADI

[1] ADI - Acceptable Daily Intake (for humans): a level of intake of a chemical (expressed mg/kg bw/day; milligrams per kilogram of body weight per day) that can be ingested daily over an entire lifetime without any appreciable risk to health

incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity.

b. The acute reference dose[2] (ARfD) for paraquat is 0.004 mg of paraquat per kg body weight based on a no observed adverse effect level of 0.45 mg per kilogram body weight in a dog dietary study, considering that pulmonary lesions would also occur after an acute exposure at the next higher dose. The ARfD incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity.

14.3. I am satisfied that an acceptable level of exposure to paraquat for workers (below which it is unlikely to have an effect that is harmful to human beings) corresponds to a greater than 100-fold margin of exposure (MOE) applied to a point of departure of 0.045 mg/kg bw/day, taking into consideration an oral NOAEL of 0.45 mg/kg bw/day and an oral availability of 10% as described in section 4.1 (Worker exposure assessment) of the *Paraquat Final Review Technical Report.*

14.4. I am satisfied that, due to little metabolism or degradation in plants or animals (section 5.1 of the *Paraquat Final Review Technical Report*), and based on available analytical methods and stability of paraquat in stored samples (section 5.2 of the *Paraquat Final Review Technical Report*), *paraquat cation* is the most appropriate residue definition for both risk assessment and enforcement of compliance with Maximum Residue Limits (MRLs) in plant and animal commodities as described in section 5.3 (Residue definition) of the *Paraquat Final Review Technical Report*.

14.5. I have considered and agree with the assessment of the fate and behaviour of paraquat in the environment (section 6.2 of the *Paraquat Final Review Technical Report*) and the toxicity of paraquat and its metabolites and residues to non-target species (section 6.3 of the *Paraquat Final Review Technical Report*), which has identified Regulatory Acceptable Levels (RALs)[3] of exposure to paraquat (below which it is unlikely to have an unintended effect that is harmful to plants or animals or things or to the environment) as detailed in section 6.3 (Effects on non-target species) and Table 31 of the *Paraquat Final Review Technical Report*.

14.6. I note that the RALs for aquatic species and terrestrial plants have been revised following consideration of new information provided to the APVMA during consultation on the proposed regulatory decisions, as described in sections 3.27 and 3.33 of the APVMA's consideration of submissions document.

a. Specifically, I note that the RAL for Aquatic species has been revised from 0.41 μg ac/L to 0.15 μg ac/L based on the refined assessment of data discussed in section 3.27, 3.28 and 3.29 of the APVMA's consideration of submissions document and sections 6.3 (Effects on non-target species) and 6.4.2 (Aquatic species) of the *Paraquat Final Review Technical Report.*

b. I also note that the RAL for terrestrial plants has been revised from 19 g ac/ha to 11 g ac/ha based on refined assessment as discussed in section 3.33 of the APVMA's consideration of submissions document and in sections 6.3 (Effects on non-target species) and 6.4.6 (non-target terrestrial plants) of the *Paraquat Final Review Technical Report.*

14.7. I am satisfied that exposure of non-target species to paraquat below the RALs listed in Table 2 below is not expected to have an unintended effect that is harmful to animals, plants, things or the environment.

Table 2: Regulatory Acceptable Levels for exposure of non-target species to paraquat

[2] ARfD - Acute Reference Dose (for humans): a level of intake of a chemical (expressed mg/kg bw; milligrams per kilogram of body weight) that can be ingested in 1 meal or in a 24 hour period without any appreciable risk to health

[3] RAL – Regulatory Acceptable Level: a level of chemical exposure that is sufficiently lower than the concentration where harmful effects are observed in the relevant species that it can be concluded harmful effects are unlikely to occur

Group	Exposure type	RAL
Mammals	Acute	6.1 mg ac/kg bw
	Chronic	3.8 mg ac/kg bw/d
Birds	Acute	5.7 mg ac/kg bw
	Chronic	2.7 mg ac/kg bw/d
Aquatic species	Chronic	0.15 µg ac/L
Sediment dwellers	Acute	3.9 mg ac/kg ds
Adult bees	Acute contact	6.4 µg ac/bee
	Acute oral	5.2 µg ac/bee
Foliar arthropods	Contact	8.2 g ac/ha
Ground arthropods	Contact	600 g ac/ha
Soil macro-organisms	Acute	100 mg ac/kg ds
Terrestrial plants	Post-emergent	11 g ac/ha

15. Section 5A(2)(a)(ii) of the Agvet Code – the method by which the constituent is, or is proposed to be, manufactured.

15.1. The APVMA's chemistry assessment, as detailed in section 2.1 of the *Paraquat Final Review Technical Report,* considered information submitted in the original applications for active constituent approval, or subsequent variation of an approval, regarding the method of manufacture for each approved paraquat active constituent.

15.2. I have considered and agree with the recommendation that the information submitted in the original applications for active constituent approval, or subsequent variation of an approval, demonstrates that the method by which each of the paraquat active constituents with the approval numbers 44249, 55966, 69493, 87171, 89426 and 91420 is manufactured is expected to result in paraquat dichloride technical concentrate that complies with the *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022* (Agricultural Active Constituents Standards 2022) made under section 6E of the Agvet Code.

15.3. I have considered and agree with the recommendation in section 2.1 of the *Paraquat Final Review Technical Report* that the information submitted in the original applications for active constituent approval or subsequent variation of an approval, does not sufficiently address the parameters specified for paraquat in the Agricultural Active Constituents Standards 2022 to allow the APVMA to conclude whether the method by which each of the paraquat active constituents with the approval numbers 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 is manufactured, will result in paraquat active constituents that comply with the Agricultural Active Constituents Standards 2022 discussed in paragraph 16 below.

16. Section 5A(2)(a)(iii) of the Agvet Code – the extent to which the constituent will contain impurities.

16.1. The APVMA's chemistry assessment has considered the following information, as described in the chemistry section of the *Paraquat Final Review Technical Report*:

a. Information submitted in the original applications for active constituent approval, or subsequent variation of an approval, regarding the purity and expected impurities for each approved paraquat active constituent.

b. The Agricultural Active Constituents Standards 2022, which are aligned with the FAO Specifications for paraquat, require that the minimum purity of paraquat dichloride technical concentrate, on a dry weight basis, is 920 g/kg, with maximum levels for two toxicologically significant impurities; 0.001 g/kg (1.0 ppm) maximum total terpyridines at and 1.0 g/kg (1000 ppm) maximum 4,4'-bipyridyl.

c. The Agricultural Active Constituent Standards 2022 specifications for paraquat requires the inclusion of an emetic, 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazole-(1,5a)pyrimidin-5-one (PP796), at not less than 0.8 g/L of technical concentrate.

16.2. I have considered and agree with the APVMA's chemistry assessments, as described in section 2.1, and the recommendations in section 2.4 of the *Paraquat Final Review Technical Report* which concluded that:

a. the formation of degradation products that are impurities of toxicological concern during storage of the manufacturing concentrate or in the formulated chemical product is not expected because these were not present in analyses previously considered and the impurities that result from manufacturing are well understood.

b. the paraquat active constituents (manufacturing concentrates) with the approval numbers 44249, 55966, 69493, 87171, 89426 and 91420, comply with the Active Constituent Standards 2022 with respect to the minimum purity of the active constituent and presence of the emetic pp796, and maximum levels of impurities.

c. the available information does not sufficiently address the parameters specified for paraquat in the Agricultural Active Constituents Standards 2022 to allow the APVMA to conclude that remaining paraquat active constituents with the approval numbers 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 comply with the *Active Constituents Standards 2022*.

d. an updated Declaration of Composition (44249, 55966), or an updated Declaration of Composition and the results of 5 batch analyses (44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565), is required demonstrate that these active constituents conform to the Agricultural Active Constituents Standards 2022 and FAO Specification for paraquat dichloride.

17. Section 5A(2)(a)(iv) of the Agvet Code – whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis.

17.1. The APVMA's chemistry assessment, as detailed in section 2.1 of the *Paraquat Final Review Technical Report,* has considered the batch analyses that were submitted and assessed by the APVMA as part of the original approval for each approved paraquat active constituent.

17.2. I agree with the APVMA's assessment of the batch analyses for active constituents 44249, 55966, 69493, 87171, 89426 and 91420 which concluded that the chemical composition of those paraquat active constituents is compliant with the *Active Constituents Standards 2022*, as detailed in the *Paraquat Final Review Technical Report*.

17.3. I am **not satisfied** that the paraquat active constituents with the approval numbers 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 meet the safety criteria. I agree with the APVMA's chemistry assessment which concluded that the available analyses of the chemical composition of the constituent was inadequate for the APVMA to determine whether the active constituent complies with the Agricultural Active Constituents Standards 2022.

18. Section 5A(2)(a)(v) of the Agvet Code – any conditions to which its approval is, or would be, subject.

18.1. I have had regard to the conditions to which the approvals are subject as prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code, including:

a. Regulation 17C(1) of the Agvet Regulations which prescribes conditions to which the approval of an active constituent for a proposed or existing chemical product is subject. Those conditions relate to matters such as the manufacture of the active constituent.

b. Section 5 of the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021* (Conditions of Approval or Registration Order) which prescribes conditions that apply to the approval of an active constituent for a proposed or existing agricultural chemical product. Those conditions include restrictions on the supply of the active constituent if its manufacture contravenes or fails to comply with any manufacturing law of the country (or part of the country) in which it is manufactured.

18.2. I have also had regard to the conditions imposed on the approval of paraquat active constituents in accordance with section 23(1)(b) of the Agvet Code through the condition referred to as the *Agricultural Active Constituents Quality Assurance Requirements* which is reproduced below.

"*Agricultural Active Constituents must meet Quality Assurance Requirements*

- *A person must not Supply the Active Constituent, or cause it to be supplied, unless the Active Constituent:*
  - *complies with the APVMA Standard for the Active Constituent; and*
  - *was manufactured at a site of manufacture listed in the Record of Approved Active Constituents.*
- *A person must at the time of Supply of a Batch of the Active Constituent to another person also supply details of the Batch Number of the Active Constituent to the person to whom the active constituent was supplied.*
- *For the purposes of these conditions a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method:*
  - *does not contain less than the minimum purity and/or content of the constituent as set out in the APVMA Standard; and*
  - *does not contain more than the maximum level of any impurity as set out in the APVMA Standard*

Definitions and Interpretation – in these conditions the following words have the following meanings:

- *'APVMA Standard' means the standard determined by the APVMA to which a constituent must comply and which is published on the APVMA website;*
- *'Batch' means a defined quantity of material produced in a single series of operations;*
- *'Batch Number' means that a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined;*
- *'Supply' has the same meaning as given to it in Section 3 of the Agvet Codes and includes the doing of those things through, or pursuant to an arrangement with another person*."

18.3. I am **not satisfied** that the current condition referred to as the 'Agricultural Active Constituent Quality Assurance Requirements' remains appropriate, noting that items 1 and 3 of the condition above are redundant in light of the Regulation 17C(1) of the Agvet Regulations.

18.4. I note that a number of paraquat active constituent approvals are subject to additional conditions imposed by the APVMA under s23(1)(b) of the Agvet Code related to the site of manufacture. I note that these conditions are now redundant with reg 17C(1)2 and 17C(1)3 of the Agvet Regulations.

18.5. I also note that number of paraquat active constituent approvals are subject to additional conditions imposed by the APVMA under s23(1)(b) of the Agvet Code requiring compliance with the outcomes of the reconsideration as below.

> *"Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 34 of the NRA / APVMA Gazette dated October 1998 (Paraquat).**
>
> ***Explanatory Note: you should be aware that the APVMA will take steps to apply the outcomes of that reconsideration to this registration/approval as it thinks fit."*

18.6. The obligations imposed by the current 'Agricultural Active Constituent Quality Assurance Requirements' condition, and the conditions noted at paragraphs 18.4 and 18.5, above, imposed in accordance with section 23(1)(b) of the Agvet Code are intended to require appropriate quality assurance processes and record keeping to ensure traceability and allow recall or other rectification action if necessary due to contamination or other fault with paraquat active constituents. Redundant or incorrect references to legislative instruments or other documents may result in failure to follow these requirements correctly, which may result in harmful effect to people or the environment.

18.7. I am satisfied that the conditions imposed by the Conditions of Approval or Registration Order in conjunction with the conditions prescribed by the Agvet Regulations, as referenced above, remain appropriate and are acceptable.

19. Section 5A(2)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Record for the constituent.

19.1. I have had regard to the relevant particulars recorded for each approved paraquat active constituent. Section 3 of the Agvet Code provide that the relevant particulars, in relation to the approval of an active constituent, are the distinguishing number, any instructions for use and any other particulars required by section 19(c) to be entered in the Record. Section 19(c) of the Agvet Code refers to any other particulars prescribed by the regulations. Regulation 15(1) of the Agvet Regulations prescribes the following particulars for the purposes of subsection 19(c) of the Agvet Code:

a. if a name is given to the active constituent by the International Union of Pure and Applied Chemistry—that name

b. if no name is given to the active constituent by the International Union of Pure and Applied Chemistry—the name given to the active constituent in the standard prescribed in respect of the active constituent for the purposes of paragraph 87(1)(a) of the Code

c. the name of the active constituent

d. the composition and purity of the active constituent

e. the name of the manufacturer of the active constituent

f. the address of each site at which the active constituent is manufactured by the manufacturer

g. identifying information for the holder of the approval of the active constituent

h. the date of entry of these particulars in the Record of Approved Active Constituents

i. identifying information for any nominated agent for the approval.

19.2. I note that the relevant particulars recorded in the APVMA's Record of Approved Active Constituents for Chemical Products have been reviewed as discussed in section 2.1 of the *Paraquat Final Review Technical Report*.

19.3. I am satisfied that all relevant particulars entered into the Record for paraquat active constituent with the approval numbers 69493, 87171, 89426 and 91420 are correct.

19.4. I am **not satisfied** that the information entered in the Record related to the composition and purity of the paraquat active constituents with the approval numbers 44249 or 55966 is correct as the Declarations of Composition that were provided with those applications do not list all relevant impurities of toxicological concern and additional components required by the Agricultural Active Constituent Standards 2022. However, I am satisfied that results of batch analyses provided with those applications demonstrates that the relevant impurities and other components comply with the Agricultural Active Constituents Standards 2022. I am satisfied that all other relevant particulars entered into the Record for the approval numbers 44249 and 55966 is correct.

19.5. I note that the information entered in the Record related to the composition and purity of the paraquat active constituents with the approval numbers 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 is not sufficient to demonstrate compliance of those active constituents with the Agricultural Active Constituents Standards 2022 and I am **not satisfied** that any other information demonstrates compliance of these active constituents with the Standard. However, I am satisfied that all other relevant particulars entered into the Record for the approval numbers 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 are correct.

20. Section 5A(2)(a)(via) of the Agvet Code – whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection 5A(1).

20.1. The Agricultural Active Constituents Standards 2022 were made under section 6E(1) of the Agvet Code for active constituents used in agricultural chemical products, including paraquat.

a. The Agricultural Active Constituents Standards 2022 require that the minimum purity of paraquat dichloride technical concentrate, on a dry weight basis, is 920 g/kg, with maximum levels for two toxicologically significant impurities; 0.001 g/kg (1.0 ppm) maximum total terpyridines at and 1.0 g/kg (1000 ppm) maximum 4,4'-bipyridyl.

b. The Agricultural Active Constituent Standards 2022 specifications for paraquat requires the inclusion of an emetic, PP796, at not less than 0.8 g/L of technical concentrate.

20.2. I note that information regarding the purity and composition of the active constituent submitted in support of the applications for approval, or subsequent variation of approvals, of paraquat active constituents has been reviewed as detailed in section 2.1.2 of the *Paraquat Final Review Technical Report.*

20.3. I accept the conclusions in section 2.1.2 of the *Paraquat Final Review Technical Report* that:

a. the information considered in relation to the paraquat active constituents with the approval numbers 44249, 55966, 69493, 87171, 89426 and 91420 demonstrates that they comply with the Active Constituent Standards 2022 with respect to the minimum purity of the active constituent and presence of the emetic pp796, and maximum levels of impurities

b. the declarations of composition provided in relation to the active constituent approvals 44249, 55966 do not list all required impurities and components for paraquat dichloride technical concentrates listed in the Agricultural Active Constituent Standards 2022

c. the available information does not sufficiently addresses the parameters specified for paraquat in the Agricultural Active Constituents Standards 2022 to allow the APVMA to conclude that remaining paraquat active constituents with the approval numbers 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 comply with the Agricultural Active Constituents Standards 2022.

20.4. I am satisfied that paraquat active constituents with the approval numbers 44249, 55966, 69493, 87171, 89426 and 91420 conform to the Agricultural Active Constituents Standards 2022, made under section 6E(1) of the Agvet Code.

20.5. I am **not satisfied** that the paraquat active constituents with the approval numbers 44249, 55966, or 44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765 comply with the Agricultural Active Constituents Standards 2022.

21. Section 5A(2)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.

21.1. Regulation 8AA of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition of the active constituent concerned as a relevant consideration in determining whether an active constituent meets the safety criteria.

21.2. I have considered and agree with the assessment of the information about the method of analysis of the chemical composition of the active constituent submitted as part of the original applications for approval and found to be acceptable by the APVMA at that time, as described in the chemistry section at 2.1.2 of the *Paraquat Final Review Technical Report*.

a. I accept the APVMA's previous findings regarding the method of analysis and note that there has not been any new information provided that would alter my satisfaction regarding the method of analysis of the chemical composition of the active constituents.

b. I am satisfied of the method of analysis of the chemical composition of each approved paraquat active constituent listed in Attachment A.

22. Section 5A(2)(b) of the Agvet Code – such other matters as the APVMA thinks relevant.

22.1. For the purposes of considering whether the active constituents meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, there were no other matters that I considered relevant in determining whether paraquat active constituents meet the safety criteria.

23. Having had regard to the matters described above, I am **not satisfied** that the paraquat active constituent approvals listed in Attachment A meet the safety criteria for the following reasons:

23.1. For the active constituent approvals 44249, 44387, 48272, 51041, 54043, 54131, 55327, 55682, 55966, 56809, 58230, 59171, 64565 and 64765, I am **not satisfied** that the information considered with respect to the method by which the constituent is, or is proposed to be, manufactured (section 5A(2)(a)(ii)) see paragraph 15 above), the extent to which the constituent will contain impurities (section 5A(2)(a)(iii) - see paragraph 16 above) or the analyses conducted on the chemical composition of the active constituent (section5A(2)(a)(iv) - see paragraph 17 above), demonstrates the active constituents meet the Active Constituents Standards 2022 for the purpose of section 5A(2)(a)(via) of the Agvet Code (see paragraph 20).

23.2. I am also **not satisfied** that the information entered in the record in relation to the composition and purity of the active constituents listed in paragraph 19.4 (44249, 55966) and 19.5 (44387, 48272, 51041, 54043, 54131, 55327, 55682, 56809, 58230, 59171, 64565 and 64765) is compliant with the Agricultural Active Constituent Standards 2022.

a. Because I do not have information listed in paragraphs 23.1 and 23.2 above, regarding potential impurities resulting from the method of manufacture, and the analyses of the chemical composition

of the active constituents are not sufficient to demonstrate compliance with the Active Constituents Standards 2022, with respect to the requirements notes at paragraph 15, 16 and 17 above, I cannot be satisfied that there is not a level of impurity of toxicological concern which would be an undue hazard to people exposed to (5A(1)(a) it and would not be likely to have an effect that is harmful to people (5A(1)(b) or to animals or plants or things or the environment (5A(1)(c).

b. Because I do not have information demonstrating the level of the emetic required by the Active Constituent Standards 2022 is present in the active constituents noted in 19.4, 19.5 I cannot be satisfied that the active constituent will not be an undue hazard to people exposed to it (5A(1)(a) as the emetic is an essential measure to mitigate the risk of accidental poisoning.

23.3. For all paraquat dichloride active constituent approvals, I am **not satisfied** that the condition of approval referred to as the '*Agricultural Active Constituent Quality Assurance Requirements*' remains appropriate as it substantially duplicates conditions imposed by the Agvet Regulations and the requirements of the Agricultural Active Constituent Standards 2022. The obligations imposed by these conditions are intended to require appropriate quality assurance processes and record keeping to ensure traceability and allow recall or other rectification action, if necessary, due to contamination or other fault with paraquat products. Redundant or incorrect references to legislative instruments or other documents may result in failure to follow these requirements correctly resulting in inability to recall or otherwise make-safe paraquat products when necessary.

a. Without appropriate quality assurance and traceability requirements in place I cannot be satisfied that active constituents will meet the Agricultural Active Constituent Standards 2022 and will not contain unacceptable levels of impurities of toxicological concern, or that faults can be appropriately rectified once identified. Therefore I am not satisfied that the active constituents with the current conditions will not be an undue hazard to people (s5A(1)(a) or likely to have an effect that is harmful to people (s5A(1)(b), or an untended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c).

23.4. Accordingly, I am not satisfied that that active constituents meet the safety criteria with the relevant particulars of their current approvals: s 34(1).

Consideration of whether active constituent approvals can be varied to meet the safety criteria and allow the approval to be affirmed

24. I have considered whether the relevant particulars or conditions of the active constituent approvals can be varied in such a way as to meet the safety criteria set out in section 5A(1) for the purposes of section 34A(1) of the Agvet Code.

24.1. I am satisfied that the conditions imposed by the APVMA on active constituent approvals 44249, 44387, 48272, 51041, 54043, 54131, 55327, 55682, 55966, 56809, 58230, 59171, 64565 and 64765 can be varied to address the concerns identified in paragraphs 15, 16, 17, and 19 above regarding the method by which the constituent is manufactured, the extent to which the constituent contains impurities, analysis of the constituent and relevant particulars that are entered in the Record. I am satisfied that there is no technical reason why these active constituents cannot be manufactured in compliance with the above-mentioned parameters, but that these need to be demonstrated to the APVMA to allow ongoing approval of these active constituents. Accordingly, I have decided to impose the following condition of approval under section 34A(1) of the Agvet Code:

Condition of approval

On or before the date 1 year after the publication of the section 34AC notice of the paraquat reconsideration decision, as the holder of the approval [HOLDER] is required to provide to the APVMA the results of 5 batch analyses and an amended Declaration of Composition demonstrating compliance of the

active constituent [insert approval number] with the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022.

24.2. I am satisfied that this adding this condition will mitigate the risks noted at paragraph 23.1 and 23.2 above because holders will demonstrate that their products comply with the Agricultural Active Constituents Standards within 1 year, or their approvals will be subject to cancellation for breach of the condition of approval as provided by section 36 of the Agvet Code.

24.3. To address concerns identified in paragraph 18.3 which relate to my consideration of the conditions of approval of all paraquat active constituents, as required by section 5A(2)(a)(v) of the Agvet Code, I have decided to vary the condition referred to as the 'Agricultural Active Constituent Quality Assurance Requirements' to remove items that are redundant with requirements set out in legislation or regulations, while ensuring that record keeping providing traceability of each batch of active constituent is retained. That condition will now read as follows:

Condition of approval: Agricultural Active Constituent Quality Assurance Requirements

A person supplying any quantity of a Batch of active constituent to another person must, at the time of supply, give the Batch Number for that Batch of active constituent to the person to whom the active constituent is being supplied.

Definitions and Interpretation

Batch means a defined quantity of material produced in a single series of operations.

Batch Number means a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined.

Supply has the same meaning as in Section 3 of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)

24.4. It is my view that it is necessary for holders and suppliers to keep records of supply of active constituent to provide traceability in the event that a batch of active constituent is contaminated or otherwise supplied in a way that means is fails to meet the safety criteria, so that affected batches of active constituent can be recalled or otherwise made safe, and that the above condition will make these requirements clear and enforceable.

24.5. I am satisfied that if I remove the conditions noted in paragraph 18.5 I will remove the potential for improper quality assurance processes and record keeping caused by redundant and inconsistent conditions and the associated risks to human health and the environment.

25. For the purposes of section 34A(1)(b), I am satisfied that the relevant particulars or conditions of the paraquat active constituent approvals listed in Table 1 in Attachment A of this notice can be varied in the ways set out in paragraph 24 above, to allow the approval of those active constituents to be affirmed. Accordingly, I must vary the relevant particulars or conditions in this manner: s 34A(1).

Consideration of whether active constituents comply with any requirement prescribed by the regulations

26. Section 34(1)(d) of the Agvet Code provides that I must affirm an active constituent approval only if I am satisfied that the constituent complies with any requirements prescribed by the regulations.

26.1. There are no other requirements prescribed by the regulations for paraquat active constituents that have not already been considered above.

Chemical Products

27. Subsections 34(1)(b) and (d) of the Agvet Code provide that the APVMA must affirm the registration for a chemical product if, and only if, it is satisfied that the product:

    a. meets the safety criteria (section 5A);

    b. meets the efficacy criteria (section 5B);

    c. meets the trade criteria (section 5C); and

    d. complies with any requirement prescribed by the regulations.

28. I have considered all matters covered by subsection 34(1)(b) in relation to the reconsideration of paraquat chemical product registrations specified at Attachment A except where those matters relate to the active constituent amitrole, co-formulated in some chemical products containing paraquat. For the avoidance of doubt, any reference to a paraquat product in my reasons refers to all products containing paraquat including products containing diquat or amitrole. Matters that apply specifically to products containing only specific active constituents are noted in the relevant paragraphs.

Consideration of whether registered chemical products meet the safety criteria

29. Section 5A(1) of the Agvet Code provides that a chemical product meets the safety criteria if use of the product, in accordance with any instructions approved, or to be approved, by the APVMA for the product or contained in an established standard:

    a. is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a));

    b. is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b)); and

    c. is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).

30. For the purposes of considering whether paraquat chemical products meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, I have had regard to the matters set out in section 5A(3)(a) of the Agvet Code.

31. Section 5A(3)(a)(i) – the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.

    31.1. I have considered assessment reports regarding the following information in relation to the toxicity of paraquat chemical products (including products containing both paraquat and diquat as active constituents, and products containing amitrole in addition to paraquat as active constituents, noting that I am not making findings with respect to amitrole) and their residues as summarised in the *Paraquat Final Review Technical Report*:

        a. the APVMA's Register of Agricultural and Veterinary Chemical Products for paraquat agricultural chemical products.

        b. information about the toxicity of paraquat and its residues, as set out in paragraph 14 above, and section 3 (Toxicology) of the *Paraquat Final Review Technical Report* and the references therein, including the paraquat health-based guidance values.

        c. information about the toxicity of products containing a combination of paraquat and diquat, for the purpose of occupational exposure risk assessments as discussed in section 4.1 of the *Paraquat*

Final Review Technical Report. I note that the toxicity of diquat is fully assessed in the *Diquat Final Review Technical Report*.

d. information about the presence and formation of impurities of toxicological concern during manufacture and storage of paraquat chemical products as described in section 2.2 (Formulated products) of the *Paraquat Final Review Technical Report*.

e. the impact of any excipients in the chemical products on the toxicity of the paraquat chemical products to relevant organisms and ecosystems, including human beings as detailed in section 2.3 of the *Paraquat Final Review Technical Report.*

f. environmental toxicity studies on the effects of formulated paraquat products on non-target species, including RALs for exposure, below which it is unlikely that the product will have an unintended effect that is harmful to plants or animals or things or the environment, as detailed in sections 6.3 (Effects on non-target species) and 6.5 (Combination toxicity) of the *Paraquat Final Review Technical Report* and listed in Table 2 above.

g. information about the combined toxicity of paraquat and diquat in relation to RALs for exposure of non-target species and environmental effects of products that contain both active constituents as detailed in section 6.5 (Combination toxicity) of the *Paraquat Final Review Technical Report*.

31.2. I have considered and agree with the recommendation that there is sufficient information on the toxicity of the impurities of toxicological concern (4,4'bipyridyl and total terpyridines), and the potential sources of these impurities in both paraquat manufacturing concentrate and formulated products to determine that formulated paraquat chemical products are not expected to contain unacceptable levels of impurities of toxicological concern as described in sections 2.1.2 and 2.3 of the *Paraquat Final Review Technical Report*.

31.3. I have considered and agree with the finding that an ADI of 0.004 mg/kg bw/day and ARfD of 0.004 mg/kg bw/day as listed in paragraph 14.2 of this statement of reasons and defined in section 3.2 (Health based guidance values) of the *Paraquat Final Review Technical Report* are applicable in assessing the risk to human health from use of paraquat chemical products.

31.4. I have considered and agree with the worker exposure risk assessment described in section 4.1 (Worker exposure assessment) and in Table 9 of the *Paraquat Final Review Technical Report* which determined that acceptable levels of occupational exposure to paraquat can be defined by applying a greater than 100-fold margin of exposure to a point of departure of 0.045 mg/kg bw/day.

31.5. I note that RALs have been calculated specifically with respect to sensitive areas considered under the APVMA's spray drift risk assessment manual and that these are listed in section 7 (Spray drift) of the *Paraquat Final Review Technical Report*.

31.6. I am satisfied that exposure of non-target organisms to paraquat below the RALs determined in sections 6.3 (Effects on non-target species) and 7 (Spray drift) of the *Paraquat Final Review Technical Report* is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

31.7. I am satisfied that there is sufficient information to assess the impact of formulation excipients and, where relevant, the co-formulated active constituent diquat, on the toxicity of paraquat chemical products and their residues in relation to relevant organisms and ecosystems, including human beings.

31.8. I am therefore satisfied that the toxicity of paraquat chemical products and those products co-formulated with the active constituent diquat, and their residues, including metabolites and degradation products, are sufficiently defined to allow assessment as to whether paraquat chemical products meet the safety criteria.

32. Section 5A(3)(a)(ii) of the Agvet Code – the relevant poison classification of the product under the law in force in this jurisdiction.

32.1. Paraquat is listed in Schedule 7 of the *Therapeutic Goods (Poisons Standard—February 2026) Instrument 2026* (Poisons Standard). This instrument is also commonly referred to as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

a. The SUSMP imposes additional requirements in recognition of the significant toxicity of paraquat, so that in addition to the signal heading "DANGEROUS POISON", aqueous solutions of paraquat must also bear the cautionary statements:

CAN KILL IF SWALLOWED
DO NOT PUT IN DRINK BOTTLES
KEEP LOCKED UP

- These statements must be printed on separate lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN". The SUSMP also requires that liquid preparations of paraquat must be coloured blue or green and must contain sufficient stenching agent to produce an offensive smell.

32.2. No change to the current poisons scheduling for paraquat is required.

32.3. I note that the information recorded in the Register for each paraquat chemical product and information submitted in support of the original applications for registration, including the product formulation information has been reviewed as described in section 2.3 of the *Paraquat Final Review Technical Report.* I agree with the findings and recommendations in sections 2.3 and 2.4 of the *Paraquat Final Review Technical Report.* I am satisfied that agricultural chemical products containing paraquat meet the requirements prescribed by the SUSMP.

33. Section 5A(3)(a)(iii) of the Agvet Code – how the product is formulated.

33.1. As above, I note that the information recorded in the Register for each paraquat chemical product and information submitted in support of the original applications for registration, including the product formulation information has been reviewed as described in section 2.3 of the *Paraquat Final Review Technical Report.*

33.2. I note that registered chemical products containing paraquat are formulated as:

a. soluble concentrates (SL) containing between 250 and 360 g/L of paraquat

b. soluble concentrates (SL) containing 135 g/L of paraquat co-formulated with 115 g/L of diquat as an additional active constituent

c. soluble concentrates (SL) containing between 250 and 300 g/L of paraquat with between 10 and 12 g/L of amitrole as an additional active constituent.

