Australian Government

Australian Pesticides and Veterinary Medicines Authority

Paraquat and diquat final regulatory decisions –

consideration of submissions

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This publication is available from the APVMA website.

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1 Public consultation

The Australian Pesticides and Veterinary Medicines Authority (APVMA) published notice of its proposed regulatory decisions in relation to the reconsiderations of paraquat and diquat in an APVMA Special Gazette on 30 July 2024. The APVMA invited submissions on the proposed decisions until 29 October 2024. The APVMA is required to have regard to all submissions made in response to an invitation in a notice of proposed decision under secton34AB(2)(f) when deciding whether to affirm, vary and then affirm, or suspend or cancel the registration of a chemical product or approval of an active constituent or label for containers of a chemical product. This document presents a summary of all submissions received and how the APVMA has considered the information provided.

The APVMA received a total of 171 submissions, including 3 that were posted prior to the end of the consultation period but received after the closing date, in response to the proposed regulatory decisions for paraquat and diquat. Many submissions provided comments relating to both reconsiderations. Summaries of all submissions are listed in Table 1. Where permission was given, the submissions have been published on the APVMA website.

The APVMA has considered the submissions from the agricultural industry, scientists and doctors and other interested parties which provided detailed scientific information or argument. Additional information has been assessed and included in the appropriate section of the paraquat or diquat final technical report as relevant. Information that was not relevant to the APVMA's decision on if the chemical products and their active constituents and labels meet the safety, efficacy and trade criteria, and labelling criteria, such as financial impact, availability of alternatives or usefulness of the product are acknowledged, but have not been assessed further.

Table 1: Submissions in response to the proposed regulatory decisions on the reconsiderations of paraquat and diquat (submissions are listed in order of date received and then alphabetically by organisation)

Number	Organisation	Summary of issues	Published
1	Bruce Brothers (1)	Concerns regarding growers' loss of ability to control glyphosate-resistant weeds such as annual ryegrass if paraquat were not available.	yes
2	Bruce Brothers (2)	Concerns regarding growers' loss of ability to control glyphosate-resistant weeds such as annual ryegrass if paraquat were not available.	yes
3	Bruce Brothers (3)	Concerns regarding growers' loss of ability to control glyphosate-resistant weeds such as annual ryegrass if paraquat were not available.	yes
4	Araluen Farming Co	Concerns regarding growers' loss of ability to control glyphosate-resistant weeds such as annual ryegrass if paraquat were not available. Use of paraquat/diquat for crop topping legume crops and spray-topping legume pastures are "vital tools".	yes
5	JWC Farming Pty Ltd	Concerns regarding growers' loss of ability to control glyphosate-resistant weeds such as annual ryegrass if paraquat were not available. Other chemicals are more costly and less effective, which will increase production costs.	yes
6	Not published	Negative impact to legume crop yields if desiccation with paraquat were not available. Loss of ability to control glyphosate resistant ryegrass if paraquat were not available.	no
7	Not published	Supports 100% ban of paraquat and diquat.	no

Number	Organisation	Summary of issues	Published
8	Doug French & Co	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	yes
9	SMS Rural Services Pty Ltd	Concerns regarding growers' loss of ability to control glyphosate resistant weeds such as annual ryegrass if paraquat were not available and consequent impact on farm business viability. Notes preharvest desiccation use for legumes is necessary for current farming strategies.	yes
10	Not published	Supports proposed changes.	yes
11	HMAg Pty Ltd	Concerns regarding growers' loss of ability to control glyphosate resistant weeds such as awnless barnyard grass if paraquat were not available and consequent impact on farm business viability. Highlights potential environmental effects of using cultivation rather than paraquat to control weeds. Provides information about use of optical spot spraying technology.	yes
12	Lott Rural Consulting	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	yes
13	N/A	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	no
14	Not published	Concerns regarding growers' loss of ability to control glyphosate resistant weeds if paraquat were not available and consequent impact on farm business viability. Also highlights potential environmental effects of using cultivation rather than paraquat to control weeds. Provides information about use of optical spot spraying technology.	yes
15	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
16	N/A	Calls for ban of paraquat	no
17	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and environment.	no
18	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease	no
19	N/A	Calls for ban of paraquat	no
20	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	no
21	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	yes

Number	Organisation	Summary of issues	Published
22	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease	yes
23	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease	yes
24	Bidstrup Farming Co	Details of changes to farming practices facilitated by no-till farming. Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
25	N/A	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	yes
26	Not published	Questions various aspects of technical reports, including residues and environment assessments, but does not provide new data.	yes
27	N/A	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
28	N/A	Calls for investigation of APVMA and ban of paraquat	yes
29	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease	no
30	N/A	Provides recommendations for specifications for gloves to be used in handling paraquat	yes
31	Australian Dried Tree Fruits INC	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability.	yes
32	N/A	Claims link between chemical properties of paraquat and Parkinson's disease	yes
33	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
34	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
35	Chris Kelly Consulting	Provides argument and references studies to refine the environmental risk assessment in relation to non-target birds. Also discusses optical spot spraying.	yes
36	Riverina Winegrape Growers	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
37	Not published	Calls for Tasmanian poppy industry to be exempt from decision	no

Number	Organisation	Summary of issues	Published
38	Not published	Calls for ban of paraquat	no
39	Not Published	Provides extensive data and argument for refinement of environmental risk assessment related to non-target birds and mammals in general.	no
40	Dowling AgriTech	Concerns specific to seed-potato industry regarding impact that removal of diquat for haulm desiccation would have on industry practices and consequent unintended environmental impacts from increased mechanical operations.	yes
41	The Warringa Trust	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
42	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available.	yes
43	Not Published	Overview of specific use patterns relevant to organisation and related concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
44	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
45	McMullen Consulting	Supports changes related to fodder relevant uses and includes information on this industry.	yes
46	Chaplin Brothers Pty Ltd	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability	yes
47	Delta Agribusiness	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
48	Not published	Crop specific data	no
49	Lucerne Australia Incorporated	Provides argument that specifics of lucerne seed production has not been considered sufficiently in relation to both paraquat and diquat and includes additional supporting information related to the areas where lucerne is grown for seed production, the type of birds and animals present in these areas and industry practices that may mitigate risks to non-target organisms.	yes
50	Not published	Provides argument that use of diquat for opium poppy production in Tasmania, under licence from the State Government has not been considered appropriately and includes information about industry practices, crop location and animal and bird species potentially present in those areas.	no

Number	Organisation	Summary of issues	Published
51	Not published	Recommendation to remove state-specific limitations in directions for use.	no
52	Tasmanian Public and Environmental Health Network (TPEHN)	Calls for ban on paraquat with claimed link to Parkinson's disease. Provides links to 2 scientific papers.	yes
53	Anasazi Agronomy Pty Ltd	Includes concerns that risk assessments have not used Australian specific data or taken into account the potential effects on managing weed resistance on business operations or the environment.	yes
54	Movement Disorder Society of Australia and New Zealand	Calls for ban on paraquat with claimed link to Parkinson's disease – provides references to 7 scientific papers.	yes
55	WA Grains Group Inc.	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Provides data related to bird populations in Western Australia and logs from optical spot spraying application on paraquat.	yes
56	Ag Insights Consulting PTY LTD	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
57	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Provides argument regarding potential routes of exposure of birds and animals without supporting data.	no
58	Not published	Detailed argument about environmental and worker health and safety risks posed by diquat used for treatment of aquatic weeds	no
59	Australian Environment Agency Pty Ltd	Detailed critique of the paraquat environmental risk assessment and recommendations, with supporting references and argument for alternative approaches to be adopted in some cases.	yes
60	Australian Environment Agency Pty Ltd	Detailed critique of the diquat environmental risk assessment and recommendations, with supporting references and argument for alternative approaches to be adopted in some cases.	yes
61	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no

Number	Organisation	Summary of issues	Published
62	N/A	Calls for ban of paraquat with claimed links to Parkinson's disease. Questions practices of regulatory science. Provides links to media articles, 1 scientific publication and a material safety data sheet for a paraquat product.	yes
63	ConsultAg	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Also notes importance of paraquat and diquat in preharvest crop desiccation.	yes
64	Cotton Australia	Detailed discussion of the implication of the proposed decisions for the cotton growing industry. Refers to the reports prepared by the Australian Environment Agency. Discusses clarity and presentation of risk mitigation statements and trade risk. Details potential economic impact on cotton industry if proposed decisions are implemented.	yes
65	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
66	Dyer Ag	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
67	Eltham Parkinson's Peer Support Group	Calls for ban on paraquat with claimed link to Parkinson's disease	yes
68	Fight Parkinson's	Calls for ban on paraquat with claimed link to Parkinson's disease, provides references to multiple scientific publications, media articles and other information.	yes
69	Not published	Raises specific concerns regarding pasture uses.	no
70	Herbert Cane Productivity Services Limited	Endorses submission made by Sugar Research Australia	yes
71	Independent Consultants Australia Network (ICAN)	Provides argument for refinement of the runoff risk assessment and survey data relevant to use of optical spot sprayers for paraquat application. Argues for retention of optical spot spraying as an approved use. Discusses possible clarifications of proposed label statements.	yes
72	Kingara Farms Pty Ltd	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes

Number	Organisation	Summary of issues	Published
73	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Supports additional restraints to protect applicator health	yes
74	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
75	Marshall Rural Holdings	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
76	National Parkinson's Alliance	Calls for ban on paraquat with claimed link to Parkinson's disease, provides references to multiple scientific publications, media articles and other information.	yes
77	Parkinson's Australia	Calls for ban on paraquat with claimed link to Parkinson's disease, provides references to multiple scientific publications, media articles and other information. Argues that international regulatory decisions should be assessed in more detail as part of the APVMA's decision.	yes
78	Poppy Growers Tasmania Inc.	Provides argument that opium poppy production in Tasmania, under licence from the State Government, has not been considered appropriately and includes information about industry practices and crop location.	yes
79	Potatoes Australia Ltd	Provides information about potato industry use of paraquat and diquat, including current practice in following the instructions on the label. Refers to environmental risk assessment completed by Australian Environment Agency Pty Ltd in arguing for changes to the proposed decisions.	yes
80	Proserpine District Canegrowers Cooperative	Writes in support of the submission made by Sugar Research Australia.	yes
81	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
82	TasFarmers	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
83	Tasmanian Agricultural Productivity Group	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes

Number	Organisation	Summary of issues	Published
84	Tooraweenah Pastoral Company	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
85	WeedSmart University of Western Australia	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
86	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
87	Not published	Questions the validity of methods used in the environment risk assessment to derive regulatory acceptable levels of exposure to paraquat.	no
88	Not published	Calls for ban of paraquat with claimed link to Parkinson's disease	no
89	Morton Agriculture Pty Ltd	Notes that paraquat is critical to current practices in the industry. Supports restraints to protect human health proportionate to the risk.	yes
90	Not published	Calls for ban of paraquat with claimed link to Parkinson's disease – 2 scientific papers referenced	yes
91	N/A	Calls for ban of paraquat with claimed link to Parkinson's disease – 1 scientific paper referenced	yes
92	Not published	Notes that paraquat is critical to current practices in the industry. Argues that further restraints are not necessary and overly burdensome.	no
93	Not published	Calls for ban based on dangers to human health	yes
94	Not published	Calls for ban based on dangers to human health	yes
95	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
96	Clinical Professor David Blacker AM	Calls for ban of paraquat with claimed link to Parkinson's disease – provides several letters of support from medical doctors and copies of scientific publications	yes
97	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Also calls for Australian specific environmental studies to be conducted, particularly with respect to optical spot spraying.	yes

Number	Organisation	Summary of issues	Published
98	N/A	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
99	Not published	Calls for ban of paraquat with claimed link to Parkinson's disease co-signed by a number of medical doctors and scientists – provides references to 16 scientific publications.	yes
100	AgForce Queensland Farmers	Provides detailed industry relevant information and argument in support of retaining several uses of paraquat and diquat, including optical spot spraying. Refers to report prepared the Australian Environment Agency Pty Ltd for supporting argument.	yes
101	AgriFutures	Endorses the submission made by the Grains Research and Development Corporation, noting the provision of alternative risk assessments for birds and mammals.	yes
102	Almond Board of Australia	Provides detailed almond industry relevant information and argument in support of retaining several uses of paraquat and diquat. In particular noting industry practices such as maintaining bare soil within the orchard to facilitate harvest. Questions the use of focal species, rather than Australian species, to assess risk of exposure to paraquat for non-target animals.	yes
103	Apple and Pear Australia Ltd.	Provides pome fruit industry relevant information and argument in support of retaining several uses of paraquat and diquat. Questions whether outcomes of human health and environment risk assessments are relevant to orchard applications.	yes
104	Architects of Arcadia	Calls for ban of paraquat with claimed link to Parkinson's disease	yes
105	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Also notes increase in withholding period for pre-harvest desiccation of pulses would affect harvestability of those crops.	no
106	Australian Grape and Wine Incorporated	Provides an overview of vineyard uses for paraquat and diquat and a detailed environment risk assessment completed by the Australian Environment Agency Pty Ltd with particular focus on birds and mammals. Endorses submission made by Australian Wine Research Institute.	yes
107	Australian Mungbean Association	Concerns regarding growers' loss of ability to control herbicide resistant weeds and to desiccate preharvest crops if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Calls for publication of full environment reports.	yes
108	Australian Wine Research Institute	Provides an overview of vineyard uses for paraquat and diquat and a detailed environment risk assessment completed by the Australian Environment Agency Pty Ltd with particular focus on birds and mammals. Provides recommendations for specific instructions compatible with risk assessment outcomes included in submission.	yes

Number	Organisation	Summary of issues	Published
109	Not published	Provides horticulture relevant information and argument for retaining specific use patterns with reference to the environmental risk assessment completed by the Australian Environment Agency Pty Ltd.	no
110	Not published	Concerns regarding growers’ loss of ability to control herbicide resistant weeds and to desiccate preharvest crops if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Also calls for increased consultation with industry and changes to legislation governing regulation of agvet chemicals in Australia.	yes
111	CBH Group	Concerns regarding growers’ loss of ability to control herbicide resistant weeds and to desiccate preharvest crops if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
112	Not published	States that evidence for a link between paraquat and Parkinson’s disease is weak. Offers recommendation for future research to address this and calls for more stringent training requirements for users of paraquat.	yes
113	Crop Consultants Australia	Provides information related to broad acre cropping systems and current practices when using paraquat and diquat. Includes data on use of optical spot sprayers. Refers to reports prepared Australian Environment Agency Pty Ltd and supports submissions made by the Grains Research and Development Corporation and Cotton Australia. Notes that closed mixing and loading technology compatible with 20L drums is available, recommends retaining these pack sizes.	yes
114	DS HM & DD Crawford	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
115	Extractas Bioscience	Provides limited poppy industry specific information. Highlights concerns regarding growers’ loss of ability to control weeds and to desiccate preharvest crops if diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
116	Fowler Farms	Concerns regarding growers’ loss of ability to control herbicide resistant weeds and to desiccate preharvest crops if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
117	GeneEthics Ltd	Provides wide ranging criticism of the proposed decisions relating to paraquat and diquat, including allegations of industry capture and lack of scientific rigour. Calls for changes to legislation and regulatory system in Australia. Calls for ban of paraquat and diquat.	yes

Number	Organisation	Summary of issues	Published
118	Grain Producers Australia	Provides extensive argument and 13 recommendations for reassessment/amendment of the paraquat and diquat review technical reports. Provides an environment risk assessment completed by the Australian Environment Agency Pty Ltd.	yes
119	Grain Producers SA	Concerns regarding growers' loss of ability to control herbicide resistant weeds and to desiccate preharvest crops if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Provides results from a grower survey highlighting role of paraquat and diquat in current practices.	yes
120	GrainGrowers Ltd	Concerns regarding growers' loss of ability to control herbicide resistant weeds and to desiccate preharvest crops if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Provides a number of recommendations to improve the review process and regarding the standard of evidence required for scientific assessments. Provides data from grower surveys related to the use of optical spot sprayers.	yes
121	Grains Research and Development Corporation	Provides extensive comments and recommendations for revision of the environment risk assessments for paraquat and diquat. Provides an environment risk assessment completed by the Australian Environment Agency Pty Ltd.	yes
122	Kalamia Cane Growers Organisation Ltd	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Supports the submission made by Sugar Research Australia. Comments on the finding of residues as a trade risk in sugarcane due to lack of data.	yes
123	Kimberley Agricultural Investment	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability.	yes
124	Lawler Farms Pty Ltd and VFF Grains Group	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Specific concerns regarding proposed increased withholding period for pulses to 14 days following spray-topping.	yes
125	Melons Australia	Provides melon-industry-specific information about current use patterns and application methods alongside argument based on risk assessment completed by the Australian Environment Agency Pty Ltd. Notes the lack of residue data available for cucurbits and argues for retaining these uses. Calls for reform of the legislation requiring consideration of the statutory criteria without a cost-benefit analysis.	yes

Number	Organisation	Summary of issues	Published
126	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
127	National Farmers Federation	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Requests the APVMA to consider risk assessment prepared by Australian Environment Agency Pty Ltd. Recommends steps to improve engagement and clarity around public consultation on the reconsideration decision making process.	yes
128	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
129	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Concerns regarding applicability of EFSA modelling to Australia.	no
130	NSW Farmers	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Provides argument to retain various use patterns based on the risk assessment prepared by the Australian Environment Agency Pty Ltd. Argues that downwind no-spray buffer zones should not be applied to paraquat and diquat products. Does not support requirements for closed mixing and loading systems or requirements for closed-cab application equipment on the basis of increased burden on small scale users in particular.	yes
131	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Provides industry relevant data on quantity of paraquat used.	no
132	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
133	Organic Operators Australia	Calls for a ban of paraquat and diquat and legislative reform to require the APVMA to adopt various regulatory measures.	yes

Number	Organisation	Summary of issues	Published
134	Pesticide Action Australia	Calls for ban of paraquat and diquat as well as legislative reform.	yes
135	Not published	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
136	Potato Processors Association of Australia	Supports submission made by Potatoes Australia.	yes
137	Queensland Cane Growers Organisation	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Endorses submission made by Sugar Research Australia, including risk assessment prepared by the Australian Environment Agency Pty Ltd.	yes
138	Not published	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Questions whether studies used to establish environmental toxicity are relevant to Australian species. Supports proposed measures to increase worker safety.	no
139	Ricegrowers’ Association of Australia Inc.	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Calls for cost-benefit analysis related to the use of paraquat and diquat in agriculture generally. Refers to environmental risk assessment of paraquat and diquat completed by the Australian Environment Agency Pty Ltd and supports the arguments for increased rates of paraquat and diquat provided therein.	yes
140	Not published	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no

Number	Organisation	Summary of issues	Published
141	Hon. Nicola Centofanti MLC – Shadow Minister for Primary Industries and Regions in the Parliament of South Australia	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Questions environmental risk assessments and provide data from the United Kingdom related to adverse events involving paraquat.	no
142	South East Premium Wheat Growers’ Association	Concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Includes concerns related to proposed restrictions on the use of diquat for pre-harvest desiccation of oilseeds and to the proposed no-spray downwind buffer zones for paraquat.	yes
143	South Pacific Seeds	Describes use of diquat as a pre-harvest desiccant. Outlines the negative impact that the proposed decision would have if this use pattern were to be removed.	yes
144	South Pacific Seeds	Second submission independent from #143 that describes use of diquat as a pre-harvest desiccant.	yes
145	Soy Australia Ltd	Outlines specific concerns regarding the potential negative impact on the soybean industry if pre-harvest desiccation of soybeans using diquat is not supported. Also lists concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Refers to environmental risk assessment of paraquat and diquat completed by the Australian Environment Agency Pty Ltd and supports the arguments for increased rates of paraquat and diquat provided therein. Highlights the issue facing many industries of lack of awareness of the need for data for contemporary risk assessments. Calls for extension of 5-10 years to allow industry to collect relevant data or develop alternative crop desiccation options.	yes
146	Sugar Research Australia Ltd	Provides several arguments related to the environment risk assessment outcomes specific to sugarcane that rely on the risk assessment completed by the Australian Environment Agency Pty Ltd. Also lists concerns regarding growers’ loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
147	Sugar Services Proserpine	Supports the submission made by sugar research Australia.	yes

Number	Organisation	Summary of issues	Published
148	Syngenta Australia Pty Ltd	Provides extensive discussion and critique of the proposed decisions for paraquat and diquat, in particular, regarding the environment and the residues and trade risk assessments. Argues that higher tier assessment of environment risks would support all current use patterns for paraquat and diquat. Supporting studies and an independent environment risk assessment were provided separately.	yes
149	Tasmanian Seed Industry Group Inc.	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Also notes specific concerns related to the proposed removal of pre-harvest desiccation of pulses and oilseeds.	yes
150	Jointly submitted by: (a) the Western Australian Farmers Federation Inc (**WAFarmers**); (b) the Pastoralist & Graziers Association of WA (**PGA**); and (c) the West Australian Grains Group (**WAGG**)	Acknowledges and supports the submission made by Grain Producers Australia and the Grains Research and development corporation, including the environment risk assessment completed by the Australian Environment Agency Pty Ltd for the GRDC. Describes concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Several recommendations regarding risk assessment methodologies and management options are discussed.	yes
151	Victorian Farmers Federation Grains Group	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects. Notes specific concerns related to the proposed removal of pre-harvest desiccation of pulses and oilseeds. Provides National Residue Survey results for paraquat in pulses to support argument for retaining crop-topping uses.	yes
152	Not published	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
153	Not published	Calls for ban of paraquat due to claimed link with Parkinson's disease. Provides references to scientific publications to support this argument.	no
154	Western AG Supplies Pty Ltd	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes

Number	Organisation	Summary of issues	Published
155	Westfield Partners	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	no
156	Yenda Producers Co-operative Society Ltd	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
157	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease.	yes
158	Organic and Regenerative Investment Cooperative	Calls for ban of paraquat due to claimed link with Parkinson's disease. Also includes a number of other recommendations, including adoption of the precautionary principle with respect to paraquat.	yes
159	N/A	Calls for immediate stop to the practice of pre-harvest desiccation using herbicides.	yes
160	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease.	no
161	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease and environmental impacts.	yes
162	N/A	Concerns regarding growers' loss of ability to control herbicide resistant weeds if paraquat and diquat were not available and consequent impact on farm business viability and the potential for unintended negative environmental effects.	yes
163	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease.	yes
164	N/A	Calls for ban of paraquat due to claimed link with Parkinson's disease. Argues that DNA damage caused by paraquat is the cause of a number of human diseases. Provides references to scientific publications to support this argument.	no
165	Not published	Supports the submission made by Potatoes Australia Ltd.	no
166	Grand Riege Organics and Growing Organics	Wide ranging critique of the APVMA and the proposed regulatory decisions for paraquat and diquat, as well as the regulatory system in general.	yes
167	Growing Organics	Wide ranging critique of the APVMA and the proposed regulatory decisions for paraquat and diquat, as well as the regulatory system in general.	yes
168	N/A	Concern that farm industry organisations do not appear to be interested in public health.	yes
169	N/A	Calls for ban of paraquat with claimed link to Parkinson's disease. Provides comments based on reanalysis of a published scientific paper that examined prevalence of Parkinson's disease in Victorian local government areas.	yes

Number	Organisation	Summary of issues	Published
170	N/A	Asserts that the state government is corrupt and ineffective, and that chemical misuse is not policed.	no
171	N/A	Various assertions about government corruption and maladministration.	no

2 General comments

2.1 Requests to improve engagement and clarity around the reconsideration process

A number of submissions, including from the National Farmers Federation, recommended that a plain English summary of the APVMA's proposed decisions would assist stakeholders to respond appropriately to public consultations. Submissions also emphasised the challenges faced by agricultural industries in responding to proposed regulatory changes that will affect their businesses, while having limited facilities or resources to provide relevant information and limited awareness of the regulatory process.