33.3. I am satisfied that all products containing paraquat also contain sufficient blue or green dye and stenching agent to comply with the requirements of the SUSMP described in paragraph 32.1 above.

33.4. I am satisfied that the formulation of chemical products containing paraquat remains acceptable with respect to the safety criteria.

34. Section 5A(3)(a)(iv) of the Agvet Code – the composition and form of the constituents of the product.

34.1. As above, I note that the information recorded in the Register for each paraquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.3 of the *Paraquat Final Review Technical Report*.

34.2. I have considered and agree with the assessment of registration records for paraquat chemical products in respect of the composition and form of the constituents of the chemical products containing paraquat, including the Declaration of Composition for the active constituent, certificates of analysis for the

formulated products and the manufacturer's specification of other constituents, as described in the *Paraquat Final Review Technical Report*.

34.3. I am satisfied that the composition and form of the constituents of the paraquat products remain acceptable with respect to the safety criteria for chemical products.

35. Section 5A(3)(a)(v) of the Agvet Code – any conditions to which a product's registration is, or would be, subject.

35.1. I have considered conditions to which the registrations are subject as prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code.

35.2. I have considered the information entered in the Register for paraquat chemical products and the relevant provisions in the Agvet Code and Agvet Regulations in considering the conditions to which paraquat chemical products are or would be subject.

a. Chemical product registrations are currently subject to the conditions prescribed by items 1, 2, 3, 4, 5, 6, and 7 of the table in regulation 17C(2) of the Agvet Regulations. Those conditions relate to matters such as the contents, manufacture and supply or the chemical product.

b. However, I note that items 3 and 4 of regulation 17C(2) do not apply to any agricultural chemical product (i.e. paraquat) pursuant to regulation 17C(3) as these are prescribed under regulation 59(1)(a) for the purposes of section 120A of the Agvet Code.

35.3. Regulation 18 of the Agvet Regulations also prescribes conditions for registration of chemical products relating to containers for chemical products. This condition requires that the container meet certain prescribed requirements.

35.4. I note that registered agricultural chemical products are also subject to the conditions of registration imposed under the Conditions of Approval or Registration Order. Those conditions include restrictions on the supply of the chemical product if its manufacture contravenes or fails to comply with any manufacturing law of the country (or part of the country) in which it is manufactured.

35.5. I am satisfied that the conditions detailed above are appropriate for the registered chemical products containing paraquat.

35.6. Paraquat chemical product registrations are also subject to additional conditions imposed by the APVMA under section 23(1)(b) of the Agvet Code.

a. Products registered after the commencement of the reconsiderations of paraquat and diquat have been registered with the following condition:

> "*Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 34 of the NRA / APVMA Gazette dated October 1998 (Paraquat).**
>
> **Explanatory Note: you should be aware that the APVMA will take steps to apply the outcomes of that reconsideration to this registration/approval as it thinks fit.*"

b. Noting that the reconsideration will be completed following my decision I consider that this condition is no longer required.

c. Paraquat products registered prior to amendment of the Agvet Regulations 2014 were registered with a condition requiring that containers for the product meet certain parameters. I note that this condition is wholly redundant with the condition prescribed by regulation 18 of the Agvet Regulations and as such is no longer required as a separate condition imposed by the APVMA.

35.7. The condition referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' which is reproduced below has previously been applied to all agricultural chemical products, including paraquat products.

"Agricultural Products must meet the Agricultural Products Active Constituent Quality Assurance Requirements

- *Manufacture of active constituent - the registrant must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:*
  - *complies with the APVMA Standard for that active constituent; and*
  - *was manufactured at a site of manufacture listed in the Record of approved active constituents.*
- *Analysis results - the registrant must not supply the chemical product or cause it to be supplied unless the registrant has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:*
  - *the active constituent contained in the chemical product complied with the APVMA Standard for that active constituent;*
  - *if there is an APVMA Standard for a constituent in the chemical product that is not an active constituent, the constituent complied with the APVMA Standard for that constituent; and*
  - *the batch number of the active constituent contained in the chemical product.*
- *Records - the registrant must, at or prior to the supply of a batch of the chemical product by the registrant or by another person on behalf of the registrant, make or have in its possession, a record that contains the following information:*
  - *The name of the chemical product.*
  - *The APVMA product number of the chemical product.*
  - *If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
  - *The date of importation into, or manufacture in, Australia as the case may be.*
  - *The batch number of the chemical product from which the supply was made.*
  - *The quantity of the chemical product that constitutes the batch.*
  - *The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product.*
- *The registrant must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.*
- *The registrant must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.*
- *Possession of batch analysis results and records - for the purposes of these conditions, batch analysis results or records are in the possession of the registrant if batch analysis results or records are:*
  - *in the possession of the registrant; or*
  - *in the possession of another person pursuant to an arrangement with the registrant.*

- *Compliance with the Standard - for the purposes of these conditions, a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method does not contain:*
  - *less than the minimum purity and/or content of the constituent as set out in the APVMA Standard for the Constituent*
  - *more than the maximum level of any impurity as set out in the APVMA Standard.*
- *Definitions and Interpretation - in these conditions the following words have the following meanings:*
  - *'APVMA Standard' means the standard determined by the APVMA to which a constituent contained in chemical products must comply and which is published on the APVMA website.*
  - *'Batch' means a defined quantity of material produced in a single series of operations.*
  - *'Batch number' means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.*
  - *'Batch analysis results' means the results of analysis from each batch of the constituent that include:*
    1. *the name of the manufacturer and the manufacturing site address*
    2. *the date of the analysis*
    3. *the batch number and date of manufacture of the batch*
    4. *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the APVMA Standard for the constituent*
    5. *full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant).*
  - *If analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.*
  - *'Record' means a document in written or electronic form that contains the particulars set out in paragraph (3) and which is readily accessible for the purposes of Part 9 of the Agvet Code (Enforcement).*
  - *'Supply' has the same meaning as given to it in section 3 of the Agvet Code and includes the doing of those things through, or pursuant to an arrangement with, another person."*

35.8. I **do not** consider that the current condition referred to as ‘Agricultural Products Active Constituent Quality Assurance Requirements’, to which each paraquat chemical product registration is subject, remains appropriate. The condition references the ‘APVMA Standard’ available on the APVMA Website, which has been replaced by the Agricultural Active Constituents Standards 2022. The condition also references a ‘registrant’ which is not defined within the Agvet Code or related legislation, rather than referring to the ‘holder’. Further, the condition is substantially redundant given the requirements already imposed by the Agvet Code or the Agvet Regulations.

35.9. The obligations imposed by conditions to which the registration is subject under section 23(1)(b) of the Regulations are intended to require appropriate quality assurance processes and record keeping to ensure traceability and allow recall or other rectification action if necessary due to contamination or other fault with paraquat products. Redundant or incorrect references to legislative instruments or other documents may result in failure to follow these requirements correctly resulting in inability to recall or otherwise make-safe

paraquat products when necessary, meaning these products may be an undue hazard to people using them or exposed to anything containing their residues (s5A(1)(a)).

36. Section 5A(3)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Register for the product.

36.1. I have had regard to the relevant particulars recorded for each approved chemical product registration. Section 3 of the Agvet Code provides that the relevant particulars, in relation to the registration of a chemical product, are the distinguishing number, any instructions for use and any other particulars required by section 20(1)(c) to be entered in the register. Section 20(1)(c) of the Agvet Code refers to any other particulars prescribed by the regulations. Regulation 16 of the Agvet Regulations prescribes the following particulars for the purposes of section 20(1)(c) of the Agvet Code:

a. the distinguishing name of the chemical product

b. the constituents of the chemical product

c. the concentration of each constituent of the chemical product

d. if possible, the composition and purity of each active constituent of the chemical product

e. the formulation type for the chemical product

f. the net contents for the chemical product

g. identifying information for the holder of the registration for the chemical product

h. the name of each manufacturer of the chemical product

i. the address of each site at which the chemical product is manufactured by the manufacturer

j. the date of entry of these particulars in the Register of Chemical Products

k. identifying information for any nominated agent for the registration.

36.2. I note that the relevant particulars recorded in the Register for each paraquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.3 of the *Paraquat Final Review Technical Report*.

36.3. I have had regard to the assessments of the relevant particulars entered in the Register for each of the products listed Attachment A and have also considered the conclusions of the chemistry (section 2.4), environment (section 6.6), human health (section 4.1.3), residues and trade (section 5.21) and spray drift (section 7) risk assessments described in the *Paraquat Final Review Technical Report*.

36.4. I am satisfied that all relevant particulars that are entered in the Register for paraquat chemical products, except for the instructions for use of the product mentioned in paragraph 36.5 below, remain acceptable.

36.5. With respect to whether the use of paraquat or paraquat plus diquat products according to the instructions for use approved by the APVMA is not an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and is not likely to have an effect that is harmful to human beings, I have considered and agree with recommendations in the relevant sections of the *Paraquat Final Review Technical Report* as noted below.

a. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* use of paraquat applied by ground boom with an open cab tractor in small scale agriculture (up to 6 ha per day) will not exceed acceptable worker exposure levels provided the operator uses the following personal protective equipment: single layer of clothing, gloves, PF10 respirator, and face shield or goggles when mixing or loading.

b. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* for use of paraquat applied by enclosed cab ground boom in broad scale agriculture (up to 500 ha per day, or 400 ha per day for cotton) handling up to 337 kg of paraquat per operator per day will not exceed acceptable worker exposure levels, provided the operator uses the following minimum personal protective equipment: enclosed mixing and loading (single layer of clothing, gloves, PF10 respirator, face shield or goggles when connecting, disconnecting or cleaning components of the mixing and loading system) and enclosed cab application.

c. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* use of paraquat applied by manually pressurised hand wand at rates up to 4.5 kg of paraquat per operator per day, or by mechanically pressurised hand wand at rates up to 3.9 kg of paraquat per operator per day, will result in acceptable occupational exposure levels provided that the operator uses the following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading.

d. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* use of paraquat, or products containing both paraquat and diquat, applied by equipment carried on the back of the user at rates exceeding 0.3 kg of paraquat per operator per day exceeds acceptable worker exposure levels at the maximum level of PPE that can be modelled.

e. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* use of chemical products containing both diquat and paraquat applied by ground boom with an open cab tractor in small scale agriculture (up to 6 ha per day) will not exceed acceptable worker exposure levels provided the operator uses the following personal protective equipment: single layer of clothing, gloves, PF10 respirator, and face shield or goggles when mixing or loading.

f. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* use of chemical products containing both diquat and paraquat applied by enclosed cab ground boom in broad scale agriculture at rates that exceed 317.7 kg of diquat (2763 L undiluted product) per operator per day will not exceed acceptable worker exposure levels, provided the operator uses the following minimum personal protective equipment: enclosed mixing and loading (single layer of clothing, gloves, PF10 respirator, face shield or goggles when connecting, disconnecting or cleaning components of the mixing and loading system) and enclosed cab application.

g. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* use of chemical products containing both diquat and paraquat applied by manually pressurised [up to 8.2 kg of diquat (71.3 L undiluted product] or mechanically pressurised hand wand [up to 2.3 kg of diquat (20 L undiluted product] per operator per day will result in acceptable worker exposure levels when the operator uses the following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading.

h. As described in section 4.1.1 of the *Paraquat Final Review Technical Report,* I note that that although mixer/loader exposure is acceptable with open mixing/loading with the specified PPE for certain uses, enclosed mixing/loading is required for all uses to minimise the likelihood of users decanting paraquat into unacceptable containers which may lead to consequential accidental exposure.

i. I note that section 4.1.2 of the *Paraquat Final Review Technical Report* recommends that workers must not re-enter treated areas until specified intervals of time have passed, which depend on the application rate and the activity that is occurring as noted in Tables 12, 13 and 14 in the *Paraquat Final Review Technical Report.* These intervals, or PPE if the re-entry interval cannot be observed, are necessary to prevent worker exposure exceeding the acceptable level discussed in section 4.1 and Table 9 of the *Paraquat Final Review Technical Report* and paragraph 14.3 above.

j. I note and agree with the recommendations in sections 5.21 (Consideration of the combined risk assessments) and 5.22 (Revised dietary exposure assessment) of the *Paraquat Final Review Technical Report* that the use of paraquat, or paraquat and diquat according to the instructions approved by the APVMA, for the uses that otherwise meet the safety criteria, are not expected to exceed acceptable levels of acute or chronic dietary exposure for paraquat or paraquat and diquat. I note and agree that use of paraquat for spray-topping to control annual rye-grass seed set in field peas, lupins, lentils, chickpeas and faba beans, does not have sufficient data to determine the quantity of residues following the 7-day harvest withholding period recorded on the labels for some products, but that there is sufficient data to determine that at 14 days after last application the residues of paraquat will be below the MRL of 1 mg/kg and will not exceed acceptable levels for dietary exposure.

k. I also note and agree with the recommendation in section 4.1.3 (Recommended Label Changes) of the *Paraquat Final Review Technical Report* that the signal headings, restraints, safety directions and re-entry statements indicated are required to be included as instructions for use of paraquat (and paraquat plus diquat) products, in order for users to know which PPE and other behaviours are necessary to safely use the products.

36.6. With respect to whether the use of paraquat or paraquat plus diquat products according to the instructions for use approved by the APVMA is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment, I have considered and agree with recommendations in the relevant sections of the *Paraquat Final Review Technical Report* as noted below.

a. I note that the environment risk assessment has considered the toxicity of paraquat (and the combined toxicity of paraquat plus diquat) to non-target plants, mammals, birds and other terrestrial vertebrates, aquatic species, bees, other arthropods, and soil organisms and has recommended that exposure below the RALs listed in Table 31 of the *Paraquat Final Review Technical Report* and in paragraph 14.7 above is not likely to have a harmful effects on non-target species.

b. I have considered and agree with the conclusion that the only instructions for use of paraquat products, including combinations of paraquat with diquat, that will not exceed the RALs are those listed in Table 46 of the *Paraquat Final Review Technical Report* and copied in Table 3 below.

Table 3: Uses of paraquat products, including combinations with diquat, that are not likely to have a harmful effect on non-target species.

Product type	Situation
Paraquat only products	Aid to cultivation (crop, pasture or fallow establishment) up to 231 g ac/ha Fallows at rates up to 770 g ac/ha for optical spot sprayers (30% area treated) Firebreaks, non-agricultural situations (around sheds, roadways, paths) up to 1140 g ac/ha Peanuts at rates up to 231 g ac/ha Rice (post-sowing, pre-crop emergence) 200 g ac/ha Spray topping to reduce annual ryegrass seed set (select pulses) 200 g ac/ha
Combination products containing 115 g/L diquat and 135 g/L paraquat[4]	Aid to cultivation (crop, pasture or fallow establishment) up to 251 g acs/ha Market gardens, nurseries, pre-emergence weed control (vegetable crops) at rates up to 251 g acs/ha (Spot-spray only) Potatoes (early emergence general weed control) at rates up to 251 g acs/ha (Spot-spray only) Public service areas and rights of way 800 g acs/ha

c. I note that the risk to aquatic species (section 6.4.2 of the *Paraquat Final Review Technical Report*) has been revised from the proposed regulatory decisions based on further refinement of the risk assessment and that the conclusion is now that the risk posed by runoff is acceptable for the currently approved use rates.

d. I note that the risk assessment for use of optical spot spraying has been revised from the recommendations in the APVMA's proposed regulatory decisions to correctly account for the current instructions limiting application to a maximum of 30% of the total treated area. Accordingly, the risk to non-target species is acceptable up to 770 g ac/ha when using optical spot spraying in fallows provided a maximum of 30% of the total area is treated.

e. I note that the risk assessment for non-agricultural situations, including around sheds, roadways, paths and firebreaks has been revised from the recommendations in the APVMA's proposed regulatory decision based on the weight of evidence argument that these areas typically amount to less than 10% of the total area and that risk assessments should be adjusted accordingly, as discussed in *Appendix C Terrestrial vertebrate assessments: weight of evidence discussion* of the *Paraquat Final Review Technical Report*. This argument has been accepted and accordingly the current instructions for use of paraquat in these situations is considered unlikely to have any harmful effects on non-target species.

f. I note that the risk assessment for bare soil scenarios, which applies to post-sowing and pre-crop emergence use of paraquat for weed control in rice, has been refined based on weight of evidence arguments related to mammals, but that the maximum acceptable application rate remains 231 g ac/ha, as described in *Appendix C Terrestrial vertebrate assessments: weight of evidence discussion* of the *Paraquat Final Review Technical Report*. Accordingly, this has been applied to the post-sowing and pre-crop emergence use of paraquat for weed control in rice which has current instructions for use at 200 g ac/ha and is therefore unlikely to have any harmful effects on non-target species.

g. I note that the risk assessment for bees (section 6.4.3 of the *Paraquat Final Review Technical Report*) has been refined from the proposed regulatory decisions. Based on the refined assessment an acceptable risk to bees can be concluded at up to 1140 g ac/ha. Therefore, no protection statement is required for bees.

[4] Application rates reflect the total active substances (diquat and paraquat)

h. I note that the proposed regulatory decisions supported use of paraquat in banana orchards at 175 g ac/ha, however review of the risk assessment has concluded that the maximum acceptable rate for wild mammals is 54 g ac/ha (see Table 32, and *Appendix C Terrestrial vertebrate assessments* of the *Paraquat Final Review Technical Report*), which is below the minimum current range of 175 g ac/ha and therefore I am unable to conclude that the use at the current rate is unlikely to result in harmful effects on non-target species.

i. I note that the weight of evidence argument regarding the risks to non-target mammals following use of paraquat for spray topping to control annual ryegrass seed set in pulses has been accepted in the environmental risk assessment, as discussed in *Appendix C Terrestrial vertebrate assessments: weight of evidence discussion* of the *Paraquat Final Review Technical Report*, given the marginal exceedance of the acceptable risk quotient (1.1, vs acceptable of 1) and the herbicidal mode of action (Table 79) will limit exposure of this group of organisms. Accordingly, I have concluded this use is unlikely to have any harmful effects to non-target species.

j. I note that the risk assessment for use of products containing co-formulated paraquat and diquat active constituents, as discussed in section 6.4 of the *Paraquat Final Review Technical Report,* has been revised and now supports use as an aid to cultivation in fallow, in market gardens for pre-emergence weed control (vegetable crops) at rates up to 251 g acs/ha (Spot-spray only) and for potatoes (general weed control) at rates up to 251 g combined active/ha. Accordingly, I have concluded these uses are unlikely to have any harmful effects to non-target species.

k. Instructions for use of products containing co-formulated paraquat and amitrole active constituents in any situation, except as an aid to cultivation prior to crop establishment for winter crops at rates up to 231 g paraquat/ha (or 770 g ac/ha for optical spot spraying with maximum of 30% of the area treated) , or in firebreaks and other non-agricultural situations exceeds the regulatory acceptable levels for exposure to paraquat for wild mammals and/or wild birds as described in the *Paraquat Final Review Technical Report.* I note that this finding has not considered the toxicity of amitrole, which is not subject to this reconsideration.

36.7. With respect specifically to spray-drift and whether the use of paraquat or paraquat plus diquat products according to the instructions for use approved by the APVMA is not likely to have an effect that is harmful to people or an unintended effect that is harmful to animals, plants or things or to the environment, I have considered and agree with recommendations in the relevant sections of the *Paraquat Final Review Technical Report* as noted below.

a. I have considered the recommendations in section 7 of the *Paraquat Final Review Technical Report* and I agree that the RALs noted in Tables 48 and 49 are the maximum level of exposure to paraquat, or a combination of paraquat and diquat that is not likely to have a harmful effect on the relevant sensitive areas, including bystander areas, natural aquatic areas, pollinator areas and vegetation areas.

b. I also have considered and agree that mandatory down-wind buffer zones between the treated area and the sensitive area are necessary to prevent exceedance of the relevant RALs.

c. I note that there are no current instructions or restraints related to spray drift contained in the relevant particulars and therefore I am not satisfied that the use of paraquat or paraquat plus diquat products will not have a harmful effect through spray drift.

37. Section 5A(3)(a)(via) of the Agvet Code – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).

37.1. The *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* is the only standard made under section 6E that relates to

matters covered by section 5A(1) of the Agvet Code and prescribes the maximum allowable variation of the concentration of constituents in registered agricultural chemical products from the nominal quantities recorded in the Register for active constituents and non-active constituents.

37.2. I have considered and agree with the chemistry assessment recommendation, as detailed in sections 2.3 and 2.4 of the *Paraquat Final Review Technical Report,* in regard to the Declarations of Composition and Certificates of Analysis for paraquat chemical products supplied as part of the original registration applications. I am satisfied that all registered paraquat chemical products comply with the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022*.

38. Section 5A(3)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.

38.1. Regulation 8AB of the Agvet Regulations prescribes matters the APVMA must have regard to for the purposes of being satisfied as to whether a chemical product meets the safety criteria.

38.2. Regulation 8AB(1)(a) of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product.

a. I have considered and accept the recommendations of the chemistry assessment, as detailed in section 2.3 of the *Paraquat Final Review Technical Report,* regarding the information about the method of analysis of the chemical composition and form of the constituents of paraquat chemical products submitted as part of the original applications for product registration.

b. There has not been any new information provided that would alter my satisfaction regarding the method of analysis of the chemical composition and form of the active constituents.

c. I am satisfied of the method of analysis of the chemical composition and form of the constituents of each registered paraquat chemical product listed in Attachment A.

38.3. Regulation 8AB(2) provides that regulations 8AB(1)(b) and (c) do not apply if the product is prescribed under subregulation 59(1) of the Agvet Regulations for the purposes of section 120A of the Agvet Code.

a. All agricultural chemical products are prescribed under regulation 59(1)(a) of the Agvet Regulations for the purposes of section 120A of the Agvet Code, therefore regulations 8AB(1)(b) and (c) are not relevant to paraquat chemical products.

38.4. Regulations 8AB(1)(d), (e) and (f) of the Agvet Regulations do not apply to paraquat chemical products because paraquat products are not molluscicides (8AB(1)(d) and (e)), or applied to seeds ((8AB(1)(f)).

39. Under section 5A(3)(b) of the Agvet Code, the APVMA may have regard to certain matters in determining whether a chemical product meets the safety criteria. For the purposes of considering whether the active constituents meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, I have had regard to matters set out in section 5A(3)(b) of the Agvet Code as discussed below.

40. Section 5A(3)(b)(i) of the Agvet Code – the acceptable daily intake of each constituent contained in the product.

40.1. I accept the recommendation of the APVMA's human health risk assessment described in section 3.2 (Health based guidance values) of the *Paraquat Final Review Technical Report*, which has determined that the acceptable daily intake for paraquat is 0.004 mg/kg bw/day as discussed in paragraph 14 above.

41. Section 5A(3)(b)(ii) of the Agvet Code – any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under section 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under section 82(4) of that Act.

41.1. There has not been a dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* because the APVMA has not notified FSANZ of variations to

the MRL standard under subsection 82(3) *Food Standards Australia New Zealand Act 1991*. Any changes to MRLs required as a result of the final regulatory decisions on the reconsideration of paraquat will be implemented following the 2-year phase out period discussed at paragraph 103 to 105, below, and a suitable further interval to ensure that stored commodities have moved through the supply chain after implementation of the final regulatory decisions.

42. Section 5A(3)(b)(iii) of the Agvet Code – whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.

42.1. I have considered and agree with the conclusions of the APVMA's Residues and Trade risk assessment, as described in sections 5.21 (Consideration of combined risk assessment outcomes for paraquat), 5.22 (Revised dietary exposure assessment) and 5.23 (Revised MRL recommendations) of the *Paraquat Final Review Technical Report*, which assessed the results of trials or experiments that have been conducted to determine the residue of paraquat products that will remain in all situations where those products are used, after considering whether those uses would otherwise meet the safety criteria as described in paragraph 36.5, or can be varied to meet the safety criteria as described in paragraph 49, to determine whether the residues of the product will not be greater than limits that the APVMA has approved or approves (Maximum Residue Levels; MRLs).

42.2. I note that trials or experiments have been conducted to determine the residue of paraquat products, including combined paraquat and diquat products, that will remain in all situations otherwise supported by human health and environment risk assessments.

42.3. I have considered and agree with the conclusions of the APVMA's Residues and Trade risk assessment, as detailed in sections 5.21 (Consideration of combined risk assessment outcomes for paraquat), 5.22 (Revised dietary exposure assessment) and 5.23 (Revised MRL recommendations) of the *Paraquat Final Review Technical Report,* for uses in the following situations that are supported by all other risk assessments:

a. Use of paraquat products or products containing a combination of paraquat and diquat as an aid to cultivation for crop, pasture or fallow establishment, or as a targeted spot-spray in market gardens and nurseries at rates up to 231 g paraquat/ha or 251 g paraquat plus diquat/ha is not expected to result in quantifiable residues of paraquat or diquat in any crops at harvest.

b. Use of products containing paraquat as an over-the-top spray on peanuts crops up to the 7-8 leaf stage is not expected to result in residues above the limit of quantification of 0.05 mg/kg in peanuts and accordingly will be below the relevant MRL.

c. Residues following use of paraquat for spray topping to control seed set of annual ryegrass at 200 g ac/ha in chickpeas, faba beans, field peas, lentils and lupins may exceed MRLs the APVMA approves (1 mg/kg) until 14 days after the last application.

d. Use of paraquat post-sowing, pre-crop emergence in rice at 200 g ac/ha is not expected to result in residues above the limit of quantification of 0.05 mg/kg and accordingly will be below the relevant MRL.

e. Residues from use in all other situations, including fodder and forage, will not exceed current MRLs approved by the APVMA.

43. Section 5A(3)(b)(iv) of the Agvet Code – the stability of the product.

43.1. I have considered and agree with the recommendation of the chemistry assessment described in sections 2.3 and 2.4 of the *Paraquat Final Review Technical Report* which has considered information provided in the applications for registration of paraquat chemical products and assessed by the APVMA at the time of

registration. I am satisfied that those products are expected to be adequately stable provided they are stored in accordance with the instructions on the approved labels.

44. Section 5A(3)(b)(v) of the Agvet Code – the specifications for containers for the product.

44.1. I have considered and agree with the recommendation of the APVMA's chemistry assessment as described in sections 2.3 and 2.4 of the *Paraquat Final Review Technical Report,* which has considered information provided in the applications for registration of paraquat chemical products regarding the containers for paraquat products. I am satisfied that the containers for paraquat products are acceptable with respect to the conditions for containers for chemical products prescribed in regulation 18 of the Agvet Regulations, except for regulation 18(e), which requires that the container must enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot harm a person or have an unintended effect that is harmful to the environment.

44.2. I have noted and agree with the recommendation in sections 4.1.1 (Ground-based application) and 4.1.3 (Recommended label changes) of the *Paraquat Final Review Technical Report* that all paraquat products must be used with enclosed mixing and loading equipment to minimise the potential for decanting the product into unacceptable containers or accidental spills, both of which may lead to consequential accidental exposure.

44.3. Accordingly, I am **not satisfied** that the containers for paraquat chemical products enable all or any part of the container's contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot harm a person or have an unintended effect that is harmful to the environment, as required by regulation 18(e), as no relevant information about the suitability of containers for currently registered paraquat chemical products for use with enclosed mixing and loading systems has been provided to the APVMA, as noted in section 2.3 of the *Paraquat Final Review Technical Report*.

45. Having had regard to the matters described above, I am **not satisfied** that the paraquat product registrations listed in Attachment A meet the safety criteria for the following reasons.

45.1. As noted in paragraph 35.6 and 35.7 the current conditions of registration imposed by the APVMA under s23(1)(b) of the Agvet Code are inconsistent and redundant with other conditions prescribed by the Agvet Regulations. Accordingly, as stated in paragraph 35.9 above, I am not satisfied that these products will be manufactured to the necessary quality assurance and record keeping standards and am not satisfied that this will not result in these products being an undue hazard to the safety of people exposed to them or using anything containing their residues (s5A(1)(a)).

45.2. As discussed in paragraph 36.5, above, I am not satisfied that the use of paraquat products according to the currently approved instructions for use will not result in worker exposures that exceed the maximum safe levels established in section 4.1 of the *Paraquat Final Review Technical Report* and noted in paragraphs 14 and 31 above. This means I am not satisfied that the use of paraquat products according to the currently approved instructions for use will not be likely to have an effect that is harmful to human beings (s5A(1)(b)). I also note that I am not satisfied the containers for paraquat products allow the products to be dispensed without creating an undue hazard to the person using the product (s5A(1)(a)), as discussed in paragraph 44 above.

45.3. As discussed in paragraph 36.6, above, I am not satisfied that the use of paraquat products according to the currently approved instructions for use will not result in exposures that exceed the maximum safe levels established for non-target species in section 6.3 of the *Paraquat Final Review Technical Report* and noted in paragraphs 14.7 above. This means I am not satisfied that the use of paraquat products according to the currently approved instructions for use will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c)).

45.4. As discussed in paragraph 36.7, above, I am not satisfied that the use of paraquat products according to the currently approved instructions for use will not result in exposures that exceed the maximum safe levels established for areas considered sensitive to spray drift as described in section 7 of the *Paraquat Final Review Technical Report* and noted in paragraphs 14.7 and 31.5 above. This means I am not satisfied that the use of paraquat products according to the currently approved instructions for use will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c)).

Consideration of whether registered chemical products can be varied to meet the safety criteria

46. Section 34A(1) of the Agvet Code provides that if the APVMA is not satisfied under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.

47. I have considered whether registered paraquat chemical products specified at attachment A can be varied in such a way as to meet the safety criteria set out in section 5A(1) of the Agvet Code for the purposes of section 34A(1).

48. To address concerns identified in paragraph 35 when considering the conditions to which the registrations of chemical products containing paraquat are subject, in accordance with section 5A(3)(a)(v), I have decided to vary the conditions referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' to remove elements that are set out in the Agvet Code and the Agvet Regulations. The varied condition shall read as follows:

> "Condition of Registration - Agricultural Chemical Products Active Constituent Quality Assurance Requirements
>
> *1. The holder of the registration for a chemical product must not supply or cause the supply of the chemical product unless the active constituent contained in the chemical product was manufactured at a site of manufacture listed in the Record.*
> *2. The holder of the registration for a chemical product must not supply or cause the supply of the chemical product unless the holder possesses a record that demonstrates:*
>
> – *the active constituent(s) in the chemical product comply with Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022; and*
>
> – *if there is a standard made under section 6E of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) for any constituent in the chemical product that is not an active constituent, that the constituent complies with that Standard; and*
>
> *3. The records referred to in condition 2 above must include batch analysis results for the constituent(s) with the following information:*
>
> – *the name and address of the manufacturer of the constituent*
>
> – *the Batch Number of the Batch of the constituent*
>
> – *the date of manufacture of the Batch of the constituent*
>
> – *the date of the analysis of the Batch of the constituent*
>
> – *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the relevant Standard for the constituent*
>
> – *reference to the validated analytical method(s) used to determine the constituent purity and/or the content and/or the isomer ratio and/or the specified impurities*

4. The holder of the registration for a chemical product must not supply or cause the supply of any quantity of a Batch of the chemical product unless the holder possesses a record that contains the following information for that Batch of the chemical product:

- *the name of the chemical product*
- *the distinguishing number of the registration of the chemical product*
- *if the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of the importer, and the date of importation*
- *if the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of the manufacturer, and the date of manufacture*
- *the batch number of the chemical product from which the quantity was supplied and the quantity of the chemical product in that batch.*

5. The records referred to in conditions 2 and 4 above must be kept by the holder for at least 2 years.
6. The APVMA may request a holder to provide any records created and maintained under these conditions and, where the APVMA requests records be produced to it, a holder must provide the records to the APVMA.
7. For the purposes of this condition:

- *Batch means a defined quantity of material produced in a single series of operations.*
- *Batch Number means a distinctive combination of numbers and/or letters that specifically identifies a batch from which the production history can be determined.*
- *Possess means in the possession of the holder or in the possession of another person pursuant to an arrangement with the holder.*
- *Record includes information stored or recorded by means of a computer.*
- *Supply has the same meaning as in Section 3 of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code).*

48.2. I have decided to remove the redundant condition identified in paragraph 35.6 The conditions relating to complying with the outcomes of the reconsideration are no longer relevant.