2.1.1 APVMA response

The APVMA has noted the recommendation for a summary to be published and will undertake to provide plain English summaries of technical reports as part of future reconsiderations. A plain English executive summary has also been added to the final Paraquat and Diquat Review Technical Reports.

2.2 International regulators reached different conclusions than the APVMA about the safety of paraquat

Relevant comment(s)
35, 39, 49, 59, 64, 70, 80, 100, 101, 102, 106, 108, 109, 110, 111, 113, 118, 119, 121, 122, 125, 129, 130, 137, 139, 146, 147, 150

Many submissions noted that international regulators, in particular the United States Environmental Protection Agency and the New Zealand Environmental Protection Authority, supported higher rates of paraquat and or diquat use in recent review or reregistration decisions. Commentors argued that these decisions show that the APVMA's risk assessments are too conservative and that the APVMA should also support higher rates of application.

2.2.1 APVMA response

There are various reasons why regulators in other jurisdictions may reach different conclusions about the acceptability of a chemical product compared to the APVMA which must consider the Australian context. A key reason why the US EPA and NZ EPA supported ongoing registration of paraquat at higher rates than proposed to be supported by the APVMA, despite identifying risks to birds and/or workers, is that both those jurisdictions have legislated assessment of risk versus benefit as part of their regulatory framework.

See for example the US EPA 2021 interim re-registration decision, which concluded, among other things, as follows:

> *"In evaluating potential risk mitigation for paraquat, EPA considered the risks, the benefits and the use pattern. Although there are potential risks of concern associated with the use of paraquat, with the adoption*

> *of the mitigation measures discussed in this section, any remaining potential worker and/or ecological risks are outweighed by the benefits associated with the use of paraquat."*

The Agvet Code does not provide the APVMA any ability to consider the potential benefits of a chemical product remaining registered for use in Australia and its assessment must be based upon the statutory safety, efficacy, trade and labelling criteria.

2.3 Efficacy of paraquat rates proposed by the APVMA

Relevant comment(s)
26

A submission included an argument to the effect that the proposed maximum rates would not be sufficient to control weeds.

2.3.1 APVMA response

The APVMA proposed to remove all instructions for use except for those on the currently approved label below the maximum supported application rate. The APVMA remains satisfied that use of paraquat on the weed species and at the growth stages indicated in the proposed labels is efficacious. Use of paraquat contrary to the instructions on the approved label is not authorised and the APVMA has not assessed information to determine whether use of lower rates would be effective in for control of other weeds or growth stages that are not currently on the labels for the supported rates.

2.4 Allegations of corruption, incompetency or industry capture and calls for legislative reform

Relevant comments
28, 117, 133, 166, 167, 168

A small number of submissions made wide ranging allegations of corruption, incompetency, and industry capture against the APVMA, or called for legislative reform.

2.4.1 APVMA response

The content of these submissions is not relevant to the risk mitigation measures included in the proposed regulatory decisions for paraquat or diquat, or the statutory criteria provided in the Agvet Code and as such are outside the scope of the reconsideration.

Submissions calling for legislative reform are likewise not within the remit of the APVMA and are best referred to the Australian Department of Agriculture Fisheries and Forestry.

2.5 State based use patterns

One submission requested the APVMA remove current state-specific instructions.

2.5.1 APVMA response

Many products include state specific instructions for use. It is open to holders to apply to vary these instructions, but the APVMA does not consider it appropriate to impose changes that are not required to satisfy the statutory criteria and where no relevant data is provided.

2.6 Clarity and presentation of proposed spray drift restraints

Relevant Comments
64, 121, 130

Cotton Australia commented that the spray drift restraint table is confusing and that it would be preferable if there were only a single buffer zone to make it easier for farmers to comply with.

NSW Farmers' Association argued that buffer zones should not be required because growers already demonstrate stewardship and good practice spraying minimises any risks.

Two submissions commented that the draft labels contained in the APVMA Special Gazette should include the current wording of the spray drift restraints including description of temperature inversions as "hazardous" so that the restraint reads "DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application"

2.6.1 APVMA response

Mandatory down-wind buffer zones, which provide an untreated area between the application area and any areas sensitive to the effects of pesticide spray drift are required to mitigate risks to those areas from spray drift. These have been calculated in accordance with the APVMA's spray drift policy. Spray drift restraints have been updated, where necessary, to be consistent with the APVMA's spray drift policy.

3 Environment

The headings for each response are structured as follows:

Broad theme – Relevant active(s) – Specific issue

Responses that are relevant to both paraquat and diquat are indicated by 'paraquat/diquat'. Responses related to a specific active (paraquat or diquat) cite the name of the active in the heading.

3.1 General – paraquat/diquat – environmental impacts of changes to cultivation practices and cost benefit analyses

Relevant comment(s)
11, 14, 15, 17, 24, 26, 27, 33, 34, 36, 40, 43, 44, 51, 55, 56, 57, 61, 63, 65, 66, 70, 71, 72, 73, 74, 75, 80, 81, 82, 83, 84, 85, 86, 95, 97, 105, 107, 110, 111, 114, 115, 116, 118, 119, 120, 122, 124, 126, 127, 128, 129, 130, 131, 132, 135, 137, 138, 139, 140, 141, 142, 145, 146, 147, 149, 150, 151, 152, 154, 155, 156, 162

Various comments contained claims related to the environmental impacts of changes to cultivation practices and/or cost-benefit arguments regarding economic impacts.

3.1.1 APVMA response

The legislation governing agricultural chemical products[1] does not include provisions for cost-benefit arguments concerning economic or other consequential impacts. The environmental assessment considers the risk from the registered uses of diquat/paraquat within the risk assessment framework agreed at the time of evaluation. Therefore, no further consideration of these lines of argument, be they related to environmental impacts or otherwise, has been included in the environmental risk assessment.

3.2 General – paraquat/diquat – animal damage to crops

Relevant comment(s)
70, 80, 122, 145, 146, 147

Comments received have noted that there are various vertebrate pest species[2] in Australia that require management to mitigate the damage to crops. The inference is then made that use of paraquat/diquat is not having an adverse impact on populations of Australian mammals or birds.

[1] Agricultural and Veterinary Chemicals Act 1994 and Agricultural and Veterinary Chemicals Code Act 1994

[2] E.g. native and introduced rodents, wild pigs, parrots

3.2.1 APVMA response

The presence of pest species in the Australian environment is not a basis for evaluating the impacts of pesticide use on Australian fauna. The perceived impact of pesticide use on abundant and/or situationally problematic species cannot be used to infer the impact of pesticide use on other non-target species.

3.3 General – paraquat/diquat – use of international/Australian studies

Relevant comment(s)
79

Comments claimed Australian specific data is required for risk assessment for products in Australia.

3.3.1 APVMA response

For environmental risk assessments conducted by the APVMA there is no requirement for Australian specific studies – all baseline studies used at the lower tiers of risk assessment are conducted in accordance with internationally accepted guidelines. This mechanism increases potential for adoption of products within the Australian market as applicants can use datasets that are applicable in multiple jurisdictions.

Australian specific information, where available, may be suitable to refine environmental risk assessments. All data provided to the APVMA has been considered.

3.4 General – paraquat – optical spot spraying technology (OSST)

Relevant comment(s)
11, 14, 35, 39, 49, 55, 64, 71, 100, 101, 107, 109, 111, 113, 118, 119, 120, 121, 125, 129, 130, 139, 150

Comments have been received regarding the use of optical spot spraying technologies (OSST): (1) to identify situations where it is believed that OSST was erroneously omitted from the risk assessment, and (2) to provide data indicating that actual use of OSST results in smaller treated areas than assumed in the risk assessment.

3.4.1 APVMA response

The risk assessment has been updated to more clearly reflect optical spot spray uses where they are explicitly included on product labels. Optical spot spraying is only specified for use in fallows and for treatment of up to a maximum of 30% weed cover.

Several sets of survey results have been submitted to support lower typical maximum treatment rates on a per hectare basis. The risk assessment is obliged to consider the current on-label claims. Therefore, optical spot spraying rates will be adjusted to 30% of the on-label rate to reflect the maximum weed cover that can be treated based on the current labels. Adjustment of the on-label claims (e.g. to propose lower maximum weed cover) is outside of the scope of the chemical review assessment and would need to be proposed in a separate registration application.

3.5 Risks to terrestrial vertebrates – paraquat/diquat – use of USEPA T-rex model for risk assessment

Relevant comment(s)
35

One comment presented assessments based on the USEPA T-REX model to support their conclusion for the risk to birds, specifically in relation to acute dietary exposure.

3.5.1 APVMA response

Environmental risk assessments are performed using the risk assessment approaches agreed at the time of evaluation. The APVMA currently uses the EFSA (2009) guidance, with some modifications, as the basis for risk assessment of terrestrial vertebrates. To ensure regulatory consistency it is not appropriate to selectively switch assessment frameworks. If dietary toxicity data were concluded to be relevant to the risk assessment for birds, it can be considered in the context of the EFSA (2009) risk assessment framework. Both the EFSA and USEPA approaches involve uncertainties, especially at lower tiers of evaluation, and no argument has been presented to justify selecting one approach over another. The current risk assessment approach for terrestrial vertebrates will be retained by the APVMA.

3.6 Risks to terrestrial vertebrates – paraquat/diquat – use of EFSA (2009) model for risk assessment

Relevant comment(s)
11, 26, 46, 49, 57, 61, 65, 79, 81, 97, 102, 107, 110, 120, 127, 141, 145

Comments have raised non-specific or non-actionable concerns[3] regarding the EFSA (2009) model for risk assessment of birds and mammals as it relates to the Australian environment.

3.6.1 APVMA response

Some comments received in relation to the EFSA (2009) guidance do not include specific, actionable proposals. Such comments have generally not been addressed in detail.

However, for clarity the following points regarding the use of the EFSA (2009) guidance in the context of Australia should be noted. The EFSA (2009) guidance uses a deterministic approach to establish the potential exposure, toxicity and hence effects for a range of model species. Data are required to support any quantitative refinements. This framework is considered a reasonable basis for risk assessment and is consistent with international practice for the regulation of agricultural chemicals. Refinement to account for specific features of the Australian environment can be considered if reliable data are provided to support the proposal(s).

3.7 Risks to terrestrial vertebrates – paraquat/diquat – mammalian daily energy expenditure for marsupials/monotremes

Relevant comment(s)
39, 49, 59, 60, 64, 70, 79, 80, 100, 101, 106, 108, 109, 111, 113, 118, 119, 121, 122, 125, 129, 130, 136, 137, 139, 146, 147, 150

Alternate allometric equations have been proposed for marsupials/monotremes, to replace the allometric equation for eutherian mammals used in EFSA (2009).

3.7.1 APVMA response

One of the parameters in the EFSA (2009) model for calculating dietary exposure of birds and mammals is estimation of daily energy expenditure (DEE)[4]. Different allometric equations to determine DEE are set for different groups of organisms in EFSA (2009). It is expected from the underlying source material (DEFRA 2007) that non-eutherian mammals (marsupials and monotremes) can have lower DEE than eutherian mammals. Therefore,

[3] Either; (1) no specific modification of the risk assessment scheme is proposed (e.g. to reflect specific features of the Australian environment); or (2) a feature of the risk assessment scheme is mentioned, but it is unclear how this should be modified.

[4] LogDEE (KJ/d) = Log(a) + b × Log(bw); where Log(a) and b are constants and bw is bodyweight (in grams).

lower food consumption and consequently dietary exposure are predicted, all else being equal. In EFSA (2009), equations for non-eutherian mammals are not used as they are not relevant in a European context. In the context of Australia, if marsupials or monotremes are established as relevant mammalian 'generic focal species' or 'focal species' for a particular feeding guild, use of an allometric equation for non-eutherian mammals would be justified[5].

Several allometric equations for non-eutherian mammals have been proposed in the comments received, the parameters for the different equations[6] are summarised in Table 2.

The AEA (2024) equation for all non-eutherian mammals represents the most comprehensive dataset, exhibits the best fit to the data (r^2) and predicts larger (i.e. more conservative) DEE values than the equivalent equation from DEFRA (2007). This equation will be used where DEE for marsupials/monotremes needs to be calculated in the risk assessment (see **Appendix – Environment – background information** for more information).

The AEA (2024) report has also considered subdivisions of species based on assigning species to dietary groups (herbivores, insectivores, omnivores). Regarding use of dietary groups (1) this does not improve the model fit to the data (r^2); (2) alternate assignments of species to dietary groups could be proposed; (3) the subdivisions can alternately be described as related to body weight[7] not feeding behaviour; and (4) a causal relationship between feeding group and energy expenditure has not been established. Therefore, the subdivisions based on dietary groups will not be used by the APVMA.

Table 2: Mammalian allometric equation parameters for determining DEE

Mammalian group	Reference/ source	Allometric equation parameters			Dataset	
		Log(a)	B	r^2	Total observations	No. species
Eutherian[8]	EFSA 2009	0.814	0.715	0.968	NR	46
All non-eutherian[9]	DEFRA 2007	0.957	0.593	0.958	NR	32
	AEA 2024	**1.011**	**0.589**	**0.968**	**91**	**39**
Herbivorous non-eutherian	AEA 2024	0.774	0.653	0.945	47	21
Insectivorous non-eutherian	AEA 2024	1.000	0.619	0.916	26	8

[5] The response in this section only considers the specific allometric equation to use for non-eutherian mammals. Discussion of 'generic focal species' and 'focal species' in relation to Australian native mammals is considered separately. That discussion establishes when specific allometric equations should be applied.

[6] The equation for non-eutherian mammals from DEFRA (2007) has been included by the APVMA for comparison. Allometric equations from Nagy (1987) and Nagy (1999) have been excluded from the table as the underlying data from these publications are used to fit the equations included in the table.

[7] Body weight for most insectivores is <100 g (3 observations out of 26 >100 g), for omnivores approximately 100-1230 g (1 observation out of 14 below this range), and all herbivores are between 720-61900 g.

[8] Placental mammals, excludes non-placental mammals (marsupials and monotremes) and desert dwelling and marine placental mammals

[9] Non-placental mammals, i.e. marsupials and monotremes

Mammalian group	Reference/ source	Allometric equation parameters			Dataset	
		Log(a)	B	r^2	Total observations	No. species
Omnivorous non-eutherian	AEA 2024	1.112	0.531	0.886	14	7

NR = not reported

Allometric equation parameters calculate daily energy expenditure (DEE) as: DEE (KJ/d) = 10^(Log(a) + b × Log(bw))

3.8 Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species

Relevant comment(s)
39, 49, 50, 59, 60, 64, 70, 79, 80, 100, 101, 106, 108, 109, 111, 113, 118, 119, 121, 122, 125, 129, 130, 136, 137, 139, 146, 147, 148, 150

Alterations to the EFSA (2009) guidance have been proposed to account for Australian native species, specifically changes to the generic model species defined in the EFSA guidance. The proposed changes are as described in the AEA (2024) report.

3.8.1 APVMA response

Changes to the parameters used for mammalian generic model species, as defined in the EFSA (2009) guidance, have been proposed. As a prelude to discussing the specific proposed changes it is prudent to define some contextually relevant terminology and principles of the risk assessment.

Indicator species, generic focal species and focal species: Depending on the risk assessment tier, ESFA (2009) considers entities referred to as indicator species, generic focal species or focal species (see Section 6.1.3 of EFSA 2009 for definitions). This discussion relates to the parameters for the generic focal species, which are not real species. They are a set of mathematical parameters that allow calculation of conservative exposure estimates. Those parameters are set on the basis of ecological knowledge to reflect the range of species that could be at risk – see *Risks to terrestrial vertebrates – paraquat/diquat – use of EFSA (2009) model for risk assessment* for an explanation of why the EFSA framework has been used in Australia. The parameters used for generic focal species are set and are not changed in the risk assessment. Generic focal species are part of a tiered scheme; the risk assessment failing for a generic focal species indicates that more information would be required to establish an acceptable risk whilst focusing the scope of the required information.

If further refinement is required related to species specific properties, this would require defining focal species, which are actual species known to occur in the scenario of interest (e.g. crop and growth stage). Where information has been submitted during the consultation period that may be relevant to defining focal species this has been considered separately.

Feeding guilds: Each generic focal species represents a particular feeding guild (e.g. herbivores, insectivores etc.). The feeding guilds are intended to be protective of all species that may exhibit a particular feeding behaviour/diet when foraging in the crop of interest at the relevant growth stage. To ensure a protective risk assessment considerations should include seasonal or situational changes in diet and ideally reflect the diet of animals foraging in the crop of interest – this point is made more clearly in the updated EFSA (2023) guidance (see pp. 21). For example, the herbivorous feeding guild is not restricted to obligate herbivores, it should enable a protective risk assessment for all species where a high percentage of foliage in the diet needs to be considered.

It should also be acknowledged that there is incomplete information regarding feeding behaviour and dietary preferences of Australian fauna, particularly information specific to agricultural settings. Therefore, some expert judgement or assumptions may be needed when defining the parameters relevant for a feeding guild.

The AEA (2024) report has proposed alterations to the parameters used for some generic focal species, specifically small insectivorous mammals, small herbivorous mammals and large herbivorous mammals. Proposals for each generic focal species are considered below.

Small insectivorous mammals and large herbivorous mammals: The only change proposed in the AEA (2024) report is to adjust the DEE by using an allometric equation for non-eutherian mammals (see *Risks to terrestrial vertebrates – paraquat/diquat – mammalian daily energy expenditure for marsupials/monotremes*). This is to reflect that Australian small insectivorous mammals (e.g. Dasyuridae) will be non-eutherian as will large herbivores (e.g. Macropodidae). The body weight and all other parameters for the generic focal species are unchanged from those used in EFSA (2009). These changes are a revision of the generic focal species for risk assessment and have been proposed for all crops and growth stages where the generic focal species are considered in the EFSA (2009) guidance. The implication being that accepting these changes would alter all risk assessments for all use situations that consider these generic focal species, across all the Australian mainland and Tasmania.

Use of an allometric equation for non-eutherian mammals to calculate daily energy expenditure is appropriate, as the Australian species represented by these generic focal species will be non-eutherian mammals. Comparing the DEE calculated using the allometric equations for non-eutherian and eutherian mammals, it is expected that the non-eutherian mammal equation will produce a higher DEE for an insectivorous mammal[10] and a lower DEE for a large herbivorous mammal[11]. This is a known issue in relation to risk assessment of non-eutherian mammals.

Currently the APVMA does not intend to adjust the default inputs for these generic focal species for the following reasons:

- Before revising the inputs used for the generic focal species it is appropriate to consider the full range of parameters for the generic focal species (e.g. body weight, crop groups, timing of application) and relate those parameters to the actual species intended to be addressed by the generic focal species. This is outside the scope of a chemical review consideration.
- Any change would be applicable to all risk assessments using these generic focal species and would be a change in regulatory practice.

[10] The small insectivorous mammal used in EFSA (2009) has a body weight of 9.7 g. At all body weights less than approximately 35 g the non-eutherian mammal allometric equation results in a larger DEE than the eutherian mammal equation.

[11] The large herbivorous mammal used in EFSA (2009) has a body weight of either 1543 or 3800 g. Regardless of the precise body weight assumed for the generic focal species, at all body weights greater than approximately 35 g the non-eutherian mammal allometric equation results in a smaller DEE than the eutherian mammal equation.

- Reconsideration of the generic focal species is more appropriately placed in the context of a revision of the guidance document, rather than an ad hoc proposal as part of a chemical review, and there should be opportunity for public consultation on any proposed changes to established risk assessment practices.
- Generic focal species are a screening tool to establish if more information or further consideration is required to demonstrate an acceptable risk. They do not represent a real species and need not mirror reality to be fit for purpose. The default parameters for the generic focal species in EFSA (2009) are sufficient in that context.
  - For large herbivorous mammals the EFSA (2009) defaults are expected to substantially over-estimate DEE. From the perspective of identifying if a refined risk assessment is required the default values are fit for purpose.
  - For small insectivorous mammals the EFSA (2009) defaults may underestimate DEE, by about 15% at a body weight of 9.7 g (see **Appendix – Environment – background information**). However, the risk assessment at this tier is relatively conservative such that the implied underestimation does not inherently mean the risk assessment is not fit for purpose. This also maintains consistency in decision making in comparison to existing assessments at this tier of risk assessment.

Until there is opportunity to fully revise the guidance for Australian conditions, refinement of DEE for non-eutherian mammals will be conducted on a case-by-case basis when the default generic focal species indicate an unacceptable risk. In the context of the risk assessment for diquat this means that the DEE refinement will need to be considered for the large herbivorous mammal only. As the risk assessment is being adjusted to reflect native mammals body weight should also be reconsidered – the body weight assumptions in EFSA (2009) reflect rabbits (1543 g) and hares (3800 g) neither of which are native Australian species. The AEA (2024) report makes no proposals regarding alternate body weights to reflect Australian fauna and uses the same body weight assumptions as EFSA (2009). Comprehensive information regarding the occurrence of potentially relevant species in the crops under assessment is not available. For simplicity a single body weight, 1500 g, will be considered for all situations where large herbivorous mammals are included in the risk assessment. For a Tier-1 risk assessment this is considered a reasonably conservative value[12]. If the risk is concluded to be unacceptable on this basis, applicants/holders have the option of conducting additional analyses of potentially relevant species that may occur in situations of interest or generating data to identify relevant focal species to support refining the body weight.

Small herbivorous mammals: The AEA (2024) report has proposed that this feeding guild should be removed entirely. It is argued that the potentially relevant Australian species are all rodents and that all small rodents in Australia should be considered omnivorous. Therefore, the risk assessment for the generic focal species ‘small omnivorous mammal’ can be considered protective of Australian rodents and it is not necessary to consider a fully herbivorous diet. This conclusion is then applied to all use situations (crops, application timings etc.) across all of Australia.

This proposal poses two linked questions: (1) can a primarily herbivorous diet be excluded for all situations, and (2) can the omnivorous feeding guild be considered protective of small rodents if the small herbivorous mammal feeding guild is removed.

[12] 1500 g is at the lower end of estimated average body weights for macropods, which are expected to be obligate herbivores. There are other marsupials which may situationally both include substantial fractions of plant material in their diet and have lower body weights. These other species should be considered further if the Tier-1 risk assessment does not result in an acceptable risk. But the proposed body weight is considered a reasonably conservative assumption at this tier of assessment.

There are 58 extant[13] rodent species in Australia all in the family Muridae (see *Appendix – Environment – background information* for the full list of species), this figure includes some non-native rodents[14]. The AEA (2024) report refers to Watts & Kemper (1989) to support the argument that all Australian rodents should be assumed to be omnivorous, and no other literature is cited to support the argument. In the absolute/strict sense an omnivorous diet can be assumed for essentially all Australian rodents, but as discussed above the risk assessment should account for situational/seasonal variability in dietary requirements. Watts & Kemper (1989) makes clear that there are exemptions to the omnivorous diet assumption, with some rodent species having anatomical adaptations suited to diets consisting of large amounts of plant material be that foliage and/or seeds. The underlying studies cited in Watts & Kemper (1989) also indicate that plant material other than seeds forms a substantial fraction of the diet of some Australian rodents[15]. Other studies from the open literature also contradict the premise that herbivory can be ignored for Australian rodents (Cheal 1987, Carron 1990) and it is understood that some species of *Melomys* should be considered effectively herbivorous for the purpose of risk assessment. Other submissions received during consultation also undermine the claim that a substantial herbivorous component to the diet can be rejected for all rodents in all circumstances (i.e. *Rattus sordidus*, Wilson & Whisson 1993). However, this is not intended as a comprehensive or systematic analysis of the full literature on Australian rodent diets. It is simply an illustration that herbivorous diets cannot be assumed to be absent for the purposes of risk assessment; at least not based on the limited supporting information provided to justify disregarding the feeding guild. It is also acknowledged that there are limitations to the literature cited, for example: faecal analysis can bias the estimated volumes of different dietary components, the data indicate there are seasonal variations in diet composition, the data do not directly measure the diet of animals in an agricultural settings, and the literature does not comprehensively account for the presence/absence of any of the species in agricultural situations (or particular crops).

Small omnivorous mammals, in all situations other than the bare soil scenario, are assumed to have a diet composition of 25% foliage, 50% weed seeds and 25% invertebrates (EFSA 2009). Increasing the foliar diet component will increase the estimated exposure of the generic focal species (see *Australian rodent species and implications for generic focal species* for a comparison of different dietary assumptions). Due to the high residues associated with foliar food items if a diet of approximately 100% foliage is assumed then even large rodents (500 g) would not be protected by a risk assessment for the small omnivorous mammal. The available information implies that in some situations there are Australian rodents that will consume greater than 25% of their diet as foliage and potentially substantially more. Therefore, the small omnivorous mammal cannot be assumed to be protective of all rodents in all situations.

The change to the generic focal species proposed does not consider situational relevance of the small herbivorous mammal[16], nor does it consider or provide evidence to support alternate dietary compositions of the small

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[13] Based on the Australian Faunal Directory (https://biodiversity.org.au/afd/home)

[14] i.e. *Mus musculus*, *Rattus exulans*, *Rattus norvegicus*, *Rattus rattus*

[15] Watts (1977) – Based on faecal pellets, stems and leaves in the diet were reported to exceed 50% by volume for *Rattus tunneyi*, *Rattus villosissimus*, *Rattus sordidus*, *Rattus colletti*, *Rattus lutreolus*, *Pseudomys nanus*, and *Pseudomys gracilicaudatus*. For some species stems and leaves were >80% of the diet.

Watts & Braithwaite (1978) – Based on faecal pellets, stems and leaves in the diet were reported to exceed 50% by volume for *Rattus lutreolus* and *Pseudomys shortridgei*.

[16] For example, it might be possible to reconsider the relevance of small herbivorous mammals based on the geographic extent of crop growing regions and the distributions of potentially relevant species.

omnivorous mammal. The proposal is for a universal alteration of the generic focal species used for risk assessment in Australia. Removing the small herbivorous mammal and relying on the small omnivorous mammal cannot be justified as a default assumption based on the currently available information.

Case-by-case consideration of specific situations may be able to justify modifications to the default assumptions for the generic focal species, be that dietary composition or relevance of a particular feeding guild. But this should be supported by argument and/or data relevant to the specific situation. Where relevant argument/data has been submitted during consultation it will be considered further in relation to that specific use in the risk assessment.

The available information does not support a blanket removal of the small herbivorous mammal. However, no direct analogue of the vole used to parameterise the generic focal species in EFSA (2009) has been identified amongst Australian rodents. Species which may be considered herbivorous for the purpose of the risk assessment are all ≥50 g, approximately, whilst the default generic focal species in EFSA (2009) is assumed to be 25 g. Ideally, refinement of generic focal species is best considered outside the context of a chemical review consideration. But this conclusion regarding the relevant body weight can be justified based on the current discussion of Australian small herbivorous mammals. Therefore, the body weight for the small herbivorous mammal will be adjusted to 50 g as a refinement of the risk assessment.

3.9 Risks to terrestrial vertebrates – paraquat/diquat – crop interception

Relevant comment(s)
118, 119, 148, 150

It has been proposed that the crop interception values used in the risk assessment for terrestrial vertebrates should be updated to reflect EFSA (2020).

3.9.1 APVMA response

Where relevant and necessary to resolve the risk, crop interception values from EFSA (2020) have been used to refine the risk assessment for terrestrial vertebrates.

3.10 Risks to terrestrial vertebrates – paraquat/diquat – dehusking behaviour of small mammals

Relevant comment(s)
148

Dehusking behaviour in small mammals has been proposed as a non-quantitative refinement for granivorous/ omnivorous species. Analysis by Brühl et al. (2011) and the Northern Zone (2020) are cited to support this qualitative argument.

3.10.1 APVMA response

No quantitative refinement for the risk assessment has been proposed and specific data related to Australian species are not cited. But the proposal that dehusking behaviour is also relevant to Australian species and could substantially reduce exposure for granivorous/omnivorous species has been considered further as a weight-of-evidence argument.

3.11 Risks to terrestrial vertebrates – paraquat/diquat – attractiveness of bare soil situations to small mammals

Relevant comment(s)
148

Data for the European wood mouse (*Apodemus sylvaticus*) (Prosser 2010) has been cited as part of a qualitative argument for limited use of bare fields by Australian rodent species.

3.11.1 APVMA response

No quantitative refinement for the risk assessment has been proposed and specific data related to Australian species are not cited. However, the cited information has been considered further as a weight-of-evidence argument, regarding rodent foraging behaviour in bare soil scenarios.

3.12 Risks to terrestrial vertebrates – paraquat/diquat – combination toxicity assessment

Relevant comment(s)
49, 59, 60, 64, 101, 106, 111, 113, 118, 119, 121, 130, 150

It has been questioned whether the full range of uses have been evaluated in terms of the combination toxicity assessments.

3.12.1 APVMA response

The APVMA revisited the combination toxicity assessments to confirm whether they are consistent with the assessments for the individual active substances (paraquat and diquat)[17], and updated the risk assessment as needed. It should be noted that the proposed regulatory decisions review technical reports only included evaluations of those use patterns where the risk for both individual actives had been determined to be acceptable, on the basis that higher rates would not be supported.

[17] Only the combination of paraquat and diquat has been considered at present

3.13 Risks to terrestrial vertebrates – paraquat/diquat – wildlife incident monitoring data

Relevant comment(s)
39, 49, 64, 81, 100, 101, 106, 109, 110, 111, 113, 118, 119, 121, 125, 129, 130, 136, 137, 138, 139, 141, 150

Comments received have made note of international wildlife incident reports, either as a general statement without specific references or by reference to specific reports. It has been stated and/or implied that this information should be interpreted as indicating a low risk from registered uses of diquat. The number of incidents reported under the APVMA Adverse Experience Reporting Program (AERP) has also been queried.

3.13.1 APVMA response

Monitoring data and incident reports are typically of limited value in the context of environmental risk assessment. They may establish that adverse effects have occurred, but they cannot exclude the occurrence of adverse effects nor reliably establish the frequency or impact of any effects. There is no monitoring data related specifically to diquat, and monitoring data for paraquat is not considered a reliable basis for decision making in the risk assessment – being at best low value anecdotal information that could possibly be considered in a weight-of-evidence argument.

3.14 Risks to terrestrial vertebrates – diquat – mammalian oral toxicity studies

Relevant comment(s)
148

A revision of the acute RAL for mammals has been proposed based on newly submitted studies (McCall & Robinson 1990, Johnson 2003, Pooles 2008).

3.14.1 APVMA response

The RAL (12 mg ac/kg bw) originally set by the APVMA was based on the data available when drafting the RTR (Rittenhouse 1979)[18]. During consultation attention was drawn to a study testing the active substance (McCall & Robinson 1990) and two newly submitted formulation studies (Johnson 2003, Pooles 2008). These studies are summarised in Table 3.

It has been argued that the new studies justify using an LD_{50} of 207.5 mg ac/kg to calculate the RAL. This proposal is consistent with the endpoint established in the EFSA (2015) assessment of diquat. However, the EFSA

[18] This is a non-GLP study conducted before the introduction of current guidelines for mammalian acute toxicity tests.

assessment used a different set of studies to reach this conclusion; specifically McCall & Robinson (1990) and another formulation study that is not currently available to the APVMA.

Neither of the two newly submitted formulation studies establish accurate LD_{50} estimates, due to the design of the test guideline which is intended to be sufficient for establishing hazard classifications. No argument has been presented to reject the endpoint from Rittenhouse (1979). Therefore, there is some uncertainty regarding the available toxicity estimates and some data used in the EFSA evaluation is missing. On balance given the nature of the available evidence and for consistency with international evaluations, the APVMA agrees to use an LD_{50} of 207.5 mg ac/kg, rather than calculating a geomean endpoint from either all or a subset of the available studies. Therefore, with an assessment factor of 10 the revised acute RAL for risk assessment is 21 mg ac/kg bw.

Table 3: Diquat – Mammalian oral acute toxicity studies

Test species	Test item	Test guideline	Toxicity value[19]	95% CI	Reference
Rattus norvegicus	Diquat dibromide	OECD 401	Male, LD_{50} 214 mg ac/kg bw	180-271	McCall & Robinson 1990
			Female, LD_{50} 222 mg ac/kg bw	203-241	
			Geomean LD_{50} 218 mg ac/kg bw		
	Formulation	Non-guideline	LD_{50} 120 mg ac/kg bw	60-230	Rittenhouse 1979
		OECD 425	LD_{50} 110 mg ac/kg bw	25-786	Johnson 2003
		OECD 425	LD_{50} 210 mg ac/kg bw	110-400	Pooles 2008

3.15 Risks to terrestrial vertebrates – diquat – avian oral toxicity studies

Relevant comment(s)
148

It has been proposed to use four acute oral toxicity studies to set the RAL for the bird acute risk assessment. Three of the studies were used in the original APVMA assessment (Fink et al. 1982, Hubbard 2013, Roberts & Farley 1980). One additional study (Hernádi 2008) has also been proposed for use – this study was reviewed in the EFSA (2015) evaluation of diquat.

3.15.1 APVMA response

The study Hernádi (2008) has not been submitted to the APVMA; a proprietary study that the APVMA does not have access to. Therefore, the APVMA has used the information available in its holdings to determine an appropriate regulatory endpoint, and the acute RAL for birds (7.0 mg ac/kg bw) has not been changed.

[19] All toxicity values are reported in terms of the active constituent which is defined as the diquat cation

3.16 Risks to terrestrial vertebrates – diquat – avian dietary toxicity studies

Relevant comment(s)
35, 39, 49, 60, 64, 70, 80, 100, 101, 106, 108, 109, 111, 113, 118, 119, 121, 122, 125, 129, 130, 136, 137, 139, 146, 147, 148, 150

It has been proposed to use short-term/sub-acute dietary toxicity studies to establish a refined RAL for the acute risk assessment of birds, rather than relying on the single oral dose studies.

3.16.1 APVMA response

For birds, the Diquat Review Technical Report included four dietary toxicity endpoints derived from the same study (Hill et al. 1975). The acute RAL for birds was based on the endpoints from acute oral toxicity studies[20] (avian acute RAL 7.0 mg ac/kg bw). It has been proposed that the dietary toxicity endpoints should be used to set a RAL for the acute risk assessment.

The underlying study (Hill et al. 1975) does not include food consumption data. It has been proposed that food consumption data from control groups in other similar studies should be used as a baseline estimate of the food consumption in the treatment groups. Depending on the specific submission different amounts of historic control data were provided and then used to either set endpoints for singular species or as a geomean LD_{50}. It has been argued that dietary toxicity endpoints should be preferred for risk assessment for the following reasons:

- Acute oral studies are based on a single dose, whilst under field conditions exposure to an active substance will reflect the feeding pattern during the day (Moore et al. 2014).
- When feeding throughout the day birds will have time to detoxify and/or eliminate the active substance, potentially reducing the peak dose and any toxicological impacts.
- Adsorption of pesticides through the gastro-intestinal tract can be less efficient in the presence of food items compared to the dosing situation in acute oral toxicity studies (Lehman-McKeeman 2008).

However, there are both general issues with dietary toxicity studies and specific issues with the available information in the Hill et al study, that should be considered in relation to the reliability of the proposed dietary toxicity endpoints:

- The inherent scientific limitations of avian dietary toxicity studies have been noted in prior reviews and guidance documents (EFSA 2007, EFSA 2009, USEPA 2020), and include:
  - Reduced food consumption and/or early mortality of exposed birds can complicate interpretation of the results.
  - Individual consumption cannot be established due to wastage and housing of birds in groups.
  - Food avoidance cannot be simply extrapolated to field conditions, due to differences in food matrixes and feeding pressure.

[20] Studies based on the OECD 223 guideline, or a similar experimental approach

  - Food consumption may vary between the laboratory and field scenarios due to differences in energy expenditure of birds and variation of assimilation efficiency between food matrixes.

- The results of dietary toxicity studies are not inherently considered refinements of avian toxicity. In the EFSA (2009) guidance, dietary exposure may be considered on a case-by-case basis, either as part of a weight-of-evidence argument or a quantitative refinement where cumulative exposure is expected to be a more sensitive endpoint, such as with the anticoagulant rodenticides.
- Hill et al. (1975) does not report time to death or food consumption data. It cannot be assumed that control group food consumption rates will provide a conservative estimate of food consumption amongst exposed birds. Impaired food consumption compared to controls is a reasonable expectation for exposed birds, either due to the toxicological effects of diquat exposure and/or due to reduced palatability of the treated food.
- The most sensitive species based on acute oral toxicity tests was the zebra finch (*Taeniopygia guttata*). Neither this species, nor any other small passerine bird, were included in the suite of species tested via dietary exposure.
- It was argued that when consumed with food diquat absorption may be reduced compared to oral toxicity studies. No new information specific to diquat has been submitted to support this claim. Diquat is rapidly but poorly absorbed following oral dosing in rats, 4-11% of the oral dose being absorbed (APVMA 2024, EFSA 2015). When dosed via gavage, as diquat absorbed to wheat chaff, diquat was excreted at low levels in urine (2.2-4.2%) with the remainder excreted in faeces (JMPR 2013).
- During consultation, it has been argued that detoxification/elimination may affect peak exposure and hence toxicity for animals foraging under natural conditions. No new information specific to diquat was submitted to support this claim. Absorbed diquat is rapidly excreted, primarily in urine (>90% within 96 hours, EFSA 2015). There is limited metabolism of diquat, with most absorbed residues being unaltered prior to excretion (EFSA 2015, JMPR 2013). It is not clear how this would translate to effects under field conditions.

Given the limitations of the Hill et al. (1975) study, the available dietary endpoints when expressed as a dose (i.e. mg ac/kg bw/d) cannot be considered sufficiently reliable for use in risk assessment – the primary issue is the lack of information regarding food consumption in the treatment groups. Therefore, the avian acute RAL for risk assessment is unchanged and will be based on the acute oral toxicity studies (RAL 7.0 mg ac/kg bw), not the dietary toxicity.

3.17 Risks to terrestrial vertebrates – diquat – energy content of oil-rich seeds

Relevant comment(s)
148

It has been proposed that the estimated energy content and assimilation efficiency can be adjusted for birds which consume oil rich seeds, based on the review by Gutiérrez-Expósito et al. (2024). This refinement would apply to small granivorous/insectivorous birds feeding in sunflower crops at BBCH 61-92.

3.17.1 APVMA response

Gutiérrez-Expósito et al. (2024) represents a review of data related to the energy content, moisture content and assimilation efficiency of several high oil content seeds (castor bean, linseed, mustard, oilseed rape, peanut, safflower, sesame, soybean and sunflower). There is a full set of measured values for sunflowers: energy content (mean 26.82 KJ/g dw), moisture content (mean 6.69%) and assimilation efficiency (mean 80.42 %) for passerine birds[21]. It was recommended to refine the risk assessment for sunflowers using this information, as the assessment at BBCH 61-92 considers a passerine bird with a diet of 100% crop seeds.

The premise of the risk assessment at Tier-1 is that the model organisms meet their daily energy requirements by consuming food items from the treated area, but no consideration is made for consumption in excess of their daily energy requirements. Use of the information in Gutiérrez-Expósito et al. (2024) is consistent with this premise and will be accepted in this case for use with sunflowers as there is a complete set of information (energy content, moisture content and assimilation efficiency). Though it is noted, this does not address any food preferences or other behaviour that may cause increased consumption of sunflower seeds.

3.18 Risks to terrestrial vertebrates – diquat – refined residue per unit dose (RUD) values, oilseeds

Relevant comment(s)
148

Refined RUD values have been proposed for some specific scenarios:

- RUD values for the dietary component 'crop leaves' of oilseed rape (maximum 37.1 mg/kg, 90th percentile 26.6 mg/kg). It has been proposed that the maximum value be used, and in the current assessment this refinement would only be applicable to the large herbivorous mammal generic focal species for the crop group oilseeds.
- RUD values for crop seeds shortly before harvest (90th percentile for cereals 18.96 mg/kg, for sunflowers 1.67 mg/kg, for oilseed rape 14.68 mg/kg, for pulses 1.33 mg/kg). It has been proposed that these values be used to refine the risk assessment for small granivorous/insectivorous birds in sunflower (BBCH 61-92) and cereals (late season/seed heads).

3.18.1 APVMA response

The underlying studies used to derive the refined RUD values do not appear to have been submitted to the APVMA. Therefore, the APVMA cannot fully evaluate the reliability of the proposed RUDs.

For the crop leaf RUD refinement, 31 trials have been identified where diquat was applied and residues on whole plants, leaves or the remaining plant were measured. These trials were in a range of crops (kohlrabi, soybean, lettuce, bean, broad-bean, and kale) and at a range of growth stages at the time of application. As noted in the comments received, EFSA (2009, Appendix F) does identify the possibility of refining RUD values by providing

[21] The same information is also available for mammals and galliform birds, but only passerine birds require refinement in the current risk assessment.

additional measured residue data for a particular compound. However, it is also necessary to fully justify why new residues data should be used to override the existing database and a comprehensive argument to this effect has not been made.

For the crop seed RUD refinement, the submitted information (Nopper et al. 2023) indicates that the proposed RUDs for cereals are based on 24 independent data points from 2 active substances: for sunflowers 6 independent data points from 2 active substances; for oilseeds 11 independent data points from 4 active substances; and for pulses 132 independent data points from 15 active substances. The data consistently indicate that the default RUD used in EFSA (2009) for all seeds (i.e. 90^{th} percentile 40.2 mg/kg) is conservative compared to the measurements for crop seeds (90^{th} percentiles of 18.96, 1.67, 14.68 and 1.33 mg/kg), although it is also noted that for some crops, particularly for sunflowers, the dataset is small.

For both refinements the data imply the RUD used in risk assessment is conservative for some scenarios. However, additional argument and access to the underlying studies would be needed to confirm the reliability of the conclusions. Therefore, at present it is not possible to reach a definitive conclusion with respect to revising the RUD values, and no change to the quantitative risk assessment will be made.