49. To address concerns related to human health identified in paragraphs 36.4 and 36.5 in relation to the instructions for use (which are relevant particulars) that are or would be entered into the Register for paraquat chemical products as required by section 5A(3)(a)(vi) of the Agvet Code, I have decided to vary the instructions for use as indicated below, noting that the specific instructions to be included on the labels of the product are dealt with below in the section of my reasons entitled Labels for chemical products.

49.1. I have decided to vary the instructions for use of paraquat applied by ground boom in small scale to require the operator to use the following minimum personal protective equipment: open cab, single layer of clothing, gloves, PF10 respirator, and face shield or goggles when mixing or loading, which will prevent exposure from exceeding the maximum acceptable level for workers.

49.2. I have decided to vary the instructions for use of paraquat applied by ground boom in broad scale agriculture to require the operator to use the following minimum personal protective equipment: enclosed cab application, with closed mixing and loading (single layer of clothing, gloves, PF10 respirator, face shield or goggles when connecting, disconnecting or cleaning components of the mixing and loading system), which will prevent exposure from exceeding the maximum acceptable level for workers.

49.3. I have decided to vary the instructions for use of paraquat applied by manually pressurised hand wand to require the operator to use the following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading. I have also decided to vary the instructions for use of paraquat by mechanically pressurised hand wand, to require following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading and in addition I have decided to add a restraint prohibiting use of more than 3.9 kg of paraquat active constituent per individual operator per day the will, which will prevent exposure from exceeding the maximum acceptable level for workers.

49.4. I have decided to vary the instructions for use of chemical products containing both diquat and paraquat applied by ground boom in broad scale agriculture to require the operator to use the following minimum personal protective equipment: enclosed cab application, with closed mixing and loading (single layer of clothing, gloves, PF10 respirator, face shield or goggles when connecting, disconnecting or cleaning components of the mixing and loading system), which will prevent exposure from exceeding the maximum acceptable level for workers.

49.5. I have decided to vary the instructions for use of chemical products containing both diquat and paraquat applied by manually pressurised hand wand to remove rates that exceed 4.5 kg of combined active constituent per operator per day, or 2.3 kg of combined active constituent per operator per day by mechanically pressurised hand wand and require the operator to use the following minimum personal protective equipment: double layer of clothing, gloves, PF10 respirator and face shield or goggles when mixing and loading, which will prevent exposure from exceeding the maximum acceptable level for workers.

49.6. I have decided to vary the instructions for use of all products listed in Attachment A to include re-entry instructions specifying the relevant minimum intervals noted in Tables 12, 13 and 14 in the *Paraquat Final Review Technical Report.* These intervals, or PPE if the re-entry interval cannot be observed, are necessary to prevent worker exposure exceeding the acceptable level discussed in section 4.1 and Table 9 of the *Paraquat Final Review Technical Report* and paragraph 14.3 above.

49.7. I have also decided to vary the instructions for use to include the relevant signal headings, restraints, first-aid and safety directions and re-entry statements recommended in section 4.3.1 of the *Paraquat Final Review Technical Report* to ensure that users are aware of the necessary PPE and other behaviours necessary to use the products safely.

50. To address concerns related to risks to the environment identified in paragraph 36.6 in relation to the instructions for use (which are relevant particulars) that are or would be entered into the Register for paraquat chemical products as required by section 5A(3)(a)(vi) of the Agvet Code, I have decided to vary the instructions for use as indicated below.

50.1. To address the concerns identified in paragraph 36.6 indicating that use of products containing paraquat, or paraquat plus diquat, will exceed regulatory acceptable levels for non-target species in all situations except the uses and rates listed in Table 3, I have decided to vary the instructions for use to remove all instructions for use of paraquat, or paraquat plus diquat products, except in the situations described in Table 3. This will make it unlikely that harmful levels of exposure of non-target animals to paraquat, or paraquat plus diquat will occur.

51. To address concerns related to risks posed to areas sensitive to spray drift identified in paragraph 36.7 in relation to the instructions for use (relevant particulars) that are or would be entered into the Register for paraquat chemical products as required by section 5A(3)(a)(vi) of the Agvet Code, I have decided to vary the instructions for use as indicated below.

51.1. I have decided to vary the instructions for use to include spray drift specific restraints as recommended in section 7 of the *Paraquat Final Review Technical Report* and the mandatory down-wind buffer zones

recommended in Table 50 and 51 of the *Paraquat Final Review Technical Report.* This will make it unlikely that harmful levels of exposure of people, or non-target animals to paraquat, or paraquat plus diquat will occur via spray drift.

52. To address the concerns identified in paragraph 42 in relation to whether any trials or laboratory experiments have been carried out to determine the residues of the product and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves as required by section 5A(3)(b)(iii), I have decided to:

    52.1. vary the instructions for use of paraquat to add a 14-day harvest withholding period for the spray topping use on chickpeas, faba beans, field peas, lentils and lupins, where not currently present, or stated as a 7-day harvest withholding period, and

    52.2. for all other uses, add a harvest withholding period statement of “Not required when used as directed” for pre-emergent or pre-sowing applications (and for post emergent application in peanuts up to 7-8 leaf stage, or potato up to 25% shoot emergence).

53. I note that the uses where other concerns related to residues were identified are not supported by the outcomes of the environment risk assessment, so do not require mitigations to address residue levels.

54. I am satisfied that following these variations the residues of the product will not exceed the limits approved by the APVMA.

55. To address the concerns identified in paragraph 44 in relation to specifications for the containers for the products (section 5A(3)(b)(v) of the Agvet Code), I have varied the conditions of product registration to add the following requirement:

    Condition of Product Registration

    This product must be supplied in a container that is sealed with a fitting compatible with closed mixing and loading systems capable of preventing contact between the contents of the container and users of the product during loading of the chemical into the application mechanism.

56. Having had regard to the matters described above, I am **satisfied** that I can vary the conditions of product registration and instructions for use of paraquat products listed in Attachment A so that those products meet the safety criteria for the following reasons.

    56.1. I am satisfied that varying the conditions of registration imposed by the APVMA under s23(1)(b) of the Agvet Code as described in paragraph 48, above, will address the risks identified in paragraphs 35.6 and 35.7. These variations will remove inconsistencies between the current conditions and provide a framework for appropriate quality assurance and record keeping standards. These conditions allow me to be satisfied that the products listed in Attachment A will not be an undue hazard to the safety of people exposed to them or using anything containing their residues (s5A(1)(a)). I am also satisfied that adding a condition of registration requiring containers to be sealed with closed mixing and loading compatible valves as described in paragraph 55 above will mitigate risks identified in paragraph 44, thereby allowing the container’s contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot harm a person or have an unintended effect that is harmful to the environment, as required by regulation 18(e).

    56.2. I am satisfied that varying the instructions for use of paraquat in the manner described in paragraph 49, above, will mitigate the risks to workers discussed in paragraph 36.5. Accordingly, I satisfied that the use of paraquat products according to the instructions for use, as varied, will not result in worker exposures that exceed the maximum safe levels established in section 4.1 of the *Paraquat Final Review Technical Report* and noted in paragraphs 14 and 31 above. I am also satisfied that varying the harvest withholding period for selected pulses as described in paragraph 52 will ensure that there are not residues of paraquat that exceed the MRL and will not pose an undue risk to human health through residues in food. This

means I can be satisfied that the use of paraquat products according to the instructions for use, as varied, will not be likely to have an effect that is harmful to human beings (s5A(1)(b)).

56.3. I am satisfied that varying the instructions for use of paraquat in the manner described in paragraph 50, above, will mitigate the risks to non-target birds and mammals discussed in paragraph 36.6, above. Accordingly, this means I can be satisfied that the use of paraquat products according to the instructions for use, as varied, will not result in exposures that exceed the maximum safe levels established for non-target species in section 6.3 of the *Paraquat Final Review Technical Report* and noted in paragraphs 14.7 above. This means I am satisfied that the use of paraquat products according to the instructions for use, as varied, will not be likely to have an unintended effect that is harmful to animals or plants or to things or to the environment (s5A(1)(c)).

56.4. I am satisfied that varying the instructions for use to include spray drift restraints, as discussed in 51 above will mitigate the risks discussed in paragraph 36.7, above. Accordingly I am satisfied that the use of paraquat products according to the instructions for use, as varied, will not result in exposures that exceed the maximum safe levels established for areas considered sensitive to spray drift as described in section 7 of the *Paraquat Final Review Technical Report* and noted in paragraphs 14.7 and 31.5 above. This means I am satisfied that the use of paraquat products according to the instructions for use, as varied, will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c)).

57. I am satisfied that the relevant particulars and conditions of registration of the products listed in Attachment A of this notice can be varied in the ways set out in paragraphs 48 to 56, above, so that the use of the products, in accordance with the instructions for use, as varied, meets the safety criteria as defined in section 5A of the Agvet Code.

Consideration of whether registered chemical products meet the efficacy criteria

58. Section 5B(1) of the Agvet Code provides that a chemical product meets the efficacy criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product, or contained in an established standard, is, or would be, effective according to criteria determined by the APVMA by legislative instrument.

59. The criteria for agricultural chemical products are listed in Part 2 of the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* (Efficacy Criteria Determination).

59.1. Section 4(a) of Part 2 of the Efficacy Criteria Determination provides that the use of an agricultural chemical product is taken to be effective in certain circumstances, including where it would, to a reasonable degree, achieve one of the effects listed in section 4(2) of the Agvet Code and this is evidenced or demonstrated by: (i) results from efficacy trials or experiments; or (ii) valid scientific argument; or (iii) demonstrated history of sale and effective use in equivalent uses; or (iv) full results from overseas efficacy trials or experiments and the associated assessment reports by an overseas regulator that are relevant to the proposed product and use; or (v) a combination of 2 or more of the above.

60. Section 5B(2) of the Agvet Code provides that, subject to section 5B(3), for the purposes of being satisfied as to whether a chemical product meets the efficacy criteria as described in section 5B(1), the APVMA must have regard to the matters set out in section 5B(2) of the Agvet Code. I have had regard to the matters set out in section 5B(2) of the Agvet Code as follows.

61. Section 5B(2)(a) – whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments.

61.1. Trials and laboratory experiments and the results of those trials and experiments were submitted in support of the registration or variation of chemical products containing paraquat and found to demonstrate efficacy of paraquat chemical products prior to registration.

61.2. I note that a number of submissions received by the APVMA in response to the proposed regulatory decisions, published on 30 July 2024, claimed that the application rates proposed to be retained in the instructions for use would be unable to control weeds. As noted in the APVMA's consideration of submissions document, I remain satisfied that use of paraquat on the weed species at the growth stages indicated in the proposed labels is efficacious. The APVMA has not assessed information to determine whether use of lower rates would be effective for control of other weed species or weeds at more advanced growth stages.

61.3. I remain satisfied that the information previously considered by the APVMA to support registration of paraquat chemical products demonstrates the efficacy of paraquat chemical products in destroying a plant for the purpose of the definition of an agricultural chemical product in section 4(2)(b) of the Agvet Code and section 4(b)(i) of the Efficacy Criteria Determination.

62. Section 5B(2)(b) – any conditions to which its registration is, or would be, subject.

62.1. I have considered the conditions of registration which apply, or would apply, to chemical products containing paraquat. I am satisfied that the conditions of registration are appropriate.

63. Section 5B(2)(c) – any relevant particulars that are, or would be, entered in the Register for the product.

63.1. I note that the relevant particulars recorded in the Register for each paraquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.3 of the *Paraquat Final Review Technical Report.*

63.2. I have considered the relevant particulars that are entered in the Register for chemical products containing paraquat. I am satisfied that the relevant particulars that are entered in the Register are appropriate with respect to the efficacy criteria.

63.3. The variations to the instructions for use proposed to satisfy the safety criteria (as set out in paragraph 47) and trade criteria (as set out in paragraph 75) are within the range of application rates and situations in the currently approved instructions for use of the products. I am satisfied that these variations are appropriate.

64. Section 5B(2)(ca) – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).

64.1. There are no standards made under section 6E which are relevant to the efficacy of chemical products containing paraquat.

65. Section 5B(2)(d) – any matters prescribed by the regulations.

65.1. There are no additional matters prescribed by regulations which are relevant to the efficacy of chemical products containing paraquat.

66. Having had regard to the maters set out above, I am satisfied that the use of chemical products containing paraquat, according to the instructions to be approved by these decisions, meets the efficacy criteria as set out in section 5B of the Agvet Code and the Efficacy Criteria Determination.

Consideration of whether registered chemical products meet the trade criteria

67. Section 5C(1) of the Agvet Code provides that a product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established

standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.

68. Section 5C(3) of the Agvet Code provides that when considering whether a chemical products meets the trade criteria, the APVMA is required to have regard to the matters set out in subsection 5C(1) and 5C(2) only to the extent prescribed by the regulations, or if there are no such regulations, to the extent that the APVMA thinks the matters are relevant.

68.1. Regulation 8AD(2) of the Agvet Regulations provides that if it can be reasonably expected that a chemical product will be used in relation to a crop or animal, a product of which might be provided to a place outside Australia; or a crop that will be fed to animals a product of which might be provided to a place outside Australia, then the APVMA must have full regard to the matters set out in section 5C(1) and (2) of the Agvet Code.

a. I note that chemical products containing paraquat are currently registered for use on crops that are considered major export commodities including berries and other small fruits (grapes), cereal grains, citrus fruit, cotton seed, oilseed {except cotton seed}, pome fruit, pulses, stone fruit and sugar cane. It is therefore reasonably expected that a product of these crops might be provided to a place outside of Australia.

b. I also note that chemical products containing paraquat are currently registered for use on crops that can be used as stockfeed for mammalian and poultry animals. Mammalian and poultry animals and their products (including cattle, dairy products, pigs, sheep, goats, poultry and eggs) are considered major export commodities. It is therefore reasonably expected that a product of these animals might be provided to a place outside of Australia.

69. For the purposes of considering whether paraquat chemical products meet the trade criteria as described in section 5C(1) of the Agvet Code, I have had full regard to the matters set out in section 5C(2) as follows.

70. Section 5C(2)(a) – any conditions to which its registration is, or would be, subject.

70.1. I have had regard to the conditions of registration prescribed by the regulations in accordance with section 23(1)(a) of the Agvet Code, namely regulation 17C(2) of the Agvet Regulations. I have also had regard to the conditions imposed by the APVMA on the registration in accordance with section 23(1)(b) of the Agvet Code.

70.2. I am satisfied that the conditions of registration, apart from the Agricultural Products Active Constituent Quality Assurance Requirements discussed at paragraphs 35.6 and 48, above, currently applied to chemical products containing paraquat remain acceptable. I am satisfied that the variations to the Agricultural Products Active Constituent Quality Assurance Requirements described in paragraph 48, above, will not result in any undue risk to trade and the conditions generally are not material to the risk to trade, beyond their relevance to the safety criteria and ensuring that the products and their containers meet minimum standards of purity and do not contain impurities of toxicological concern above maximum limits.

71. Section 5C(2)(b) – any relevant particulars that are, or would be, entered in the Register for the product.

71.1. The relevant particulars required to be entered in the Register for a chemical product identified in section 3 of the Agvet Code, as well as the additional matters prescribed by regulation 16 of the Agvet Regulations for the purposes of section 20(1)(c) of the Agvet Code, are as follows:

a. the distinguishing number

b. any instructions for the use of the product

c. the distinguishing name of the chemical product

d. the constituents of the chemical product

e. the concentration of each constituent of the chemical product

f. if possible, the composition and purity of each active constituent of the chemical product

g. the formulation type for the chemical product

h. the net contents for the chemical product

i. identifying information for the holder of the registration for the chemical product

j. the name of each manufacturer of the chemical product

k. the address of each site at which the chemical product is manufactured by the manufacturer

l. the date of entry of these particulars in the Register of Chemical Products

m. identifying information for any nominated agent for the registration.

71.2. I note that the relevant particulars recorded in the Register for each paraquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.3 of the *Paraquat Final Review Technical Report*.

71.3. I have had regard to the assessments of the relevant particulars entered in the Register for each of the products listed in Table 1 of Attachment A and have also considered the conclusions of the residues and trade (section 5.21) risk assessments described in the *Paraquat Final Review Technical Report*.

71.4. I am satisfied that all relevant particulars that are entered in the Register for paraquat chemical products, except for the instructions for use of the product mentioned in paragraph 71.5 below, remain acceptable with respect to the trade criteria.

71.5. I have had regard to the recommendations of the Trade assessment, as described in section 5.21.6 (Trade) of the *Paraquat Final Review Technical Report*, which considered the instructions for the use of chemical products containing paraquat that are otherwise supported by all risk assessments and the potential for those uses to result in finite paraquat residues on major export commodities, which may subsequently be detected in international export markets and, if exceeding the levels accepted in those markets, may pose an undue risk to trade.

71.6. Based on the recommendations in section 5.21.6 (Trade) of the *Paraquat Final Review Technical Report*, I am satisfied that the use of paraquat according to the instructions approved by the APVMA will not unduly prejudice trade between Australia and places outside Australia because the only crops where finite residues are expected are chickpeas, faba beans (broad bean), field peas, lentils and lupins where the residues are not expected to exceed the current MRL when the harvest withholding period is varied to 14 days for all products as I have stated I must do at paragraph 56.2, above, to be satisfied of the safety criteria for paraquat products.

71.7. I note that although MRLs at 1 mg/kg are higher than tolerances established overseas, the risk is unchanged to that which has currently been managed. The National Working Party on Grain Protection (NWPGP) indicated that it did not have any concerns with industry's ability to continue to manage the potential risks to international trade for pre-harvest uses of paraquat for spray topping treatment to reduce seed set of ryegrass in selected pulses (chickpeas, faba beans (broad bean), field peas, lentils and lupins).

71.8. I note that the potential for paraquat or paraquat plus diquat spray drift to affect animal food or forage has been considered in section 7 of the *Paraquat Final Review Technical Report* and that down-wind no spray buffer zones are not required for livestock areas.

71.9. I have considered and agree with the recommendation that the residues in animal commodities that may result from grazing or feeding treated forage to animals will not exceed current MRLs and that the grazing WHPs and recommended Export Slaughter Interval (ESI) will ensure there are no detectable residues in any animal commodities from livestock allowed to graze treated crops.

72. Section 5C(2)(ba) – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).

72.1. There are no standards made under section 6E of the Agevet Code that are relevant to the risk to trade or commerce between Australia and places outside Australia for the products containing paraquat listed in Attachment A.

73. Section 5C(2)(c) – any matters prescribed by the regulations.

73.1. There are no matters prescribed by the regulations for the purposes of section 5C(2)(c) of the Agvet Code

74. Having considered the matters discussed above with respect to the trade criteria, I am **not satisfied** that chemical products containing paraquat used according to the current instructions for use recorded in the register and indicated in paragraph 71.2, above, meet the trade criteria. However I note that following variations to address the risks identified in relation to human health and the environment discussed above, the remaining risks to trade are managed by amending the grazing WHPs and ESIs noted in paragraph 71.9, because these variations will mean that no residues exceeding the relevant MRL are expected in any commodity and the relevant industries have indicated that the risk to trade posed by these residues is currently effectively managed.

Consideration of whether registered chemical products can be varied to meet the trade criteria

75. I have considered whether the instructions for use for registered paraquat products can be varied in such a way as to meet the trade criteria set out in section 5C(1) for the purposes of section 34A(1) of the Agvet Code.

76. I am satisfied that the instructions for use that are recorded in the Register for the chemical products containing paraquat listed in Attachment A of this notice can be varied in the ways set out in paragraph 71.9 above to allow me to be satisfied that those products meet the trade criteria set out in section 5D of the Agvet Code.

Consideration of whether registered chemical products comply with any requirement prescribed by the regulations

77. Section 34(1)(d) of the Agvet Code provides that I must affirm the registration of a product only if I am satisfied that the product complies with any requirements prescribed by the regulations.

78. Regulation 42 of the Agvet Regulations prescribes standards for chemical products for the purposes of section 87 of the Agvet Code.

78.1. Regulation 42(3) prescribes standards that apply to a chemical product if the chemical product meets specific requirements listed in that regulation.

78.2. Regulation 42(3)(b) prescribes: “for a product or constituent (other than a product or constituent to which paragraph (a) applies) in respect of which a standard has been made under section 6E of the Code—that standard”.

a. The APVMA has made the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* under section 6E of the Agvet Code, which applies to all paraquat products listed in Attachment A.

b. I accept the recommendation from the APVMA’s chemistry assessment of the information submitted to support registration of the chemical products listed in Attachment A, including declarations of composition and 5-batch analyses as described in the *Paraquat Final Review*

Technical Report, and I am satisfied that registered agricultural chemical products containing paraquat conform to the specifications listed in the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022.*

79. I am satisfied that registered paraquat chemical products meet the requirements prescribed by regulation 42 of the Agvet Regulations for the purposes of section 87 of the Agvet Code.

80. I am satisfied that there are no other requirements prescribed by the regulations that have not been considered.

Labels for chemical products

81. Sections 34(1) of the Agvet Code provides that I must affirm the approval of a label if, and only if, I am satisfied that the label:

    81.1. meets the labelling criteria (section 5D); and

    81.2. complies with any requirement prescribed by the Agvet Regulations.

82. I have considered all matters covered by subsection 34(1) in relation to the reconsideration of paraquat label approvals specified at Attachment A, except where those matters relate to the active constituent amitrole, co-formulated in some chemical products containing paraquat, or to other excipients.

Consideration of whether approved labels for paraquat chemical products meet the labelling criteria and comply with any requirement prescribed by the regulations

83. Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product 'meets the labelling criteria' if the label contains adequate instructions relating to such of the following as are appropriate:

    83.1. the circumstances in which the product should be used (section 5D(1)(a));

    83.2. how the product should be used (section 5D(1)(b));

    83.3. the times when the product should be used (section 5D(1)(c));

    83.4. the frequency of the use of the product (section 5D(1)(d));

    83.5. the withholding period after the use of the product (section 5D(1)(e));

    83.6. the re-entry period after the use of the product (section 5D(1)(f));

    83.7. the disposal of the product when it is no longer required (section 5D(1)(g));

    83.8. the disposal of containers of the product (section 5D(1)(h));

    83.9. the safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i));

    83.10. any matters prescribed by the regulations (section 5D(1)(j)). In relation to this consideration, I note that regulation 8AE(1) of the Agvet Regulations prescribes the following:

        a. Regulation 8AE(1)(a) – for a chemical product that is a veterinary chemical product, the duration of the treatment.

        b. Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.

        c. Regulation 8AE(1)(c) – the appropriate signal words (if any) required by the current Poisons Standard.

d. Regulation 8AE(1)(d) – for a chemical product that is a date-controlled product, the storage of containers for the product.

e. Regulation 8AE(1)(e) – any other matter determined by the APVMA CEO under regulation 8AE(2).

84. I note that the Agvet Code provides a definition for adequate in relation to instructions on a label for containers for a chemical product. The instructions are adequate if they ensure, as far as reasonably practicable, that the product meets the safety criteria and the trade criteria: section 3 of the Agvet Code.

85. For the purposes of considering whether the labels meet the labelling criteria as described in section 5D(1) of the Agvet Code, I have had regard to the matters set out in section 5D(2) of the Agvet Code as follows.

86. Section 5D(2)(a) of the Agvet Code - any conditions to which the label's approval is, or would be, subject.

86.1. I have considered conditions to which the label approvals are subject as prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code.

86.2. I am satisfied that the conditions to which label approvals are subject pursuant to section 23(1)(a) of the Agvet Code, as prescribed by regulations 18B to 18J of the Agvet Regulations, are appropriate for the labels for containers for products listed in Attachment A of this notice.

a. I note that Regulation 18E prescribes a condition for label approvals that requires that if a labelling standard has not been made by the APVMA, then the label must comply with the requirements of either the *Veterinary Labelling Code*, if the product is a veterinary chemical product, or the *Agricultural Labelling Code*, if the product is an agricultural chemical product.

b. I am **not satisfied** that the approved labels for paraquat (and paraquat plus diquat) agricultural chemical products comply with the current *Agricultural Labelling Code,* in particular in relation to the instructions for disposal of the product when it is no longer required (section 5D(1)(g)) and the disposal of containers for the product (section 5D(1)(h)) as noted in paragraph 88 which do not contain the disposal statements required by the current *Agricultural Labelling Code*, and noting that it may be an offence to bury chemical products and used containers in some jurisdictions.

c. I also note that I have decided to require that all containers for paraquat (and paraquat plus diquat) chemical products must be sealed with fittings compatible with enclosed mixing and loading systems (see paragraph 55) and that these require specific disposal instructions, which are described in the Agricultural Labelling Code and which are not currently contained on the approved labels for these products.

86.3. Labels approved for containers for paraquat chemical products are also subject to additional an additional condition imposed by the APVMA under section 23(1)(b) of the Agvet Code, known as the date of manufacture condition, which is reproduced below.

The approved label affixed to containers must be supplied with a Date of Manufacture and Batch Number and where:

(a) The Date of Manufacture and Batch Number must be either printed on the container or affixed by way of a sticker to either:

(i) the base of the main or ancillary panel of the approved label; or

(ii) to the container.

The Date of Manufacture and Batch Number must comprise of numbers or letters, or a combination of numbers and letters and be in English.

(b) Suitable prefixes may be used for the Date of Manufacture and Batch Number. These must be distinguishable from one another. For example, Date of Manufacture may include the prefix 'DOM', and Batch Number the prefix 'BN'. These details must be presented on the label or container (in

accordance with (a) above) adjacent to one another and not in a position to be confused with any other numerical codes

86.4. I am satisfied that this condition remains appropriate for labels for containers for paraquat products, noting that the condition is supplementary to the conditions prescribed by regulation 18D and stipulates that a date of manufacture is required to be recorded on the label (i.e. is applicable for reg. 18D) and further stipulates the minimum requirements for the information to be recorded.

87. Section 5D(2)(b) of the Agvet Code - any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label.

87.1. I have had regard the APVMA's chemistry, human health, environment, and residues and trade risk assessments as described in the *Paraquat Final Review Technical Report* and discussed in paragraphs 36 and 71 above in regard to the to the relevant particulars and instructions entered in the file for each approved label listed in Attachment A and I am satisfied that all relevant particulars remain appropriate, except for the instructions for use as related to the matters listed in section 5D(1) of the Agvet Code.

88. I have had regard to the instructions entered in the relevant APVMA file relating to each matter listed in section 5D(1) as follows:

88.1. the circumstances in which the product should be used (section 5D(1)(a))

a. I am not satisfied that the use of products containing paraquat, or paraquat plus diquat as the active constituents, according to the currently approved instructions for use will not result will not result in exceedance of the RALs for wild birds, wild mammals or both, except for the situations listed in Table 3 above.

b. I note that section 6.6 (Recommendations) of the *Paraquat Final Review Technical Report* includes recommendations for inclusion of contemporary protection statements and restraints to inform users of generally applicable actions that are necessary to manage risks to aquatic species noted in sections 6.4.2 (Aquatic species), 6.3 (Effects on non-target species) and 6.4.4 (Other arthropods) to prevent unacceptable levels of exposure to paraquat (or paraquat and diquat) for non-target species. I note that these statements and restraints are not presently included on currently approved labels.

c. I am not satisfied the instructions on the currently approved labels are adequate with respect to the circumstances in which the product should be used, because I cannot be satisfied that use according to those instructions will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment, as described in paragraph 36.6, above, regarding my consideration of the safety criteria.

88.2. How the product should be used (section 5D(1)(b))

a. I am not satisfied that the use of products containing paraquat, or paraquat plus diquat as the active constituents, according to the currently approved instructions for use is not likely to result in effects that are harmful to people, or unintended effects that are harmful to animals or plants or things or the environment.

b. I have considered the instructions for how paraquat products should be used that are contained on the currently approved labels and I am not satisfied that the instructions are adequate in certain instances because they may result in exposure of workers to levels of paraquat or paraquat plus diquat that exceed the maximum that is unlikely to have an effect that is harmful as described in detail in paragraph 36.5 above and in section 4.1 (Worker exposure assessment) of the *Paraquat Final Review Technical Report.*

c. I note that additional restraints are recommended in order for users to know which PPE and other behaviours are necessary to safely use the products in section 4.1.3 of the *Paraquat Final Review Technical Report.* I am not satisfied that the current restraints are adequate to prevent exceedance of the acceptable occupational exposure levels.

d. I am **not satisfied** that the approved labels contain adequate instructions for how the products should used, to prevent paraquat spray drift from exceeding RALs in sensitive areas as described in section 7 (Spray drift) of the *Paraquat Final Review Technical Report* and also discussed in paragraph 36.7 (in relation to risks to the environment and bystanders) and paragraph 71.8 (in relation to livestock areas).

88.3. The times when the product should be used (section 5D(1)(c))

a. I have considered the instructions for the times when the product should be used and am satisfied that the instructions contained on the labels for paraquat (and paraquat plus diquat) products remain adequate because the time when the product is used is not material to the risk assessments discussed in the *Paraquat Final Review Technical Report.*

88.4. the frequency of the use of the product (section 5D(1)(d))

a. I have considered the instructions for frequency of the use of the product and am satisfied that the instructions contained by the labels for paraquat products remain adequate in this respect as detailed in the *Paraquat Final Review Technical Report*. I note that this was specifically discussed in section 3.34 of the APVMA's consideration of submissions document and I agree with the conclusion that the currently approved instructions refer to use of the products in specified circumstances, eg as an aid to cultivation, that effectively limits the frequency of the use of the product in a way that is unlikely to result in harmful effects to people or the environment.

88.5. The withholding period after the use of the product (section 5D(1)(e))

a. I have considered the instructions for the withholding periods after the use of paraquat (and paraquat plus diquat) products and I am **not satisfied** that the instructions are adequate in the following instances:

- the harvest withholding period following use of paraquat for spray-topping on chickpeas, faba beans, field peas, lentils, and lupins is currently recorded as either 7 or 14 days, while the available information indicated that a 14-day withholding period is required to ensure that residues will not exceed MRLs in these crops as described section 5.7 (pulses) in the *Paraquat Final Review Technical Report*
- the presentation of the necessary grazing withholding periods contained by the labels is not consistent with the current Agricultural Labelling Code, although the withholding periods themselves are sufficient to prevent exceedance of MRLs in animal commodities, as recommended in section 5.15 of the *Paraquat Final Review Technical Report*
- the current "3-day Slaughter Interval" statement contained by the labels is not consistent with contemporary presentation of the information and is not adequate to ensure that paraquat (or paraquat plus diquat) residues in animal commodities will not exceed international MRLs, as described in section 5.19 (Trade) of the *Paraquat Final Review Technical Report*.