3.19 Risks to terrestrial vertebrates – diquat – residue decline and DT_{50}

Relevant comment(s)
60, 148

Queries were raised about use of refined DT_{50} values, and the calculation method for multiple application factors (MAF).

3.19.1 APVMA response

Regarding refined DT_{50} values, the APVMA has established refined DT_{50} values of 2.2 d for insects, 1.6 d for foliage and 7.9 d for seeds. These values can be used to refine the exposure estimate when the food items are part of the modelled diet; DT_{50} values are relevant to the MAF for acute risk assessments, or the MAF and/or the time weighted average factor for long-term risk assessments. In the assessments presented in the original chemical review report, refinement based on the DT_{50} was considered where relevant. In any updated risk assessment the refined DT_{50} values will be considered if necessary and useful to establish an acceptable risk.

Regarding the MAF calculation, the EFSA (2009) guidance uses different multiple assessment factor equations for acute (90^{th} percentile MAF) and long-term (mean MAF) risk assessments. Current practice by the APVMA is to only calculate a mean MAF to establish the cumulative application rate for both aspects of the risk assessment (acute and long-term). For consistency with existing practice no change will be made in the current assessment.

3.20 Risks to terrestrial vertebrates – paraquat – avian dietary toxicity studies

Relevant comment(s)
35, 39, 49, 59, 64, 100, 101, 106, 108, 109, 111, 113, 118, 119, 121, 125, 129, 130, 136, 137, 139, 148, 150

It has been proposed to use short-term/sub-acute dietary toxicity studies to establish a refined RAL for the acute risk assessment of birds, rather than relying on the single oral dose studies.

3.20.1 APVMA response

For birds, the Paraquat Review Technical Report included four dietary toxicity endpoints derived from the same study (Hill et al. 1975). In that report the APVMA did not rely on those endpoints to set the acute RAL for birds, instead, it relied on endpoints from acute oral toxicity studies[22] to establish an avian acute RAL of 5.7 mg ac/kg bw. It has been proposed that the dietary toxicity endpoints should be used to set a RAL for the acute risk assessment.

The underlying study (Hill et al. 1975) does not include food consumption data. In the APVMA report the endpoints were presented as doses (mg ac/kg bw/d); these were converted from the concentration in the food (mg ac/kg feed) using a default conversion factor (0.1). It has been proposed that food consumption data from control groups in other similar studies should be used as a baseline estimate of the food consumption in the treatment groups; this is to account for the age of the birds in the dietary toxicity study, as the default conversion factor used by the APVMA is applicable to older birds. Depending on the specific submission different amounts of historic control data were provided and then used to either set endpoints for singular species or as a geomean LD_{50}. It has been argued that dietary toxicity endpoints should be prioritised for setting the RAL for risk assessment for the following reasons:

- Acute oral studies are based on a single dose, whilst under field conditions exposure to an active substance will reflect the feeding pattern during the day (Moore et al. 2014).
- When feeding throughout the day birds will have time to detoxify and/or eliminate the active substance, potentially reducing the peak dose and any toxicological impacts.
- Adsorption of pesticides through the gastro-intestinal tract can be less efficient in the presence of food items compared to the dosing situation in acute oral toxicity studies (Lehman-McKeeman 2008).

However, there are both general issues with dietary toxicity studies and specific issues with the available information that should be considered in relation to the reliability of the proposed dietary toxicity endpoints:

- The inherent scientific limitations of avian dietary toxicity studies have been noted in prior reviews and guidance documents (EFSA 2007, EFSA 2009, USEPA 2020), and include:
  - Reduced food consumption and/or early mortality of exposed birds can complicate interpretation of the results.
  - Individual consumption cannot be established due to wastage and housing of birds in groups.
  - Food avoidance cannot be simply extrapolated to field conditions, due to differences in food matrixes and feeding pressure.
  - Food consumption may vary between the laboratory and field scenarios due to differences in energy expenditure of birds and variation of assimilation efficiency between food matrixes.

[22] Studies based on the OECD 223 guideline, or a similar experimental approach

- The results of dietary toxicity studies are not inherently considered refinements of avian toxicity in the EFSA (2009) guidance. They may be considered on a case-by-case basis, either as part of a weight-of-evidence argument or a quantitative refinement.
- Hill et al. (1975) does not report time to death or food consumption data. It cannot be assumed that control group food consumption rates will provide a conservative estimate of food consumption amongst exposed birds. Impaired food consumption compared to controls is a reasonable expectation for exposed birds, either due to the toxicological effects of paraquat exposure[23] and/or due to reduced palatability of the treated food.
- The most sensitive species based on acute oral toxicity tests was zebra finch (*Taeniopygia guttata*). Neither this species, nor any other small passerine birds, were included in the suite of species tested via dietary exposure.
- During consultation, it was argued that when consumed with food, paraquat absorption may be reduced compared to oral toxicity studies. No new information specific to paraquat has been submitted to support this claim. Mammalian toxicological studies imply that even for orally dosed toxicity studies paraquat absorption is limited (10 to 18% adsorbed; APVMA 2024, JMPR 2004). However, comparable information for paraquat absorption following dietary exposure has not been identified.
- During consultation, it was argued that detoxification/elimination may affect peak exposure and hence toxicity may reduce for animals foraging under natural conditions. No new information specific to paraquat was submitted to support this claim. Based on observations of mammals and birds, metabolism of absorbed paraquat is expected to be limited (JMPR 2004, APVMA 2016). Excretion via faeces and urine is expected to occur relatively rapidly and will be the major route of elimination of paraquat for both mammals and birds (JMPR 2004, APVMA 2016). However, it is not clear how this would translate to effects under field conditions, nor has it been established if dose reciprocity can/cannot be assumed for short-term (acute) exposure to paraquat.

Given the limitations of the Hill et al. (1975) study, the available dietary endpoints when expressed as a dose (i.e. mg ac/kg bw/d) cannot be considered sufficiently reliable for use in risk assessment – the primary issue is the lack of information regarding food consumption in the treatment groups. This conclusion is unchanged from the APVMAs original assessment. Therefore, the avian acute RAL for risk assessment is unchanged from that provided in the Review Technical Report and will be based on the acute oral toxicity studies (RAL 5.7 mg ac/kg bw), not the dietary toxicity study.

3.21 Risks to terrestrial vertebrates – paraquat – residue decline and DT_{50}

Relevant comment(s)
59, 148

Queries were raised about the use of the refined DT_{50} values and the calculation method for multiple application factors (MAF).

[23] Symptoms in humans following oral exposure include vomiting, abdominal pain, nausea, diarrhoea, ulceration of the oral and/or pharyngeal mucosa and gastrointestinal tract, irritability, dyspnoea, and tachycardia (APVMA 2024).

3.21.1 APVMA response

Regarding refined DT_{50} values, for insect food items the APVMA has established a DT_{50} of 4.6 d[24]. This value can be used to refine the exposure estimate when this food item is part of the modelled diet; DT_{50} values are relevant to calculating the MAF for acute risk assessments, or the MAF and/or the time weighted average factor for long-term risk assessments. In the assessments presented in the original chemical review report it was either (1) not necessary to consider this refinement as an acceptable risk could already be established, or (2) the refinement would not be able to resolve the risk. Therefore, for simplicity the outcomes of using this refinement were not explicitly presented. In any updated risk assessment the refined DT_{50} will be considered where necessary.

Regarding the MAF calculation, the EFSA (2009) guidance uses different multiple assessment factor equations for acute (90th percentile MAF) and long-term (mean MAF) risk assessments. Current practice by the APVMA is to only calculate a mean MAF to establish the cumulative application rate for both aspects of the risk assessment (acute and long-term). For consistency with existing practice, no change will be made in the current assessment.

3.22 Risks to aquatic organisms – diquat – Kf for exposure modelling

Relevant comment(s)
60

The choice of K_f and K_p values used in the runoff exposure model has been questioned. Comments received have noted there isn't a strong relationship ($r^2 = 0.093$) between clay content and log(K_f) and therefore questioned the cut-off of 10% clay content in soil. It has also been queried if the mean K_f values are protective given the range of values in the dataset. The choice of K_p for sediment has also been queried.

3.22.1 APVMA response

The regulatory data used to set endpoints (K_f / K_p) for risk assessment are summarised in Table 4. The 2024 Diquat RTR set mean K_f values of 2932 mL/g (1/n 0.63) and 11298 mL/g (1/n 0.78) for soils with ≤10% clay or >10% clay, respectively. The mean K_p for sediment was 136759 mL/g.

Freundlich adsorption constants (K_f) are available for 13 soils (Dixon & Gilbert 2012b, Mônego 2005, Pack 1987). Plotting the available log(K_f) values against clay content does not indicate a strong correlation between a linear regression and the available data ($r^2 = 0.093$). A relationship between clay content and absorption capacity of soils is however indicated by other studies for diquat (Ferguson et al. 1994)[25] and paraquat (Dyson et al. 1994), i.e. the

[24] Some submissions have attributed the DT_{50} of 4.6 d to the seed component of the diet. This is incorrect, for paraquat a refined DT_{50} is only available for insect food items.

[25] A summary of this study can be found in EFSA (2015). The reported K_d estimates provide supporting information for a relationship between clay content and absorption capacity of soils. The K_d values cannot be directly compared to the Freundlich adsorption constants (K_f) as they are extrapolated from SAC-WB bioassays, nor is concentration dependant absorption considered for the soils tested. Therefore, the study has not been used to set endpoints for risk assessment in the current evaluation.

estimated K_d at a soil's SAC-WB[26] concentration increases with soil clay content, although with high variability around the linear regression.

For soils with a low capacity to absorb diquat, a risk from runoff following repeated annual applications cannot be excluded – though it is the case that many soils have the capacity to absorb hundreds of years of applications of diquat at registered use rates and a risk from runoff for such soils would not be expected. The diquat draft RTR used a criterion of 10% clay to simplistically differentiate between soils, as the data supports a weak relationship between clay content and absorption capacity, and to ensure that the risk assessment considers soils with low capacity to absorb diquat.

There are no agreed assumptions for soil or sediment clay content for exposure modelling, and as noted above there is considerable variability in the K_f even in relation to soil clay content. Therefore, the K_f and K_p values originally proposed by the APVMA for exposure assessment aimed to establish a conservative runoff assessment at the screening stage, including some simplifying assumptions given the uncertainties. It should be noted that the approach is only intended to identify at the screening stage whether additional consideration is required, i.e. in the event that an acceptable risk is not concluded.

As noted during consultation the mean K_f for soils with <10% clay (2932 mL/g) is not necessarily reflective of soils with a low capacity to absorb diquat – the mean is heavily weighted by a single value for a loam soil and is greater than the 50th percentile (1519 mL/g) of all values in the dataset. Alternative approaches to setting a screening stage K_f are available (e.g. geomean, percentile of the data, lowest value). The aim is to establish reasonably conservative parameters for risk assessment, not necessarily to identify an absolute worst-case. However, establishing how conservative any value is would require information regarding how the proposed parameters relate to actual Australian soils, which is not available. The submission recommended to use the geomean K_f (349 mL/g) and 1/n (0.59) values from soils with a clay content ≤10% at the screening stage. However, it is noted that this may underestimate runoff for soils in the dataset with the lowest capacity to absorb diquat (10th percentile of all 13 tested soils K_f 62 mL/g and 1/n 0.47).

For sediment exposure the default screening approach is based on equilibrium partitioning between the water phase and the sediment[27]. A definition of a reasonable worst-case scenario for diquat accumulation in sediment is absent. Experimental observation indicates that the majority of diquat in solution will rapidly partition to sediment (Fujie 1988), and the screening level runoff risk assessment should reflect this unless additional information allows more realism for specific circumstances. There is a small selection of adsorption estimates for sediment. The mean value based on the available studies (136759 mL/g) was recommended for use in risk assessment. In the default screening stage assessment this is considered reasonably conservative as it will result in a significant fraction of the diquat in solution being associated with the sediment. This is consistent with experimental observations and is considered sufficient for the purposes of a screening level assessment.

[26] SAC-WB (strong adsorption capacity – wheat bioassay) - A system of calibration by laboratory bioassay for the capacity of a soil to deactivate paraquat by adsorption. Measured as the soil concentration (mg cation/kg dry soil) at which 50% reduced root growth is observed in wheat seedlings. This is approximately equivalent to the soil concentration which, at equilibrium, results in a soil pore water concentration of 0.01 mg/L.

[27] $PEC(sediment) = PEC(water) \times (0.8 + (0.2 \times K_p / 1000 \times 2400)) / 1280 \times 1000$

Table 4: Diquat – adsorption/desorption

Study	Result				Reference
Adsorption/ desorption	Soil	% clay	Kf	1/n	
	Loam	12	144	0.59	Dixon & Gilbert 2012b
	Sandy clay loam	25	9011	0.89	
	Silty clay	39	12932	0.93	
	Sandy loam	19	70308	1.06	
	Sandy clay loam	46	507	0.56	Mônego 2005
	Clay	61	1519	0.69	
	Sand	10	910	0.68	
	Sandy loam	21	484	0.59	
	Sand	2	36	0.40	Pack 1987
	Sand	4	42	0.45	
	Sandy clay loam	21	4895	0.94	
	Loam	9	10740	1.00	
	Sandy loam	13	1882	0.75	
	~~Mean Kf 2932 mL/g, 1/n 0.63 for ≤10% clay~~ Geomean Kf 349 mL/g, 1/n 0.59 for ≤10% clay ~~Mean Kf 11298 mL/g, 1/n 0.78 for ≤10% clay~~ Geomean Kf 2517 mL/g, 1/n 0.76 for >10% clay				
	Sediment	% clay/silt	Kf	1/n	
	Fine	54.8	400809	1.41	Mônego 2005
	Coarse	3.8	9452	1.02	
	Sand	4.0	15	0.52	Pack 1987
	Mean Kf 136759 mL/g, 1/n 0.98				

3.23 Risks to aquatic organisms – diquat – regulatory acceptable level for primary producers

Relevant comment(s)
60, 87

Three linked queries have been made in relation to the RAL for aquatic primary producers:

- The sources of information used in the assessment and the scope of any literature review have been queried, along with the criteria for evaluation for the endpoints quoted in the diquat draft RTR.
- Further justification of the use of the time-weighted-average (TWA) adjustment has been requested.

- Clarification of the methods used to derive the HR_5 for primary producers and the assessment factor has been requested.

3.23.1 APVMA response

The studies considered in the environmental risk assessment are those in the APVMAs holdings at the time of the chemical review assessment, after requesting data from the relevant holders.. All studies available in the APVMA's holdings have been assessed for scientific relevance and reliability either by the APVMA[28] or another international regulatory authority.

All the studies used to establish endpoints for risk assessment fit one of four categories:

- Published studies available in the public literature. Reliability/relevance of the studies was considered by the APVMA.
- Unpublished studies already evaluated by another international regulatory authority, the conclusions of which were accepted, and further evaluation by the APVMA was not required.
- Unpublished studies already evaluated by another international regulatory authority, for which further evaluation was required by the APVMA.
- Unpublished studies without evaluation by another international regulatory authority. These studies were evaluated by the APVMA.

Commenters have identified additional information from the open literature, i.e. Emmett (2002). However, this is not a primary source of information. The APVMA would need the underlying studies to consider their reliability, and the APVMA cannot consider studies that are not in its holdings.

Use of adjusted (TWA) toxicity values by the APVMA to establish the RAL for aquatic animals and primary producers has been queried. Diquat can rapidly partition to sediment and/or suspended particulates (Ford et al. 2012, Mônego 2006b), limiting the exposure via water (DT_{50} in water 0.50 d). This partitioning behaviour is not observed in standard toxicity tests, which lack sediment/suspended particulates, and in which hydrolysis and photolysis are either not expected or result in much slower dissipation. The TWA adjustment is used to reflect the

[28] The APVMA uses the following data rating system. It should be noted that these ratings are derived from the OECD. Some allowances are made in addressing the validity of a non-GLP study that was well reported and conducted according to sound scientific practices. Therefore, a degree of expert judgement has been used in applying the validity rankings associated with studies assessed.

1) Fully reliable: GLP compliant and fully compliant with the Test Guideline specified.
2) Reliable with restrictions: GLP compliant but not fully compliant with the Test Guideline specified, but nevertheless judged to provide a reliable basis for regulatory decision-making. Also non-GLP and/or non-standard studies that are judged to be reliable for the purpose conducted.
3) Not reliable: Not GLP compliant and/or not compliant with the Test Guideline specified, and judged to not provide a reliable basis for regulatory decision-making.
4) Not assignable: Insufficient information provided to allow the reliability of the test or study report to be assessed (e.g. published literature).

expected behaviour of diquat under natural conditions where lower average exposure concentrations are expected, given the same starting concentration, due to rapid dissipation in the presence of sediment.

The APVMA spray drift and first tier runoff exposure estimates are expressed as peak, not average, exposure. Therefore, RALs can be based on toxicity values back calculated to the equivalent peak exposure, i.e. the adjusted (TWA) toxicity values calculated by the APVMA[29]. Use of this approach to TWA adjustment can be justified when the underlying toxicity endpoints are based on average exposure estimates (e.g. either mean measured endpoints or nominal endpoints where the test substance concentration was maintained within ±20% of the initial exposure concentration). The specific endpoints used to establish the RALs for aquatic animals and primary producers are considered fit for deriving adjusted (TWA) endpoints for the following reasons:

- **Aquatic animals** – The endpoint from the study used to set the RAL (Bender 2006a) is based on initial measured concentrations, and there was no confirmation of the exposure concentration at the end of the test. However, other similar acute studies with aquatic invertebrates (Hoberg 1987, Volz 2004, Dionne 1987) and fish (Paul et al. 1994, Nicholson 1987) indicate little to no dissipation of diquat under similar test conditions and exposure durations. Therefore, whilst there is uncertainty over the actual behaviour of diquat in Bender (2006a) the other supporting information implies that the diquat concentration should be stable. Therefore, the endpoint is considered equivalent to a mean measured concentration despite the uncertainty.
- **Primary producers** – The endpoints for primary producers are either based on mean measured concentrations (Smyth et al. 1998a, Smyth et al. 1998b, Magor & Shillabeer 2001) or the concentration was maintained within ±20% of the initial exposure concentration (Smyth et al. 1998c). The report for Nagai (2009) does not clearly establish if nominal or mean measured endpoints were used for each species but based on the published methods all the endpoints can be considered to reflect average exposure concentrations. Therefore, all the endpoints used to set the RAL for primary producers are considered suitable for TWA adjustment.

The RAL for primary producers has been set based on a species sensitivity distribution (SSD); use of SSDs is consistent with international regulatory practice. However, the APVMA guidance for aquatic organisms[30] does not fully describe the use of SSDs to determine an RAL. Current practice is to use an assessment factor of 1 with the HC_5 to set the RAL, and for primary producers the E_rC_{50} is the preferred endpoint if available[31]. If there are endpoints to the left of the HC_5 (i.e. more sensitive than) it may be necessary to consider using the lower 95% CI of the HC_5 to ensure a protective risk assessment, given that the assessment factor is 1. Comments have noted that, consistent with EFSA (2013a), an assessment factor of 3 was used in the assessment of diazinon for an SSD. Given the precedent there is a basis to consider altering the assessment factor in this case.

For clarity and transparency the APVMA has recalculated the HC_5 using shinyssdtools[32] (version 0.4.0), see the aquatic risk assessment in the diquat final RTR. The assessment factor has also been considered further in relation to the updated SSD, see the aquatic risk assessment in the diquat final RTR.

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[29] TWA adjustments are typically applied to the exposure value, rather than toxicity. However, this approach is used by the APVMA for simplicity in aligning exposure and toxicity.

[30] https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals/environment/appendix-b

[31] If not available an E_yC_{50} or other EC_{50} value can be used instead.

[32] Dalgarno (2021) https://bcgov-env.shinyapps.io/ssdtools/

It should be noted that if the additional information from Emmett (2002) was to be included the resulting HC_5 estimate would be similar to the HC_5 derived from the current regulatory dataset[33]. Therefore, the additional information would only has a limited influence on the RAL for risk assessment, and as such the current dataset can be considered a reasonable basis for decision making.

3.24 Risks to aquatic organisms – diquat – runoff risks

Relevant comment(s)
39, 49, 60, 71, 101, 111, 113, 118, 119, 121, 130, 148, 150

The assumptions of the assessment for runoff have been questioned.

3.24.1 APVMA response

An explanation to the approach to assessment is included below, for three elements of the runoff assessment: (1) exposure estimation for residues in solution at the screening stage, (2) the relevance of diquat absorbed to soil particles in runoff, and (3) the issues related to estimating the risk for sediment dwelling organisms.

1. It has been noted during consultation that the runoff scenario for the screening stage is based on a clay dominated soil profile (Queensland)[34]. This is inconsistent with the risk assessment for diquat where the primary source of concern is expected to be soils with low clay content, which are expected to have a lesser capacity to absorb diquat. However, the standard assumptions/parameters of the screening stage assessment will remain unchanged. The screening stage uses a conservative set of assumptions to identify situations where further, higher tier, consideration is required. It is still considered fit for purpose in that regard, noting that for diquat the assessment is arguably more conservative than is typical for other substances because of this issue. If an acceptable risk cannot be established at the screening stage higher tiers of runoff assessment can be conducted, where alternate soil profiles and other features can be considered.

   Diquat exhibits concentration dependent absorption, because of the finite capacity of any given soil to strongly absorb diquat. This property of diquat is inconsistent with the standard approach to runoff risk assessment at screening stage, in addition to uncertainty over the scenario(s) to consider. The original runoff exposure assessment was parameterised to establish a conservative runoff assessment at the screening stage, including simplifying assumptions given the uncertainties. To better account for the expected behaviour of diquat a revised set of inputs are proposed.

   The inputs for exposure modelling that account for absorption of diquat, i.e. the K_f and 1/n values, are discussed in *Risks to aquatic organisms – diquat – Kf for exposure* modelling and are not considered further

[33] The HC_5 from the regulatory dataset, without TWA modification, is 0.00069 mg ac/L (95% CI 0.000008-0.010) (see Section 3.3). If the endpoints related to growth rate from Emmett (2002), for species not already represented in the regulatory dataset, were included in the dataset a HC_5 of 0.00082 mg ac/L (95% CI 0.000042-0.0048) can be calculated. Without evaluating the underlying studies and without a full literature review this comparison cannot be considered definitive and is only intended to illustrate the potential impact of the data cited during consultation.

[34] https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals/environment/appendix-b (see attachment 2, section 3.1)

here. An additional consequence of the absorption behaviour of diquat is that the degradation rate is expected to differ depending on the state of diquat – strongly absorbed diquat will undergo little to no degradation, whilst diquat in solution will be available for more rapid degradation. A DT_{50} of 1000 d has been used as an estimate of degradation of diquat residues in solution, where microbial degradation is expected to occur; this is a default value for persistent substances. It is expected that this DT_{50} would underestimate the persistence of any strongly bound residues. For diquat the available DT_{50} estimates in field soils range between 1.2 to 41 years (Cole et al. 1991, Dyson et al. 1995a, 1995b, Dyson & Chapman 1991). However, it should be noted that these DT_{50} values were obtained using multi-compartment degradation kinetics and for the values from the UK (DT_{50} 11 to 41 years) the r^2 values were relatively low (r^2 0.44 to 0.65). Despite these limitations and noting the ostensibly biphasic degradation observed in the studies, to ensure a conservative approach to estimating accumulation of residues in soil it is proposed to use the longest field soil DT_{50} (41 years) to represent the persistence of strongly bound residues in soil.

2. With regard to diquat absorbed to soil particulates in runoff, the properties of diquat imply that residues bound to clay particles are not biologically available. Freely available diquat (i.e. in pore water or overlying water) is the fraction that is primarily expected to contribute to toxicity estimates for sediment dwelling organisms, not the total concentration in the sediment. Any fraction of diquat in runoff that is absorbed to soil clay particles will not increase the freely available concentration of diquat, as it is bound to the clay particles. Therefore, diquat absorbed to soil particles in runoff is assumed to be irrelevant in terms of the exposure assessment. Only residues of diquat in solution within the runoff are expected to be relevant to the risk assessment.
3. For sediment dwelling organisms, the toxicological data are limited in that they reflect the properties of the test system. As such, the data reflect the capacity of the test sediment to absorb diquat and this will not necessarily be reflective of other sediments or the modelled exposure; given that diquat strongly absorbed to clay particles will not be biologically available, and higher capacity to absorb diquat will lead to greater concentrations in the bulk sediment but not necessarily more adverse toxicological outcomes. It is arguably more appropriate to evaluate the risk based on the concentration in the pore water. This will be considered further in the risk assessment if necessary.

3.25 Risks to aquatic organisms – paraquat – Kd/Kf for exposure modelling

Relevant comment(s)
59

The choice of K_d and K_p values used in the runoff exposure model has been questioned.

3.25.1 APVMA response

Paraquat's behaviour in soil has been well studied, see Sartori & Vidrio (2018), Roberts et al. (2002) and USEPA (2019) for a more expansive discussion of the available literature. In brief, the absorption of paraquat to soil is very strong, with soils having differing capacities to absorb paraquat largely in proportion to their clay content, although other factors can also markedly influence this relationship. For many soils this capacity will be equivalent to hundreds of years of applications of paraquat at the approved use rates. However, for soils with lower absorption capacity this may be tens of years, at least in situations where interception by plant foliage is limited. Strongly absorbed paraquat is expected to be highly stable (DT_{50} 6.6-20 years) and biologically unavailable. Paraquat in solution, e.g. where a soil's absorption capacity has been exceeded, is expected to be biologically available and can be subject to more rapid degradation. At soil concentrations where paraquat is primarily associated with the solid fraction of the soil matrix, the K_d will be undefined as the fraction in solution is too low to measure. At soil concentrations near to or exceeding the capacity of the soil to absorb paraquat the K_d will be definable and will exhibit concentration dependence; in these scenarios lower K_d values will be recorded with increasing concentrations of paraquat (1/n 0.19 to 0.41, USEPA 2019).

The studies available to the APVMA for estimating K_d are summarised in Table 5. Dyson et al. (1994) reports the K_d based on the SAC-WB concentration[35,36] for 242 soils, while Robbins et al. 1988 reports the K_d at a range of concentrations for four soils. The results are not directly comparable given the same baseline is not used in both studies. It can be stated that the sand soil with a clay content of 2% in Robbins et al. (1988) would have a lower SAC-WB concentration than any of the soils in Dyson et al. (1994) (lowest reported SAC-WB 11 mg ac/kg ds). Additionally, it should be noted that the reported relationship with clay content (Dyson et al. 1994) indicates there is considerable variability in K_d for the same clay content, with K_d varying by up to a factor of approximately 10 between the minimum and maximum observed values for any given percentage of clay in soil. Due to the calculation method, all the K_d values from Dyson et al. (1994) are only applicable when the concentration of paraquat in solution within the soil is 0.01 mg ac/L, while all the values from Robbins et al. (1988) reflect higher concentrations of paraquat in solution. Freundlich isotherms, along with the associated K_f and 1/n values, have been established for a small number of soils in Thailand (Amondham et al. 2006), in the submitted information. One soil (number 6) appears to have a relatively low absorption capacity; there is no measured SAC-WB value for this soil for direct comparison with the other studies but based on the K_f and 1/n the SAC-WB would be estimated at 46 mg ac/kg ds (i.e. the soil concentration where the concentration in solution is predicted to be 0.01 mg ac/L).

There are no agreed assumptions for soil or sediment clay content for exposure modelling, and as noted above there is considerable variability in the K_d even after accounting for clay content. The standard approach to runoff risk assessment at screening stage is poorly applicable because of the properties of paraquat, and there is uncertainty over the approach(es) to consider. Therefore, the K_d and K_p values originally proposed by the APVMA for exposure assessment were set to establish a conservative runoff assessment at the screening stage, including some simplifying assumptions given the uncertainties. It should be noted that this approach is only intended to identify at the screening stage whether additional consideration is required, i.e. if an acceptable risk is not concluded.

Soil K_d – In the draft RTR, the APVMA set two values, one for sand soils (K_d 480 mL/g, clay content assumed to be ≤10%) and one for non-sand soils (K_d 9400 mL/g, clay content assumed to be >10%). The K_d 480 mL/g is the lowest reported value for any soil with a clay content of ≤10%. This is a highly conservative approach and does not reflect all the data. To account for the full set of observations the 1.0th and 10th percentile of K_d values for soils with a clay content ≤10% has been determined[37], i.e. 1100 and 2250 mL/g respectively. Furthermore, given the inconsistency between the standard approach to risk assessment, the properties of paraquat, and the nature of the

[35] SAC-WB (strong adsorption capacity – wheat bioassay) - A system of calibration by laboratory bioassay for the capacity of a soil to deactivate paraquat by adsorption. Measured as the soil concentration (mg cation/kg dry soil) at which 50% reduced root growth is observed in wheat seedlings. This is approximately equivalent to the soil concentration which, at equilibrium, results in a soil pore water concentration of 0.01 mg/L.

[36] Dyson et al. (1994) calculates K_d based on the equation $K_d = Cs/Cl$, where Cs (concentration in soil) is the measured SAC-WB concentration for a given soil and Cl (concentration in solution) is assumed to be 0.01 mg/L.

[37] This calculation uses all K_d values from Dyson et al. 1994 for soils with ≤10% clay content including peat soils where the clay content was undefined. The K_d values for soils with ≤10% clay content from Robbins et al. 1988 not been included in the data set as they are not reported in terms of the SAC-WB value and are not directly comparable.

available data, a modified version of the risk assessment has been applied using the information from Dyson et al. (1994) and Amondham et al. (2006) (see *Risks to aquatic organisms – paraquat – runoff risks*).

Sediment K_p – The risk assessment for sediment is limited both by uncertainty over the properties to assume for modelling exposure in sediment (discussed above) and the by the toxicological data (see *Risks to aquatic organisms – paraquat – regulatory acceptable level for sediment dwellers*). The APVMAs standard approach to exposure calculation for sediment[38] is based on equilibrium partitioning between the dissolved phase and the sediment using a fixed value of K_p – it is acknowledged that this is not well suited to the properties of paraquat. The sediment K_p value has been set by taking the maximum K_d (50000 mL/g) reported in Robbins et al. 1988. This is simply a conservative value to establish a modelling scenario where a substantial fraction of the paraquat in solution is associated with the sediment. This is not intended to define the properties of the modelled sediment, as there are no defined default assumptions for this situation and the toxicological data (see *Risks to aquatic organisms – paraquat – regulatory acceptable level for sediment dwellers*) impose assumptions on the risk assessment. It is simply to reflect the experimental information that indicates paraquat quickly dissipates from the water column and accumulates in sediment, at least when the sediment retains some capacity to absorb paraquat.

Table 5: Paraquat – Adsorption/desorption

Study	Result					Reference
Adsorption/ desorption	Soil	Clay content (%)	Soil concentration (mg ac/kg ds)	Aqueous concentration (mg ac/L)	K_d (mL/g)	Robbins et al. 1988
	Loam	21	999.5	0.0240	42000	
			799.7	0.0160	50000	
			>9.9	<0.0075	>1300	
	Loamy sand	8	149.5	0.0255	5900	
			>99.9	<0.0075	>13000	
	Silty clay loam	29	498.2	0.0930	5400	
			299.4	0.0320	9400	
			>9.9	<0.0075	>1300	
	Sand	2	30.9	0.455	68	
			18.2	0.090	200	
			9.6	0.020	480	
			>0.85	<0.0075	>110	
	$\log_{10} K_d = (1.32 \times \log_{10} \% \text{ clay}) + 2.84$ at the SAC-WB concentration of the soil, based on data from 242 soils					Dyson et al. 1994
	Soil	Clay content (%)	K_f (µL/g)[39]	1/n		
	1	46	787	0.247		
	2	33	844	0.274		
	3	59	709	0.261		
	4	67	513	0.281		
	5	49	868	0.193		
	6	8.7	17.9	0.412		
	7	31	337	0.328		
	8	29	1095	0.204		Amondham et al. 2006

[38] $PEC(sediment) = PEC(water) \times (0.8 + (0.2 \times K_p / 1000 \times 2400)) / 1280 \times 1000$

[39] These K_f values are based on conversion between mg ac/kg ds and µg ac/L, exposure calculations should be adjusted accordingly (K_f values for risk assessment are typically based on conversion between mg ac/kg ds and mg ac/L)

3.26 Risks to aquatic organisms – paraquat – regulatory acceptable level for primary producers

Relevant comment(s)
59, 87

Three linked queries have been made in relation to the RAL for aquatic primary producers:

- The sources of information used in the assessment and the scope of any literature review have been queried, along with the criteria for evaluation of the endpoints quoted in the RTR.
- Further justification of the use of the time-weighted-average (TWA) adjustment has been requested.
- Clarification of the methods used to derive the HR_5 for primary producers and the assessment factor has been requested.

3.26.1 APVMA response

The studies considered in the environmental risk assessment are those in the APVMA's holdings at the time of the chemical review assessment, after requesting data from the relevant holders. All studies available in the APVMA's holdings have been assessed for scientific relevance and reliability either by the APVMA[40] or another international regulatory authority.

The studies used to establish endpoints for risk assessment fit one of four categories:

- Published studies available in the public literature. Reliability/relevance of the studies was considered by the APVMA.
- Unpublished studies already evaluated by another international regulatory authority, the conclusions of which were accepted, and for which further evaluation by the APVMA was not required.
- Unpublished studies already evaluated by another international regulatory authority, for which further evaluation was required by the APVMA.

[40] The APVMA uses the following data rating system. It should be noted that these ratings are derived from the OECD. Some allowances are made in addressing the validity of a non-GLP study that was well reported and conducted according to sound scientific practices. Therefore, a degree of expert judgement has been used in applying the validity rankings associated with studies assessed.

1) Fully reliable: GLP compliant and fully compliant with the Test Guideline specified.
2) Reliable with restrictions: GLP compliant but not fully compliant with the Test Guideline specified, but nevertheless judged to provide a reliable basis for regulatory decision-making. Also non-GLP and/or non-standard studies that are judged to be reliable for the purpose conducted.
3) Not reliable: Not GLP compliant and/or not compliant with the Test Guideline specified and judged to not provide a reliable basis for regulatory decision-making.
4) Not assignable: Insufficient information provided to allow the reliability of the test or study report to be assessed (e.g. published literature).

- Unpublished studies without evaluation by another international regulatory authority. These studies were evaluated by the APVMA.

Commenters have identified additional information from the open literature, i.e. Fairchild et al. (1997)[41], Schrader et al. (1997)[42] and Michel et al. (2004)[43]. These studies do not indicate if the tested species are particularly sensitive/insensitive, and they are not considered sufficiently reliable to include in the set of regulatory endpoints for risk assessment.

Use of adjusted (TWA) toxicity values by the APVMA to establish the RAL for primary producers has been queried. Paraquat is expected to rapidly partition to sediment and/or suspended particulates (Long et al. 1996, Hamer & Ashwell 1997), limiting the exposure via water. Due to the limitations of the available information related to the fate of paraquat in water a DT_{50} of 7 days has been set, though this is considered a conservative estimate. This partitioning behaviour is not observed in standard toxicity tests, which lack sediment/suspended particulates, and in which hydrolysis and photolysis are either not expected or result in much slower dissipation of paraquat. Non-standard exposure of algae in the presence of sediment (Smyth & Shillabeer 2000)[44] supports the prediction that sediment will reduce exposure/toxicity via the water – though this study was not considered suitable to set an endpoint for use in risk assessment, as the exposure was not reflective of a reasonable worst-case scenario due to unquantified amounts of sediment suspended in solution. The TWA adjustment is used to reflect the expected behaviour of paraquat under natural conditions where lower average exposure concentrations are expected, given the same starting concentration, due to dissipation in the presence of sediment. However, the DT_{50} (7 d) limits the impact of this refinement on the RAL.

The APVMA spray drift and first tier runoff exposure estimates are expressed as peak, not average, exposure. Therefore, RALs can be based on toxicity values back calculated to the equivalent peak exposure, i.e. the adjusted (TWA) toxicity values calculated by the APVMA[45]. Use of this approach to TWA adjustment can be justified when the underlying toxicity endpoints are based on average exposure estimates (e.g. either mean measured endpoints or nominal endpoints where the test substance concentration was maintained within ±20% of the initial exposure concentration). There are limitations to the reliability of some of the studies, and expert judgement has been used to support retaining some endpoints and applying the TWA refinement, noting that the

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[41] The study by Fairchild et al. (1997) reports results related to biomass, not growth rate, for both *Raphidocelis subcapitata* and *Lemna minor*. More importantly the study does not indicate that there was any analytical verification of the treatment concentrations. Therefore, the study is not considered sufficiently reliable to set an endpoint for use in risk assessment, particularly given that there are already more reliable endpoints for both species in the regulatory dataset.

[42] The study by Schrader et al. (1997) reports results related to the growth rate of *R. subcapitata* and *Oscillatoria chalybea*; neither species is indicated to be more sensitive than other algae in the existing regulatory dataset. However, the study does not indicate that there was any analytical confirmation of the treatment concentrations. There is also limited information to allow comparison with the validity criteria for standard guidelines. Therefore, the study is not considered sufficiently reliable to set an endpoint for use in risk assessment.

[43] The study by Michel et al. (2004) reports results related to the growth of *Lemna paucicostata*; the species is not indicated to be more sensitive than other aquatic plants in the existing regulatory dataset. Furthermore, there is no analytical verification of the treatment concentrations, and the study is not considered suitable to include in the regulatory dataset.

[44] Under standard laboratory conditions *Navicula pelliculosa* E_rC_{50} is estimated to be 0.00034 mg ac/L (Smyth et al. 1992b). In the presence of sediment E_rC_{50} >0.29 mg ac/L (Smyth & Shillabeer 2000).

[45] TWA adjustments are typically applied to the exposure value, rather than toxicity. The APVMA approach is used for simplicity in aligning exposure and toxicity.

TWA refinement is based on a conservative DT_{50} estimate and paraquat is typically expected to be relatively stable under standard laboratory toxicity test conditions.

Table 6 summarises the studies in the regulatory dataset and includes notes on substantive issues/uncertainties with the studies, responses in relation to concerns raised regarding specific studies, and justifications for use of the TWA refinement.

The RAL for primary producers has been set based on a species sensitivity distribution (SSD); use of SSDs is consistent with international regulatory practice. However, the APVMA guidance for aquatic organisms[46] does not fully describe the use of SSDs to determine a RAL. Current practice is to use an assessment factor of 1 with the HC_5 to set the RAL, and for primary producers the E_rC_{50} is the preferred input value if available[47]. Depending on the distribution of endpoints within the SSD it may be necessary to consider using the lower 95% CI of the HC_5 to ensure a protective risk assessment, given that the assessment factor is 1. Comments have noted that, consistent with EFSA (2013a), an assessment factor of 3 was used in the assessment of diazinon for an SSD. Given the uncertainty in the underlying endpoints used for the SSD (Table 6) there is a basis to consider altering the assessment factor in this case.

For clarity and transparency the APVMA has recalculated the HC_5 using shinyssdtools[48] (version 0.4.0), see the aquatic risk assessment in the paraquat final RTR. The assessment factor has been considered further in relation to the updated SSD, see the aquatic risk assessment in the paraquat final RTR.

Table 6: Paraquat – Effects on primary producers

Group	Species	Toxicity value	Reference	Notes
Algae	*Navicula pelliculosa*	E_rC_{50} 0.00034 mg ac/L	Smyth et al. 1992b	Nominal endpoint. Limited analytical verification during the study. Stock solutions did not exhibit significant loss of test item under test conditions, but there was no verification of the test solution concentrations. The endpoint has been retained due to apparent sensitivity of test species despite the limitations of the study. Uncertainty in use of the TWA refinement is noted, along with inherent uncertainty over base endpoint, but applied for consistency with the rest of the dataset.
	Anabaena flos-aquae	E_rC_{50} 0.0078 mg ac/L	Smyth et al. 1992c	Mean measured endpoint. TWA adjustment is appropriate.
	Chlamydomonas reinhardtii	~~E_rC_{50} 0.0056 mg ac/L~~	Tanaka et al. 2011	Included in error. Removed from dataset.
		EC_{50} 0.043 mg ac/L	Cheloni & Slaveykova 2021	Nominal endpoint with no analytical verification reported in the study. The results are based on biomass (E_bC_{50}) not growth rate, of which growth rate would be the preferred endpoint. Study retained as supporting information for Jamers & de Coen 2010.

[46] https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals/environment/appendix-b

[47] If not available an E_yC_{50} or other EC_{50} value can be used instead.

[48] Dalgarno (2021) https://bcgov-env.shinyapps.io/ssdtools/

Group	Species	Toxicity value	Reference	Notes
		E_rC_{50} 0.048 mg ac/L	Jamers & de Coen 2010	Nominal endpoint with no analytical verification reported in the study. The E_rC_{50} has been adjusted to reflect the paraquat ion concentration, rather than paraquat dichloride. Whilst analytical verification should normally be available the study has been retained as there is supporting information from Cheloni & Slaveykova 2021, that implies the reported endpoint is a reasonable approximation of the E_rC_{50}. Uncertainty in use of the TWA refinement is noted but applied for consistency with the rest of the dataset.
	Geomean E_rC_{50} 0.045 mg ac/L			
	Raphidocelis subcapitata	E_rC_{50} 0.20 mg ac/L	Smyth et al. 1990a	Mean measured endpoint. TWA adjustment is appropriate.
		E_rC_{50} 0.23 mg ac/L	Smyth et al. 1992a	Mean measured endpoint. TWA adjustment is appropriate.
		E_rC_{50} 0.20 mg ac/L	Scheerbaum 2007b	Mean measured endpoint. TWA adjustment is appropriate.
		~~E_rC_{50} 0.48 mg ac/L~~	Grillo et al. 2015	On review endpoint removed from dataset. Due to lack of reported analytical verification of test concentrations and the availability of several more reliable endpoints.
		E_rC_{50} 0.26 mg ac/L	Smyth et al. 1990b	Mean measured endpoint. TWA adjustment is appropriate.
	Geomean E_rC_{50} 0.22 mg ac/L			
	Chlorella vulgaris	E_rC_{50} 0.53 mg ac/L	Baltazar et al. 2014	Paraquat concentration indicated to be stable during the test. TWA adjustment is appropriate.
	Skeletonema costatum	E_rC_{50} 5.9 mg ac/L	Smyth et al. 1992d	Mean measured endpoint[49]. TWA adjustment is appropriate.
Aquatic plants	*Lemna minor*	E_rC_{50} 0.015 mg ac/L	Tagun & Boxall 2018	Concentration maintained within ±20% of initial concentration. TWA adjustment is appropriate.
	Lemna gibba	E_rC_{50} 0.031 mg ac/L	Mohammad et al. 2010	Nominal endpoint. No analytical confirmation of the treatment concentrations. However, the independent experiments were each conducted twice, which provides some insurance against potential errors in initial dosing. The study is retained in the dataset as supporting information for Smyth et al. (1992e).
		EC_{50} 0.037 mg ac/L E_rC_{50} 0.047 mg ac/L	Smyth et al. 1992e	Analytical measurements were limited due to interference in the HPLC analysis. Therefore, there were measured concentrations for only 4 of 8 treatment groups in fresh solutions on day 8 and aged solutions on day 14. These results did not indicate significant dissipation of the test item, though they cannot be considered fully reliable. The study was retained as there was supporting

[49] This is correct based on the study report, despite what might be inferred from other sources. Mean measured concentrations in all treatment groups are within ±20% of nominal.