88.6. The re-entry period after the use of the product (section 5D(1)(f))

a. I have considered the re-entry instructions contained on the labels and the worker exposure risk assessments discussed in paragraph 36.5.i, above and sections 4.1 (Worker exposure) and 4.1.2 (Re-entry periods) of the *Paraquat Final Review Technical Report.* I am **not satisfied** that the

current instructions are adequate to prevent exposure of people to levels of paraquat exceeding the acceptable occupational exposure levels.

88.7. the disposal of the product when it is no longer required (section 5D(1)(g)), and the disposal of containers for the product (section 5D(1)(h))

a. I have considered the instructions for disposal of the product when it is no longer required and the instructions for disposal of containers for paraquat products contained on the label and the current Agricultural Labelling Code, and I am **not satisfied** that the instructions are adequate, noting that it may be an offence to bury chemical products and used containers in some jurisdictions.

b. In addition, as discussed in paragraph 36.5.h and 44 above, I have decided to require that closed mixing and loading be used for paraquat chemical products. Containers compatible with closed mixing and loading require specific disposal instructions, which are not currently included on the approved labels.

88.8. The safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i))

a. I have considered the hazards and risks of exposure to paraquat in an accident caused by handling the product, as discussed in paragraphs 36.5 and 36.5.k above, and I am **not satisfied** that the first aid instructions and safety directions contained on the approved labels are adequate to mitigate the worker exposure risks identified in section 4.1.1 (Worker Exposure) of the *Paraquat Final Review Technical Report* as described in sections 4.1.3.3 and 4.1.4.4 (First aid statements) and (Safety Directions) of the *Paraquat Final Review Technical Report*.

88.9. Any matters prescribed by the regulations (section 5D(1)(j))

a. Regulation 8AE(1)(a) of the Agvet Regulations – for a chemical product that is a veterinary chemical product, the duration of the treatment.

- I note that chemical products containing paraquat are not veterinary chemical products.

b. Regulation 8AE(1)(b) of the Agvet Regulations – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.

- I have considered the instructions contained on the labels relevant to the prevention of prejudice to trade or commerce and I am **not satisfied** that the current withholding period, export slaughter interval (ESI), and trade advice statements are adequate, because the statements recommended in section 5.20 (Conclusions from the residues and trade assessment) *Paraquat Final Review Technical Report* are not included on those labels.

c. Regulation 8AE(1)(c) of the Agvet Regulations – the appropriate signal words (if any) required by the current Poisons Standard.

- Chemical products containing paraquat are listed in Schedule 7 of the Poisons Standard and are required to bear the signal words "**DANGEROUS POISON"** on the first line of the main label.

- Chemical products are also required to bear the cautionary statement "**KEEP OUT OF REACH OF CHILDREN**" written immediately on a separate line immediately below the signal words.

- Aqueous solutions of Paraquat require the following cautionary statements in addition to the signal words to be written immediately below the KEEP OUT OF REACH OF CHILDREN statement:

CAN KILL IF SWALLOWED

DO NOT PUT IN DRINK BOTTLES
KEEP LOCKED UP

- As safety directions are required on all labels, the signal heading must also include the statement "**READ SAFETY DIRECTIONS BEFORE OPENING OR USING**".
- I have considered the signal words contained on the labels for products containing paraquat and I am satisfied that the labels listed in Attachment A bear the appropriate signal words and cautionary statements.

d. Regulation 8AE(1)(d) of the Agvet Regulations – for a chemical product that is a date-controlled product, the storage of containers for the product.

- Regulation 4 of the Agvet Regulations defines a date-controlled chemical product as "each veterinary chemical product and an agricultural chemical product specified in Schedule 1 to the Agvet Regulations".
- I note that chemical products containing paraquat are not specified in Schedule 1 to the Agvet Regulations and are therefore not date-controlled chemical products.

e. Regulation 8AE(1)(e) of the Agvet Regulations – any other matter determined by the APVMA CEO under regulation 8AE(2).

- There are no other matters determined by the APVMA CEO under regulation 8AE(2) in relation to paraquat label approvals.

89. Section 5D(2)(c) of the Agvet Code - whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).

89.1. There is no standard made for paraquat label approvals under section 6E.

90. Section 5D(2)(d) of the Agvet Code - any matters prescribed by the regulations.

90.1. There are not matters prescribed by the regulations for the purpose of section 5D(2)(d) of the Agvet Code.

91. I am **not satisfied** that currently approved labels for containers for paraquat chemical products contain adequate instructions relating to the matters set out in paragraph 87 above.

92. I am satisfied that all particulars, excluding the instructions contained on the label, that are recorded in the relevant APVMA file remain appropriate.

Consideration of whether approved labels for chemical products can be varied to meet the labelling criteria and comply with any requirement prescribed by the regulations

93. I have considered whether the labels approved for containers for paraquat chemical products can be varied in such a way as to meet the labelling criteria set out in section 5D(1) of the Agvet Code for the purposes of section 34A(1).

94. I have decided to vary the instructions contained on labels for containers for paraquat (and paraquat plus diquat) products to address concerns identified in paragraph 88 above, when considering the matters in section 5D(2)(b) of the Agvet Code regarding whether the instructions are adequate, as follows.

94.1. I have decided to vary the instructions relating to the circumstances in which the products should be used (section 5D(1)(a)) as follows.

a. To address my concern noted in paragraph 88.1.a, above, I have decided to remove instructions for use in all situations except the situations listed in Table 3, which I have stated I am satisfied are not likely to result in an unintended effect that is harmful to plants or animals or things or to the environment.

b. To address my concern noted in paragraph 88.1.b, above, I have decided to add the following protection statements and restraints for the protection of non-target species:

- DO NOT apply if heavy rains or storms are forecast within 3 days
- DO NOT irrigate to the point of field runoff for at least 3 days after application.
- Toxic to birds and native mammals. However, the use of this product as directed is not expected to have adverse effects on birds and native mammals.
- Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
- Toxic to beneficial arthropods. Not compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Minimise spray drift to reduce harmful effects on beneficial arthropods in non-crop areas.

94.2. I have decided to vary the instructions in relation to how the product should be used (section 5D(1)(b)) to address the concerns identified in paragraph 88.2, above, as follows.

a. To address my concern noted in paragraph 88.2.b, I have decided to add the following restraints to limit occupational exposure:

General Restraints

DO NOT remove contents except for immediate use.

DO NOT apply by spraying equipment carried on the back of the user.

DO NOT continue to use if eye irritation or bleeding from the nose occurs.

DO NOT use open mixing/loading equipment. Closed mixing and loading MUST be used.

Restraints for specific uses

For broadacre boom spray applications

DO NOT apply using open cab equipment. Enclosed cab application MUST be used.

For small scale applications up to 6 ha per day:

DO NOT apply using open cab equipment unless using a PF10 respirator.

For hand spray applications

DO NOT use hand wand sprays by spraying out of the window of a vehicle.

b. To address my concern noted in paragraph 88.2.d above, regarding the effects of spray drift from paraquat (or paraquat plus diquat) products onto sensitive areas I have decided to add the following spray drift restraints to prevent paraquat (or paraquat plus diquat) spray drift from exceeding RALs in sensitive areas:

PARAQUAT SPRAY DRIFT RESTRAINTS

Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The advisory buffer zones in the relevant buffer zone table/s below provide guidance but may not be

sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are surface temperature inversion conditions present at the application site during the time of application. These conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.

DO NOT apply by a boom sprayer unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category

- minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Paraquat - buffer zones for boom sprayers						
Application rate	**Boom height above the target canopy**	**Mandatory downwind buffer zones (metres)**				
		Bystander areas	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**	**Livestock areas**
Up to 200 g ac/ha	0.5 m or lower	5	250	0	0	0
	1.0 m or lower	Not supported				
150 g ac/ha or lower	0.5 m or lower	0	160	0	0	0
	1.0 m or lower	Not supported				
100 g ac/ha lower	0.5 m or lower	0	100	0	0	0
	1.0 m or lower	20	325	0	15	0

PARAQUAT PLUS DIQUAT SPRAY DRIFT RESTRAINTS

Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The advisory buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are surface temperature inversion conditions present at the application site during the time of application. These conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.

DO NOT apply by a vertical sprayer.

DO NOT apply by aircraft

DO NOT apply by a boom sprayer unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category

- minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Diquat-paraquat co-formulated chemical products – buffer zones for boom sprayers						
Application rate	**Boom height above the target canopy**	**Mandatory downwind buffer zones (metres)**				
		Bystander areas	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**	**Livestock areas**
250 g acs/ha or lower	0.5 m or lower	10	40	0	0	0
	1.0 m or lower	50	120	0	20	0
200 g acs/ha or lower	0.5 m or lower	10	35	0	0	0
	1.0 m or lower	40	100	0	20	0
150 g acs/ha or lower	0.5 m or lower	5	30	0	0	0
	1.0 m or lower	30	80	0	15	0

94.3. I have decided to vary the instructions contained on labels for containers for paraquat (and paraquat plus diquat) products to address concerns identified in paragraph 88.5 above in relation to the withholding period after the use of the product (section 5D(1)(e)) as follows:

a. Vary the Harvest Withholding Period following use of paraquat for spray-topping on chickpeas, faba beans, field peas, lentils, and lupins to 14 days, for labels where it is not already 14 days

b. Vary the harvest Withholding Period statement for all other uses (as supported by other assessment outcomes) to "not required when used as directed"

c. Vary the current grazing withholding periods to read:

LIVESTOCK: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 1 DAY AFTER APPLICATION.

HORSES: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 7 DAYS AFTER APPLICATION.

94.4. I have decided to vary the instructions contained on labels for containers for paraquat products to address concerns identified in paragraph 88.6 in relation to the re-entry period after the use of the product (section 5D(1)(f)) to read as follows for paraquat products.

Re-entry period

DO NOT allow entry to treated areas until the spray has dried unless using an enclosed cab or wearing cotton overalls and gloves. Workers performing scouting and hand-set irrigation activities must comply with the re-entry periods specified in Table 4

Table 4: Re-entry intervals for paraquat products

Activity	Non-Re-Entry Period (Days)[1]
Scouting (application rate of up to 500 g/ha)	0
Scouting (application rate of 501 to ≤ 600 g/ha)	1
Scouting (application rate of 601 to ≤ 750 g/ha) (optical spraying up to 2250 g/ha)[2]	3
Irrigation (hand set) (application rate of up to 300 g/ha)	0
Irrigation (hand set) (application rate of 301 to ≤ 400 g/ha)	3
Irrigation (hand set) (application rate of 401 to ≤ 500 g/ha)	5
Irrigation (hand set) (application rate of 501 to ≤ 600 g/ha)	7
Irrigation (hand set) (application rate of 601 to ≤ 750 g/ha) (optical spraying up to 2250 g/ha)[2]	9

[1]Day of spraying is Day 0.
[2]Optical spraying is considered to result in up to a 30% of a field being sprayed. Therefore, the optical spray label concentrations have been reduced by a factor of 70% for whole-of-field re-entry worker exposure considerations.

94.5. I have decided to vary the instructions contained on labels for containers for paraquat plus diquat products to address concerns identified in paragraph 88.6 in relation to the re-entry period after the use of the product (section 5D(1)(f)) to read as follows.

Re-entry period

DO NOT allow entry to treated areas until the spray has dried unless using an enclosed cab or wearing cotton overalls and gloves. Workers performing scouting and irrigation activities must comply with the re-entry periods specified in Table 5.

Table 5: Re-entry intervals for 135 g/L paraquat plus 115 g/L diquat products

Activity	Non-Re-Entry Period (Days)[1]
Scouting at application rate of up to 368 g diquat/ha	0
Irrigation (hand set) at application rate of up to 276 g diquat/ha	0
Irrigation (hand set) at application rate of 277 to ≤ 368 g diquat/ha	2

[1]Day of spraying is Day 0.

94.6. Noting that specific uses are acceptable for products containing paraquat plus amitrole as active constituents, but that amitrole is otherwise not under reconsideration, I have decided to vary the instructions contained on labels for containers for paraquat plus amitrole products to address concerns identified in paragraph 88.6 in relation to the re-entry period after the use of the product (section 5D(1)(f)) to read as follows:

Re-entry period

DO NOT allow entry to treated areas until the spray has dried unless using an enclosed cab or wearing cotton overalls and gloves. Workers performing scouting and irrigation activities must comply with the re-entry periods specified in Table 6.

Table 6: Re-entry intervals for paraquat plus amitrole products

Activity	Non-Re-Entry Period (Days)[1]
Scouting at application rate of up to 510 g paraquat/ha (optical spraying up to 1680 g/ha)[2]	0
Scouting at application rate of 511 to ≤ 600 g paraquat/ha	1
Scouting at application rate of 601 to ≤ 840 g paraquat/ha	5
Scouting at application rate of 841 to ≤ 1000 g paraquat/ha	6
Irrigation (hand set) at application rate of up to 510 g paraquat/ha (optical spraying up to 1680 g/ha)[2]	5
Irrigation (hand set) at application rate of 511 to ≤ 600 g paraquat/ha	7
Irrigation (hand set) at application rate of 601 to ≤ 840 g paraquat/ha	10
Irrigation (hand set) at application rate of 841 to ≤ 1000 g paraquat/ha	11

[1]Day of spraying is Day 0.
[2]Optical spraying is considered to result in up to a 30% of a field being sprayed. Therefore, the optical spray label concentrations have been reduced by a factor of 70% for whole-of-field re-entry worker exposure considerations.

94.7. I have decided to vary the instructions contained on labels for containers for paraquat plus diquat products to address concerns identified in paragraph 88.7 in relation to the disposal of the product when it is no longer required (section 5D(1)(g)) and the disposal of containers for the product (section 5D(1)(h)) to read:

Storage and Disposal

Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers. Store in the closed, original container in a cool, well-ventilated area. DO NOT store for prolonged periods in direct sunlight.

Empty contents fully into application equipment. Close all valves and return to [point of supply/designated collection point/other specific collection details] for refill or storage.

94.8. I have decided to vary the instructions contained on labels for containers for paraquat plus diquat products to address concerns identified in paragraph 88.8 in relation to the safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i)) to read as follows:

First aid statements (all products)

If poisoning occurs, get to a doctor or hospital quickly. If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

Safety Directions (all products)

Very dangerous, particularly the concentrate. Do not swallow. The product, particularly the concentrate, can kill if swallowed, absorbed through the eyes or absorbed by skin contact. The liquid can cause burns particularly to the eyes. Will irritate the nose, throat and skin. When handling, do not touch or rub eyes, nose or mouth with hand. Avoid contact with eyes and skin, open wounds and clothing. Protect eyes while using. If clothing becomes contaminated with product or with wet spray remove clothing immediately. Do not inhale spray mist. Do not allow children to play with containers or any equipment that is used. When connecting, disconnecting and cleaning equipment wear cotton overalls buttoned to

the neck and wrist (or equivalent clothing) and a washable hat, impervious footwear, elbow-length chemical resistant gloves and a full face respirator with canister specified for paraquat/diquat OR half face-piece respirator with canister specified for paraquat/diquat and face shield or goggles. When applying by low (manual pressurised) or high (mechanically pressurised) hand wand wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, impervious footwear, elbow-length chemical resistant gloves, and a full face piece respirator with a canister specified for paraquat/diquat. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each days use wash gloves, face shield or goggles, respirator (and if rubber wash with detergent and warm water) clothing and footwear

94.9. I have decided to vary the instructions contained on labels for containers for paraquat plus diquat products to address concerns identified in paragraph 88.9.b in relation to the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia (regulation 8AE(1)(b) of the Agvet Regulations) to include the following statements:

LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the export slaughter interval is observed before stock are sold or slaughtered.

EXPORT SLAUGHTER INTERVAL (ESI) 13 DAYS

Livestock that has grazed on or been fed treated crops should be placed on clean feed for 13 days prior to slaughter.

EXPORT OF TREATED PRODUCE

Growers should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for [edible produce name] treated with [chemical product name]. If you are growing [edible produce name] for export, please check with [company name, industry body, etc.] for the latest information on MRLs and import tolerances before using [chemical product name].

95. Section 34A(3) of the Agvet Code provides that if the variation would affect any instructions for the use of an active constituent or chemical product, or any instructions on a label, the APVMA must not make the variation until it has consulted each co-ordinator designated for a jurisdiction and taken into account any recommendations made by the co-ordinators.

95.1. I note that the APVMA has consulted with each co-ordinator designated for a jurisdiction on the above variations to the instructions on the label, which are also the instructions for use of the products. All recommendations received have been taken into account.

96. I am satisfied that the relevant particulars of the label approvals listed in Table 1 of Attachment A can be varied in the ways set out in paragraph 94, so that the labels contain adequate instructions so as to meet the labelling criteria and comply with any requirement prescribed by the regulations.

Consideration of whether approved labels comply with any requirement prescribed by the regulations

97. Section 34(1)(d) of the Agvet Code provides that I must affirm an approval of a label only if I am satisfied that the label complies with any requirements prescribed by the regulations.

97.1. There are no other requirements prescribed by the regulations for relevant labels that have not already been considered above.

Conclusions

98. Having had regard to the matters set out above regarding paraquat active constituent approvals:

98.1. I am **not satisfied** that the paraquat active constituent approvals listed in Attachment A currently meet the safety criteria;

98.2. I am satisfied that the conditions of the paraquat active constituent approvals listed in Attachment A of this notice can be varied as described in paragraph 24 of this statement of reasons to meet the safety criteria and allow the approvals to be affirmed; and

98.3. I am satisfied that the active constituents listed in Attachment A comply with any other requirement prescribed by the regulations.

99. Having had regard to the matters set out above regarding paraquat chemical products:

99.1. I am **not satisfied** that the paraquat chemical products currently meet the safety criteria and trade criteria;

99.2. I am satisfied that the paraquat chemical products meet the efficacy criteria; and any requirement prescribed by the regulations; and

99.3. I am satisfied that the relevant particulars and conditions of paraquat (and paraquat plus diquat) chemical product registrations listed in Attachment A can be varied in such a way, as set out in paragraphs 49, 50, 51, 52 and 55 of this statement of reasons in relation to the safety criteria and paragraph 75 of the statement of reasons in relation to the trade criteria, to allow the chemical product registrations to be affirmed.

100. Having had regard to the matters set out above regarding paraquat label approvals:

100.1. I am **not satisfied** that the label approvals for containers for paraquat chemical products listed in Attachment A of this notice meet the labelling criteria;

100.2. I am satisfied that the label approvals for containers for paraquat chemical products listed in Attachment A comply with any requirement prescribed by the regulations; and

100.3. I am satisfied that the particulars of paraquat label approvals listed in Attachment A of this notice can be varied, as set out in paragraph 94 of this statement of reasons, to allow the me to be satisfied that the labels meet the labelling criteria in 5D of the Agvet Code and to allow the label approvals to be affirmed.

101. Consequently, pursuant to section 34A(1) of the Agvet Code, I have decided to:

101.1. vary the conditions of paraquat active constituent approvals listed in Table 1 in Attachment A of this notice, in a manner set out in paragraph 24 of the statement of reasons, to allow affirmation under section 34(1) of the Agvet Code; and

101.2. vary the relevant particulars and conditions of the chemical product registrations listed in Table 1 in Attachment A, in a manner set out in paragraphs 49, 50, 51, 52 and 55 of this statement of reasons in relation to the safety criteria and paragraph 75 of the statement of reasons in relation to the trade criteria of the statement of reasons, to allow affirmation under section 34(1) of the Agvet Code; and

101.3. vary the relevant particulars of the label approvals listed in Table 1 in Attachment A the manner set out in paragraph 93 of the statement of reasons to allow affirmation under section 34(1) of the Agvet Code.

102. In light of my decision to vary the matters as set out above, and subject to those variations, I have decided to affirm the varied active constituent approvals, product registrations and label approvals listed in Attachment A of this notice pursuant to section 34(1) of the Agvet Code.

Phase-out period

103. Noting that the risk assessments completed during the reconsideration of paraquat have not identified any imminent risks of serious injury or serious illness for people, or other risks that have led to the cancellation of approvals or registrations, I have determined under section 81(3)(c) of the Agvet Code that subsection 81(3) of the Agvet Code applies to the supply of registered chemical products bearing labels that were approved prior to my decisions described above, for a period of two years from 22 June 2026.

104. I consider the default period of 2 years provided by section 81(3) of the Agvet Code is appropriate because of the above-mentioned absence of imminent risk to human health and recognising the considerations provided in section 1A regarding implementing the Agvet Code, particularly 1A(2)(c) which requires that I balance the regulatory burden imposed by the system of regulation against the risk of use of the products for people and the environment.

105. I note that this determination under section 81(3)(c) does not authorise manufacture of chemical products bearing previously approved labels.

Attachment C: Information on which the reasons are based

1. The information on which the reasons in the Statement of Reasons is based is set out below. All studies available to the APVMA for consideration in the final regulatory decisions are listed in the data list which will be published on the APVMA website.

    1.1. Information recorded in the APVMA's record and register, submitted to support applications for active constituent approval or chemical product registration or label approval for each of the approvals and registrations listed in Attachment A, which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code.

    1.2. Information provided to the APVMA in response to notices:

        a. Issued to Holders under section 32 of the Agvet Code on 27 October 1997, and additional notices issued under section 32 of the Agvet Code on 1 July 2015, 10 May 2016, 16 August 2017, and 28 February 2024

        b. Published in the APVMA Gazette under section 32 of the Agvet Code on 2 December 1997

        c. Issued to Holders under section 33 of the Agvet Code on 2 September 2021 and 28 August 2023

        d. Issued to Holders and published in the APVMA Gazette under section 34AB of the Agvet Code on 30 July 2024.

    1.3. Other information assessed by the APVMA and summarised in the following published reports, which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code:

        a. Paraquat toxicology report – summary, 26 October 2016

        b. Paraquat toxicology report – supplement I toxicology, 26 October 2016

        c. Paraquat toxicology report – supplement II neurotoxicology, 26 October 2016

        d. *Paraquat Final Review Technical Report*, June 2026

        e. *Diquat Final Review Technical Report*, June 2026

        f. APVMA consideration of submissions – paraquat and diquat

        g. Final Regulatory Decisions on Paraquat – Consideration of Neurotoxicity Submissions

    1.4. Other information assessed by the APVMA summarised in the following unpublished reports (these are internal APVMA reports which include confidential commercial information belonging to multiple parties), which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code:

        a. Paraquat and Diquat - Review on toxicology and occupational uses - HHRA FTR - APVMA COPY

        b. Residues and Trade assessment – Paraquat Reconsideration

        c. Paraquat - chemical review - environment 7.1 – fate

        d. Paraquat - chemical review - environment 7.2 – effects

        e. Paraquat - chemical review - environment 7.3 – risk

        f. Paraquat - chemical review - environment 7.4 - combo with diquat

        g. Paraquat – assessment against chemistry standard

1.5. Other information which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code

a. Therapeutic Goods (Poisons Standard—February 2026) Instrument 2026 (i.e. the Standard for the Uniform Scheduling of Medicines and Poisons)

b. The APVMA's risk assessment manuals as published on the APVMA website at https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals

- Chemistry and manufacture
- Environment
- Human health
- Residues and trade
- Spray Drift Risk Assessment Manual

Notice under section 34AC of the *Agricultural and Veterinary Chemicals Code*: diquat reconsideration – decisions on reconsideration

1) I, James Deller, Executive Director, Science and Assurance, am a delegate of the Australian Pesticides and Veterinary Medicines Authority (APVMA), for the purpose of reconsidering an approval or registration and making a decision under sections 34, 34A and 34AA of the Agricultural and Veterinary Chemicals Code (scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) (Agvet Code).

2) This notice is published in the APVMA Gazette pursuant to section 34AC(1)(b) of the Agvet Code and relates to the reconsideration of diquat active constituent approvals, product registrations and label approvals listed in Attachment A of this notice.

3) The Statement of Reasons for my decisions is included as Attachment B of this notice.

4) The information on which the reasons are based is set out in Attachment C of this notice.

5) Pursuant to section 34A(1) of the Agvet Code, I have decided to:

a. vary the conditions of diquat active constituent approvals listed in Attachment A of this notice, in a manner set out in paragraph 24 of the Statement of Reasons, to allow the approvals to be affirmed under section 34(1) of the Agvet Code; and

b. vary the relevant particulars and conditions of the chemical product registrations listed in Attachment A, in a manner set out in paragraph 55 of the Statement of Reasons, to allow affirmation under s34(1) of the Agvet Code; and

c. vary the relevant particulars of the label approvals listed in Attachment A in the manner set out in paragraph 91 of the Statement of Reasons to allow the approvals to be affirmed under section 34(1) of the Agvet Code.

6) Pursuant to section 34(1) of the Agvet Code, and following my decisions above to vary the relevant particulars and conditions for the active constituent approvals, product registration and label approvals, I have also decided to affirm the active constituent approvals, product registration and label approvals listed in Attachment A as varied.

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Date: 22 June 2026

Attachments:

Note: The below attachments form part of this decision.

Attachment A: Active constituent approval(s), product registration(s) and approved label(s) that have been reconsidered.
Attachment B: Statement of Reasons
Attachment C: Information on which the reasons are based.

Attachment A: Active constituent approvals, product registrations and label approvals that have been reconsidered

Table 7: Active constituent approval(s), product registration(s) and associated label approval(s) that have been reconsidered

Active Constituent(s)	Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
Diquat	Active	44219	Diquat Dibromide Manufacturing Concentrate	Syngenta Australia Pty Ltd	N/A	N/A
Diquat	Active	56655	Diquat Dibromide Manufacturing Concentrate	Halley International Enterprise (Australia) Pty Ltd	N/A	N/A
Diquat	Active	56808	Diquat Dibromide Manufacturing Concentrate	Conquest Crop Protection Pty Ltd	N/A	N/A
Diquat	Active	58221	Diquat Dibromide Manufacturing Concentrate	Sinon Australia Pty Limited	N/A	N/A
Diquat	Active	58386	Diquat Dibromide Manufacturing Concentrate	ADAMA Australia Pty Limited	N/A	N/A
Diquat	Active	59111	Diquat Dibromide Manufacturing Concentrate	Pacific Agriscience Pty Ltd	N/A	N/A
Diquat	Active	62650	Diquat Dibromide	Agrogill Chemicals Pty Ltd	N/A	N/A
Diquat	Active	64501	Diquat Dibromide	Sharda Worldwide Exports Pvt Ltd	N/A	N/A
Diquat	Active	67123	Diquat Dibromide	Titan Ag Pty Ltd	N/A	N/A
Diquat	Active	87160	Diquat Dibromide Manufacturing Concentrate	Agrogill Chemicals Pty Ltd	N/A	N/A
Diquat	Active	88034	Diquat Dibromide Manufacturing Concentrate	Foison Scitech Co., Limited	N/A	N/A
Diquat	Active	88714	Diquat Dibromide Manufacturing Concentrate	Foison Scitech Co., Limited	N/A	N/A
Diquat	Product	46534	Reglone Non-Residual Herbicide	Syngenta Australia Pty Ltd	46534/03, 46534/04, 46534/05, 46534/0502, 46534/0606, 46534/0799, 46534/1000, 46534/1004, 46534/54411, 46534/62108, 46534/105980	46534/RV2026
Diquat	Product	58411	Imtrade Diquat 200 Non-Residual Herbicide	Imtrade Australia Pty Ltd	58411/0605, 58411/51114, 58411/106301,	58411/RV2026

Active Constituent(s)	Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Affirmed label approval number associated with the product
					58411/141286, 58411/141286A	
Diquat	Product	58833	Conquest Sanction 200 Non-Residual Herbicide	Conquest Crop Protection Pty Ltd	58833/0704, 58833/54698	58833/RV2026
Diquat	Product	59332	Kenso Agcare Diquat 200 Herbicide	Kenso Corporation (M) Sdn. Bhd.	59332/0605, 59332/61317, 59332/116863	59332/RV2026
Diquat	Product	60297	Dia-Kill 200 Herbicide	Sinon Australia Pty Limited	60297/0106, 60297/62335	60297/RV2026
Diquat	Product	63173	Accensi Diquat 200 Non-Residual Herbicide	Australian Agribusiness (Holdings) Pty Ltd	63173/0908, 63173/59906	63173/RV2026
Diquat	Product	64311	Farmalinx Diquat 200 Herbicide	Farmalinx Pty Ltd	64311/0809, 64311/58258	64311/RV2026
Diquat	Product	64889	Genfarm Diquat 200 Non-Residual Herbicide	Nutrien Ag Solutions Ltd	64889/0610, 64889/58177	64889/RV2026
Diquat	Product	65909	Rainbow Diquat 200 Non-Residual Herbicide	Shandong Rainbow International Co Ltd	65909/53424	65909/RV2026
Diquat	Product	66064	KDPC Desiquat Non-Residual Herbicide	KD Plant Care Pty Ltd	66064/52662	66064/RV2026
Diquat	Product	81984	AQ200 Aquatic Herbicide	Aquatic Site Maintenance Pty Ltd	81984/107598, 81984/104562	81984/RV2026
Diquat	Product	82741	Water Treats Aquatic Weed Killer	Clearwater Lakes And Ponds Pty Ltd	82741/106581	82741/RV2026
Diquat	Product	84436	4Farmers Diquat 200 Herbicide	4 Farmers Australia Pty Ltd	84436/110412	84436/RV2026
Diquat	Product	88533	Barmac Diquat 200 Herbicide	Australian Agribusiness (Holdings) Pty Ltd	88533/121617	88533/RV2026
Diquat	Product	88796	Foison Diquat 200SL Herbicide	Foison Scitech Co., Limited	88796/122345	88796/RV2026
Diquat	Product	89075	Agrevo Diquat 200SL Herbicide	Agrevo Australia Pty Ltd	89075/123546	89075/RV2026
Diquat	Product	90843	Slash 200 SL Herbicide	Asiatic Agricultural Industries Pte Ltd	90843/130192	90843/RV2026
Diquat	Product	92386	KELPIE DIQUAT 200SL Herbicide	Sinochem International Australia Pty. Ltd.	92386/135349	92386/RV2026

Attachment B: Statement of Reasons

Contents

Material findings of fact and reasons for my decisions

1. Subsection 34(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (**Agvet Code**) provides that I must affirm the approval or registration if, and only if, I am satified:

    1.1. for an active constituent—that the constituent meets the safety criteria; and

    1.2. for a chemical product—that the product meets the safety criteria, the trade criteria and the efficacy criteria; and

    1.3. for a label—that the label meets the labelling criteria; and

    1.4. that the constituent, product or label complies with any requirement prescribed by the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth) (**Agvet Code Regulations**).

2. Subsection 34(2) of the Agvet Code provides that section 34(1) applies only to the extent that I decide to reconsider matters covered by that subsection.