Group	Species	Toxicity value	Reference	Notes
				information from Mohammad et al. 2010 indicating similar endpoints. Uncertainty in use of the TWA refinement is noted but applied for consistency with the rest of the dataset. An E_rC_{50} has been estimated during the consultation period. This value has been adopted in place of the EC_{50} to enhance the consistency of the endpoints used in to establish the SSD.
	Geomean E_rC_{50} 0.038 mg ac/L			

Post consultation changes are highlighted in yellow

3.27 Risks to aquatic organisms – paraquat – regulatory acceptable level for sediment dwellers

Relevant comment(s)
59

The RAL for sediment dwellers has been queried given the properties of paraquat and the differences in clay content between the studies.

3.27.1 APVMA response

As discussed in relation to the K_d value (see *Risks to aquatic organisms – paraquat – Kd/Kf for exposure modelling*), paraquat is strongly bound to soils/sediments and in this form paraquat is very stable and not expected to be biologically available. But for each soil/sediment the absorption capacity is related to the clay content. Above this absorption capacity the behaviour of paraquat changes, i.e. there becomes potentially more rapid degradation/dissipation and more biologically available paraquat as the concentration increases. This behaviour impacts the interpretation of the toxicity studies.

The reliable toxicity data available for sediment dwellers exposed to paraquat and some notes regarding the studies are included in Table 7. The absorption capacity of the tested sediments is unknown. Lower clay content to a degree will be associated with a lower absorption capacity. Non-expanding forms of clay, such as the kaolin clay used in some studies, are understood to have a more limited capacity to absorb paraquat. Given the variability of absorption capacity between soils/sediments (Dyson et al. 1994), knowing the clay content is not a particularly precise basis from which to infer properties of the test system or extrapolate results to other situations. The differences in the test sediments complicate comparison of the relative sensitivity of the tested species – the observed effects are a function of the specific exposure system and the relative sensitivity of the organisms to different routes of exposure (pore-water, overlying water, sediment).

For the most sensitive species *Hyalella azteca* (Bradley 2015a), the nominal treatment concentrations were 6.3, 13, 25, 50 and 100 mg ac/kg ds. Statistically significant effects on survival were only observed at 50 and 100 mg ac/kg ds (16 and 0% survival respectively). Unfortunately, defined concentrations in pore water and overlying water were only established for the 6.3 and 100 mg ac/kg ds treatment groups (Table 7). Therefore, the relationship between survival and routes of exposure other than the bulk sediment (e.g. concentrations in pore-water and/or overlying water) are uncertain. The concentration in porewater as a geometric mean of the reported values at 6.3 and 100 mg ac/kg ds would be 0.041 mg ac/L.

At the treatment levels of 6.3 and 100 mg ac/kg ds, the exposure of *Leptocheirus plumulosus* (Bradley 2015b) is indicated to be lower, based on measured porewater concentrations, than for *H. azteca*. *Chironomus dilutus* (Bradley 2015c) had similar average exposure to *H. azteca* via measured porewater concentrations, indicating lower sensitivity to paraquat; chronic toxicity studies on *Chironomus riparius* also indicate that other chironomids are less sensitive than *H. azteca*.

Ideally for risk assessment, an estimate of the absorption capacity of the tested sediment would be known. Also, it should be possible to reliably define the toxicological effect of exposure to paraquat in different states, i.e. the concentration in sediment and the concentration in solution (porewater concentration). This is not currently the case for the available studies. The LC_{50} from Bradley (2015a) is used to set the RAL (3.9 mg ac/kg ds, with an assessment factor of ten). The risk assessment will therefore reflect the conditions in the test, and comparison with this value implies that the same conditions apply to any exposure estimate used in risk assessment.

Table 7: Paraquat – Effects on sediment dwellers

Group	Exposure	Species	Toxicity value	Reference	Notes
Sediment-dwellers	Acute	*Hyalella azteca*	LC_{50} 39 mg ac/kg ds	Bradley 2015a	Dose response study with 5 treatment concentrations. Natural sediment, clay content 1%, spiked sediment, 20-day equilibration period before addition of test organisms.

Nominal sediment (mg ac/kg ds)		6.3	13	25	50	100
Measured sediment (mg ac/kg ds)	Day 0	6.5	19	27	62	94
	Day 10	4.4	16	32	60	72
Measured porewater (mg ac/L)	Day 0	0.013	<0.026	<0.050	<0.10	0.12
	Day 10	0.013	<0.026	<0.050	<0.10	0.14
Measured overlying water (mg ac/L)	Day 0	0.00060	<0.0052	<0.010	<0.020	0.014
	Day 10	0.00027	<0.0052	<0.010	<0.020	<0.0017

Group	Exposure	Species	Toxicity value	Reference	Notes
		Leptocheirus plumulosus	LC_{50} >100 mg ac/kg ds	Bradley 2015b	Dose response study with 5 treatment concentrations. Natural sediment, clay content 25%, spiked sediment, 20-day equilibration period before addition of test organisms.

Nominal sediment (mg ac/kg ds)		6.3	13	25	50	100
Measured sediment (mg ac/kg ds)	Day 0	5.8	22	23	49	97
	Day 10	6.4	19	29	54	100
Measured porewater (mg ac/L)	Day 0	0.0038	<0.024	<0.046	<0.091	0.048
	Day 10	<0.00052	<0.024	<0.046	<0.091	<0.0072
Measured overlying water (mg ac/L)	Day 0	0.00081	<0.0047	<0.0093	<0.018	0.015
	Day 10	0.00036	<0.0047	<0.0093	<0.018	0.0067

Group	Exposure	Species	Toxicity value	Reference	Notes
		Chironomus dilutus	LC_{50} >100 mg ac/kg ds	Bradley 2015c	Dose response study with 5 treatment concentrations. Artificial sediment, clay content 17% (kaolin clay), spiked sediment, 20-day equilibration period before addition of test organisms.

<table>
<tr><th>Group</th><th>Exposure</th><th>Species</th><th>Toxicity value</th><th>Reference</th><th>Notes</th></tr>
<tr><td></td><td></td><td colspan="4">
<table>
<tr><td>Nominal sediment (mg ac/kg ds)</td><td></td><td>6.3</td><td>13</td><td>25</td><td>50</td><td>100</td></tr>
<tr><td>Measured sediment (mg ac/kg ds)</td><td>Day 0</td><td>4.9</td><td>19</td><td>30</td><td>57</td><td>79</td></tr>
<tr><td></td><td>Day 10</td><td>5.5</td><td>21</td><td>18</td><td>34</td><td>100</td></tr>
<tr><td>Measured porewater (mg ac/L)</td><td>Day 0</td><td>0.046</td><td>0.17</td><td>0.19</td><td>0.34</td><td>0.32</td></tr>
<tr><td></td><td>Day 10</td><td>0.0022</td><td><0.037</td><td><0.071</td><td><0.14</td><td>0.037</td></tr>
<tr><td>Measured overlying water (mg ac/L)</td><td>Day 0</td><td>0.0055</td><td>0.033</td><td>0.035</td><td>0.14</td><td>0.18</td></tr>
<tr><td></td><td>Day 10</td><td>0.00025</td><td><0.0074</td><td><0.014</td><td><0.029</td><td><0.0016</td></tr>
</table>
</td></tr>
<tr><td></td><td>Chronic</td><td>Chironomus riparius</td><td>NOEC 0.37 mg ac/L</td><td>Hamer & Ashwell 1997</td><td>Limit test using spiked water. Artificial sediment, clay content 14% (kaolin clay), no equilibrium period before addition of test organisms. Measured overlying water concentrations were 0.295, 0.013 and 0.0036 mg ac/L on days 0, 7 and 21 at the limit concentration (0.367 mg ac/L, nominal). On day 21, 92.5% of the nominal paraquat concentration was associated with the sediment (equivalent to 3.2 mg ac/kg ds).</td></tr>
<tr><td></td><td></td><td></td><td>NOEC 100 mg ac/kg ds</td><td>Hamer 1998</td><td>Limit test using spiked sediment. Artificial sediment, clay content 20% (kaolin clay), 3-day equilibration period before addition of test organisms.</td></tr>
</table>

All measured concentrations are based on LSC (liquid scintillation counting). HPLC (high performance liquid chromatography) was also used to confirm the concentrations in sediment for the treatments 6.3 and 100 mg ac/kg ds (in Bradley 2015a,b,c), results not shown.

3.28 Risks to aquatic organisms – paraquat – runoff risks

Relevant comment(s)
39, 49, 59, 70, 71, 80, 101, 111, 113, 118, 119, 121, 122, 130, 146, 147, 148, 150

The assumptions of the assessment for runoff have been questioned.

3.28.1 APVMA response

As noted elsewhere (see *Risks to aquatic organisms – paraquat – Kd/Kf for exposure modelling* and *Risks to aquatic organisms – paraquat – regulatory acceptable level for sediment dwellers*), there are limitations on the ability of runoff assessment to reliably describe the behaviour of paraquat. An explanation to the approach to assessment is included below, for three elements of the runoff assessment (1) exposure estimation for residues in solution at the screening stage, (2) the relevance of paraquat absorbed to soil particles in runoff, and (3) the issues related to estimating the risk for sediment dwelling organisms.

- The properties of paraquat and the nature of the available information suggest some modification of the standard approach to runoff exposure estimation is warranted at the screening stage. Two approaches have been used to estimate exposure from runoff, as discussed below.

a) Due to the calculation method, the available K_d estimates are only valid when the concentration in porewater solution in soil is 0.01 mg ac/L (Dyson et al. 1994) or >0.01 mg ac/L (Robbins et al. 1998); this relationship also defines the concentration in soil for which a K_d value is valid, i.e. the SAC-WB concentration[50]. The screening stage runoff assessment defines a theoretical situation in which runoff occurs; a 10-hectare catchment is treated, half of which contributes to runoff into a defined water body. If the SAC-WB concentration had been reached for all soils in the catchment[51], this implies that whichever K_d value from Dyson et al. (1994) were used the same amount of paraquat would be available in solution for runoff. Because the concentration of paraquat in porewater solution will be the same for any soil at the SAC-WB concentration.

   Therefore, the screening stage risk assessment can be used to establish if there would be cause for concern from runoff in the event that soil in a catchment were to reach the SAC-WB concentration – accepting the assumption that all the paraquat in solution will contribute to runoff. As a corollary, if the inputs for the runoff model are a K_d and its associated SAC-WB soil concentration from Dyson et al. (1994), then selection of a specific numerical value does not matter, as all values will produce the same result[52].

   For this approach to exposure estimation it is not possible to extrapolate the assessment to soil concentrations other than the SAC-WB concentration. Consequently, it is necessary to consider whether reaching the SAC-WB concentration of soils is a reasonable proposition. This scenario is further addressed after considering the outcomes of screening risk assessments for selected SAC-WB concentrations (see the aquatic risk assessment in the paraquat final RTR).

   In addition to the considerations noted above, it is also accepted that when the concentration in soil is defined as the SAC-WB concentration, foliar interception is not relevant as the exposure concentration is set. Therefore, interception is set at 0%.

   Further, in this approach to exposure estimation, the soil DT_{50} is only relevant to determining degradation/dissipation during the period between the final application and when a runoff event occurs (i.e. 3 days after application). A DT_{50} of 1000 d has been used as an estimate of degradation of paraquat residues in solution, where microbial degradation is expected to occur; the SAC-WB value is assumed to have been reached and some paraquat will be in solution. Noting that due to the relatively long DT_{50} (1000 d) and short time interval (3 d) the modelled exposure estimate will be insensitive to this parameter. For paraquat bound to the soil the DT_{50} is expected to be considerably longer (e.g. >10 years) and if accumulation of bound residues need to be estimated a DT_{50} of 1000 d would not be appropriate.

b) In the available literature, a limited number of soils have been tested to determine Freundlich absorption values (K_f) (Amondham et al. 2006). One of the tested soils appears to represent a soil with a relatively low absorption capacity for paraquat (soil number 6, clay content 8.7%). Direct comparison with the larger dataset from Dyson et al. (1994) is not possible as no SAC-WB value was determined for this soil; though

[50] The K_d values from Robbins et al. (1998) are for concentrations greater than the SAC-WB value. For simplicity the rest of the discussion only considers the situation based on Dyson et al. (1994).

[51] A conservative simplification for this tier of risk assessment.

[52] Minor variations in outcome will occur due to measurement and rounding errors.

using the K_f and 1/n it is estimated to be 46 mg ac/kg ds which is within the 40^{th} percentile of SAC-WB values for soils with ≤10% clay according to Dyson et al. (1994). It is proposed to use the K_f (17.9 µL/g) and 1/n (0.412) values for this soil to conduct a screening stage assessment that accounts for concentration dependence. This is intended to be illustrative of a low absorption capacity soil, exactly how conservative it is relative to Australian soils is unknown.

For this approach a reliable soil DT_{50} is required for residues bound to soil so that accumulation of paraquat can be modelled appropriately. The available data is lacking in this regard. Estimates of degradation of paraquat in field soils are undefined (DT_{50} >10 years), are approximations without reliable kinetic modelling (DT_{50} 6.6 or 20 years, Hance et al. 1980 and Dyson & Chapman 1995, respectively) or are not expected to reflect typical Australian agricultural situations (DT_{50} 41 d, Amondham et al. 2006). The most conservative defined DT_{50} value is 20 years (Dyson & Chapman 1995). However, the modelling reported in this study had poor fits to the data (r^2 0.05, 0.31 and 0.37 for soils dosed at 50, 110 and 400% of the SAC-WB value) and the reported DT_{50} is a visual estimate, by the study authors, of the time to reach ~50% of the initial residues. For the higher rate treatments (110 and 400% of the SAC-WB) on which the reported DT_{50} is based there is arguably biphasic degradation and the DT_{50} would not necessarily reflect a single first order (SFO) approximation of the slow phase degradation. Without a more robust analysis of the data the rate of degradation can only be crudely estimated. Assuming two-compartment degradation kinetics, a SFO approximation of the slow phase degradation could be 60 years or more (this being an extrapolation outside the experimental period, 20 years). To reflect the limitations of the available endpoints cumulative soil concentrations have been modelled using DT_{50} values of both 20 and 60 years. There is considerable uncertainty in using these values, and additional information or analysis would be needed to establish more reliable estimates.

- With regard to paraquat absorbed to soil particulates in runoff, the properties of paraquat imply that residues bound to clay particles are not biologically available. Freely available paraquat (i.e. in pore water or overlying water) is the fraction that is expected to contribute to toxicity estimates for sediment dwelling organisms, not the total concentration in the sediment. Any fraction of paraquat in runoff that is absorbed to soil clay particles will not increase the freely available concentration of paraquat, as it is bound to the clay particles. Therefore, paraquat absorbed to soil particles in runoff is assumed to be irrelevant in terms of the exposure assessment. Only residues of paraquat in solution within the runoff are expected to be relevant to the risk assessment.
- The critical endpoint for setting the RAL (3.8 mg ac/kg ds) for sediment dwelling organisms (see *Risks to aquatic organisms – paraquat – regulatory acceptable level for sediment dwellers*) can currently only be reliably described in terms of the total sediment concentration. This limits its utility to the risk assessment. For sediment dwelling organisms, the APVMAs default approach to risk assessment only considers equilibrium partitioning to sediment from the overlying water. A conservative K_p value (50000 mL/g, i.e. the maximum value directly measured in soil from Robbins et al 1988) has been proposed so that the screening stage model predicts a substantial fraction of the paraquat in solution partitions to sediment. This is for consistency with the experimental observations of partitioning to sediment in systems with unsaturated sediment. It is not intended to define specific properties of the modelled sediment. The properties of the sediment are ultimately defined by the conditions in the toxicological study used to set the RAL. The limitations of the available data are noted. Whilst also imperfect, an alternate line of evidence is to compare the predicted concentration in the overlying water with the geomean concentration in porewater observed in the study with *H. azteca* (0.041 mg ac/L, see *Risks to aquatic organisms – paraquat – regulatory acceptable level for sediment dwellers*).

3.29 Risks to bees – diquat – regulatory acceptable level and refined RUD values

Relevant comment(s)
60, 64, 102, 118, 119, 150

Refinement of the risk assessment was recommended based on 90th percentile RUD values for pollen and nectar from EFSA (2013b).

3.29.1 APVMA response

Regarding refining the RUD estimate, the APVMA will update the risk assessment to include the 90th percentile RUD values for nectar (11 mg/kg) and pollen (52 mg/kg) from EFSA (2013b).

3.30 Risks to bees – paraquat – regulatory acceptable level and refined RUD values

Relevant comment(s)
59, 64, 102, 118, 119, 150

The endpoints cited for bees from the study Bull & Wilkinson (1987) have been questioned as they do not match the values reported by the US EPA for the same study. Refinement of the risk assessment was recommended based on 90th percentile RUD values for pollen and nectar from EFSA (2013b).

3.30.1 APVMA response

Bull & Wilkinson (1987) includes the results from oral and contact tests for both paraquat and a 200 g/L formulation, and for each of these four combinations three repeated tests were performed. The tests were conducted before introduction of GLP and current guidance, but the study broadly meets the recommendations of the current OECD guidance (OECD 213 and 214). The US EPA reports 48-hour LD_{50} values determined using the aggregated data from all three tests for each combination. However, there was increasing mortality between 24 and 48 hours so the study was extended up to 120 hours – current guidance (OECD 213 and 214) recommends that when mortality increases by 10% between 24 and 48 hours the test should be extended up to a maximum duration of 96 hours. Not all tests reported in Bull & Wilkison (1987) could be considered valid at all time points due to control mortality or failures of control replicates. The endpoints quoted by the APVMA are the geomean 96-hour LD_{50} values for those tests that were considered valid at 96 h, see Table 8 – the endpoints at 120 h have not been reported as this is beyond the currently recommended duration of the study. The 96-hour LD_{50} values established by the APVMA will be retained for use in risk assessment to account for the increasing mortality observed in the study.

Regarding refining the RUD estimate, the APVMA will update the risk assessment to include the 90th percentile RUD values for nectar (11 mg/kg) and pollen (52 mg/kg) from EFSA (2013b).

Table 8: Paraquat – Endpoints, LD50 values at 24, 48, 72 and 96-hours, of paraquat technical and an SL formulation (expressed as μg ac/bee; 95% CI in parentheses)

Hours after dosing	Test	Contact		Oral	
		Paraquat technical	SL formulation	Paraquat technical	SL formulation
24	1	>144 (n/a)	>200 (n/a)	>144 (n/a)	Not reported
	2	>144 (n/a)	207 (197-218)*	154 (145-162)*	Not reported
	3	>144 (n/a)	>200 (n/a)	>144 (n/a)	72 (60-86)
	Geomean	>144	>200	>144	72
48	1	**	91 (not calculated)	58 (44-76)	31 (23-40)
	2	>144 (n/a)	86 (not calculated)	40 (28-52)	Not reported
	3	>144 (n/a)	69 (53-82)	60 (34-121)	31 (25-38)
	Geomean	>144	81	52	31
72	1	**	28 (9.6-53)	23 (16-30)	**
	2	171 (115-687)*	24 (4.6-46)	26 (18-35)	**
	3	>144 (n/a)	34 (22-44)	32 (18-53)	23 (18-28)
	Geomean	>144	28	27	23
96	1	**	19 (14-25)	18 (14-24)	**
	2	106 (67-257)	13 (1.6-25)	**	**
	3	64 (35-129)	**	26 (14-48)	13 (9.7-18)
	Geomean	82	16	22	13

* Estimated LD_{50} exceeds the maximum tested dose.

** Endpoint considered invalid due to control mortality exceeding 10% or due to failure of a control replicate

3.31 Risks to terrestrial non-target plants – diquat – regulatory acceptable level and species sensitivity distribution

Relevant comment(s)
60, 87

Clarification of the method used to derive the RAL for terrestrial non-target plants has been requested. Additionally, ambiguity in the APVMA's published guidance[53] was noted, specifically in relation to which endpoints to use with SSDs and the appropriate assessment factor. It was also noted that the most recent chemical review for 2,4-D applied an assessment factor of 3.1 which is not the case for diquat.

[53] https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals/environment/appendix-f

3.31.1 APVMA response

Current practice for use of SSDs to determine a RAL is to use an assessment factor of 1 with the HR_5 to set the RAL, and the ER_{50} is the preferred input value. If there are endpoints (ER_{50} values) to the left of the HR_5 (i.e. more sensitive than) it may be necessary to consider using the lower 95% CI of the HR_5 to ensure a protective risk assessment, given that the assessment factor is 1.

It has also been noted that an assessment factor of 3.1 was used in the assessment of 2,4-D. This assessment factor was applied with the argument that there were some effects on the test organisms that were unaccounted for in the endpoints used for assessment. Similar ambiguity is not present for diquat. Therefore, use of a larger assessment factor is not recommended.

For clarity and transparency, the APVMA has recalculated the HR_5 using shinyssdtools[54] (version 0.4.0), see the non-target terrestrial plant risk assessment in the diquat final RTR.

3.32 Risks to terrestrial non-target plants – paraquat – regulatory acceptable level and species sensitivity distribution

Relevant comment(s)
59, 87

Clarification of the method used to derive the RAL for terrestrial non-target plants has been requested. Additionally, ambiguity in the APVMA's published guidance[55] has been noted, specifically in relation to which endpoints to use with SSDs and the appropriate assessment factor. It has also been noted that the most recent chemical review for 2,4-D applied an assessment factor of 3.1 which is not the case for paraquat.

3.32.1 APVMA response

Current practice is to use an assessment factor of 1 with the HR_5 to set the RAL, and the ER_{50} is the preferred input value. Depending on the distribution of endpoints within the SSD it may be necessary to consider using the lower 95% CI of the HR_5 to ensure a protective risk assessment, given that the assessment factor is 1.

It has also been noted that an assessment factor of 3.1 was used in the assessment of 2,4-D. This assessment factor was applied with the argument that there were some effects on the test organisms that were unaccounted for in the endpoints used for assessment. Similar ambiguity is not present for paraquat. Therefore, use of a larger assessment factor is not recommended.

[54] Dalgarno (2021) https://bcgov-env.shinyapps.io/ssdtools/

[55] https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals/environment/appendix-f

For clarity and transparency, the APVMA has recalculated the HR_5 using shinyssdtools[56] (version 0.4.0), see non-target terrestrial plant risk assessment in the paraquat final RTR.