3. For the purposes of making a decision on the reconsideration of the approval or registration, section 34(3) of the Agvet Code provides that I must:

    3.1. have regard to:

        a. any information given, or submissions made, to the APVMA in response to a notice given under subsection 32(1); and

        b. any submissions made to the APVMA in response to an invitation under paragraph 32(2A)(b) or 34AB(2)(f); and

        c. any information given by the holder in response to an invitation given by the APVMA (whether or not under this Code) in relation to the constituent, product or label; and

        d. any information, report, results or sample given to the APVMA in response to a notice given under section 33; and

        e. any information given to the APVMA as required by section 161 in relation to the constituent, product or label; and

        f. any other information that I consider necessary to enable me to make a decision on the reconsideration; but

    3.2. not take into account any submission, information, report, results or sample not covered by the above.

4. I have outlined at Attachment C, the information covered by subsection 34(3)(a) that I have had regard to in making the reconsideration decisions.

5. Subsection 34A(1) of the Agvet Code provides that, if I:

    5.1. am not satisfied as mentioned in subsection 34(1); but

    5.2. am satisfied that the relevant particulars or conditions of the approval or registration can be varied in such a way as to allow the approval or registration to be affirmed;

    I must vary the relevant particulars or conditions.

6. In considering whether the relevant particulars or conditions of the approval or registration can be varied in such a way as to allow the approval or registration to be affirmed, subsection 34A(2) provides that I may only have regard to the following:

    6.1. submissions, information, reports, results or samples that I had regard to under section 34; and

6.2. submissions made to the APVMA in response to the invitation under subsection 34AB(2)(f) (notice of proposed decision).

7. I have reconsidered diquat active constituent approvals, registrations of chemical products containing diquat as the active constituent and associated label approvals under Part 2, Division 4 of the Agvet Code to determine whether:

7.1. the active constituents meet the safety criteria (section 5A of the Agvet Code);

7.2. the chemical products meet the safety criteria (section 5A of the Agvet Code), the trade criteria (section 5C of the Agvet Code), and the efficacy criteria (section 5B of the Agvet Code);

7.3. the labels meet the labelling criteria (section 5D of the Agvet Code); and

7.4. the active constituents, chemical products and labels comply with any requirements prescribed by the Agvet Regulations.

8. Where I was not satisfied of the relevant matters in subsection 34(1) of the Agvet Code in relation to the active constituent approvals, registrations of chemical products containing diquat as the active constituent and associated label approvals as discussed in my reasons below, I considered whether the relevant particulars or conditions of the approval or registration could be varied in such a way as to allow the approval or registration to be affirmed in accordance with section 34A of the Agvet Code.

Active constituents

9. Subsection 34(1) of the Agvet Code provides that I must affirm the approval of an active constituent if, and only if, I am satisfied that the constituent:

9.1. meets the safety criteria (section 5A), and

9.2. complies with any requirement prescribed by the Agvet Regulations.

10. I have considered all matters covered by subsection 34(1) in relation to the reconsideration of diquat active constituent approvals specified at Attachment A.

Consideration of whether active constituents meet the safety criteria

11. Subsection 5A(1) of the Agvet Code provides that an active constituent meets the safety criteria if use of the active constituent, in accordance with any instructions approved or to be approved by the APVMA for the constituent or contained in an established standard:

11.1. is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a)).

11.2. is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b)).

11.3. is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).

12. For the purpose of being satisfied as to whether the active constituents meet the safety criteria, I must have regard to the matters specified under subsection 5A(2)(a), and I may also have regard to such other matters as I think are relevant (subsection 5A(2)(b)).

13. For the purposes of considering whether the active constituents specified at Attachment A meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, I have had regard to the matters set out in subsection 5A(2)(a) of the Agvet Code as follows.

14. Section 5A(2)(a)(i) of the Agvet Code – the toxicity of the constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.

14.1. I have considered assessment reports by the APVMA's relevant expert staff regarding the following information in respect of the toxicity of diquat and its residues as summarised in the *Diquat Final Review Technical Report*:

a. studies examining the absorption, metabolism and excretion of diquat in animal models and humans exposed through occupational, accidental or intentional exposure as described in section 3.1 (Evaluation of Toxicology) of the *Diquat Final Review Technical Report*.

b. studies on the toxicological effects of diquat, including the toxicological mode of action, acute and chronic toxicity, genotoxicity, reproductive and developmental toxicity in animal models and humans exposed through occupational, accidental or intentional exposure as described in section 3.1 (Evaluation of Toxicology) of the *Diquat Final Review Technical Report.*

c. studies on the potential for diquat to cause neurotoxicity as described in the section 3.1.10.1 of the *Diquat Final Review Technical Report*.

d. studies on the metabolism and degradation of diquat on treated crops and the residues and metabolites that are present in commodities following harvest as described in section 5 (Residues and Trade) of the *Diquat Final Review Technical Report*.

e. studies on the environmental fate and behaviour of diquat in the environment, including degradation and environmental toxicity studies as detailed in section 6 (Environmental Safety) of the *Diquat Final Review Technical Report*.

f. The APVMA's Record of Approved Active Constituents for diquat active constituents for use in agricultural chemical products.

14.2. Based on the assessment of relevant toxicity studies, as set out in section 3.2 (Health-based guidance values) of the *Diquat Final Review Technical Report,* I am satisfied that the following health-based guidance values remain appropriate. These diquat health-based guidance values include:

a. The acceptable daily intake[5] (ADI) of 0.006 milligrams per kilogram body weight per day (mg/kg bw/day) based on a no observed adverse effect level (NOAEL) of 0.6 mg/kg bw/day in a two-year rat dietary study, which showed lenticular cataract formation at the next higher dose. The ADI incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity.

b. The acute reference dose[6] (ARfD) of 0.8 mg of diquat per kg body weight based on a no observed adverse effect level of 75 mg per kilogram body weight in a rat acute neurotoxicity study, based on increased clinical signs, lack of appetite and reduced bodyweight gain at the next highest dose. The ADI incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity.

14.3. I am satisfied that an acceptable level of exposure to diquat for workers (below which it is unlikely to have an effect that is harmful to human beings) corresponds to a greater than 100-fold margin of exposure

[5] ADI - Acceptable Daily Intake (for humans): a level of intake of a chemical (expressed mg/kg bw/day; milligrams per kilogram of body weight per day) that can be ingested daily over an entire lifetime without any appreciable risk to health

[6] ARfD - Acute Reference Dose (for humans): the amount of a substance in food or drinking-water, (expressed as mg/kg of body weight), that can be ingested or absorbed over 24 hours or less, without appreciable health risk.

(MOE) applied to a point of departure of 0.282 mg/kg bw/day, taking into consideration an ocular NOAEL of 4.7 mg/kg bw/day based on a 13-week rat dietary repeat study and an oral availability of 6% as described in section 4.1 of the *Diquat Final Review Technical Report.*

14.4. I am satisfied that, due to little metabolism or degradation in plants or animals (section 5.1 of the *Diquat Final Review Technical Report*), and based on available analytical methods and stability of diquat in stored samples (section 5.2 of the *Diquat Final Review Technical Report*) *diquat cation* is the appropriate residue definition for both risk assessment and enforcement of compliance with Maximum Residue Limits (MRLs) in plant and animal commodities as described in section 5.3 (Residue definition) of the *Diquat Final Review Technical Report*.

14.5. I have considered and agree with the assessment of the fate and behaviour of diquat in the environment (section 6.2 of the *Diquat Final Review Technical Report*) and the toxicity of diquat and its metabolites and residues to non-target species, which has identified Regulatory Acceptable Levels (RALs[7]) of exposure to diquat (below which it is unlikely to have an unintended effect that is harmful to plants or animals or things or to the environment) as detailed in section 6.3 (Effects on non-target species) and Table 28 of the *Diquat Final Review Technical Report.*

14.6. I note that the RALs for mammals, aquatic primary producers and terrestrial plants have been revised following consideration of new information provided to the APVMA during consultation on the proposed regulatory decisions, as described in sections 3.15, 3.24 and 3.32 of the APVMA's consideration of submissions document.

a. Specifically, I note that the RAL for acute toxicity in mammals has been revised from 12 mg/kg bodyweight (bw) to 21 mg/kg bw based on a mammalian LD_{50} of 208 mg ac/kg bw (including a 10-fold assessment factor) based on the endpoint determined in the EFSA (European Food Safety Authority) 2015 report on the toxicity of diquat and the review of additional studies submitted to the public consultation and discussed in section 3.15 of the APVMA's *Consideration of Submissions* document.

b. I note that the RAL for chronic toxicity to aquatic primary producers has been revised from 2.1 μg ac/L to 1.4 μg ac/L based on amendments and clarifications of the modelling used to generate a species sensitivity distribution (SSD) from the EC_{50}[8] of 11 species. The SSD analysis yielded an HC_5[9] of 0.0042 mg ac/L, to which an assessment factor of 3 was applied, as per standard practice. The modelling parameters for this assessment and the final endpoint are set out in Table 26 and 28 of the *Diquat Final Review Technical Report* and discussed in section 3.24 of the APVMA's *Consideration of Submissions* document.

c. I note that the RAL for terrestrial plants has been revised from 12 g/ha to 15 g/ha due to recalculation of the RAL. The RAL of 15 g/ha was generated using an SSD of the ER_{50}[10] from 10 terrestrial plant species to produce an HR_5[11] of 15 g ac/ha with no assessment factor required. The modelling parameters for this assessment and the final endpoint are set out in Table 27 and 28 of the *Diquat Final Review Technical Report* and discussed in section 3.32 of the APVMA's *Consideration of Submissions* document.

[7] Regulatory Acceptable Level: a level of chemical exposure that is sufficiently lower than the concentration where harmful effects are observed in the relevant species that it can be concluded harmful effects are unlikely to occur

[8] EC_{50}- The concentration of a test substance that results in half the maximal response

[9] HC_5 – The adjusted concentration of a test substance that is hazardous to 5 % of species tested.

[10] ER_{50} – The application rate of a test substance at which there is a 50% reduction in a specific parameter (e.g biomass production), compared to control.

[11] HR_{50} – The application rate of a test substance that is hazardous to 5 % of species tested.

14.7. The assessment of environmental toxicity studies for chronic exposure to mammals, acute and chronic exposure to birds, acute exposure to aquatic animals, chronic exposure to sediment dwellers, acute contact and oral exposure to adult bees, contact exposure to foliar and ground arthropods, acute and chronic exposure to soil macroorganisms and chronic exposure to soil microorganisms were not amended from the proposed regulatory decision and are set out below:

a. The RAL of 4.0 mg/kg bw for chronic exposure to mammals was based on the most sensitive, reliable reproductive toxicity study in rats, where a NOAEL of 4.0 mg/kg bw/d was identified based on reproductive toxicity effects were observed at the next highest dose of 12 mg ac/kg bw/d, as set out in Table 46 and section 6.3 of the *Diquat Final Review Technical Report.*

b. The RAL of 7.0 mg/kg bw for acute exposure to birds was generated from a geomean LD_{50} [12]of 70 mg ac/kg bw from 3 different bird species and a standard 10-fold assessment factor as set out in Table 46 and section 6.3 of the *Diquat Final Review Technical Report*. I note that there was a submission suggesting revision of this RAL which has been considered by expert staff but not actioned as set out section 3.16 of APVMA's *Consideration of Submissions* document.

c. The RAL of 3.2 mg/kg bw/d for chronic exposure of birds was based on the most sensitive, reliable reproductive toxicity study in birds, where a NOEC (no observed effect concentration) of 20 mg ac/kg food, equivalent to a NOEL (no observed effect level) of 3.2 mg ac/kg bw/d, was identified based on reduction in egg production at the next highest level (NOEC of 40 mg ac/kg food), as set out in Table 46 and section 6.3 of the *Diquat Final Review Technical Report*.

d. The RAL of 47 μg/L for acute exposure of aquatic animals was based on an LC_{50}[13] 468 μg/L, adjusted to account for rapid dissipation of diquat from the water column and an assessment factor of 10, based on an LC_{50} of 84 μg ac/L, for the most sensitive aquatic organism *Hyallella azteca*, as set out in Table 47 and section 6.3 of the *Diquat Final Review Technical Report*.

e. The RAL of 11 mg/kg ds for chronic exposure of sediment dwellers was based on a NOEC of 11 mg ac/kg dry sediment, with reduced reproduction demonstrated at the next highest test concentration of 23 mg ac/kg dry sediment, as set out in Table 47 and section 6.3 of the *Diquat Final Review Technical Report*.

f. The RALs of 42 μg/bee for acute contact and 8.8 μg/bee for acute oral exposure of adult bees were determined based on the LD_{50} (105 μg ac/bee and 22 μg ac/bee respectively) and a standard 2.5-fold assessment factor and set out in Table 49 and section 6.3 of the *Diquat Final Review Technical Report.*

g. The RALs for acute exposure of arthropods of 4.1 g/ha for foliar arthropods was derived from the LR_{50}[14] of 4.1 g ac/ha for the predatory mite, which was the most sensitive species tested, under natural substrate conditions. The RAL for ground arthropods was set at 1000 g/ha, based on an ER50 of >1000 g/ha, with soil dwelling species unaffected by diquat exposure at field relative rates. These analyses were set out in Table 50 and section 6.3 of the *Diquat Final Review Technical Report.*

h. The acute and chronic RALs of 9.4 mg/kg dry soil (ds) for soil macroorganisms were based on an LC_{50} 94 mg/kg ds (acute) in earthworms with a standard 10-fold assessment factor and a NOEC of

[12] LD_{50} – The dose or amount of an active constituent that, when taken through the mouth or absorbed through the skin, kills 50 % of the experimental animals under stated test conditions.

[13] LC_{50} - The concentration of a substance in air that produces death by inhalation in 50 % of a population of experimental organisms within a specified period.

[14] LR_{50} – The residue concentration of an active constituent in the organism's body that is required to kill 50 % of the experimental organisms under stated test conditions.

9.4 mg/kg ds respectively, with reduced reproduction in the most sensitive species demonstrated at 12 mg/kg ds. Soil microorganisms, as measured by soil nitrification were not affected by diquat at rates up to 500 mg/kg ds, resulting in a RAL of 500 mg/kg ds for chronic exposure of soil microorganisms. These analyses were set out in Table 28 and section 6.3 of the *Diquat Final Review Technical Report.*

14.8. Having considered the revised assessment of environmental toxicity studies, as set out in section 6.3 of the *Diquat Final Review Technical Report*, I find that exposure of non-target species to diquat below the RALs set out in Table 28 of the *Diquat Final Review Technical Report*, and Table 8 below are not expected to have an unintended effect that is harmful to animals, plants, things or the environment:

Table 8: Regulatory Acceptable Levels for exposure of non-target species to diquat

Group	Exposure type	RAL
Mammals	Acute	21 mg/kg bw
	Chronic	4.0 mg/kg bw/d
Birds	Acute	7.0 mg/kg bw
	Chronic	3.2 mg/kg bw/d
Aquatic animals	Acute	47 μg/L
Aquatic primary producers	Chronic	1.4 μg/L
Sediment dwellers	Chronic	11 mg/kg ds
Adult bees	Acute contact	42 μg/bee
	Acute oral	8.8 μg/bee
Foliar arthropods	Contact	4.1 g/ha
Ground arthropods	Contact	1000 g/ha
Soil macro-organisms	Acute	9.4 mg/kg ds
	Chronic	9.4 mg/kg ds
Soil micro-organisms	Chronic	500 mg/kg ds
Terrestrial plants	Post-emergent	15 g/ha

15. Section 5A(2)(a)(ii) of the Agvet Code – the method by which the constituent is, or is proposed to be, manufactured.

15.1. The APVMA's chemistry assessment, as detailed in section 2.1 of the *Diquat Final Review Technical Report*, considered information submitted in the original applications for active constituent approval, or subsequent variation of an approval, regarding the method of manufacture for each approved diquat active constituent.

15.2. I have considered and agree with the recommendation that the information submitted in the original applications for active constituent approval demonstrates that the method by which each of the diquat active constituents with the approval numbers 44219 and 88714 is manufactured is expected to result in diquat dibromide technical concentrate that complies with the *Agricultural and Veterinary Chemicals Code*

(Agricultural Active Constituents) Standards 2022 (Agricultural Active Constituents Standards 2022) made under section 6E of the Agvet Code and the *Food and Agriculture Organization of the United Nations Specifications for Pesticides: Diquat* (FAO Specifications for Diquat).

15.3. I have considered and agree with the recommendation in section 2.1 of the *Diquat Final Review Technical Report*, that the information submitted in the original applications for active constituent approval or subsequent variation of an approval, does not sufficiently address the parameters specified for diquat in the Agricultural Active Constituents Standard 2022 and the FAO Specifications for Diquat to allow the APVMA to conclude whether the method by which each of the diquat active constituents with the approval numbers 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 is manufactured, will result in diquat active constituents that comply with the Agricultural Active Constituents Standard 2022 and FAO Specifications for Diquat discussed in paragraph 16 below.

16. Section 5A(2)(a)(iii) of the Agvet Code – the extent to which the constituent will contain impurities.

16.1. The APVMA's chemistry assessment has considered the following information, as described in the chemistry section of the *Diquat Final Review Technical Report*:

a. information submitted in the original applications for active constituent approval, or subsequent variation of an approval, regarding the purity and expected impurities for each approved diquat active constituent.

b. The Active Constituents Standards 2022 require that diquat dibromide manufacturing concentrate must have a purity of 375 – 485 g/kg of diquat dibromide (200 – 260 g/kg of diquat ion) and a minimum purity of 940 g/kg diquat dibromide on a dry weight basis.

c. The Active Constituent Standards 2022 further requires that diquat dibromide manufacturing concentrate must not exceed maximum levels for two toxicologically significant impurities; 10 mg/kg for ethylene dibromide and 2.5 g/kg for free 2,2'-bipyridyl (0.25% w/w maximum of the diquat dibromide content).

d. The FAO Specifications for Diquat requires that the diquat dibromide manufacturing concentrate should contain no less than 377 g/kg (467 g/L) of diquat dibromide and that the maximum levels of three toxicologically significant impurities should not exceed 10 mg/kg for ethylene dibromide, 0.75 g/kg for free 2,2'-bipyridyl and 1 mg/kg for total terpyridines.

16.2. I have considered and agree with the APVMA's chemistry assessments, as described in section 2.1 of the *Diquat Final Review Technical Report* which concluded that:

a. the formation of degradation products that are impurities of toxicological concern during storage of the manufacturing concentrate or in the formulated chemical product is not expected because these were not present in analyses previously considered and the impurities that result from manufacturing are well understood.

b. there is the potential for the presence or formation of impurities of toxicological concern during the synthesis of diquat dibromide manufacturing concentrate, as described above and in sections 2.1.1 and 2.1.2 of the *Diquat Final Review Technical Report.*

c. the FAO Specifications for Diquat represents consensus among the international regulatory authorities that are members of the FAO[15] regarding the acceptable composition and purity, and maximum levels of impurities of toxicological concern of diquat dibromide.

d. the FAO Specifications for Diquat includes a maximum impurity level for 1 mg/kg for total terpyridines which is not included in the Active Constituent Standards 2022 as an impurity of

[15] Food and Agriculture Organization of the United Nations

concern, and a more conservative value for free 2,2'-bipyridyl (0.75 g/kg compared with 2.5 g/kg in the Active Constituent Standards 2022). Due to the toxicity of these impurities, section 2.1 of the *Diquat Final Review Technical Report* recommends that the APVMA should adopt the FAO Specifications for Diquat as the applicable parameters for diquat dibromide active constituents, to be met in the next amendment of the Active Constituents Standard

e. the diquat active constituents (manufacturing concentrates) with the approval numbers 44219 and 88714 will contain impurities below the limit specified in the FAO Specifications for Diquat, which is considered adequately protective to human health, as detailed in the *Diquat Final Review Technical Report*

f. the available information does not sufficiently address the parameters specified for diquat in the FAO Specifications for Diquat to allow the APVMA to conclude that remaining diquat active constituents with the approval numbers 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 comply with the FAO Specifications for Diquat.

g. An updated Declaration of Composition and the results of 5 batch analyses is required demonstrate that these active constituents 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 conform to the FAO Specifications for diquat and the Agricultural Active Constituents Standards 2022.

17. Section 5A(2)(a)(iv) of the Agvet Code – whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis.

17.1. The APVMA's chemistry assessment, as detailed in the *Diquat Final Review Technical Report,* has considered the batch analyses that were submitted and assessed by the APVMA as part of the original approval for each diquat active constituent.

17.2. I agree with the APVMA's assessment of the batch analyses for active constituents 44219 and 88714 concluded that the chemical composition of those diquat active constituents is compliant with the FAO Specifications for Diquat, as detailed in section 2.1 of the *Diquat Final Review Technical Report*.

17.3. I am **not satisfied** that the diquat active constituents with the approval numbers 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 meet the safety criteria. I agree with the APVMA's chemistry assessment which concluded that the available analyses of the chemical composition of the constituent were inadequate for the APVMA to determine whether the active constituent complies with the FAO Specifications for Diquat.

18. Section 5A(2)(a)(v) of the Agvet Code – any conditions to which its approval is, or would be, subject.

18.1. I have had regard to the conditions to which the approvals are subject as prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code, including:

a. Regulation 17C(1) of the Agvet Regulations which prescribes conditions to which the approval of an active constituent for a proposed or existing chemical product is subject. Those conditions relate to matters such as the manufacture of the active constituent.

b. Section 5 of the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021* (Conditions of Approval or Registration Order) which prescribes conditions that apply to the approval of an active constituent for a proposed or existing agricultural chemical product. Those conditions include restrictions on the supply of the active constituent if its manufacture contravenes or fails to comply with any manufacturing law of the country (or part of the country) in which it is manufactured.

18.2. I have also had regard to the conditions the APVMA has imposed on the approval of diquat active constituents in accordance with section 23(1)(b) of the Agvet Code through the condition referred to as the Agricultural Active Constituents Quality Assurance Requirements which is reproduced below.

"*Agricultural Active Constituents must meet Quality Assurance Requirements*

- *A person must not Supply the Active Constituent, or cause it to be supplied, unless the Active Constituent:*
  - *complies with the APVMA Standard for the Active Constituent; and*
  - *was manufactured at a site of manufacture listed in the Record of Approved Active Constituents.*
- *A person must at the time of Supply of a Batch of the Active Constituent to another person also supply details of the Batch Number of the Active Constituent to the person to whom the active constituent was supplied.*
- *For the purposes of these conditions a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method:*
  - *does not contain less than the minimum purity and/or content of the constituent as set out in the APVMA Standard; and*
  - *does not contain more than the maximum level of any impurity as set out in the APVMA Standard*

Definitions and Interpretation – in these conditions the following words have the following meanings:

- *'APVMA Standard' means the standard determined by the APVMA to which a constituent must comply and which is published on the APVMA website;*
- *'Batch' means a defined quantity of material produced in a single series of operations;*
- *'Batch Number' means that a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined;*
- *'Supply' has the same meaning as given to it in Section 3 of the Agvet Codes and includes the doing of those things through, or pursuant to an arrangement with another person."*

18.3. I am **not satisfied** that the current condition referred to as the 'Agricultural Active Constituent Quality Assurance Requirements' remains appropriate, noting that items 1 and 3 of the condition above are redundant in light of the Regulation 17C(1) of the Agvet Regulations.

18.4. I note that a number of diquat active constituent approvals are subject to additional conditions imposed by the APVMA under s23(1)(b) of the Agvet Code related to the site of manufacture. I note that these conditions are now redundant with reg 17C(1)2 and 17C(1)3 of the Agvet Regulations.

18.5. I also note that number of diquat active constituent approvals are subject to additional conditions imposed by the APVMA under s23(1)(b) of the Agvet Code requiring compliance with the outcomes of the reconsideration as below.

*"Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 34 of the NRA Gazette dated October 1998 (Diquat).**

Explanatory Note: you should be aware that the NRA will take steps to apply the outcomes of that reconsideration to this registration/approval as it thinks fit.

18.6. The obligations imposed by the current 'Agricultural Active Constituent Quality Assurance Requirements' condition, and the conditions noted at paragraphs 18.4 and 18.5, above, imposed in accordance with section 23(1)(b) of the Agvet Code are intended to require appropriate quality assurance processes and record keeping to ensure traceability and allow recall or other rectification action if necessary due to contamination or other fault with diquat active constituents. Redundant or incorrect references to legislative instruments or other documents may result in failure to follow these requirements correctly, which may result in harmful effect to people or the environment.

18.7. I am satisfied that the conditions imposed by the Conditions of Approval or Registration Order in conjunction with the conditions prescribed by the Agvet Regulations, as referenced above, remain appropriate and are acceptable.

19. Section 5A(2)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Record for the constituent.I have had regard to the relevant particulars recorded for each approved diquat active constituent. Section 3 of the Agvet Code provides that the relevant particulars, in relation to the approval of an active constituent, are the distinguishing number, any instructions for use and any other particulars required by section 19(c) to be entered in the Record. Section 19(c) of the Agvet Code refers to any other particulars prescribed by the regulations. Regulation 15(1) of the Agvet Regulations prescribes the following particulars for the purposes of subsection 19(c) of the Agvet Code:

a. if a name is given to the active constituent by the International Union of Pure and Applied Chemistry—that name

b. if no name is given to the active constituent by the International Union of Pure and Applied Chemistry—the name given to the active constituent in the standard prescribed in respect of the active constituent for the purposes of paragraph 87(1)(a) of the Code

c. the name of the active constituent

d. the composition and purity of the active constituent

e. the name of the manufacturer of the active constituent

f. the address of each site at which the active constituent is manufactured by the manufacturer

g. identifying information for the holder of the approval of the active constituent

h. the date of entry of these particulars in the Record of Approved Active Constituents

i. identifying information for any nominated agent for the approval.

19.2. I note that the relevant particulars recorded in the APVMA's Record of Approved Active Constituents for Chemical Products have been reviewed as discussed in section 2.1 of the *Diquat Final Review Technical Report*.

19.3. I am satisfied that all relevant particulars entered into the Record for diquat active constituents with the approval numbers 44219 and 88714 are correct.

19.4. I note that the information entered in the Record related to the composition and purity of the diquat active constituents with the approval numbers 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 is not sufficient to demonstrate compliance of those active constituents with the FAO Specifications for Diquat and I am not satisfied that any other information demonstrates compliance of these active constituents with the Specification. However, I am satisfied that all other relevant particulars entered into the Record for the approval numbers 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 are correct.

20. Section 5A(2)(a)(via) of the Agvet Code – whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection 5A(1).

    20.1. The Agricultural Active Constituents Standards 2022 were made under section 6E(1) of the Agvet Code for active constituents used in agricultural chemical products, including diquat.

        a. The APVMA's chemistry assessment, as detailed in the *Diquat Final Review Technical Report,* concluded that all diquat active constituents conform to the Agricultural Active Constituents Standard 2022.

        b. I accept the recommendation from the APVMA' s chemistry assessment in section 2.1.2 of the *Diquat Final Review Technical Report* and find that all diquat active constituent approvals conform to the Agricultural Active Constituents Standards 2022.

    20.2. The APVMA's chemistry assessment, as detailed in the *Diquat Final Review Technical Report,* also concluded that the Agricultural Active Constituents Standard 2022 should be amended to include specifications for additional impurities of toxicological concern that have been identified as relevant by the FAO. The FAO Specifications for Diquat requires that diquat dibromide manufacturing concentrate contains not less than 377 g/kg (467 g/L) of diquat dibromide and maximum levels of three toxicologically significant impurities; 10 mg/kg for ethylene dibromide, 0.75 g/kg for free 2,2'-bipyridyl and 1 mg/kg for total terpyridines.

        a. I note the recommendation of the APVMA' s chemistry assessment that active constituents with the approval numbers 44219 and 88714 would conform to the proposed amended Agricultural Active Constituents Standard.

        b. I note that the APVMA's chemistry assessment was unable to conclude whether the active constituents 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 would conform with the proposed amendments to the Agricultural Active Constituents Standard due to inadequate information.

    20.3. I am satisfied that the diquat active constituents listed in Attachment 1 conform to the Agricultural Active Constituents Standards 2022, made under section 6E(1) of the Agvet Code.

21. Section 5A(2)(a)(vii) of the Agvet Code - any matters prescribed by the regulations.

    21.1. Regulation 8AA of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition of the active constituent concerned as a relevant consideration in determining whether an active constituent meets the safety criteria.

    21.2. I have considered and agree with the assessment of the information about the method of analysis of the chemical composition of the active constituent submitted as part of the original applications for approval and found to be acceptable by the APVMA at that time, as described in the chemistry section at 2.1.2 of the *Diquat Final Review Technical Report*.

        a. I accept the APVMA's previous findings regarding the method of analysis and note that there has not been any new information provided that would alter my satisfaction regarding the method of analysis of the chemical composition of the active constituents.

        b. I am satisfied of the method of analysis of the chemical composition of each approved diquat active constituent listed in Attachment A.

22. Section 5A(2)(b) of the Agvet Code – such other matters as the APVMA thinks relevant.

22.1. For the purposes of considering whether the active constituents meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, there were no other matters that I considered relevant in determining whether diquat active constituents meet the safety criteria.

23. Having had regard to the matters described above, I am **not satisfied** that the diquat active constituent approvals listed in Attachment A meet the safety criteria for the following reasons:

23.1. For the following active constituent approvals, 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034, I am **not satisfied** that the information considered with respect to the method by which the constituent is, or is proposed to be, manufactured (section 5A(2)(a)(ii)) see paragraph 15 above), the extent to which the constituent will contain impurities (section 5A(2)(a)(iii) - see paragraph 16 above) or the analyses conducted on the chemical composition of the active constituent (section5A(2)(a)(iv) - see paragraph 17 above), demonstrates the active constituents meet the FAO Specifications for Diquat, although the active constituents do meet the current Active Constituents Standards 2022.

a. The Chemistry section of the *Diquat Final Review Technical Report* recommends that the Active Constituents Standards 2022 be updated separately to this reconsideration decision, to align with the FAO Specifications for Diquat to incorporate the more stringent impurity limit for 2,2'-bipyridyl and to include a limit of 1 mg/kg for total terpyridines as set out in section 20.

23.2. I am also **not satisfied** that the information entered in the record in relation to the composition and purity of the active constituents listed in paragraph 19.4 (56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034) is compliant with the FAO Specifications for Diquat.

a. Because I do not have information listed in paragraphs 15.3 and 17.3 above, regarding potential impurities resulting from the method of manufacture, and the analyses of the chemical composition of the active constituents are not sufficient to demonstrate compliance with the FAO Specifications for Diquat, with respect to the requirements noted at paragraph 15, 16 and 17 above, I cannot be satisfied that there is not a level of impurity of toxicological concern which would be an undue hazard to people exposed to (5A(1)(a) it and would not be likely to have an effect that is harmful to people (5A(1)(b) or to animals or plants or things or the environment (5A(1)(c)).

23.3. For all diquat dibromide active constituent approvals, I am **not satisfied** that the condition of approval referred to as the '*Agricultural Active Constituent Quality Assurance Requirements'* remains appropriate as it substantially duplicates conditions imposed by the Agvet Regulations and the requirements of the Agricultural Active Constituent Standard 2022. The obligations imposed by these conditions are intended to require appropriate quality assurance processes and record keeping to ensure traceability and allow recall or other rectification action, if necessary, due to contamination or other fault with diquat products. Redundant or incorrect references to legislative instruments or other documents may result in failure to follow these requirements correctly resulting in inability to recall or otherwise make-safe diquat products when necessary.

a. Without appropriate quality assurance and traceability requirements in place I cannot be satisfied that active constituents will meet the FAO Specifications for Diquat and will not contain unacceptable levels of impurities of toxicological concern, or that faults can be appropriately rectified once identified. Therefore I am not satisfied that the active constituents with the current conditions will not be an undue hazard to people (s5A(1)(a) or likely to have an effect that is harmful to people (s5A(1)(b), or an untended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c).