3.33 Use situation – paraquat/diquat – maximum seasonal rates and double knocking

Relevant comment(s)
118, 119, 150

The practical implications of defining maximum seasonal rates have been raised during commenting. Clarification regarding the intent and interpretation has been requested. Additionally, questions have been raised regarding double knocking application and the implications of the risk assessment outcomes.

3.33.1 APVMA response

The maximum seasonal rate terminology (or similarly maximum application rate) is used in relation to the terrestrial vertebrate risk assessment. It refers to the maximum cumulative application rate that can concluded to be acceptable based on the quantitative risk assessment for a given use situation[57]. Risk assessments require a defined use (e.g. application rate, number of applications, application interval, timing of application) to allow for evaluation. For a defined use and RAL, a maximum supportable rate can be calculated.

During the consultation period the definition of the maximum seasonal rate and its interpretation has been queried, e.g.:

- What is considered a season? Should this be read as the four seasons in a year?
- How is a between-cropping season fallow application considered?
- How would weed control in long-fallows (12 months+) be viewed?
- Would an in-crop application for spray topping be considered in the same season as a pre-crop fallow spray?
- How would double/continuous cropping be assessed?

Each use situation as described on a product label is evaluated separately. The risk assessment does not explicitly consider either the interaction between use situations in the same crop (e.g. use in fallow followed by pre-harvest desiccation in the same crop) or use in double/continuous cropping. The impact of these scenarios would depend on the interval between the separate uses. However, if the uses are separated (e.g. between different crops, or at the beginning and end of a single crop) and the risk from the individual use situation is acceptable there is not expected to be cause of concern, especially given the primary concern for terrestrial vertebrates is acute exposure. Specific labelling restrictions would not be expected to be necessary.

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[56] Dalgarno (2021) https://bcgov-env.shinyapps.io/ssdtools/

[57] Weight of evidence arguments may indicate a maximum supported rate, but this will be based on subjective argument and will not reflect a clearly defined outcome of the assessment.

Double knock application is not specifically cited on paraquat or paraquat/diquat combination product labels. Double knock application is cited on labels of products containing diquat, i.e. for wheat a single application of diquat (140 g ac/ha)[58] is made between 14 to 21 days before application of another herbicide, also with activity on wild radish. The maximum seasonal rate referred to in the risk assessment relates only to the amount of the active under assessment (i.e. paraquat or diquat) that can be supported. It does not imply a limit on the use of other actives in a crop management regime. Double knock application in combination with other uses of paraquat and/or diquat in the same crop or sequential crops is addressed by the preceding discussion of the maximum seasonal rate.

3.34 Use situation – paraquat/diquat – cereal situations

Relevant comment(s)
49, 55, 101, 111, 113, 118, 119, 121, 130, 150

Comments have been submitted that propose only particular species of mammals that may be present in grain growing regions of Australia, and some background information has been provided to make a claim that risks to species that may be present in these areas will be low. The arguments and information presented are discussed in more detail below.

3.34.1 APVMA response

Some of the arguments received during consultation have premised parts of their submissions on meeting a protection goal of maintaining *"abundance and persistence of populations of* (sic) *species scale"*. As mentioned in the terrestrial vertebrate risk assessment (Appendix A, weight-of-evidence discussion) and alluded to in the APVMA risk assessment manual[59], this is not the aim of the risk assessment. The population of relevance for protection is the local population in the immediate vicinity of the treated area.

The different lines of argument presented in relation to cereal situations have been outlined and discussed below.

Crop distribution and potential mammalian focal species

Commenters have identified species of hopping mouse, native rats, possums and bettongs that could occur in grain producing regions of Australia. From this process 14 potentially relevant species[60] were identified; the potentially relevant species were determined based on species distribution records from the Atlas of Living

[58] Label directions indicate a maximum of one application per crop

[59] https://www.apvma.gov.au/registrations-and-permits/data-guidelines/risk-assessment-manuals/environment/appendix-a

[60] *Pseudomys apodemoides, Pseudomys albocinereus, Pseudomys higginsi, Pseudomys patrius, Pseudomys occidentalis, Pseudomys australis, Pseudomys delicatulus, Pseudomys shortridgei, Melomys burtoni, Melomys cervinipes, Leporillus conditor, Bettongia gaimardi, Bettongia lesueur, Hydromys chrysogaster*

Australia website[61], crop distribution information from the DAFF Land use and Management web site[62] and a selection of publications (Dickman et al 2000a, 2000b, Morris 2000, Robinson et al. 2000 and Seebeck & Menkhorst 2000). Commenters obtained expert advice regarding whether any of these species might inhabit grain growing/broadacre cropping[63] regions, and 8 species[64] were considered as possibly occurring in such areas. Of these, 5 species[65] were judged, based on expert advice, to have the potential to spend time in broadacre cropping zones – the remaining three species were argued to be *"highly unlikely to inhabit fallow or crop zones"*. For the 8 species identified as possibly occurring in grain growing/broadacre cropping regions a Google Scholar search was conducted by commenters (for records from the last 20 years) and the results reported along with information related to body weight, habitat preferences, distribution and conservation status.

Crop distribution information in conjunction with species distribution records, as used by the commenters, can be considered to inform what are potentially relevant species for risk assessment. However, comments received have not clearly described the process used to define the proposed initial list of potentially relevant species. The specific crop distribution data used have not been identified (see *Appendix – Environment – background information*), and it is not clear how the crop distribution data were interpreted, nor is it clear what the limits on their applicability might be. The information used, crops included, spatial resolution of the records, and temporal changes in land use could alter the species that would be included in the initial screening exercise. Similarly, it is not clear how the species distribution records were interpreted: e.g. species, such as *Rattus fuscipes* or any other *Rattus* species, with distributions that arguably overlap with grain crop growing regions, at least in part, have been excluded without explanation[66]. Therefore, it cannot be confirmed how comprehensive or conservative the proposed potentially relevant species are in relation to the crop distribution information used by the commenters.

Mouse monitoring program

The GRDC/CSIRO mouse monitoring program has been cited during consultation as relevant to informing what species might be present in grain cropping regions. This program has used the live trapping methods described in Brown et al. (2022). It is claimed that the monitoring program has been running for 10 years at 13 sites in Qld, NSW, Vic and SA, deploying 51 traps per night for 3 nights, 3 times per year. Additionally, lower frequency monitoring has been conducted at another 39 sites over the same period. On only two occasions have species other than *Mus musculus* (house mouse) been trapped during this program; specifically one dunnart (*Sminthopsis* sp.) and a black rat (*Rattus rattus*). It is argued that the mouse abundance data[67] indicate that mouse numbers *"generally increase during the times of paraquat application during early summer (crop desiccation and spray*

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[61] https://www.ala.org.au/

[62] https://www.agriculture.gov.au/abares/aclump/publications#land-use-change

[63] Both terms (grain growing and broadacre cropping) are used in the submitted information apparently interchangeably.

[64] *Pseudomys apodemoides, Pseudomys albocinereus, Pseudomys higginsi, Pseudomys patrius, Pseudomys occidentalis, Pseudomys australis, Pseudomys delicatulus, Pseudomys shortridgei*

[65] *Pseudomys apodemoides, Pseudomys albocinereus, Pseudomys higginsi, Pseudomys patrius, Pseudomys occidentalis*

[66] Arguments could be made for exclusion of particular species (e.g. due to habitat preferences) but the submissions do not explain the decision-making process.

[67] See the mouse monitoring reports at https://grdc.com.au/resources-and-publications/resources/mouse-management, the August 2024 edition was cited during commenting.

topping), during summer fallow and in autumn pre crop sowing (i.e. April) indicating no adverse impact of paraquat use, on mice numbers".

Details of the monitoring sites[68] have not been provided to the APVMA, so neither the locations nor the surrounding land use can be established. As such, it is unclear what species of native rodents could even potentially be sampled in the monitoring program – in highly modified agricultural environments, many native Australian rodents are associated with fragments of native vegetation and monitoring locations separated from such habitats would be less likely to detect species other than *M. musculus.* Given the available information, sampling only *M. musculus* is not necessarily unexpected and may simply reflect the properties of the sampling locations used in the monitoring program.

The study Carthew et al. (2013) was also cited during consultation to demonstrate that CSIRO mouse trapping is suitable to capture other native rodents. It was also noted that agricultural land opposite remnant (native vegetation) areas had the lowest capture rate of any of the categories of trapping sites in the study; 4 mammals were captured on farm sites including two *Mus musculus*, one *Cercartetus concinnus* and one *Cercartetus lepidus*.

It should be noted that the study (Carthew et al. 2013) only reflects one region within southern Australia. Sampling within agricultural areas was at least 50-100 m into the crop and as such would not sample rodents foraging near the boundary with native vegetation. The status of agricultural sites is not stated in the study (e.g. crop and growth stage is unknown), though trapping was during April, June, July and August of 2004 and January of 2005. Also, even within fragments of native vegetation and near roadsides, the number of native rodents was low in the study area; in total ten *Pseudomys apodemoides* (from two native vegetation sites) and one *Rattus fuscipes* (from a roadside site) were captured.

Summary for mammals

The process used by commenters to identify and evaluate potentially relevant species of small mammals that might occur in grain cropping regions is unclear. More peripheral (low production volume) or less extensively developed grain production areas have not necessarily been considered, and the rational for including/excluding species from the initial list of potential candidate species is not presented.

The supporting observational data (GRDC/CSIRO mouse monitoring program and Carthew et al. 2013) are also incompletely reported and have limitations for informing the assessment about the behaviour of native rodents. However, the mouse monitoring provides clear evidence that at the monitored sites the presence of native rodents was negligible.

For heavily modified agricultural settings it is reasonable to expect low abundance of native rodents, as indicated by the available information. Habitat loss and modification are amongst the primary drivers of the current distribution of species, i.e., due to reduced cover in grain production settings and/or limited access to native vegetation or other food sources. Fragmented and/or sparse populations of native rodents are a feature of more extensively developed agricultural environments in Australia. For such fragmented populations, the influence of any chemical treatments would depend on a range of factors such as the size of the residual habitat, species abundance within the habitat fragment(s), availability of suitable diet, foraging behaviour at the margins of the preferred habitat and the toxicity of the chemical substance. The information provided during consultation is not

[68] Brown et al (2022) identifies 2 benchmark sites and a third benchmark site can be determined from the GDRC mouse monitoring reports. The locations of the remaining ten sites referred to during commenting are unknown.

well suited to describing the dynamics of species restricted to small habitat fragments. For less extensively modified environments with less land converted to broadacre cropping and/or grain production the expectation of low abundance of native rodents does not necessarily apply.

Assessment of the weight-of-evidence arguments are discussed in the Paraquat Final Review Technical Report and Diquat Final Review Technical Report.

Bird population monitoring in Western Australia

Several surveys and population monitoring projects have been referenced during consultation[69]. However, no published studies or other reports have been provided to the APVMA. Therefore, it is not possible to establish how useful or reliable any of the underlying information might be for establishing potential focal species or otherwise refining the risk assessment.

3.35 Use situation – paraquat/diquat – non-agricultural situations

Relevant comment(s)
148

Argument has been submitted to propose a refinement of the treated area for non-agricultural uses (e.g. industrial vegetation management, around sheds, on roadways, paths, public service areas, rights of way, fence-lines and firebreaks).

3.35.1 APVMA response

The non-agricultural uses have been assessed in the grassland crop group for the terrestrial vertebrate risk assessment. It is claimed that application is typically targeted to a strip generally about 2 m wide. This represents a sprayed area in the range of 5-10% of a hectare, and often less than this. It was argued that a reasonable assumption for this type of use would be to consider 10% of the total area as treated. Rodents are not expected to routinely use exposed areas; as noted in *Risks to terrestrial vertebrates – paraquat/diquat – attractiveness of bare soil situations to small mammals* and *Use situation – paraquat/diquat – fallow situations*. Therefore, whether the treatment of non-agricultural areas can be assessed assuming of 10% of the area is treated depends on the surrounding land use. This argument has been considered further as a weight-of-evidence argument in the terrestrial vertebrate risk assessment.

3.36 Use situation – paraquat/diquat – almond situations

[69] (1) Huggett, Andrew. Protecting remnants and revegetation for threatened and declining biodiversity in Waddy Forest Catchement:2012-2013 Bird Survey Report; (2) Birds On Farms Project In Western Australia 1996-1999; (3) Birds On Farms Project 2023-Ongoing; (4) Waddy Forest Land Conservation District Committee - A Survey Of The Flora Of Remnants Within The Waddy Forest Land Conservation District March 2000; (5) Protecting Remnants And Revegetation For Threatened Declining Biodiversity In Waddy Forest Catchment - 2012-13 Bird Survey Report

Relevant comment(s)
102

Comments received stated that almond production systems are maintained with orchard floors free of plant growth to facilitate nut harvest and claimed that ninety percent of almond production is based on drip irrigation and when taken in conjunction with low rainfall in growing regions there is expected to be limited weed growth on the orchard floors. Paraquat/diquat application is targeted at juvenile weeds early in the season. Data related to birds feeding in almond plantations (Luck et al. 2013) has been cited.

3.36.1 APVMA response

This review considers assessment of the risks related to the current instructions for use for paraquat and diquat as they appear on the approved labels. Almonds fall within the uses related to orchards and plantations and have been assessed accordingly. Any future applications to add almond specific instructions for use incorporating the information noted in the submission will be assessed on their merit.

The study cited in relation to birds feeding in almond plantation situations appears to be focused on species that forage in the canopy. This is not relevant to the current risk assessment, as only species that would forage on the plantation floor would be relevant.

3.37 Use situation – paraquat/diquat – melon situations

Relevant comment(s)
125

Comments received have noted that there are currently two use patterns for paraquat and diquat in the melon industry:

- Broad spectrum spraying, during fallow period or pre-planting (generally using a boom sprayer)
- Inter-row shielded spraying, 2 to 3 weeks after planting seeds or transplanting seedlings and before flowering. Claimed industry standard is for a maximum of 2 m between rows and 1.2 m wide beds

It is also stated in relation to melon cropping situations that: (1) spray application is early in the crop lifecycle limiting the material present in the melon blocks that would be attractive to birds/mammals; (2) under Australian environmental conditions leaf material is 'burnt off' within ~2 h after application, limiting the potential for consumption; (3) risk mitigation measures will typically be in place to excluded birds/mammals (e.g. bird deterrents, scare guns, scarecrows and fencing).

3.37.1 APVMA response

This review considers assessment of the risks related to the current instructions for use for paraquat and diquat as they appear on the approved labels. Melons are part of the vegetables, market gardens and row crops use pattern – these uses have all been assessed using the bare soil scenario for terrestrial vertebrates which implies an early growth stage of the crop consistent with the description of use in melons. Directed spraying away from the crop using shielded spraying is referenced for these uses so refinement of the assessment to consider this application method is possible. However, this requires the identification of a reasonable worst-case situation for the full range of uses represented on the label. Any future applications to add melon specific instructions for use incorporating the information noted in the submission will be assessed on their merit.

The use of measures to exclude vertebrates from production areas has been cited as a mitigation measure for the environmental risk assessment. Use of exclusion measures would need to be a mandatory condition on the label for it to be relevant to the risk assessment. Additionally, it would be necessary to establish the efficacy of the proposed measures at excluding the organisms that are relevant to the risk assessment. The submissions received during consultation to not provide sufficient information to consider these issues. Therefore, they have not been considered further in the risk assessment.

3.38 Use situation – paraquat/diquat – soybean situations

Relevant comment(s)
145

Comments received have argued that soybean is not a preferred feed for terrestrial vertebrates. It is argued that soybeans are not readily digested by animals and soybean used for stockfeed must be heat treated to improve digestion, due to the presence of high levels of trypsin inhibitors.

3.38.1 APVMA response

No information has been provided that would allow a quantitative refinement of the risk assessment (e.g. refinement of avoidance factor, PT or PD). No information has been provided that relates to foraging of wild mammals/birds in soybean crop situations. It cannot be established from the submissions made what, if any, species would feed in soybean crop situations and/or what their feeding behaviour might be under these circumstances. Therefore, neither a quantitative nor qualitative argument can be supported.

3.39 Use situation – paraquat/diquat – cotton situations

Relevant comment(s)
64

Data have been cited in relation to bird and bat foraging in and around cotton farms (Smith et al. 2019, Kolkert et al. 2019, Kolkert 2020a, Kolkert et al. 2021a, Kolkert et al. 2021b), primarily to argue that there is a diverse population and diversity of species in these situations.

3.39.1 APVMA response

This information has been noted and where relevant included in risk assessments. It is noted that the bat data is not relevant to the current risk assessment.

3.40 Use situation – paraquat/diquat – fallow situations

Relevant comment(s)
118, 119, 150

For uses in fallow, it has been proposed that a PT of 0.33 should be applied to the risk assessment for small mammals. This is argued to be a conservative approach to account for the qualitative evidence of limited small mammal occurrence in this use situation. Other submissions have also made similar arguments regarding the low attractiveness of situations where limited vegetation is present (see *Risks to terrestrial vertebrates – paraquat/diquat – attractiveness of bare soil situations to small mammals)*.

3.40.1 APVMA response

A weight-of-evidence argument has been made to support this refinement. However, no specific studies to measure PT of small mammals in fallow situations have been provided and no evidence has been included to support the specific value proposed in the comments (PT 0.33). Also, it should be noted that PT values are not used for acute risk assessments, which is the main point of concern for paraquat and diquat. The specific PT value proposed will not be adopted in the risk assessment.

3.41 Use situation – diquat – aquatic weed situations

Relevant comment(s)
58, 148

Clarification of the use pattern has been provided and modifications to the directions for use have been proposed to mitigate potential environmental impacts.

To address the risks identified in the draft RTR, it has been proposed to restrict use to farm dams, irrigation channels, artificial watercourses, and managed waterways, thereby excluding natural water bodies and limiting the potential for adverse environmental effects. It was also proposed to remove use by application by aircraft from the label, to change the droplet size for spray application and consider small scale application by drones.

3.41.1 APVMA response

Issues related to spray drift (removal of use by aircraft, droplet size and use of drones) have not been considered specifically in the environment risk assessment, as any risk from spray drift and associated mitigation measures are considered separately.

The proposal to restrict use to farm dams, irrigation channels, artificial watercourses, and managed waterways has been considered as a mitigation measure in the risk assessment.

3.42 Use situation – diquat – potato situations

Relevant comment(s)
39, 43, 49, 64, 79, 100, 101, 109, 111, 113, 118, 119, 121, 129, 130, 136, 139, 150, 165

Comments received have noted there are multiple on-label uses of diquat for use in potatoes:

- Diquat only products[70]:
  - Use for haulm desiccation[71].
  - Use for pre-harvest weed control, targeting young and established weeds before potato harvest but when there is no remaining green potato foliage.
- Combination products (containing paraquat and diquat):
  - Use for pre-emergence weed control, up to emergence of 25% of potato seedlings.
  - Use for pre-harvest weed control, targeting young and established weeds before potato harvest but when there is no remaining green potato foliage.

Additionally, the suitability of potato crops to support terrestrial vertebrates has been questioned and it has been requested that this is considered in the relevant section of the risk assessment.

3.42.1 APVMA response

For potatoes, where needed the risk assessment has been updated to account for all use situations, including the relevant on-label rates in each case. The crop groups for the terrestrial vertebrate risk assessment have also been altered, to include both bare soil and potato, given that uses include use near emergence, haulm desiccation and post-emergence use near harvest.

Regarding comments related to terrestrial vertebrate risk assessment, those comments that reference the AEA (2024) report have been addressed separately (see *Risks to terrestrial vertebrates – paraquat/diquat – mammalian daily energy expenditure for marsupials/monotremes* and *Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species*). The assertion that potato fields are unlikely to be able to support 100% of vertebrate organisms' (bird/mammal) diet is noted. However, no data has been submitted to support the claim or establish what, if any, species use potato fields in Australia. Therefore, no quantitative refinement of the risk assessment is possible.

3.43 Use situation – diquat – Tasmanian poppy situations

Relevant comment(s)
49, 50, 64, 78, 100, 101, 111, 113, 115, 116, 118, 119, 121, 129, 130, 139, 150, 155

[70] For diquat only products no specific use has been identified for potatoes regarding pre-emergence application. Pre-emergence use for the generic crop groups vegetables and row crops are considered separately.

[71] This use pattern also addresses use for desiccation on sweet potato

Submissions have been made which provide background information regarding cultivation practices in Tasmanian poppy growing situations. Additionally, arguments regarding the risk assessments for large herbivorous mammals, small herbivorous mammals and granivorous birds have been presented. The relevance of this information is considered in more detail below.

3.43.1 APVMA response

Some anecdotal observations that are generically applicable to poppy production in Tasmania have been made, as follows:

- Commenters have described the Tasmanian agricultural environment as being characterised by smaller scale production, compared to broadacre cropping regions on the mainland representing a matrix of crops, pasture and remnant native vegetation. It is then argued that therefore there will be foraging opportunities for birds and mammals outside the poppy crop.
- Submissions have reported that no residues of diquat have been detected in poppy seeds after treatment of the crop following normal practice. No studies have been submitted or cited to support this claim.
- The presence of alkaloids in the foliage of *Papaver somniferum* has been argued to be a deterrent for foraging animals – noting that poppy seeds do not contain alkaloids (EFSA 2018) and can be consumed by foraging organisms. No data has been provided to substantiate/evidence this claim, though it is a reasonable proposition. This argument would only be applicable to situations where the crop itself is assumed to be a dietary component.
- It has been argued that poppies should not be classified as oilseeds for the terrestrial vertebrate risk assessment, due to the proposed difference in palatability. This is not accepted. Palatability of poppy foliage can be considered as a mitigating factor in a weight-of-evidence argument where it is relevant, but the underlying crop group has not been altered.
- Anecdotal reports of mammals that occur and/or forage in poppy crops, or the absence of, have not been considered further. This is not considered a reliable basis for decision making.

Arguments regarding the risk assessment for large herbivorous mammals, small herbivorous mammals and granivorous birds in Tasmania have been made and they are considered under the relevant sub-headings below.