23.4. Accordingly, I am not satisfied that that active constituents meet the safety criteria with the relevant particulars of their current approvals: s 34(1).

Consideration of whether active constituent approvals can be varied to meet the safety criteria

24. I have considered whether the relevant particulars or conditions of the active constituent approvals can be varied in such a way as to meet the safety criteria set out in section 5A(1) for the purposes of section 34A(1) of the Agvet Code.

24.1. I am satisfied that the conditions imposed by the APVMA on active constituent approvals 56655, 56808, 58221, 58386, 59111, 62650, 64501, 67123, 87160 and 88034 can be varied to address the concerns identified in paragraphs 15, 16, 17 and 19.4 above regarding the the method by which the constituent is manufactured, the extent to which the constituent contains impurities and analysis of the constituent and relevant particulars that are entered in the Record. I am satisfied that there is no technical reason why these active constituents cannot be manufactured in compliance with the above-mentioned parameters, but that these need to be demonstrated to the APVMA to allow ongoing approval of these active constituents. Accordingly, I have decided to impose the following condition of approval under section 34A(1) of the Agvet Code:

Condition of approval

On or before the date 1 year after the publication of the section 34AC notice of the diquat reconsideration decision, as the holder of the approval, [insert HOLDER NAME] is required to provide to the APVMA the results of 5 batch analyses and an amended Declaration of Composition demonstrating compliance of the active constituent [insert approval number] with the FAO Specifications for Diquat.

24.2. I am satisfied that adding this condition will mitigate the risks noted at paragraph 23.1 and 23.2 above because holders will demonstrate that their products comply with the FAO Specifications for Diquat within 1 year, or their approvals will be subject to cancellation for breach of the condition of approval as provided by section 36 of the Agvet Code.

24.3. To address concerns identified in paragraph 18.3 which relate to my consideration of the conditions of approval of all diquat active constituents, as required by section 5A(2)(a)(v) of the Agvet Code, I have decided to vary the condition referred to as the 'Agricultural Active Constituent Quality Assurance Requirements' to remove items that are redundant with requirements set out in legislation or regulations, while ensuring that record keeping providing traceability of each batch of active constituent is retained. That condition will now read as follows:

Condition of approval: Agricultural Active Constituent Quality Assurance Requirements

A person supplying any quantity of a Batch of active constituent to another person must, at the time of supply, give the Batch Number for that Batch of active constituent to the person to whom the active constituent is being supplied.

Definitions and Interpretation

Batch means a defined quantity of material produced in a single series of operations.

Batch Number means a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined.

Supply has the same meaning as in Section 3 of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)

24.4. It is my view that it is necessary for holders and suppliers to keep records of supply of active constituent to provide traceability in the event that a batch of active constituent is contaminated or otherwise supplied in a way that means is fails to meet the safety criteria, so that affected batches of active constituent can be recalled or otherwise made safe, and that the above condition will make these requirements clear and enforceable.

24.5. I am satisfied that if I remove the conditions noted in paragraph 18.5 I will remove the potential for improper quality assurance processes and record keeping caused by redundant and inconsistent conditions and the associated risks to human health and the environment

25. For the purposes of section 34A(1)(b), I am satisfied that the relevant particulars or conditions of the diquat active constituent approvals listed in Table 1 in Attachment A of this notice can be varied in the ways set out in paragraph 24 above, to allow the approval of those active constituents to be affirmed. Accordingly, I must vary the relevant particulars or conditions in this manner: s 34A(1).

Consideration of whether active constituents comply with any requirement prescribed by the regulations

26. Section 34(1)(d) of the Agvet Code provides that I must affirm an active constituent approval only if I am satisfied that the constituent complies with any requirements prescribed by the regulations.

26.1. There are no other requirements prescribed by the Agvet Regulations for diquat active constituents that have not already been considered above.

Chemical Products

27. Section 34(1)(b) and (d) of the Agvet Code provides that the APVMA must affirm the registration for a chemical product if, and only if, it is satisfied that the product:

a. meets the safety criteria (section 5A)

b. meets the efficacy criteria (section 5B)

c. meets the trade criteria (section 5C) and

d. complies with any requirement prescribed by the regulations.

28. I have considered all matters covered by subsection 34(1)(b) in relation to the reconsideration of diquat chemical product registrations specified at Attachment. Matters that apply to specific products are noted in the relevant paragraphs.

Consideration of whether registered chemical products meet the safety criteria

29. Section 5A(1) of the Agvet Code provides that a chemical product meets the safety criteria if use of the product, in accordance with any instructions approved, or to be approved, by the APVMA for the product or contained in an established standard:

29.1. is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a))

29.2. is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b))

29.3. is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c).

30. For the purposes of considering whether diquat chemical products meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, I have had regard to the matters set out in section 5A(3)(a) of the Agvet Code.

31. Section 5A(3)(a)(i) – the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.

31.1. I have considered assessment reports regarding the following information in relation to the toxicity of diquat chemical products and their residues as summarised in the *Diquat Final Review Technical Report*:

a. The APVMA's Register of Agricultural and Veterinary Chemical Products for diquat agricultural chemical products.

b. information about the toxicity of diquat and its residues, as set out in paragraph 14 above, and in Section 3 (Toxicology) of the *Diquat Final Review Technical Report* and the references therein, including the diquat health-based guidance values.

c. information on the presence and formation of impurities of toxicological concern during manufacture and storage of diquat chemical products as described in section 2.2 (Formulated products) of the *Diquat Final Review Technical Report*

d. the impact of any excipients in the chemical products on the toxicity of the diquat chemical products to relevant organisms and ecosystems, including human beings as detailed in section 2.3 of the *Diquat Final Review Technical Report*

e. environmental toxicity studies on the effects of formulated diquat products on non-target species, including Regulatory Acceptable Levels (RALs) for exposure, below which it is unlikely that the product will have an unintended effect that is harmful to plants or animals or things or the environment, as detailed in section 6.3 (Effects on non-target species) of the *Diquat Final Review Technical Report* and listed in Table 8 above.

31.2. I have considered and agree with the recommendation that there is sufficient information on the toxicity of the impurities of toxicological concern; ethylene dibromide, 2,2'bipyridyl and total terpyridines, and the potential sources of these impurities in both diquat manufacturing concentrate and formulated products to determine that formulated diquat chemical products are not expected to contain unacceptable levels of impurities of toxicological concern, as described in sections 2.1, 2.2 and 2.3 of the *Diquat Final Review Technical Report.*

31.3. I have considered and agree with the finding that an ADI of 0.006 mg/kg bw/day and ARfD of 0.8 mg bw/day, as listed in in paragraph 14.2 of this statement of reasons and defined in section 3.2 (Health based guidance values) of the *Diquat Final Review Technical Report* are applicable in assessing the risk to human health from diquat chemical products.

31.4. I have considered and agree with the worker exposure assessment described in section 4.1 (Worker exposure assessment) and Table 9 of the *Diquat Final Review Technical Report*, which has determined that acceptable levels of occupational exposure to diquat can be defined by applying a 100-fold margin of exposure to a point of departure of 0.282 mg/kg bw/day, as set out paragraph 14.3 of this statement of reasons.

31.5. I note that spray drift RALs have been calculated specifically with respect to sensitive areas considered under the APVMA's *Spray Drift Risk Assessment Manual* and that these are listed in section 7 (Spray drift) of the *Diquat Final Review Technical Report.*

31.6. I am satisfied that exposure of non-target organisms to diquat below the regulatory acceptable levels (RALs) determined in section 6.3 (Effects on non-target species) and 7 (Spray drift) of the *Diquat Final Review Technical Report*, and as set out in paragraphs 14.6 and 14.7 of this statement of reasons, is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

31.7. I am satisfied that there is sufficient information to assess the impact of formulation excipients on the toxicity of diquat chemical products and their residues in relation to relevant organisms and ecosystems, including human beings.

31.8. I am therefore satisfied that the toxicity of diquat chemical products and their residues, including metabolites and degradation products, is sufficiently defined to allow assessment as to whether diquat chemical products meet the safety criteria.

32. Section 5A(3)(a)(ii) of the Agvet Code - the relevant poison classification of the product under the law in force in this jurisdiction.

    32.1. Diquat is currently included in Schedule 7 of the SUSMP except when included in Schedule 6. Diquat is included in Schedule 6 in preparations containing 20% or less of diquat. The relevant poison classification of the product under the law in force in this jurisdiction is stipulated by Therapeutic Goods (Poisons Standard—June 2026) Instrument 2026. This instrument is also commonly referred to as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

    32.2. No changes to the current poisons scheduling are required, as set out in section 3.3 (Poisons scheduling) of the *Diquat Final Review Technical Report*.

    32.3. I note that the information recorded in the Register for each diquat chemical product and information submitted in support of the original applications for registration, including the product formulation information has been reviewed as described in section 2.3 of the *Diquat Final Review Technical Report.* Based on the findings and recommendations in section 2.3 and 2.4 of the *Diquat Final Review Technical Report,* I am satisfied that agricultural chemical products containing diquat meet the requirements prescribed by the SUSMP.

33. Section 5A(3)(a)(iii) of the Agvet Code – how the product is formulated.

    33.1. As above, I note that the information recorded in the Register for each diquat chemical product and information submitted in support of the original applications for registration, including the product formulation information has been reviewed as described in section 2.3 of the *Diquat Final Review Technical Report*.

    33.2. I note that registered chemical products containing diquat are formulated as:

        a. soluble concentrates (SL) containing 200 g/L of diquat

        b. soluble concentrates containing 135 g/L of paraquat co-formulated with 115 g/L of diquat as an additional active constituent.

    33.3. I am satisfied that the formulation of chemical products containing diquat remains acceptable with respect to the safety criteria.

34. Section 5A(3)(a)(iv) of the Agvet Code - the composition and form of the constituents of the product.

    34.1. As above, I note that the information recorded in the Register for each diquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.3 of the *Diquat Final Review Technical Report*.

    34.2. I have considered and agree with the assessment of registration records for diquat chemical products in respect to the composition and form of the constituents of the chemical products containing diquat including the Declaration of Composition for the active constituent, certificates of analysis for the formulated products and the manufacturer's specification of other constituents, as described in the *Diquat Final Review Technical Report*.

    34.3. I am satisfied that the composition and form of the constituents of the registered diquat products remain acceptable with respect to the safety criteria for chemical products.

35. Section 5A(3)(a)(v) of the Agvet Code - any conditions to which a product's registration is, or would be, subject.

    35.1. I have considered conditions to which the registrations are subject as prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code.

35.2. I have considered the information entered in the Register for diquat chemical products and the relevant provisions in the Agvet Code and Agvet Regulations in considering the conditions to which diquat chemical products are or would be subject.

a. Chemical product registrations are currently subject to the conditions prescribed by items 1, 2, 3, 4, 5, 6, and 7 of the table in regulation 17C(2) of the Agvet Regulations. Those conditions relate to matters such as the contents, manufacture and supply or the chemical product.

b. However, I note that items 3 and 4 of regulation 17C(2) do not apply to any agricultural chemical product (i.e. diquat) pursuant to regulation 17C(3) as these are prescribed under regulation 59(1)(a) for the purposes of section 120A of the Agvet Code.

35.3. Regulation 18 of the Agvet Regulations also prescribes conditions for registration of chemical products relating to containers for chemical products. This condition requires that the container meet certain prescribed requirements.

35.4. I note that registered agricultural chemical products are also subject to the conditions of registration imposed under the Conditions of Approval or Registration Order. Those conditions include restrictions on the supply of the chemical product if its manufacture contravenes or fails to comply with any manufacturing law of the country (or part of the country) in which it is manufactured.

35.5. I am satisfied that the conditions detailed above are appropriate for the registered chemical products containing diquat.

35.6. Diquat chemical product registrations are also subject to additional conditions of registration imposed by the APVMA under section 23(1)(b) of the Agvet Code.

a. Products registered after the commencement of the reconsideration of diquat have been registered with the following condition:

*"Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 34 of the NRA Gazette dated October 1998 (Diquat).**

Explanatory Note: you should be aware that the NRA will take steps to apply the outcomes of that reconsideration to this registration/approval as it thinks fit.

b. Noting that the reconsideration will be completed following my decision I consider that this condition is no longer required.

c. Diquat products registered prior to amendment of the Agvet Regulations 2014 were registered with a condition requiring that containers for the product meet certain parameters. I note that this condition is wholly redundant with the condition prescribed by regulation 18 of the Agvet Regulations and as such is no longer required as a separate condition imposed by the APVMA.

35.7. The condition referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' which is reproduced below has previously been applied to all agricultural chemical products, including diquat products.

"Agricultural Products must meet the Agricultural Products Active Constituent Quality Assurance Requirements

- *Manufacture of active constituent - the registrant must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:*
  - *complies with the APVMA Standard for that active constituent; and*
  - *was manufactured at a site of manufacture listed in the Record of approved active constituents.*

- *Analysis results - the registrant must not supply the chemical product or cause it to be supplied unless the registrant has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:*
  - *the active constituent contained in the chemical product complied with the APVMA Standard for that active constituent;*
  - *if there is an APVMA Standard for a constituent in the chemical product that is not an active constituent, the constituent complied with the APVMA Standard for that constituent; and*
  - *the batch number of the active constituent contained in the chemical product.*
- *Records - the registrant must, at or prior to the supply of a batch of the chemical product by the registrant or by another person on behalf of the registrant, make or have in its possession, a record that contains the following information:*
  - *The name of the chemical product.*
  - *The APVMA product number of the chemical product.*
  - *If the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
  - *If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
  - *The date of importation into, or manufacture in, Australia as the case may be.*
  - *The batch number of the chemical product from which the supply was made.*
  - *The quantity of the chemical product that constitutes the batch*
  - *The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product*
- *The registrant must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.*
- *The registrant must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.*
- *Possession of batch analysis results and records - for the purposes of these conditions, batch analysis results or records are in the possession of the registrant if batch analysis results or records are:*
  - *in the possession of the registrant; or*
  - *in the possession of another person pursuant to an arrangement with the registrant.*
- *Compliance with the Standard - for the purposes of these conditions, a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method does not contain:*
  - *less than the minimum purity and/or content of the constituent as set out in the APVMA Standard for the Constituent*
  - *more than the maximum level of any impurity as set out in the APVMA Standard.*
- *Definitions and Interpretation - in these conditions the following words have the following meanings:*
  - *'APVMA Standard' means the standard determined by the APVMA to which a constituent contained in chemical products must comply and which is published on the APVMA website.*

- *'Batch' means a defined quantity of material produced in a single series of operations.*
- *'Batch number' means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.*
- *'Batch analysis results' means the results of analysis from each batch of the constituent that include:*
- *the name of the manufacturer and the manufacturing site address*
- *the date of the analysis*
- *the batch number and date of manufacture of the batch*
- *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the APVMA Standard for the constituent*
- *full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant).*
- *If analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.*
- *'Record' means a document in written or electronic form that contains the particulars set out in paragraph (3) and which is readily accessible for the purposes of Part 9 of the Agvet Code (Enforcement).*
- *'Supply' has the same meaning as given to it in section 3 of the Agvet Code and includes the doing of those things through, or pursuant to an arrangement with, another person."*

35.8. I **do not** consider that the current condition referred to as 'Agricultural Products Active Constituent Quality Assurance Requirements', to which each diquat chemical product registration is subject, remains appropriate. The condition references the 'APVMA Standard' available on the APVMA Website, which has been replaced by the Agricultural Active Constituents Standards 2022. The condition also references a 'registrant' which is not defined within the Agvet Code or related legislation, rather than referring to the 'holder'. Further, the condition is substantially redundant given the requirements already imposed by the Agvet Code or the Agvet Regulations.

35.9. The obligations imposed by conditions to which the registration is subject under section 23(1)(b) of the Regulations are intended to require appropriate quality assurance processes and record keeping to ensure traceability and allow recall or other rectification action, if necessary, due to contamination or other fault with diquat products. Redundant or incorrect references to legislative instruments or other documents may result in failure to follow these requirements correctly resulting in inability to recall or otherwise make-safe diquat products when necessary, meaning these products may be an undue hazard to people using them or exposed to anything containing their residues (s5A(1)(a)).

36. Section 5A(3)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Register for the product:

36.1. I have had regard to the relevant particulars recorded for each approved chemical product registration. Section 3 of the Agvet Code provides that the relevant particulars, in relation to the registration of a chemical product, are the distinguishing number, any instructions for use and any other particulars required by section 20(1)(c) to be entered in the register. Section 20(1)(c) of the Agvet Code refers to any other particulars prescribed by the regulations. Regulation 16 of the Agvet Regulations prescribes the following particulars for the purposes of section 20(1)(c) of the Agvet Code

a. the distinguishing name of the chemical product

b. the constituents of the chemical product

c. the concentration of each constituent of the chemical product

d. if possible, the composition and purity of each active constituent of the chemical product

e. the formulation type for the chemical product

f. the net contents for the chemical product

g. identifying information for the holder of the registration for the chemical product

h. the name of each manufacturer of the chemical product

i. the address of each site at which the chemical product is manufactured by the manufacturer

j. the date of entry of these particulars in the Register of Chemical Products

k. identifying information for any nominated agent for the registration.

36.2. I note that the relevant particulars recorded in the Register for each diquat chemical product and information submitted in support of the original applications for registration, including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.3 of the *Diquat Final Review Technical Report*.

36.3. I have had regard to the assessment of the relevant particulars entered in the Register for each of the products listed in Attachment A and have also considered the conclusions of the chemistry (section 2.4), environment (section 6.6), human health (section 3.4), and residues and trade risk (section 5.11 and 5.12) and spray drift (section 7) assessments described in the *Diquat Final Review Technical Report*.

36.4. I am satisfied that all relevant particulars that are entered in the Register for diquat chemical products, except for the instructions for use of the product mentioned in paragraph 36.5, 36.6 and 36.7 below, remain acceptable.

36.5. With respect to whether the use of diquat chemical products according to the instructions for use approved by the APVMA is not an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and is not likely to have an effect that is harmful to human beings, I have considered and agree with recommendations in the relevant sections of the *Diquat Final Review Technical Report* as noted below:

a. As described in section 4.1.1 of the *Diquat Final Review Technical Report*, use of diquat applied by ground boom with an open cab tractor in small scale agriculture (up to 6 ha per day) will not exceed acceptable worker exposure levels provided the operator uses the following personal protective equipment: single layer of clothing, gloves, PF10 respirator, and face shield or goggles when mixing or loading.

b. As described in section 4.1.1 of the *Diquat Final Review Technical Report*, for use of diquat applied by enclosed cab ground boom in broad scale agriculture (up to 500 ha per day, or 400 ha per day for cotton), handling up to 317.7 kg of diquat per operator per day will not exceed acceptable occupational exposure levels, provided the operator uses the following minimum personal protective equipment: enclosed mixing and loading (single layer of clothing, gloves, PF10 respirator, face shield or goggles when connecting, disconnecting or cleaning components of the mixing and loading system) and enclosed cab application.

c. As described in section 4.1.1 of the *Diquat Final Review Technical Report*, use of diquat applied by manually pressurised hand wand at rates up to 8.2 kg of diquat per operator per day, or by mechanically pressurised hand wand at rates up to 2.3 kg of diquat per operator per day, will result in acceptable occupational exposure levels provided the operator uses the following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading.

d. As described in section 4.1.1 of the *Diquat Final Review Technical Report*, use of diquat applied by equipment carried on the back of the user at rates exceeding 0.2 kg diquat per operator per day, exceeds acceptable worker exposure levels at the maximum level of PPE that can be modelled.

e. As described in section 4.1.1 of the *Diquat Final Review Technical Report,* I note that that although mixer/loader exposure is acceptable with open mixing/loading with the specified PPE for certain uses, enclosed mixing/loading is required for all uses to minimise the likelihood of users decanting diquat into unacceptable containers which may lead to consequential accidental exposure.

f. I note that section 4.1.2 of the *Diquat Final Review Technical Report* recommends that workers must not re-enter treated areas until specified intervals of time have passed, which depend on the application rate and the activity that is occurring as noted in Table 11 of the *Diquat Final Review Technical Report.* These intervals, or PPE if the re-entry interval cannot be observed, are necessary to prevent worker exposure exceeding the acceptable level discussed in section 4.1 and Table 9 of the *Diquat Final Review Technical Report* and paragraph 14.3 above.

g. I note and agree with the recommendations in section 5.12 (Consideration of the combined risk assessments) and 5.13 (Revised dietary exposure assessment) of the Diquat Final Review Technical Report that the use of diquat according to instructions approved by the APVMA, for the uses that otherwise meet the safety criteria, are not expected to exceed acceptable levels of acute or chronic dietary exposure for diquat.

h. As described in section 5.11 (Conclusions from the residues and trade assessment) of the *Diquat Final Review Technical Report,* I note that instructions for use of diquat on "row crops, vegetables, and market gardens" "orchards and vineyards (including bananas)" and "winter cereals" are not consistent are not consistent with the APVMA crop group guidelines[16], which require assessment of residues on specific crops, or current methods for assessing human dietary exposure to residues of diquat following its use in those situations, as described in the residues and trade assessment in the *Diquat Final Review Technical Report*. Therefore, I am not able to be satisfied that these broad uses will not result in human dietary exposure exceeding the ADI or ARfD.

i. I also note and agree with the recommendation in section 4.2 (Recommended Label Changes) of the *Diquat Final Review Technical Report* that the signal headings, restraints, safety directions and re-entry statements indicated are required to be included as instructions for use of diquat products, in order for users to know which PPE and other behaviours are necessary to safely use the products.

36.6. With respect to whether the use of diquat products according to the instructions for use approved by the APVMA is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment, I have considered and agree with recommendations in the relevant sections of the *Diquat Final Review Technical Report* as noted below:

a. I note that the environmental risk assessment has considered the toxicity of diquat to non-target plants, mammals, birds and other terrestrial vertebrates, aquatic species, bees, other arthropods, and soil organisms and has recommended that exposure below the RALs listed in Table 28 of the *Diquat Final Review Technical Report* and in paragraphs 14.6 and 14.7 above is not likely to have any harmful effects on non-target species.

b. I have considered and agree with the conclusion that the only instructions for use for diquat products that will not exceed the RALs are those listed in Table 35 of the *Diquat Final Review Technical Report* and reproduced in Table 3 below.

[16] https://www.apvma.gov.au/crop-groups

Table 9: Uses of diquat products, that are not likely to have any harmful effect on non-target species

Product type	Situation
Diquat products	Aquatic areas (farm dams and artificial water bodies only), application by boomspray, surface spray and injection below surface
	General weed control: pasture at rates up to 188 g ac/ha, lucerne at rates up to 140 g ac/ha.
	General weed control: row crops, market gardens, vegetables at rates up to 283 g ac/ha, pre-emergent or shielded interrow spray.
	Pre-harvest crop desiccation: cotton, poppies (Tas only), sugarcane
	General weed control: asparagus, hops, infested areas, lucerne, oil seed poppies, and oats and wheat (up to tillering)

c. I note that the risk assessment for aquatic species (section 6.4.2 of the *Diquat Final Review Technical Report*) has been revised from the recommendations in the APVMA's proposed regulatory decision based on the argument that use of diquat could be restricted to situations where exposure of natural aquatic areas will not occur, including farm dams, irrigation channels, artificial watercourses and managed waterways and that conclusion is now that the risk posed to aquatic species is acceptable when used in farm dams and artificial waterways only.

d. I note that the risk assessment for the use of directed, inter-row spraying for general weed control in orchards and vineyards has been revised from the recommendations in the APVMA's proposed regulatory decisions based on the argument that current instructions referring to directed application under vines and trees should be considered as spot spraying, and exposure calculations adjusted to 40% of the cropping area (Table 29 of the *Diquat Final Review Technical Report*). This argument was accepted, however it was then noted that this use of diquat products involves an obligatory tank mix with 400 g ac/ha paraquat which is not supported by the environment assessment, as set out in Table 32 of the *Paraquat Review Technical Report.* Therefore, I am unable to conclude that the use at the current rate is unlikely to result in harmful effects on non-target species.

e. I note that the risk assessment for the use of diquat for pre-harvest crop desiccation in sugarcane has been revised from the recommendations in the APVMA's proposed regulatory decisions based on the weight of evidence argument (set out in *Appendix C Terrestrial vertebrate assessments: weight of evidence discussion* of the *Diquat Final Review Technical Report*) that due to the minimal exceedance of the risk quotient for medium herbivorous/granivorous birds (at rates >504 g ac/ha) and small insectivorous birds (at rates >556 g ac/ha), rates up to 600 g ac/ha are unlikely to pose population level effects to these birds. Accordingly, I have concluded that this use is unlikely to have any harmful effects to non-target species.

f. I note that the risk assessment for pre-harvest crop desiccation for poppies has been refined from the recommendations in the APVMA's proposed regulatory decisions based on the weight of evidence argument that native Tasmanian granivorous bird species likely to forage in poppies are larger than the default values used in the modelling and that exposure to poppy seeds is expected to be overestimated due to crop interception and seed capsules, therefore it is considered that this use, in Tasmania (the only State where the use is currently approved) is unlikely to have harmful effects on native birds. Accordingly, I have concluded that this use is unlikely to have any harmful effects to non-target species

g. I note that the risk assessment for general weed control in lucerne up to 276 g ac/ha has been revised from the recommendations in the APVMA's proposed regulatory decisions based on the weight of evidence argument that although there are unresolved acute risks associated with the use

for small insectivorous birds, the exceedance of the risk quotient is minimal (1.1, vs acceptable of 1) and is unlikely to be associated with population levels effect. Accordingly, I have concluded that this use pattern is unlikely to have any harmful effects to non-target species.

h. I note that the risk assessment for general weed control in infested areas, public service areas and rights of way has been revised from the recommendations in the APVMA's proposed regulatory decisions based on the weight of evidence argument that only a portion of the area (10 %) is treated in this use pattern, which is able to resolve the risk to terrestrial animal and birds, who in addition are expected to be more mobile than mammals and unlikely to obtain a significant fractions of diet from treated sites. Accordingly, I have concluded that this use pattern is unlikely to have any harmful effects to non-target species.

36.7. With respect specifically to spray drift and whether the use of diquat products according to the instructions for use approved by the APVMA is not likely to have an effect that is harmful to people or an unintended effect that is harmful to animals, plants or things or to the environment, I have considered and agree with recommendations in the relevant sections of the *Diquat Final Review Technical Report* as noted below.

a. I have considered the recommendations in section 7 of the *Diquat Final Review Technical Report* and I agree that the RALs noted in Table 37 are the maximum level of exposure of diquat that is not likely to have a harmful effect on the relevant sensitive areas, including bystander areas, natural aquatic areas, pollinator areas, livestock areas and vegetation areas.

b. I also have considered and agree that the mandatory down-wind buffer zones set out in Tables 38 and 39 of the *Diquat Final Review Technical Report* between the treated area and the sensitive area are necessary to prevent exceedance of the relevant RALs for bystander areas, natural aquatic areas and vegetation areas.

c. I note that there are no current instructions or restraints related to spray drift contained in the relevant particulars and therefore I am **not satisfied** that the use of diquat products will not have a harmful effect through spray drift.

37. Section 5A(3)(a)(via) of the Agvet Code – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).

37.1. The *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* is the only standard made under section 6E that relates to matters covered by section 5A(1) of the Agvet Code and prescribes the maximum allowable variation of the concentration of constituents in registered agricultural chemical products from the nominal quantities recorded in the Register for active constituents and non-active constituents.

37.2. I have considered and agree with the APVMA's chemistry assessment, as detailed in sections 2.2 and 2.3 of the *Diquat Final Review Technical Report*, in regard to the Declarations of Composition and Certificates of Analysis for diquat chemical products supplied as part of the original registration applications I am satisfied that all registered diquat chemical products comply with the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022*.

38. Section 5A(3)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.

38.1. Regulation 8AB prescribes matters the APVMA must have regard to for the purposes of being satisfied as to whether a chemical product meets the safety criteria.

38.2. Regulation 8AB(1)(a) of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product.

a. I have considered and accept the recommendations of APVMA's chemistry assessment, as detailed in section 2.3 of the *Diquat and Review Technical Report*, regarding the information about the method of analysis of the chemical composition and form of the constituents of diquat chemical products submitted as part of the original applications for product registration.

b. There has not been any new information provided that would alter my satisfaction regarding the method of analysis of the chemical composition and form of the active constituents.

c. I remain satisfied of the method of analysis of the chemical composition and form of the constituents of each registered diquat chemical product listed in Attachment A.

38.3. Regulation 8AB(2) provides that regulations 8AB(1)(b) and (c) do not apply if the product is prescribed under subregulation 59(1) of the Agvet Regulations for the purposes of section 120A of the Agvet Code.

a. All agricultural chemical products are prescribed under regulation 59(1)(a) of the Agvet Regulations for the purposes of section 120A of the Agvet Code, therefore regulations 8AB(1)(b) and (c) are not relevant to diquat chemical products.

38.4. Regulations 8AB(1)(d), (e) and (f) of the Agvet Regulations do not apply to diquat chemical products because diquat products are not molluscicides (8AB(1)(d) and (e)), or applied to seeds ((8AB(1)(f)).

39. Under section 5A(3)(b) of the Agvet Code, the APVMA may have regard to certain matters in determining whether a chemical product meets the safety criteria. For the purposes of considering whether the active constituents meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, I have had regard to matters set out in section 5A(3)(b) of the Agvet Code as discussed below.

40. Section 5A(3)(b)(i) of the Agvet Code – the acceptable daily intake of each constituent contained in the product.

40.1. I accept the recommendation of the APVMA's human health risk assessment described in section 3.2 (Health based guidance values) of the *Diquat Final Review Technical Report*, which has determined that the acceptable daily intake for diquat is 0.006 mg/kg bw/day as discussed in paragraph 14 above.

41. Section 5A(3)(b)(ii) of the Agvet Code – any dietary exposure assessment prepared under subsection 82(4) of the Food Standards Australia New Zealand Act 1991 as a result of any proposed variation notified under section 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under section 82(4) of that Act.

41.1. There has not been a dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* because the APVMA has not notified FSANZ of variations to the MRL standard under subsection 82(3) of the *Food Standards Australia New Zealand Act 1991*. Any changes to MRLs required as a result of the diquat reconsideration decisions will be implemented following the 2-year phase out period discussed at paragraph 97, below, and a suitable further interval to ensure that stored commodities have moved through the supply chain after implementation of the diquat reconsideration decisions.

42. Section 5A(3)(b)(iii) of the Agvet Code – whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.

42.1. I have considered and agree with the conclusions of the APVMA's Residues and Trade risk assessment, as described in sections 5.12 (Consideration of proposed APVMA reconsideration outcomes for diquat), section 5.13 (Revised dietary exposure assessment) and section 5.14 (Revised MRL changes) of the *Diquat Final Review Technical Report,* which assessed the results of trials or experiments that have been conducted to determine the residue of diquat products, that will remain in all situations where those products are used after considering whether those uses would otherwise meet the safety criteria as

described in paragraph 35.9 to determine whether the residues of the product will not be greater than limits that the APVMA has approved or approves (Maximum Residue Levels; MRLs).

42.2. I note that trials or experiments have been conducted to determine the residue of diquat products that will remain in all situations except for residues remaining on cotton seed and sugarcane following pre-harvest desiccation, residues remaining on pineapples, green onions, brassica vegetables other than crops with specific residue data, i.e. broccoli, head cabbages, cauliflower and Chinese cabbage (type Pe-tsai), fruiting vegetables (cucurbits, other than cucumber), stalk and stem vegetables (other than asparagus), herbs and spices as set out in section 5.12 of the *Diquat Final Review Technical Report.*

a. In the absence of suitable data to allow quantification of residues I am **not satisfied** that residues of diquat remaining after pre-harvest desiccation in cotton or sugarcane will not be greater than the limits that the APVMA has approved or approves.

b. In the absence of suitable data to allow quantification of residues I am **not satisfied** that residues of diquat remaining after general weed control in pineapples, green onions, brassica vegetables other than crops with specific residue data, i.e. broccoli, head cabbages, cauliflower and Chinese cabbage (type Pe-tsai), fruiting vegetables (cucurbits, other than cucumber), stalk and stem vegetables (other than asparagus), herbs and spices will not be greater than the limits that the APVMA has approved or approves.

42.3. I am **not satisfied** that the use of diquat on the crops listed above will result in residues of diquat that will not be greater than limits that the APVMA has approved or approves.

42.4. I note that additional residues studies were submitted during the consultation to the proposed regulatory decision that were assessed and found suitable to support uses in the following situations that are supported by all other risk assessments:

a. Use of diquat for general weed control in asparagus only is not expected to result in quantifiable residues of diquat at harvest, noting that there was insufficient data to support the stalk and stem vegetable crop group of which asparagus is a member, as set out in section 5.12.9 of the *Diquat Final Review Technical Report*.

b. Use of diquat for general weed control in cucumber only, is not expected to result in quantifiable residues of diquat at harvest, noting that there was insufficient data to support the curcubit vegetable crop group, in the absence of studies from cantaloupe and summer squash, as set out in section 5.12.13 of the *Diquat Final Review Technical Report*.

42.5. I have considered and agree with the conclusions of the APVMA's Residues and Trade risk assessment, as described in sections 5.12 (Consideration of proposed APVMA reconsideration outcomes for diquat), section 5.13 (Revised dietary exposure assessment) and section 5.14 (Revised MRL changes) of the *Diquat Final Review Technical Report* for uses in the following situations that are supported by all other risk assessments:

a. Use of diquat products in row crops (noting these have been assessed against specific crops as follows: berries and other small fruit (except grapes), brassica vegetables (broccoli, head cabbages, cauliflower and Chinese cabbage (type pe-tsai)), bulb vegetables (except green onions), fruiting vegetables (other than cucurbits), leafy vegetables, legume vegetables, pineapple, root and tuber vegetables) for pre-emergent applications or applications by a shielded spray is not expected to result in quantifiable residues of diquat in any crop at harvest.

b. Use of diquat products for pre-harvest desiccation in oilseed poppies is not expected to result in residues above the limit of quantification of 0.01 mg/kg when used in conjunction with a 2-day withholding period.

c. Residues from all other uses, including fodder and forage, will not exceed current MRLs approved by the APVMA.

43. Section 5A(3)(b)(iv) of the Agvet Code – the stability of the product.

43.1. I have considered and agree with the recommendation of the chemistry assessment described in sections 2.3 and 2.4 *Diquat Final Review Technical Report,* which considered the information provided in the applications for registration of diquat chemical products. I am satisfied that those products are expected to be adequately stable provided they are stored in accordance with the instructions on the approved labels.

44. Section 5A(3)(b)(v) of the Agvet Code – the specifications for containers for the product.

44.1. I have considered and agree with the recommendation of the APVMA's chemistry assessment, as described in sections 2.2 and 2.3 of the *Diquat Final Review Technical Report*, which has considered information provided in the applications for registration of diquat chemical products regarding the containers for diquat products. I am satisfied that the containers for diquat products are acceptable with respect to the conditions for containers for chemical products set out in Regulation 18 of the Agvet Regulations, except for regulation 18(e), which requires that the container must enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot harm a person or have an unintended effect that is harmful to the environment.

44.2. I have noted and agree with the recommendation in sections 4.1.1 (Ground-based and aerial application) and 4.2 (Recommended label changes) of the *Diquat Final Review Technical Report* that all diquat products must be used with enclosed mixing and loading equipment to minimise the potential for decanting the product into unacceptable containers or accidental spills, both of which may lead to consequential accidental exposure.

44.3. Accordingly, I am **not satisfied** that the containers for diquat chemical products enable all or any part of the container's contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot harm a person or have an unintended effect that is harmful to the environment, as required by regulation 18(e), as no relevant information about the suitability of containers for currently registered diquat chemical products for use with enclosed mixing and loading systems has been provided to the APVMA, as noted in section 2.2.1 of the *Diquat Final Review Technical Report*.

45. Having had regard to the matters described above, I am **not satisfied** that the diquat product registrations listed in Attachment A meet the safety criteria for the following reasons.

45.1. As noted in paragraph 35.6 and 35.7 the current conditions of registration imposed by the APVMA under s23(1)(b) of the Agvet Code are inconsistent and redundant with other conditions prescribed by the Agvet Regulations. Accordingly, as stated in paragraph 35.9 above, I am not satisfied that these products will be manufactured to the necessary quality assurance and record keeping standards and am not satisfied that this will not result in these products being an undue hazard to the safety of people exposed to them or using anything containing their residues (s5A(1)(a)).

45.2. As discussed in paragraph 36.5, above, I am **not satisfied** that the use of diquat products according to the currently approved instructions for use will not result in worker exposures that exceed the maximum safe levels established in section 4.1 of the *Diquat Final Review Technical Report* and noted in paragraphs 14.2 and 31 above. This means I am not satisfied that the use of diquat products according to the currently approved instructions for use will not be likely to have an effect that is harmful to human beings (s5A(1)(b)). I also note that I am not satisfied the containers for diquat products allow the products to be dispensed without creating an undue hazard to the person using the product (s5A(1)(a)), as discussed in paragraph 44 above.

45.3. As discussed in paragraph 36.6, above, I am **not satisfied** that the use of diquat products according to the currently approved instructions for use will not result in exposures that exceed the maximum safe levels

established for non-target species in section 6.3 of the *Diquat Final Review Technical Report* and noted in paragraphs 14.6 and 14.7 above. This means I am not satisfied that the use of diquat products according to the currently approved instructions for use will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c)).

45.4. As discussed in paragraph 36.7, above, I am **not satisfied** that the use of diquat products according to the currently approved instructions for use will not result in exposures that exceed the maximum safe levels established for areas considered sensitive to spray drift as described in section 7 of the *Diquat Final Review Technical Report* and noted in paragraphs 14.8, 31.531.5 and 31.6 above. This means I am not satisfied that the use of diquat products according to the currently approved instructions for use will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c)).

45.5. As discussed in paragraph 42.2, above, I am **not satisfied** that the use of diquat products according to the currently approved instructions for use will result in diquat residues on crops greater than the limits that the APVMA has approved or approves, as described in section 5.12 of the *Diquat Final Review Technical Report* and noted in paragraphs 42.2 above. I also note that I am **not satisfied** that the broad crop groupings set out in 36.5.h would prevent human dietary exposure exceeding the ADI or ARfD. This means that I am not satisfied that the use of diquat products according to the currently approved instructions for use will not result in these products being an undue hazard to the safety of people exposed to them or using anything containing their residues (s5A(1)(a)) or likely to have an effect that is harmful to human beings (s5A(1)(b)).

Consideration of whether relevant particulars or conditions of registered chemical products can be varied to meet the safety criteria

46. Section 34A(1) of the Agvet Code provides that if the APVMA is not satisfied under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.

47. I have considered whether registered diquat chemical products can be varied in such a way as to meet the safety criteria set out in Section 5A(1) of the Agvet Code for the purposes of section 34A(1).

48. To address concerns identified in paragraph 35 when considering the conditions to which the registrations of chemical products containing diquat are subject, in accordance with section 5A(3)(a)(v), I have decided to vary the conditions referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' to remove elements that are set out in the Agvet Code and the Agvet Regulations. The varied condition shall read as follows:

> ‘Condition of registration: ‘Agricultural Chemical Products Active Constituent Quality Assurance Requirements’
>
> *1. The holder of the registration for a chemical product must not supply or cause the supply of the chemical product unless the active constituent contained in the chemical product was manufactured at a site of manufacture listed in the Record.*
>
> *2. The holder of the registration for a chemical product must not supply or cause the supply of the chemical product unless the holder possesses a record that demonstrates:*
>
> *i. the active constituent(s) in the chemical product comply with Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022; and*
>
> *ii. if there is a standard made under section 6E of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)*

for any constituent in the chemical product that is not an active constituent, that the constituent complies with that Standard; and

3. The records referred to in condition 2 above must include batch analysis results for the constituent(s) with the following information:

i. the name and address of the manufacturer of the constituent

ii. the Batch Number of the Batch of the constituent

iii. the date of manufacture of the Batch of the constituent

iv. the date of the analysis of the Batch of the constituent

v. the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the relevant Standard for the constituent

vi. *reference to the validated analytical method(s) used to determine the constituent purity and/or the content and/or the isomer ratio and/or the specified impurities*

4. The holder of the registration for a chemical product must not supply or cause the supply of any quantity of a Batch of the chemical product unless the holder possesses a record that contains the following information for that Batch of the chemical product:

i. the name of the chemical product

ii. the distinguishing number of the registration of the chemical product

iii. if the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of the importer, and the date of importation

iv. if the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of the manufacturer, and the date of manufacture

v. the batch number of the chemical product from which the quantity was supplied and the quantity of the chemical product in that batch.

5. The records referred to in conditions 2 and 4 above must be kept by the holder for at least 2 years.

6. The APVMA may request a holder to provide any records created and maintained under these conditions and, where the APVMA requests records be produced to it, a holder must provide the records to the APVMA.

7. For the purposes of this condition:

i. Batch means a defined quantity of material produced in a single series of operations.

ii. Batch Number means a distinctive combination of numbers and/or letters that specifically identifies a batch from which the production history can be determined.

iii. Possess means in the possession of the holder or in the possession of another person pursuant to an arrangement with the holder.

iv. Record includes information stored or recorded by means of a computer.

v. Supply has the same meaning as in Section 3 of the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code).

48.1. I have decided to remove the redundant condition identified in paragraph 35.6.

49. To address concerns related to human health identified in paragraphs 36.4 and 36.5 in relation to the instructions for use (which are relevant particulars) that are or would be entered into the Register for diquat chemical products as required by section 5A(3)(a)(vi) of the Agvet Code, I have decided to vary the instructions for use as indicated below, noting that the specific instructions to be included on the labels of the product are dealt with below in the section of my reasons entitled **Labels for chemical products**.

    49.1. I have decide to vary the instructions for use of diquat applied by ground boom in small scale agriculture, i.e. row crops, vegetables and market gardens, to require the operator to use the following minimum personal protective equipment: open cab, single layer of clothing, gloves, PF10 respirator, and face shield or goggles when mixing or loading, which will prevent exposure from exceeding the maximum acceptable level for workers.

    49.2. I have decided to vary the instructions for use of diquat applied by ground boom in broad scale agriculture to require the operator to use the following minimum personal protective equipment: enclosed cab application, with closed mixing and loading (single layer of clothing, gloves, PF10 respirator, face shield or goggles when connecting, disconnecting or cleaning components of the mixing and loading system), which will prevent exposure from exceeding the maximum acceptable level for workers.

    49.3. I have decided to vary the instructions for use of diquat applied by manually pressurised hand wand to require the operator to use the following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading, which will prevent exposure from exceeding the maximum acceptable level for workers. I have also decided to vary the instructions for use of diquat by mechanically pressurised hand wand, to require following minimum personal protective equipment: double layer of clothing, gloves, PF50 respirator and face shield or goggles when mixing and loading.

    49.4. I have decided to vary the instructions for use of all products listed in Attachment A to include re-entry instructions specifying the relevant minimum intervals noted in Table 11 of the *Diquat Final Review Technical Report*. These intervals, or PPE if the re-entry interval cannot be observed, are necessary to prevent worker exposure exceeding the acceptable level discussed in section 4.1 and Table 9 of the *Diquat Final Review Technical Report* and paragraph 14.3 above.

    49.5. I have also decided to vary the instructions for use to include relevant signal headings, restraints, first aid and safety directions and re-entry statements recommended in section 4.2 of the *Diquat Final Review Technical Report* to ensure that users are aware of the necessary PPE and other behaviours necessary to use the products safely.

50. To address concerns related to risks to the environment identified in paragraph 36.6 in relation to the instructions for use (which are relevant particulars) that are or would be entered into the Register for diquat chemical products as required by section 5A(3)(a)(vi) of the Agvet Code, I have decided to vary the instructions for use as indicated below.

    50.1. To address the concerns identified in paragraph 36.6 indicating that the use of products containing diquat will exceed regulatory acceptable levels for non-target species in all situations except the uses and rates listed in Table 8, I have decided to vary the instructions for use to remove all instructions for use of diquat products, except in the situations described in Table 9. This will make it unlikely that harmful levels of exposure of non-target animals to diquat will occur.

51. To address concerns related to risks posed to areas sensitive to spray drift identified in paragraph 36.7 in relation to the instructions for use (relevant particulars) that are or would be entered into the Register for diquat chemical products as required by section 5A(3)(a)(vi) of the Agvet Code, I have decided to vary the instructions for use as indicated below.

51.1. I have decided to vary the instructions for use to include spray drift specific restraints as recommended in section 7 of the *Diquat Final Review Technical Report* and the mandatory down-wind buffer zones recommended in Table 38 and 39 of the *Diquat Final Review Technical Report.* This will make it unlikely that harmful levels of exposure of non-target animals, human bystanders or non-target vegetation to diquat will occur via spray drift.

52. To address concerns related to the use of broad crop groupings identified in paragraph 36.5.h in the instructions for use of diquat I have decided to:

52.1. Vary the instructions for use of diquat on "row crops, vegetables, and market gardens" to refer to specific crops or use situations, consistent with the APVMA crop group guidelines where those uses are supported by all other risk assessments as below:

a. replace the broad claims for row crops, vegetables and market gardens with the following crops: berries and other small fruit (except grapes), brassica vegetables (broccoli, head cabbages, cauliflower and Chinese cabbage (type pe-tsai)), bulb vegetables (except green onions), fruiting vegetables (other than cucurbits), cucumbers, leafy vegetables, legume vegetables, pineapple, root and tuber vegetables.

52.2. I note that I have not varied the instructions for use on "orchards and vineyards" or "winter cereals" as outlined in 36.5.h as these use patterns have not been supported by environment risk assessments.

53. To address the concerns identified in paragraph 42 in relation to whether any trials or laboratory experiments have been carried out to determine the residues of the product and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves as required by section 5A(3)(b)(iii), I have decided to:

53.1. remove instructions for use of products containing diquat in the following situations which are present in Table 3 but are not supported by sufficient residues information:

a. pineapple

b. green onions

c. brassica vegetables other than crops with specific residue data,

d. fruiting vegetables (cucurbits), other than cucumbers

e. stalk and stem vegetables, other than asparagus

f. herbs and spices,

g. cotton for pre-harvest desiccation,

h. sugar cane for pre-harvest desiccation

53.2. Vary the instructions for use of products containing diquat, in the following situations, to include the indicated withholding period statements:

a. the harvest withholding period statement for row crops, vegetables and market gardens for pre-emergent applications or applications by a shielded sprayer is "Not required when used as directed", noting the requirement to provide directions for specific crops as indicated in paragraph 36.5.h.

b. the supported grazing withholding period statement for general weed control in cereals up to tillering (wheat and oats only; up to 140 g ac/ha), pastures grazed before spraying (up to 188 g ac/ha) and lucerne, grazed before spraying (140 g ac/ha) in relation to diquat is "DO NOT graze or cut for stock food for 1 day after application".

c. the recommended withholding period statement for water from treated aquatic areas in relation to diquat is “DO NOT use treated water for human consumption, livestock watering or irrigation purposes for 10 days after application”.

53.3. I note that the current withholding period statements for products containing diquat for aquatic areas, poppies and hops as set out below remain appropriate:

a. the harvest withholding period statement for hops is “Not required when used as directed” and the grazing withholding period statement for sprayed vegetation is 1 day.

b. the harvest withholding period statement for general weed control up to 283 g ac/ha in oil seed poppies and pre-harvest desiccation for poppies is “DO NOT harvest for at 2 days after application”

53.4. I note that the uses where other concerns related to residues were identified are not supported by the outcomes of the environment risk assessment, so do not require mitigations to address residue levels.

53.5. I am satisfied that following these variations the residues of the product will not exceed the limits approved by the APVMA.

54. To address the concerns identified in paragraph 44 in relation to specifications for the containers for the products (section 5A(3)(b)(v) of the Agvet Code), I have varied the conditions of product registration to add the following requirement:

Condition of Product Registration

This product must be supplied in a container that is sealed with a fitting compatible with enclosed mixing and loading systems capable of preventing contact between the contents of the container and users of the product during loading of the chemical into the application mechanism.

55. Having had regard to the matters described above, I am satisfied that I can vary the conditions of product registration and instructions for use of diquat products listed in Attachment A so that those products meet the safety criteria for the following reasons:

55.1. I am satisfied that varying the conditions of registration imposed by the APVMA under s23(1)(b) of the Agvet Code as described in paragraph 48, above, will address the risks identified in paragraphs 35.6 and 35.7. These variations will remove inconsistencies between the current conditions and provide a framework for appropriate quality assurance and record keeping standards. These conditions allow me to be satisfied that the products listed in Attachment A will not be an undue hazard to the safety of people exposed to them or using anything containing their residues (s5A(1)(a)). I am also satisfied that adding a condition of registration requiring containers to be sealed with closed mixing and loading compatible valves as described in paragraph 54 above will mitigate risks identified in paragraph 44, thereby allowing the container’s contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot harm a person or have an unintended effect that is harmful to the environment, as required by regulation 18(e).

55.2. I am satisfied that varying the instructions for use of diquat in the manner described in paragraph 49, above, will mitigate the risks to workers discussed in paragraph 36.5. Accordingly, I am satisfied that the use of diquat products according to the instructions for use, as varied, will not result in worker exposures that exceed the maximum safe levels established in section 4.1 of the *Diquat Final Review Technical Report* and noted in paragraphs 14 and 31 above. I am also satisfied that removing uses for selected crops for which there is not sufficient residues data as described in paragraph 53.1 and varying harvest withholding period as described in paragraph 53.2 will ensure there are not residues of diquat that exceed the MRL and will not pose an undue risk to human health through residues in food. This means I can be satisfied that the use of diquat products according to the instructions for use, as varied, will not be likely to have an effect that is harmful to human beings (s5A(1)(b)).

55.3. I am satisfied that varying the instructions for use of diquat in the manner described in paragraph 50, above, will mitigate the risks to non-target birds and mammals discussed in paragraph 36.6, above. Accordingly, this means I can be satisfied that the use of diquat products according to the instructions for use, as varied, will not result in exposures that exceed the maximum safe levels established for non-target species in section 6.3 of the *Diquat Final Review Technical Report* and noted in paragraphs 14.6 and 14.7 above. This means I am satisfied that the use of diquat products according to the instructions for use, as varied, will not be likely to have an unintended effect that is harmful to animals or plants or to things or to the environment (s5A(1)(c)).

55.4. I am satisfied that varying the instructions for use to include spray drift restraints, as discussed in paragraph 51 above will mitigate the risks discussed in paragraph 36.7, above. Accordingly I am satisfied that the use of diquat products according to the instructions for use, as varied, will not result in exposures that exceed the maximum safe levels established for areas considered sensitive to spray drift as described in section 7 of the *Diquat Final Review Technical Report* and noted in paragraphs 14.8 and 36.7 above. This means I am satisfied that the use of diquat products according to the instructions for use, as varied, will not be likely to have an unintended effect that is harmful to animals or plants or things or to the environment (s5A(1)(c)).

56. I am **satisfied** that the relevant particulars and conditions of the registration of the products listed in Attachment A of this notice can be varied in the ways set out in paragraphs 48 to 55, above, so that the use of the products, in accordance with the instructions for use, as varied, meets the safety criteria as defined in section 5A of the Agvet Code.

Consideration of whether registered chemical products meet the efficacy criteria

57. Section 5B(1) of the Agvet Code provides that a chemical product meets the efficacy criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product, or contained in an established standard, is, or would be, effective according to criteria determined by the APVMA by legislative instrument.

58. The criteria for agricultural chemical products is listed in Part 2 of the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* (Efficacy Criteria Determination).

58.1. Section 4(a) of Part 2 of the Efficacy Criteria Determination provides that the use of an agricultural chemical product is taken to be effective in certain circumstances, including where it would, to a reasonable degree, achieve one of the effects listed in section 4(2) of the Agvet Code and this is evidenced or demonstrated by: (i) results from efficacy trials or experiments; or (ii) valid scientific argument; or (iii) demonstrated history of sale and effective use in equivalent uses; or (iv) full results from overseas efficacy trials or experiments and the associated assessment reports by an overseas regulator that are relevant to the proposed product and use; or (v) a combination of 2 or more of the above.

59. Section 5B(2) of the Agvet Code provides that, subject to section 5B(3), for the purposes of being satisfied as to whether a chemical product meets the efficacy criteria as described in section 5B(1), the APVMA must have regard to the matters set out in section 5B(2) of the Agvet Code. I have had regard to the matters set out in section 5B(2) of the Agvet Code as follows.

60. Section 5B(2)(a) - whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments.

60.1. Trials and laboratory experiments and the results of those trials and experiments were submitted in support of the registration or variation of chemical products containing diquat and found to demonstrate efficacy of diquat chemical products prior to registration.

60.2. I remain satisfied that this information considered demonstrates the efficacy of diquat chemical products in destroying a plant for the as per the definition of an agricultural chemical product in section 5AA of the Agvet Code.

61. Section 5B(2)(b) - any conditions to which its registration is, or would be, subject;

61.1. I have considered the conditions of registration which apply to chemical products containing diquat. I am satisfied that the conditions of registration are appropriate.

62. Section 5B(2)(c) - any relevant particulars that are, or would be, entered in the Register for the product;

62.1. I note that the relevant particulars recorded in the Register for each diquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.2 of the *Diquat Final Review Technical Report.*

62.2. I have considered the relevant particulars that are entered in the Register for chemical products containing diquat. I am satisfied that the relevant particulars that are entered in the Register are appropriate with respect to the efficacy criteria.

62.3. The variations to the instructions for use proposed to satisfy the safety criteria (as set out in paragraph 55 and trade criteria (as set out in paragraph 71) are within existing use patterns. I am satisfied that these variations are appropriate.

63. Section 5B(2)(ca) - whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);

63.1. There are no standards made under section 6E which are relevant to the efficacy of chemical products containing diquat.

64. Section 5B(2)(d) any matters prescribed by the regulations.

64.1. There are no additional matters prescribed by regulations which are relevant to the efficacy of chemical products containing diquat.

65. Having had regard to the maters set out above, I am satisfied that the use of chemical products containing diquat, according to the instructions to be approved by these decisions, meets the efficacy criteria as set out in section 5B of the Agvet Code and the Efficacy Criteria Determination.

Consideration of whether registered chemical products meet the trade criteria

66. Section 5C(1) of the Agvet Code provides that a product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.

67. Section 5C(3) of the Agvet Code provides that when considering whether a chemical products meets the trade criteria, the APVMA is required to have regard to the matters set out in subsection 5C(1) and 5C(2) to the extent prescribed by the regulations, or if there are no such regulations, to the extent that the APVMA thinks the matters are relevant.

67.1. Regulation 8AD(2) of the Agvet Regulations provides that if it can be reasonably expected that a chemical product will be used in relation to a crop or animal, a product of which might be provided to a place outside Australia; or a crop that will be fed to an animal a product of which might be provided to a place outside Australia then I must have full regard to the matters set out in section 5C(1) and (2) of the Agvet Code.

a. I note that chemical products containing diquat are registered for use on crops that are considered major export commodities including berries and other small fruits (grapes), cereal grains, citrus fruit,

cotton seed, oilseed {except cotton seed}, pome fruit, pulses, stone fruit and sugar cane. It is therefore reasonably expected that a product of these crops might be provided to a place outside of Australia.

b. I also note that chemical products containing diquat are registered for use on crops that can be used as stockfeed for mammalian and poultry animals. Mammalian and poultry animals and their products (including cattle, dairy products, pigs, sheep, goats, poultry and eggs) are considered major export commodities. It is therefore reasonably expected that a product of these animals might be provided to a place outside of Australia.

68. For the purposes of considering whether diquat chemical products meet the trade criteria as described in section 5C(1) of the Agvet Code, I have had full regard to the matters set out in section 5C(2) as follows.

69. Section 5C(2)(a) - any conditions to which its registration is, or would be, subject.

69.1. I have had regard to the conditions of registration prescribed by the regulations in accordance with section 23(1)(a) of the Agvet Code, namely regulation 17C(2) of the Agvet Regulations. I have also had regard to the conditions imposed by the APVMA on the registration in accordance with section 23(1)(b) of the Agvet Code.

69.2. I am satisfied that the conditions of registration, apart from the reconsideration condition discussed in paragraph 35.6 and 48 and the Agricultural Products Active Constituent Quality Assurance Requirements discussed at paragraphs 35.7 and 48 above, currently applied to chemical products containing diquat remain acceptable. I am satisfied that the variations to the reconsideration condition and Agricultural Products Active Constituent Quality Assurance Requirements described in paragraph 48, above, will not result in any undue risk to trade and the conditions generally are not material to the risk to trade, beyond their relevance to the safety criteria and ensuring that the products and their containers meet minimum standards of purity and do not contain impurities of toxicological concern above maximum limits.

70. Section 5C(2)(b) - any relevant particulars that are, or would be, entered in the Register for the product.

70.1. The relevant particulars required to be entered in the Register for a chemical product identified in section 3 of the Agvet Code, as well as the additional matters prescribed by regulation 16 of the Agvet Regulations for the purposes of section 20(1)(c) of the Agvet Code, are as follows:

a. the distinguishing number

b. any instructions for the use of the product

c. the distinguishing name of the chemical product

d. the constituents of the chemical product

e. the concentration of each constituent of the chemical product

f. if possible, the composition and purity of each active constituent of the chemical product

g. the formulation type for the chemical product

h. the net contents of the chemical product

i. identifying information for the holder of the registration for the chemical product

j. the name of each manufacturer of the chemical product

k. the address of each site at which the chemical product is manufactured by the manufacturer

l. the date of entry of these particulars in the Register of Chemical Products

m. identifying information for any nominated agent for the registration.

70.2. I note that the relevant particulars recorded in the Register for each diquat chemical product and information submitted in support of the original applications for registration including the relevant particulars and information regarding composition and form of the constituents of the product have been reviewed, as described in section 2.2 of the *Diquat Final Review Technical Report*.

70.3. I have had regard to the assessments of the relevant particulars entered in the Register for each of the products listed in Table 7 of Attachment A and have also considered the conclusions of the residues and trade (section 5.12- Consideration of the combined risk assessments) risk assessments described in the *Diquat Final Review Technical Report.*

70.4. I am satisfied that all relevant particulars that are entered in the Register for diquat chemical products remain acceptable with respect to the trade criteria.

70.5. I have had regard to the recommendations of the Trade assessment, as described in section 5.12.21 of the *Diquat Final Review Technical Report* which considered the instructions for the use of chemical products containing diquat that are otherwise supported by all risk assessments and the potential for those uses to result in finite diquat residues on major export commodities, which may subsequently be detected in international export markets and, if exceeding the levels accepted in those markets, may pose an undue risk to trade.

70.6. I note that the recommendations in section 5.11.6 (Trade) of the *Diquat Final Review Technical Report* identified that a trade advice notice would be appropriate for pre-harvest application of diquat to cereals (barley, oats, rye, triticale, wheat) pulses and canola, however these uses are not supported by environment assessments and therefore not listed in Table 3, or are not supported by residues assessments due to inadequate data, as set out in paragraph 42.

70.7. Based on the recommendations in section 5.12.21 (Trade) of the *Diquat Final Review Technical Report*, which considered the instructions for the use of chemical products containing diquat that are otherwise supported by all risk assessments, I am satisfied that the use of diquat according to the instructions approved by the APVMA will not unduly prejudice trade between Australia and places outside Australia because there are no crops where finite residues are expected to occur at harvest, other than application to wheat and oats up to early tillering, for which reduced MRLs have been recommended and poppies, where finite residues are not expected to exceed the current MRL after the current 2-day WHP.

70.8. I note that the potential for diquat spray drift to affect animal food or forage has been considered in section 7 of the *Diquat Final Review Technical Report* and that down-wind no spray buffer zones are not required for livestock areas.

70.9. I have considered and agree with the recommendations set out in section 5.12.21 (Trade) of the *Diquat Final Review Technical Report*, that the residues in animal commodities that may result from grazing or feeding treated forage to animals will not exceed current MRLs and that the grazing WHP will ensure that there are no detectable residues in any animal commodities from livestock allowed to graze treated crops.

70.10. I am satisfied that the use of diquat according to the instructions that I propose to affirm for the uses that meet the safety criteria will not unduly prejudice trade between Australia and places outside Australia as discussed in the *Diquat Final Review Technical Report*.

71. Section 5C(2)(ba), whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);

71.1. There are no standards made under section 6E that are relevant to the risk to trade or commerce between Australia and places outside Australia for the products containing diquat listed in Attachment A.

72. Section 5C(2)(c), any matters prescribed by the regulations.

72.1. There are no matters prescribed by the regulations for the purposes of section 5C(2)(c) of the Agvet Code.

73. Having considered the matters discussed above with respect to the trade criteria, I am **not satisfied** that the use of chemical products containing diquat used according to the current instructions for use and recorded in the Register, meet the trade criteria, however I note that following variations to address the risks identified in relation to human health (including residues) and the environment discussed elsewhere in these reasons, there are no remaining risks to trade. Therefore, once these variations are made, I am **satisfied** that the use of diquat products meet the trade criteria.

Consideration of whether registered chemical products comply with any requirement prescribed by the regulations

74. Section 34(1)(d) of the Agvet Code provides that I must affirm the registration of a product only if I am satisfied that the product complies with any requirements prescribed by the regulations.

75. Regulation 42 of the Agvet Regulations prescribes standards for chemical products for the purposes of section 87 of the Agvet Code.

    75.1. Regulation 42(3) prescribes standards that apply to a chemical product if the chemical product meets specific requirements listed in that regulation.

    75.2. Regulation 42(3)(b) prescribes: "for a product or constituent (other than a product or constituent to which paragraph (a) applies) in respect of which a standard has been made under section 6E of the Code—that standard".

        a. The APVMA has made the A*gricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* under section 6E of the Agvet Code, which applies to all diquat products listed in Attachment A.

        b. I accept the recommendation from the APVMA's chemistry assessment of the information submitted to support registration of the chemical products listed in Attachment A, including declarations of composition and 5-batch analyses as described in the *Diquat Final Review Technical Report* and I am satisfied that registered agricultural chemical products containing diquat conform to the specifications listed in the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022*.

76. I am satisfied that registered diquat chemical products meet the requirements prescribed by regulation 42 of the Agvet Regulations for the purposes of section 87 of the Agvet Code.

77. I am satisfied that there are no other requirements prescribed by the regulations that have not been considered.

Labels for chemical products

78. Sections 34(1) of the Agvet Code provides that I must affirm the approval of a label if, and only if, I am satisfied that the label:

    78.1. meets the labelling criteria (section 5D); and

    78.2. complies with any requirement prescribed by the Agvet Regulations.

79. I have considered all matters covered by subsection 34(1) in relation to the reconsideration of diquat label approvals specified at Attachment A.

Consideration of whether approved labels for diquat chemical products meet the labelling criteria and comply with any requirement prescribed by the regulations

80. Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product 'meets the labelling criteria' if the label contains adequate instructions relating to such of the following as are appropriate:

80.1. the circumstances in which the product should be used (5D(1)(a))

80.2. how the product should be used (5D(1)(b))

80.3. the times when the product should be used (5D(1)(c))

80.4. the frequency of the use of the product (5D(1)(d))

80.5. the withholding period after the use of the product (5D(1)(e))

80.6. the re-entry period after the use of the product (5D(1)(f))

80.7. the disposal of the product when it is no longer required (5D(1)(g))

80.8. the disposal of containers of the product (5D(1)(h))

80.9. the safe handling of the product and first aid in the event of an accident caused by the handling of the product (5D(1)(i))

80.10. any matters prescribed by the regulations (5D(1)(j). In this regard, regulation 8AE(1) of the Agvet Regulations prescribes the following:

a. Regulation 8AE(1)(a) – for a chemical product that is a veterinary chemical product, the duration of the treatment

b. Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia

c. Regulation 8AE(1)(c) – the appropriate signal words (if any) required by the current Poisons Standard

d. Regulation 8AE(1)(d) – for a chemical product that is a date-controlled product, the storage of containers for the product

e. Regulation 8AE(1)(e) – any other matter determined by the APVMA CEO under regulation 8AE(2).

81. I note that the Agvet Code provides a definition for adequate in relation to instructions on a label for containers for a chemical product, which means the instructions are adequate if they ensure, as far as reasonably practicable, that the product meets the safety criteria and the trade criteria.

82. For the purposes of considering whether the labels meet the labelling criteria as described in section 5D(1) of the Agvet Code, I have had regard to the matters set out in section 5D(2) of the Agvet Code as follows.

83. Section 5D(2)(a) of the Agvet Code - any conditions to which the label's approval is, or would be, subject.

83.1. I have considered conditions to which the label approvals are subject as prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code.

83.2. I am satisfied that the conditions to which label approvals are subject pursuant to section 23(1)(a) of the Agvet Code, as prescribed by regulations 18B to 18J of the Agvet Regulations, are appropriate for the labels for containers for products listed in Attachment A of this notice.

a. I note that Regulation 18E prescribes a condition for label approvals that requires that if a labelling standard has not been made by the APVMA, then the label must comply with the requirements of

either the Veterinary Labelling Code, if the product is a veterinary chemical product, or the Agricultural Labelling Code, if the product is an agricultural chemical product.

b. I am **not satisfied** that the approved labels for diquat agricultural chemical products comply with the current *Agricultural Labelling Code,* in particular in relation to the instructions for disposal of the product when it is no longer required (section 5D(1)(g)) and the disposal of containers for the product (section 5D(1)(h)) as noted in paragraph 85 which do not contain the disposal statements required by the current *Agricultural Labelling Code*, and noting that it may be an offence to bury chemical products and used containers in some jurisdictions.

c. I also note that I have decided to require that all containers for diquat chemical products must be sealed with fittings compatible with enclosed mixing and loading systems (see paragraph 54) and that these require specific disposal instructions, which are described in the Agricultural Labelling Code and which are not currently contained on the approved labels for these products.

83.3. Labels approved for containers for diquat chemical products are also subject to additional an additional condition imposed by the APVMA under section 23(1)(b) of the Agvet Code, known as the date of manufacture condition, which is reproduced below.

The approved label affixed to containers must be supplied with a Date of Manufacture and Batch Number and where:

(a) The Date of Manufacture and Batch Number must be either printed on the container or affixed by way of a sticker to either:

(i) the base of the main or ancillary panel of the approved label; or

(ii) to the container.

The Date of Manufacture and Batch Number must comprise of numbers or letters, or a combination of numbers and letters and be in English.

(b) Suitable prefixes may be used for the Date of Manufacture and Batch Number. These must be distinguishable from one another. For example, Date of Manufacture may include the prefix 'DOM', and Batch Number the prefix 'BN'. These details must be presented on the label or container (in accordance with (a) above) adjacent to one another and not in a position to be confused with any other numerical codes

83.1. I am satisfied that this condition remains appropriate for labels for containers of diquat products, noting that the condition is supplementary to the conditions prescribed by regulation 18D and stipulates that a date of manufacture is required to be recorded on the label (i.e. is applicable for reg. 18D) and further stipulates the minimum requirements for the information to be recorded.

84. Section 5D(2)(b) of the Agvet Code - any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label.

84.1. I have had regard to the APVMA's chemistry, human health, environment, and residues and trade risk assessments as described in the *Diquat Final Review Technical Report* and discussed in paragraph 36 above in regard to the relevant particulars and instructions entered in the file for each approved label listed in Attachment A and I am satisfied that all relevant particulars remain appropriate, except for the instructions for use as related to the matters listed in section 5D(1) of the Agvet Code.

85. I have had regard to the instructions entered in the relevant APVMA file relating to each matter listed in section 5D(1) as follows:

85.1. the circumstances in which the product should be used (section 5D(1)(a))

a. I am **not satisfied** that the use of products containing diquat as the active constituent, according to the currently approved instructions for use will not result in exceedance of the RALs for wild birds, wild mammals or both, except for the situations listed in Table 3 above.

b. I am **not satisfied** that use of products containing diquat as the active constituent, according to the currently approved instructions for use will not result in residues of diquat that will not be greater than the limits that the APVMA has approved or approves, when used in the situations set out below and in section 42 of this statement of reasons:

- Pre-harvest crop desiccation in cotton
- Pre-harvest desiccation in sugarcane
- General weed control in pineapples, green onions, brassica vegetables other than crops with specific residue data, i.e. broccoli, head cabbages, cauliflower and Chinese cabbage (type Pe-tsai), fruiting vegetables (cucurbits, other than cucumber), stalk and stem vegetables (other than asparagus), herbs and spices.

c. I am **not satisfied** that the instructions for use of diquat products on "row crops, vegetables, and market gardens" are adequate as these general definitions are not consistent with the APVMA crop group guidelines or current methods for assessing human dietary exposure to residues of diquat following its use in those situations as discussed in paragraph 36.5.h and 52 above. Therefore, I am not able to be satisfied that these uses will not result in human dietary exposure exceeding the ADI or ARfD.

d. I note that section 6.5 (Recommendations) of the *Diquat Final Review Technical Report* includes recommendations for inclusion of contemporary protection statements and restraints to inform users of generally applicable actions that are necessary to manage risks to terrestrial vertebrates, aquatic species and beneficial arthropods noted in sections 6.4.1 (Terrestrial vertebrates), 6.4.2 (Aquatic species), 6.3 (Effects on non-target species) and 6.4.4 (Other arthropod species) to prevent unacceptable levels of exposure to diquat for non-target species. I note that these statements and restraints are not presently included on currently approved labels.

e. I am not satisfied the instructions on the currently approved labels are adequate with respect to the circumstances in which the product should be used, because I cannot be satisfied that use according to those instructions will not be likely to:

- have an unintended effect that is harmful to animals or plants or things or to the environment, as described in paragraph 36.6, above, regarding my consideration of the safety criteria
- have an effect that is harmful to human beings or pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, as described in paragraph 42, above, regarding my consideration of the safety criteria

85.2. How the product should be used (section 5D(1)(b)):

a. I am not satisfied that the use of products containing diquat as the active constituents, according to the currently approved instructions for use is not likely to result in effects that are harmful to people, or unintended effects that are harmful to animals or plants or things or the environment.

b. I have considered the instructions for how diquat products should be used that are contained on the currently approved labels and I am not satisfied that the instructions are adequate in the following instances because they may result in exposure of workers to levels of diquat that exceed the maximum that that is unlikely to have an effect that is harmful as described in detail in paragraph 36.5 above and in section 4.1 (Worker exposure assessment) of the *Diquat Final Review Technical Report*.

c. I note that additional restraints are recommended in order for users to know which PPE and other behaviours are necessary to safely use the products in section 4.2.2 of the *Diquat Final Review*

Technical Report. I am not satisfied that the current restraints are adequate to prevent exceedance of the acceptable occupational exposure levels.

d. I am **not satisfied** that the approved labels contain adequate instructions for how the products should be used, to prevent diquat spray drift from exceeding RALs in sensitive areas as described in section 7 (Spray drift) of the *Diquat Final Review Technical Report* and also discussed in paragraph 36.7 (in relation to risks to the environment and bystanders) and paragraph 71.8 (in relation to livestock areas).

85.3. The times when the product should be used (s5D(1)(c)):

a. I have considered the instructions for the times when the product should be used and I am satisfied that the instructions contained in the labels for diquat products remain adequate because the time when the product is used is not material to the risk assessments discussed the *Diquat Final Review Technical Report*.

85.4. The frequency of the use of the product (section 5D(1)(d)):

a. I have considered the instructions for frequency of the use of the product and I am satisfied that the instructions contained by the labels for diquat products remain adequate in this respect as described in the *Diquat Final Review Technical Report*. I note that this was specifically discussed in section 3.34 of the APVMA's consideration of submissions document and I agree with the conclusion that the currently approved instructions refer to use of the products in specified circumstances, e.g. pre-harvest desiccation, that effectively limits the frequency of the use of the product in a way that is unlikely to result in harmful effects to people or the environment.

85.5. The withholding period after the use of the product (section 5D(1)(e)):

a. I have considered the instructions for the withholding periods after the use of diquat products, and I am **not satisfied** that the current instructions are adequate in the following instances:

- The presentation of the withholding period for water from treated aquatic areas, including farm dams and artificial water bodies which is not consistent with the current Agricultural Labelling Code, although the withholding periods themselves are sufficient to prevent exceedance of MRLs in animal or crop commodities, as recommended in section 5.12.19 of the *Diquat Final Review Technical Report.*
- for row crops including asparagus, berries and other small fruit (except grapes), broccoli, head cabbages, cauliflower and Chinese cabbage (type Pe-tsai), bulb onions, fruiting Vegetables: other than cucurbits, cucumbers, leafy vegetables, legume vegetables and root and tuber vegetables, for pre-emergent applications or applications by a shielded spray I note that the recommended withholding periods for these crops in section 5.12.8 to 5.12.17 of the *Diquat Final Review Technical Report* is "Not required when used as directed".
- for lucerne, pastures, wheat and oat forage I note the recommended withholding period in section 5.12.5 and 5.12.20 of the *Diquat Final Review Technical Report* is "DO NOT graze or cut for stock food for 1 day after application"

85.6. The re-entry period after the use of the product (section 5D(1)(f)):

a. I have considered the re-entry instructions contained in the labels and the worker exposure risk assessments discussed in paragraph 36.5.f above, and sections 4.1 (Worker exposure) and 4.1.2 (Re-entry periods) of the *Diquat Final Review Technical Report* and I am **not satisfied** that the instructions are adequate to prevent exposure of people to levels of diquat exceeding the acceptable occupational exposure levels.

85.7. The disposal of the product when it is no longer required (section 5D(1)(g)) and the disposal of containers for the product (section 5D(1)(h)):

a. I have considered the instructions for disposal of the product when it is no longer required and the instructions for disposal of containers for diquat products contained in the label and the current Agricultural Labelling Code, and I am **not satisfied** that the instructions are adequate, noting that it may be an offence to bury chemical products and used containers in some jurisdictions.

b. In addition, as discussed in paragraphs 36.5.e and 44.2 I have decided to require closed mixing and loading be used for diquat chemical products. Containers compatible with closed mixing and loading require specific disposal instructions as described in the Agricultural Labelling Code, which are not currently included on the approved labels

85.8. The safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i).

a. I have considered the hazards and risks of exposure to diquat in an accident caused by handling the product, as discussed in paragraphs 36.5 and 36.5.i and I am **not satisfied** that the first aid instructions and safety directions contained on the approved labels are adequate to mitigate the worker exposure risks identified in section 4.1. (Worker Exposure) of the *Diquat Final Review Technical Report* as described in sections 4.2.3 and 4.2.4 (First aid statements) and (Safety Directions) of the *Diquat Final Review Technical Report.*

85.9. Any matters prescribed by the regulations (section 5D(1)(j).

a. Regulation 8AE(1)(a) of the Agvet Regulations – for a chemical product that is a veterinary chemical product, the duration of the treatment.

- I note that chemical products containing diquat are not veterinary chemical products.

b. Regulation 8AE(1)(b) of the Agvet Regulations – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.

- I have considered the instructions contained on the labels relevant to the prevention of prejudice to trade or commerce and I am satisfied that the current withholding period, and trade advice statements are adequate, because there are no additional statements recommended in section 5.12 (Consideration of the combined risk assessments) *Diguat Review Technical Report*.

c. Regulation 8AE(1)(c) of the Agvet Regulations – the appropriate signal words (if any) required by the current Poisons Standard.

- Diquat is included in Schedule 7 of the current Poisons Standard, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), except when included in Schedule 6.
- Diquat is included in Schedule 6 of the SUSMP in preparations containing 20% or less of diquat. All diquat products in Attachment A contain 200 g/L, or 20 % of diquat. These products are required to bear the signal heading **'POISON'** on the first line of the main label.
- Chemical products are also required to bear the cautionary statement **"KEEP OUT OF REACH OF CHILDREN"** written immediately on a separate line immediately below the signal words.
- As safety directions are required on all labels, the signal heading must also include the statement "**READ SAFETY DIRECTIONS BEFORE OPENING OR USING**".

- I have considered the signal words contained on the labels for products containing diquat and am satisfied that the labels listed in Attachment A bear the appropriate words and cautionary statements.

d. Regulation 8AE(1)(d) of the Agvet Regulations – for a chemical product that is a date-controlled product, the storage of containers for the product.

- Regulation 4 of the Agvet Regulations defines a date-controlled chemical product as "each veterinary chemical product and an agricultural chemical product specified in Schedule 1 to the Agvet Regulations".
- I note that chemical products containing diquat are not specified in Schedule 1 to the Agvet Regulations and are therefore not date-controlled chemical products.

e. Regulation 8AE(1)(e) of the Agvet Regulations – any other matter determined by the APVMA CEO under regulation 8AE(2).

- There are no other matters determined by the APVMA CEO under regulation 8AE(2) in relation to diquat label approvals.

86. Section 5D(2)(c) of the Agvet Code - whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).

86.1. There is no standard made for diquat label approvals under section 6E.

87. Section 5D(2)(d) of the Agvet Code - any matters prescribed by the regulations.

87.1. There are not matters prescribed by the regulations for the purpose of section 5D(2)(d) of the Agvet Code.

88. I am **not satisfied** that currently approved labels for containers for diquat chemical products contain adequate instructions relating to the matters set out in paragraph 87 above.

89. I am satisfied that all particulars, excluding the instructions contained on the label, that are recorded in the relevant APVMA file remain appropriate.

Consideration of whether approved labels for chemical products can be varied so as to meet the labelling criteria and comply with any requirement prescribed by the regulations

90. I have considered whether the labels approved for containers for diquat chemical products can be varied in such a way as to meet the labelling criteria set out in Section 5D(1) of the Agvet Code for the purposes of section 34A(1).

91. I have decided to vary the instructions contained on labels for containers for diquat chemical products to address concerns identified in paragraphs 87 and 85 above when considering the matters in section 5D(2)(b) of the Agvet Code regarding whether the instructions are adequate, as follows.

91.1. I have decided to vary the instructions relating to the circumstances in which the products should be used (s5D(1)(a)) as follows.

a. To address my concern noted in paragraph 85.1.a, above, I have decided to remove instructions for use in all situations except the situations listed in Table 3, which I have stated I am satisfied are not likely to result in an unintended effect that is harmful to plants or animals or things or to the environment.

b. To address my concerns noted in paragraph 85.1.b, above, I have decided to remove instructions for use in situations listed in this paragraph, where due to a lack of appropriate residues data I am not satisfied that the currently approved instructions for use will result in residues of diquat in crops or commodities that are lower than the limits that the APVMA has approved or approves.

c. To address my concerns noted in paragraph 85.1.c, above, I have decided to replace the broad terms “row crops, vegetables, and market gardens”, with the specific crops set out in paragraph 52 as follows:

- replace the broad claims for row crops, vegetables and market gardens with
    - berries and other small fruit (except grapes), brassica vegetables (broccoli, head cabbages, cauliflower and Chinese cabbage (type pe-tsai)), bulb vegetables (except green onions), fruiting vegetables (other than cucurbits), leafy vegetables, legume vegetables, pineapple, root and tuber vegetables.

d. To address my concerns noted in paragraph 85.1.d, above, I have decided to add the following protection statements and restraints for the protection of non-target species:

- DO NOT apply if heavy rains or storms are forecast within 3 days.
- DO NOT irrigate to the point of field runoff for at least 3 days after application.
- Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
- Toxic to beneficial arthropods. Not compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Minimise spray drift to reduce harmful effects on beneficial arthropods in non-crop areas.
- DO NOT apply to water bodies from which the product may contaminate natural aquatic areas
- Toxic to birds. However, the use of this product as directed is not expected to have adverse effects on birds.

e. To address my concerns noted in paragraph 85.1.d, above, I have decided to include the following critical comments for uses of diquat to aquatic areas and amend the description from ‘aquatic areas’ to ‘aquatic areas:farm dams and artificial water bodies only’

- DO NOT apply to water bodies from which the product may contaminate natural aquatic areas

91.2. I have decided to vary the instructions in relation to how the product should be used (section 5D(1)(b)) to address the concerns identified in paragraph 85.2, above, as follows:

a. To address my concern noted in paragraph 85.2.c I have decided to add the following restraints to limit occupational exposure:

- For all diquat products:
    - DO NOT remove contents except for immediate use.
    - DO NOT apply by spraying equipment carried on the back of the users.
    - DO NOT use open mixing/loading equipment. Closed mixing and loading must be used.
    - DO NOT continue to use if eye irritation or bleeding from the nose occurs.
- For broadacre boom spray applications:
    - DO NOT apply using open cab equipment. Enclosed cab application MUST be used.
- For small scale agriculture boom spray application (up to 6 ha per day):

- DO NOT apply using open cab equipment unless using a PF10 respirator.

- For hand spray applications:
  - DO NOT use hand wand sprays by spraying out of the window of a vehicle.

b. To address my concern noted in paragraph 85.2.d above, regarding the effects of spray drift from diquat products onto sensitive areas I have decided to add the following spray drift restraints to prevent diquat spray drift from exceeding RALs in sensitive areas.

SPRAY DRIFT RESTRAINTS

Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The advisory buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are surface temperature inversion conditions present at the application site during the time of application. These conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.

DO NOT apply by a boom sprayer unless the following requirements are met:

– spray droplets not smaller than a MEDIUM spray droplet size category

– minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Diquat - buffer zones for boom sprayers (metres; MEDIUM droplet size)						
Application rate	**Boom height above the target canopy**	**Bystander areas**	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**	**Livestock areas**
2 kg ac/ha or lower	0.5 m or lower	110	275	0	35	0
	1.0 m or lower	Not supported				
1 kg ac/ha or lower	0.5 m or lower	50	110	0	20	0
	1.0 m or lower	160	350	0	60	0
800 g ac/ha or lower	0.5 m or lower	40	85	0	20	0
	1.0 m or lower	130	250	0	55	0
600 g ac/ha or lower	0.5 m or lower	35	65	0	10	0
	1.0 m or lower	100	180	0	45	0
300 g ac/ha or lower	0.5 m or lower	20	40	0	5	0
	1.0 m or lower	60	110	0	25	0

Diquat - buffer zones for boom sprayers (metres; MEDIUM droplet size)						
140 g ac/ha or lower	*0.5 m or lower*	*5*	*20*	*0*	*0*	*0*
	1.0 m or lower	*35*	*60*	*0*	*15*	*0*
80 g ac/ha or lower	*0.5 m or lower*	*0*	*10*	*0*	*0*	*0*
	1.0 m or lower	*20*	*10*	*0*	*10*	*0*

DO NOT apply by a vertical sprayer.

DO NOT apply by aircraft unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category
- for maximum release heights above the target canopy of 3m or 25% of wingspan or 25% of rotor diameter whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed.

Diquat - buffer zones for aircraft (metres; MEDIUM droplet size)					
Type of aircraft (rate)	**Bystander areas**	**Natural aquatic areas**	**Pollinator areas**	**Vegetation areas**	**Livestock areas**
Fixed-wing (280 g ac/ha)	275	525	0	100	0
Fixed-wing (150 g ac/ha)	170	275	0	65	0
Helicopter (280 g ac/ha)	180	300	0	65	0
Helicopter (150 g ac/ha)	120	190	0	50	0

91.3. I have decided to vary the instructions contained on labels for containers for diquat products to address concerns identified in paragraph 88.5 above in relation to the withholding period after the use of the product (s5D(1)(e)) as follows:

a. vary the statement for aquatic areas, excluding natural aquatic areas, to 'DO NOT use treated water for human consumption, livestock watering or irrigation purposes for 10 days after application' for labels where it is not already 10 days.

b. vary the harvest withholding period for pre-harvest desiccation of poppies to 2 days, for labels where it is not already 2 days

c. vary the harvest withholding periods for all other uses (as supported by other assessment outcomes) to "not required when used as directed"

d. vary the current grazing withholding period for lucerne, pastures, wheat and oat forage to read: LIVESTOCK: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 1 DAY AFTER APPLICATION, for labels where it is not already present.

91.4. I have decided to vary the instructions contained on labels for containers of diquat products to address concerns identified in paragraph 85.6 in relation to the re-entry period after the use of the product (s5D(1)(f)) to read as following for diquat products:

Re-entry period

DO NOT allow entry to treated areas until the spray has dried unless using an enclosed cab or wearing cotton overalls and gloves. Workers performing scouting and irrigation activities must comply with the re-entry periods specified in Table 9

Table 10: Re-entry intervals for diquat products

Activity	Non-Re-Entry Period (Days)[1]
Scouting (application rate up to 400 g/ha)	0
Scouting (application rate of 401 to ≤ 600 g/ha)	1
Scouting (application rate of 601 to ≤ 800 g/ha)	4
Irrigation (hand set) (application rate of up to 300 g/ha)	0
Irrigation (hand set) (application rate of 301 to ≤ 400 g/ha)	3
Irrigation (hand set) (application rate of 401 to ≤ 600 g/ha)	7
Irrigation (hand set) (application rate of 601 to ≤ 800 g/ha)	9

91.5. I have decided to vary the instructions contained on labels for containers for diquat products to address concerns identified in paragraph 85.7 in relation to the disposal of the product

Storage and Disposal

Store in the closed, original container in a cool, well-ventilated area. DO NOT store for prolonged periods in direct sunlight.

Empty contents fully into application equipment. Close all valves and return to [point of supply/designated collection point/other specific collection details] for refill or storage.

91.6. I have decided to vary the instructions contained on labels for containers for diquat products to address concerns identified in paragraph 85.8 in relation to the safe handling of the product and first aid in the event of an accident caused by the handling of the products (section 5D(1)(i)) to read as follows:

First aid statements (all products)

If poisoning occurs, get to a doctor or hospital quickly. If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

Safety Directions (all products)

Very dangerous, particularly the concentrate. Do not swallow. The product, particularly the concentrate, can kill if swallowed, absorbed through the eyes, or absorbed by skin contact. The liquid can cause burns particularly to the eyes. Will irritate the nose, throat, and skin. When handling, do not touch or rub eyes, nose, or mouth with hand. Avoid contact with eyes and skin, open wounds, and clothing. Protect eyes while using. If clothing becomes contaminated with product or with wet spray remove clothing immediately. Do not inhale spray mist. Do not allow children to play with containers or any equipment that is used. When connecting, disconnecting, and cleaning equipment wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, impervious footwear, elbow-length chemical resistant gloves and a full face respirator with canister specified for diquat OR half face-piece respirator with canister specified for diquat and face shield or goggles. When applying by low (manual pressurised) or high (mechanically pressurised) hand wand wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, impervious footwear and a full face piece respirator with a canister specified for diquat. After use and before eating, drinking, or smoking, wash hands, arms, and face thoroughly with soap and water. After each day's use wash gloves, face shield or goggles, respirator (and if rubber wash with detergent and warm water) clothing, and footwear.

92. Section 34A(3) of the Agvet Code provides that if the variation would affect any instructions for the use of an active constituent or chemical product, or any instructions on a label, the APVMA must not make the variation

until it has consulted each co-ordinator designated for a jurisdiction and taken into account any recommendations made by the co-ordinators.

92.1. I note that the APVMA has consulted with each co-ordinator designated for a jurisdiction on the above variations to the instructions on the label, which are also the instructions for use of the products. All recommendations received have been taken into account.

92.2. I am satisfied that the relevant particulars of the label approvals listed in Table 7 of Attachment A can be varied in the ways set out in paragraph 91, so that the labels contain adequate instructions so as to meet the labelling criteria and comply with any requirement prescribed by the regulations.

Conclusions

93. Having had regard to the matters set out above regarding diquat active constituent approvals,

93.1. I am **not satisfied** that the diquat active constituent approvals listed in Attachment A currently meet the safety criteria;

93.2. I am satisfied that the conditions of the diquat active constituent approvals listed in Table 1 in Attachment A can be varied as described in paragraph 24 of this statement of reasons to meet the safety criteria and allow the approvals to be affirmed; and

93.3. I am satisfied that the active constituents listed in Table 7 in Attachment A comply with any other requirement prescribed by the regulations.

94. Having had regard to the matters set out above regarding diquat chemical products:

94.1. I am **not satisfied** that the diquat chemical products currently meet the safety criteria, trade criteria and any relevant requirements prescribed by the Agvet Regulations;

94.2. I am satisfied that the diquat chemical products meet the efficacy criteria;

94.3. I am satisfied that the relevant particulars and conditions of diquat chemical product registrations listed in Table 7 of Attachment A can be varied in such a way, as set out in paragraphs 49, 50, 51, 52 and 53 of this statement of reasons in relation to the safety criteria to allow the chemical product registrations to be affirmed.

95. Having regard to the matters set out above regarding diquat label approvals, I am:

95.1. I am **not satisfied** that the labels approved for containers for diquat chemical products meet the labelling criteria and comply with identified relevant requirement prescribed by the Agvet Regulations; and

95.2. I am satisfied that the particulars of diquat label approvals listed in Table 7 of Attachment A can be varied, as set out in paragraph 91 of this statement of reasons and as reflected in the template labels in Attachment D, to allow me to be satisfied that the labels meet the labelling criteria in section 5D of the Agvet Code and to allow the label approvals to be affirmed;

96. Consequently, pursuant to section 34A(1) of the Agvet Code, I have decided to:

96.1. vary the conditions of diquat active constituent approvals listed in in Attachment A of this notice, in a manner set out in paragraph 24 of this statement of reasons, to allow affirmation under section 34(1) of the Agvet Code; and

96.2. vary the relevant particulars and conditions of the chemical product registrations listed in of Attachment A, in a manner set out in paragraphs 49, 50, 51, 52 and 53 of this statement of reasons in relation to the safety criteria to allow affirmation under section 34(1) of the Agvet Code; and

96.3. vary the relevant particulars of the label approvals listed in of Attachment A in the manner set out in paragraph 91 of this draft statement of reasons, and as reflected in the proposed labels in Attachment D, to allow affirmation under section 34(1) of the Agvet Code.

96.4. affirm the varied active constituent approvals, product registrations and label approvals listed in Attachment A of this notice.

Phase-out period

97. Noting that the risk assessments completed during the reconsideration of diquat have not identified any imminent risks of serious injury or serious illness for people, or other risks that have led to the cancellation of approvals or registrations, I have determined under section 81(3)(c) of the Agvet Code that subsection 81(3) of the Agvet Code applies to the supply of registered chemical products bearing labels that were approved prior to my decisions described above, for a period of two years from 22 June 2026.

98. I consider the default period of 2 years provided by section 81(3) of the Agvet Code is appropriate because of the abovementioned absence of imminent risk to human health recognising the considerations provided in section 1A regarding implementing the Agvet Code, particularly 1A(2)(c) which requires that I balance the regulatory burden imposed by the system of regulation against the risk of use of the products for people and the environment.

99. I note that this determination under section 81(3)(c) does not authorise manufacture of chemical products bearing previously approved labels.

Attachment C: Information on which the reasons are based

1. The information on which the reasons in the Statement of Reasons is based is set out below. All studies available to the APVMA for consideration in the final regulatory decisions are listed in the data list that will be published on the APVMA website.

    1.1. Information recorded in the APVMA's record and register, submitted to support applications for active constituent approval or chemical product registration or label approval for each of the approvals and registrations listed in Attachment A, which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code.

    1.2. Information provided to the APVMA in response to notices:

        a. Issued to Holders under section 32 of the Agvet Code on 27 October 1997, and additional notices issued under section 32 of the Agvet Code on 1 July 2015, 10 May 2016, 16 August 2017, and 28 February 2024

        b. Published in the APVMA Gazette under section 32 of the Agvet Code on 2 December 1997

        c. Issued to Holders under section 33 of the Agvet Code on 3 March 2023, 22 August 2023 and 23 October 2023

        d. Issued to Holders and published in the APVMA Gazette under section 34AB of the Agvet Code on 30 July 2024.

    1.3. Other information assessed by the APVMA summarised in the following published reports, which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code:

        a. Diquat Final Review Technical Report, June 2026

        b. Paraquat Final Review Technical Report, June 2026

        c. APVMA consideration of submissions – paraquat and diquat

    1.4. Other information assessed by the APVMA summarised in the following unpublished reports (these are internal APVMA reports which include confidential commercial information belonging to multiple parties), which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code:

        a. Diquat - Assessment - Review Mammalian Toxicology, Metabolism, Kinetics Report - Final

        b. Paraquat and Diquat - Review on toxicology and occupational uses - HHRA FTR - APVMA COPY

        c. Residues and Trade assessment – Diquat Reconsideration – Final Recommendations

        d. Diquat - chemical review - environment 7.1 – fate

        e. Diquat - chemical review - environment 7.2 – effects

        f. Diquat - chemical review - environment 7.3 – risk

        g. Diquat - chemical review - environment CCI attachment

    1.5. Other information which I consider necessary to enable me to make a decision on the reconsideration for the purpose of subsection 34(3)(vi) of the Agvet Code

        a. Therapeutic Goods (Poisons Standard—February 2026) Instrument 2026 (i.e. the Standard for the Uniform Scheduling of Medicines and Poisons)

b. The APVMA's risk assessment manuals as published on the APVMA website at https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals

- Chemistry and manufacture
- Environment
- Human health
- Residues and trade
- Spray Drift Risk Assessment Manual