Large herbivorous mammals

It has been argued that the interception factor for the risk assessment of large herbivorous mammals in poppy crops should be 0.75 (deposition 0.25, from Appendix E of EFSA 2009). The food item for the generic focal species is crop leaves according to EFSA (2009). It has been argued that only the lower leaves of poppy plants should be considered as part of the diet at the time of application (BBCH ≥80, for pre-harvest desiccation at the stripy capsule stage), and hence interception by the upper leaves should be considered when calculating the exposure.

This proposal is not accepted. No data has been provided to support the contention that only the lower leaves should be considered in the diet. As discussed in *Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species* the generic focal species (see EFSA 2009) are not intended to define real species, and the representative species cited in the appendices of EFSA (2009) cannot be used to justify modifications to the Tier-1 risk assessment.

Small herbivorous mammals

Confidential data submitted for a prior application has been cited in relation to the occurrence of small mammals in poppy fields. Weight of evidence arguments have been included in relevant risk assessments described in the Diquat Final Review Technical Report.

Granivorous birds

Candidate focal species of granivorous birds in Tasmania[72] have been proposed during consultation. The candidate species were established based on a list of Tasmanian birds[73]**.** All the species of finch, dove, button-quail, parrot, quail, dove and canary were considered potentially granivorous and therefore were considered potentially relevant granivorous bird species for risk assessment in Tasmania. For this group of species, body weight estimates, qualitative evaluations of dietary preferences and notes regarding distribution were included in the submission to the APVMA.

No observation data has been provided to determine which, if any, species forage in poppy situations, so the identified species would not be considered true focal species (as per EFSA 2009). The proposed list of species does reflect a clear evaluation of Tasmanian species that might be relevant for consideration in risk assessment. Therefore, the identified cohort of bird species will be considered further as necessary in the risk assessment of granivorous birds for Tasmanian poppy growing situations.

[72] *Neophema chrysostoma, Coturnix ypsilophora, Platycerus eximius, Cacatua roseicapilla, Platycercus caledonicus, Pezoporus wallicus, Neophema chrysogaster, Turnix varia, Cinclosoma punctatum, Coturnix pectoralis, Cacatua galerita, Lathamus discolor, Calyptorhynchus funereus, Melopsittacus undulatus, Lophortyx californicus, Nymphicus hollandicus, Carduelis carduelis, Carduelis chloris, Cacatua sanguinea, Cacatua tenuirostris, Columba livia, Streptopelia chinensis*

[73] https://nre.tas.gov.au/wildlife-management/fauna-of-tasmania/birds/complete-list-of-tasmanian-birds

3.44 Use situation – diquat – lucerne situations

Relevant comment(s)
39, 49, 64, 100, 101, 111, 113, 118, 119, 121, 129, 130, 139, 150

Comments received have noted there are multiple on-label uses of diquat for use in lucerne:

- Diquat only products:
  - Pre-harvest desiccation.
  - Early autumn application. Grazing, to a height of 2 cm, should occur before application.
  - Late winter application. Grazing, to a height of 2 cm, should occur before application.
- Combination products (containing paraquat and diquat):
  - Autumn application. Grazing, to a height of 2-4 cm, should occur before application.
  - Winter application. Grazing, to a height of 2-4 cm, should occur before application.

Comments received have proposed revisions to the on-label uses and some mitigation measures for use in lucerne to address environmental concerns.

Comments received indicate that lucerne seed production is primarily based in the upper southeast of South Australia[74]. Listed threatened species, birds and mammals, that may occur in this primary seed production area have been identified.

3.44.1 APVMA response

The risk assessment for lucerne has been updated to account for all use situations, including the relevant on-label rates in each case. The crop group for the terrestrial vertebrate risk assessment has also been altered to include legume forage, given that use is on existing stands of lucerne.

Only on-label uses have been considered in this chemical review assessment. New use patterns would have to be considered as part of a separate application. Any proposed mitigation for the on-label uses will be considered in the context of the relevant aspects of the risk assessment.

The geographic extent of lucerne production and the local threatened species have been discussed further in the terrestrial vertebrate risk assessment, though it is noted that the presence/absence of threatened species is not part of the risk assessment framework.

[74] With 85% in the upper southeast of South Australia (around Tintinara, Bordertown, Frances and Keith) and the remaining 15% located within the northern region of South Australia, New South Wales and Victoria.

3.45 Use situation – diquat – sugar cane situations

Relevant comment(s)
39, 49, 64, 70, 80, 100, 101, 111, 113, 118, 119, 121, 122, 129, 130, 137, 139, 146, 147, 150

Comments received have indicated that the actual use situations in sugarcane are different from those previously assessed.

- Diquat only products, current on-label uses:
  - Desiccant prior to harvest.
- Combination products (containing paraquat and diquat), current on-label uses:
  - Over the top spray at up to the 3-4 leaf stage (BBCH 10-19).
  - Inter-row spray (using octopus leg, spider leg or Irvin spray system) between the 3-4 leaf stage and formation of the true stem. This targets the inter-row space and the base of the sugarcane plants, resulting in treatment of the whole cropped area but without treatment of the crop foliage.

Also, additional argument and supporting information has been provided regarding impacts on small mammals in the context of sugarcane fields.

3.45.1 APVMA response

The risk assessment has been updated to reflect the on-label use situations where relevant.

Maize has been used as a surrogate crop group for the terrestrial vertebrate risk assessment based on similar row cropping practices, as there is no specific sugarcane crop group defined in the EFSA (2009) guidance. Comments received have also argued that for the inter-row spray the diet composition should be changed for some generic focal species (small omnivorous birds and small herbivorous mammals), as there will be no treated crop foliage. Excluding the crop foliage dietary component will be considered as a refinement of the risk assessment for the small omnivorous bird but not the small herbivorous mammal[75]. The argument in relation to small omnivorous birds has been considered further in the terrestrial vertebrate risk assessment.

The additional information related to small mammals in sugarcane has been considered in the terrestrial vertebrate risk assessment.

3.46 Use situation – diquat – vineyard situations

Relevant comment(s)
49, 64, 100, 101, 106, 108, 111, 113, 118, 119, 121, 129, 130, 139, 148, 150

[75] Small herbivorous mammals are assumed to eat either crop shoots or grass. The inter-row spray would not exclude grass of other weeds as dietary items for ground foraging organisms, and there will be no interception for these food items.

Comments received have stated that current usage in vineyard situations involves directed application in a strip under the vines (~30% of the cropped area). Other comments have indicated that use in vineyards should be considered as spot spray uses and exposure calculations should be adjusted accordingly (i.e. an assumption of application to 40% of the cropped area)[76].

Applications are indicated to be typically between September and January[77], targeting weeds before flowering or seed set. This temporal use pattern is proposed as a mitigation measure for birds and mammals.

It has been argued that, given the above-described use cases in vineyards, EFSA (2009) shortcut values for 'non-crop directed' application in orchards should be used in the assessment of the risk to birds.

3.46.1 APVMA response

The risk assessment has been updated to reflect situations where product labels specify inter-row use or targeted application at the base of vines. Where spot spraying is referenced on the product labels this application method has been more clearly identified in the risk assessment (the assessment is based on a default assumption that 40% of the area is treated). No data have been submitted to support adjusting the default assumption for the treated area in vineyards (i.e. 30% as opposed to the default of 40%). Therefore, there has been no change to the exposure assumption used in the risk assessment.

The stated typical timing of applications between September and January is noted. However, it is not clear how this would refine the acute risk assessment for terrestrial vertebrates, nor is this condition specified on the product labels. Therefore, it has not been considered further.

For uses in vineyards, the APVMA assessment in the draft RTR used the bare soil scenario for birds. As proposed in the comments the crop group has been adjusted to reflect 'non-crop directed' application for orchards.

3.47 Use situation – paraquat – potato situations

Relevant comment(s)
39, 43, 49, 64, 79, 100, 101, 109, 111, 113, 118, 119, 121, 129, 130, 136, 139, 150, 165

Comments received have noted multiple on-label uses of paraquat for use in potatoes:

- Paraquat only products, current on-label uses:
  - Use for pre-emergence weed control, up to emergence of 25% of potato seedlings.
  - Use for pre-harvest weed control, targeting young and established weeds before potato harvest but when there is no remaining green potato foliage.

[76] The assumption of a 40% treated area for spot spray uses is consistent with the default assumption applied by the APVMA for other spot sprayed use patterns (e.g. avocados, custard apples, lychees and mangoes).

[77] For the 2023-2024 growing season, from a total of 3430 spray application records 84% were between September and January inclusive

- Combination products (containing paraquat and diquat), current on-label uses:
  - Use for pre-emergence weed control, up to emergence of 25% of potato seedlings.
  - Use for pre-harvest weed control, targeting young and established weeds before potato harvest but when there is no remaining green potato foliage.
- Combination products (containing paraquat and amitrole), current on-label uses:
  - Use for pre-harvest weed control, targeting young and established weeds before potato harvest but when there is no remaining green potato foliage.

Additionally, the suitability of potato crops to support terrestrial vertebrates has been questioned and it has been requested that this is considered in the relevant section of the risk assessment.

3.47.1 APVMA response

The risk assessment for potatoes has been updated to account for all use situations, including the relevant on-label rates in each case. The crop groups for the terrestrial vertebrate risk assessment have been altered to include both bare soil and potato, given that uses include pre-emergence and post-emergence uses. The comments received have also implied that only the maximum rate was assessed for potatoes. This is not the case. The APVMA identified the maximum acceptable rate for a range of scenarios including potatoes, the explicit implication being that lower rates are acceptable. The APVMA did not present individual line-by-line assessments of each use.

Regarding comments related to terrestrial vertebrate risk assessment. Those comments that reference the AEA (2024) report have been addressed separately (see *Risks to terrestrial vertebrates – paraquat/diquat – mammalian daily energy expenditure for marsupials/monotremes* and *Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species*). The assertion that potato fields are unlikely to be able to support 100% of vertebrate organisms' (bird/mammal) diet is noted. However, no data has been submitted to support this claim or establish what, if any, species use potato fields in Australia. Therefore, no quantitative refinement of the risk assessment is possible.

3.48 Use situation – paraquat – lucerne situations

Relevant comment(s)
39, 49, 64, 100, 101, 111, 113, 118, 119, 121, 129, 130, 139, 150

Comments received have noted there are multiple on-label uses of paraquat for use in lucerne:

- Paraquat only products, current on-label uses:
  - Autumn/early-winter application.
  - Late-winter/early-spring application.
- Combination products (containing paraquat and diquat), current on-label uses:
  - Autumn application. Grazing, to a height of 2-4 cm, should occur before application.

– Winter application. Grazing, to a height of 2-4 cm, should occur before application.

Comments received have proposed revisions to the on-label uses and some mitigation measures for use in lucerne to address environmental concerns.

Comments received indicate that lucerne seed production is primarily based in the upper southeast of South Australia[78]. Listed threatened species of birds and mammals that may occur in this primary production area have been identified.

3.48.1 APVMA response

The risk assessment for lucerne has been updated to account for all use situations, including the relevant on-label rates in each case. The crop group for the terrestrial vertebrate risk assessment has also been altered to include legume forage, given that use is on existing stands of lucerne.

Only on-label uses have been considered in this chemical review assessment. New use patterns would have to be considered as part of a separate application. Any proposed mitigation for the on-label uses will be considered in the context of the relevant aspects of the risk assessment.

3.49 Use situation – paraquat – pasture situations

Relevant comment(s)
39, 69

It has been noted that hay freezing was not specifically included as a use in the original assessment.

3.49.1 APVMA response

The risk assessment has been updated to clarify which uses are included under the assessment for pasture, which includes hay freezing, spray topping to reduce seed set, prevention of ryegrass toxicity, perennial grass seed crops and kikuyu/paspalum pasture.

[78] With 85% in the upper southeast of South Australia (around Tintinara, Bordertown, Frances and Keith) and the remaining 15% located within the northern region of South Australia, New South Wales and Victoria.

3.50 Use situation – paraquat – sugar cane situations

Relevant comment(s)
39, 49, 64, 70, 80, 100, 101, 111, 113, 118, 119, 121, 122, 129, 130, 137, 139, 146, 147, 150

Comments received have stated that the actual use situations in sugarcane are different from those previously assessed.

- Paraquat only and combination products (containing paraquat and diquat), current on-label uses:
  - Over the top spray at up to the 3-4 leaf stage (BBCH 10-19).
  - Inter-row spray (using octopus leg, spider leg or Irvin spray system) between the 3-4 leaf stage and formation of the true stem. This targets the inter-row space and the base of the sugarcane plants, resulting in treatment of the whole cropped area but without treatment of the crop foliage.

Also, additional argument and supporting information has been provided regarding impacts on small mammals in the context of sugarcane fields.

3.50.1 APVMA response

The risk assessment for sugarcane has been updated to reflect the on-label use situations where relevant.

Maize has been used as a surrogate crop group for the terrestrial vertebrate risk assessment for both use situations based on similar row cropping practices, as there is no specific sugarcane crop group defined in the EFSA (2009) guidance. Comments received have argued that for the inter-row spray the diet composition should be changed for some generic focal species (small omnivorous birds and small herbivorous mammals), as there will be no treated crop foliage. Excluding the crop foliage dietary component may be a relevant refinement of the risk assessment for the small omnivorous bird but not the small herbivorous mammal[79]. The argument in relation to small omnivorous birds has been considered further in the terrestrial vertebrate risk assessment in the Paraquat Final Review Technical Report.

The additional information relating to small mammals in sugarcane has been considered in the terrestrial vertebrate risk assessment.

3.51 Use situation – paraquat – peanut situations

Relevant comment(s)
39, 49, 64, 100, 101, 111, 113, 118, 119, 121, 129, 130, 139, 150

[79] Small herbivorous mammals are assumed to eat either crop shoots or grass. The inter-row spray would not exclude grass or other weeds as dietary items for ground foraging organisms, and there will be no interception for these food items.

Comments received have stated that the actual use situations in peanuts are different from those previously assessed.

- Paraquat only products, current on-label uses:
  - Application up to the 7-8 leaf stage (BBCH 10-19).

3.51.1 APVMA response

The risk assessment has been updated to reflect the specific use pattern for peanuts.

3.52 Use situation – paraquat – vineyard situations

Relevant comment(s)
39, 49, 64, 100, 101, 106, 108, 111, 113, 118, 119, 121, 129, 130, 139, 148, 150

Comments received have stated that current usage in vineyard situations involves directed application in a strip under the vines (~30% of the cropped area). Other comments have indicated that use in vineyards should be considered as spot spray uses and exposure calculations should be adjusted accordingly (i.e. an assumption of application to 40% of the cropped area)[80].

Applications are indicated to be typically between September and January[81], targeting weeds before flowering or seed set. This temporal use pattern is proposed as a mitigation measure for birds and mammals.

It has been argued that, given the above-described use cases in vineyards, EFSA 2009 shortcut values for 'non-crop directed' application in orchards should be used in the assessment of the risk to birds.

3.52.1 APVMA response

The current risk assessment considers the approved instructions for use on-label as described. The labels for paraquat products to not specify use as a directed spray to the base of the vines. Therefore, directed spraying has not been assessed further. Spot spraying is referenced on the product labels, and this application method has been more clearly identified in the risk assessment (using a default assumption that 40% of the area is treated).

The stated typical timing of applications between September and January is noted. However, it is not clear how this would refine the acute risk assessment for terrestrial vertebrates, nor is this condition specified on the product labels. Therefore, it has not been considered further.

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[80] The assumption of a 40% treated area for spot spray uses is consistent with the default assumption applied by the APVMA for other spot sprayed use patterns (e.g. avocados, custard apples, lychees and mangoes).

[81] For the 2023-2024 growing season, from a total of 3430 spray application records 84% were between September and January inclusive

For uses in vineyards, the APVMA assessment in the draft RTR used the bare soil scenario for birds. As proposed in the comments the crop group has been adjusted to reflect 'non-crop directed' application for orchards.

3.53 Use situation – paraquat – rice situations

Relevant comment(s)
57, 139

Use of paraquat in rice is described as being in the weeks prior to sowing or shortly after sowing but before crop emergence and typically follows cultivation and/or stubble burns to prepare the seedbed. Weeds present at the time are expected to be at early vegetative stages.

3.53.1 APVMA response

Regarding the terrestrial vertebrate risk assessment, the exposure scenario assessed by the APVMA at Tier 1 was the bare soil scenario. This is consistent with the description of use in rice provided in the comments received. No change to the risk assessment scenario is proposed.

3.54 New data – paraquat – vapour pressure

Relevant comment(s)
n/a

A new study (Markell 2023) testing the vapour pressure of paraquat dichloride has been submitted to the APVMA.

3.54.1 APVMA response

The newly submitted study evaluating the vapour pressure of paraquat (Markell 2023) has been evaluated by the USEPA[82] and concluded to be acceptable. The vapour pressure is reported as 4.0×10^{-4} Pa (at 20°C) or 5.3×10^{-4} Pa (at 25°C). These estimates differ from the vapour pressure estimate previously available to the APVMA (i.e. $<1.0 \times 10^{-5}$ Pa at 25°C, as per the 2024 Review Technical Report). The updated vapour pressure would result in paraquat being classified as semi-volatile and indicates paraquat may volatilise from plant surfaces and soil.

[82] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0326

As discussed elsewhere, paraquat is readily absorbed to and strongly bound to soil and as such volatilisation of residues applied to soil is not expected. Volatilisation from plant surfaces cannot be excluded based on the newly submitted information, however technical examination suggests further evaluation is not required. A screening assessment based on the UBA exposure model[83] indicates that for the uses currently supported (i.e. up to 231 g ac/ha, as per the terrestrial vertebrate risk assessment) the risk would be acceptable (for aquatic organisms and terrestrial non-target plants) when crop interception under realistic field conditions is considered.

[83] https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/zul_umwelt_eva_prog-EN.html?nn=11010942

4 Residues

4.1 Cotton trash and cotton seed – combined paraquat and diquat residues

Relevant comment(s)
64, 148

Cotton Australia argued that the current controls in place for processing of cotton trash for use as animal feed, which include accreditation of participating cotton gins and participation in a residue monitoring program, are adequate to mitigate any risk posed by combined paraquat and diquat residues present in cotton trash following desiccation of cotton prior to harvest.

Syngenta note the APVMA's recommendation regarding cotton trash following desiccation of cotton prior to harvest and agreed that label statement prohibiting the feeding of cotton trash to animals should be sufficient to manage this concern.

4.1.1 APVMA response

No new information related to paraquat or diquat residues in cotton trash was submitted. The statement 'DO NOT feed cotton fodder, stubble or trash to livestock' remains appropriate.

4.2 Cotton seed – diquat residues

Relevant comment(s)
148

Syngenta submitted diquat residue studies in cotton seed, along with further argument aimed at retaining pre-harvest desiccation uses of diquat on cotton.

4.2.1 APVMA response

The submitted studies have been assessed and included in the Diquat Final Review Technical Report.

4.3 Canola – diquat

Relevant comment(s)
148

Syngenta submitted diquat residue studies in canola, along with further argument aimed at retaining pre-harvest desiccation uses of diquat on canola with a 4-day WHP.

4.3.1 APVMA response

The submitted studies have been assessed and included in the Diquat Final Review Technical Report.

4.4 Melons and Cucurbits – diquat

Relevant comment(s)
125, 148

Melons Australia noted that although there is a lack of residue data available for cucurbits they request for support retaining these uses. Syngenta submitted diquat residue studies on field and protected cucumbers.

4.4.1 APVMA response

The submitted studies have been assessed and included in the Diquat Final Review Technical Report.

4.5 Sorghum – diquat

Relevant comment(s)
148

Syngenta submitted diquat residue studies in sorghum that were already considered in the initial APVMA review, with further argument in support of retaining the pre-harvest desiccation use.

4.5.1 APVMA response

The submitted studies have been assessed and included in the Diquat Final Review Technical Report.

4.6 Sugarcane – paraquat and diquat

Relevant comment(s)
70, 80, 122, 137, 146, 147, 148

The sugar industry argued that the absence of data relevant to sugarcane does not equate to a risk to trade and that use of paraquat and diquat in sugarcane should be retained.

Syngenta provided paraquat residue studies in sugarcane conducted in Brazil and the USA.

4.6.1 APVMA response

The submitted paraquat residue studies have been assessed and included in the Paraquat Final Review Technical Report

4.7 Stalk and Stem vegetables – diquat

Syngenta provided 2 studies on diquat residues in asparagus.

4.7.1 APVMA response

The APVMA has considered these studies and the assessments have been included in the Diquat Final Review Technical Report.

4.8 Potatoes – paraquat

Relevant comment(s)
40, 79, 136, 148, 165

Several submissions highlighted the importance of pre-harvest haulm desiccation for the potato industry.

In response to the APVMA's proposed decision to remove the instructions for pre-harvest desiccation of potato haulms, Syngenta provided 3 studies in potatoes conducted in Brazil and the USA.

4.8.1 APVMA response

The submitted paraquat residue studies have been assessed and included in the Paraquat Final Review Technical Report.

4.9 Pulses – diquat

Relevant comment(s)
148

Syngenta has submitted additional data relevant to use of diquat in pulses to provide further support for these uses.

4.9.1 APVMA response

The submitted diquat residue studies have been assessed and included in the Paraquat Final Review Technical Report.

4.10 Pulses –paraquat

Relevant comment(s)
105, 124, 145, 148, 149,151

Commentors provided differing points of view on the proposed change to the harvest withholding period from 7 days to 14 days for pulses following spray-topping with paraquat.

4.10.1 APVMA response

Without data demonstrating the quantity of paraquat residue remaining at 7 days after last application, the APVMA cannot be satisfied that a 7-day harvest withholding period will not result in residues exceeding the MRL.

4.11 Wheat – paraquat

Relevant comment(s)
91

A publicly available journal article by Gupta et al (Environmental Science and Pollution Research (2023) 30:54242–54243), which explored paraquat residues in wheat grain in field experiments conducted in India from 2018 - 2020 was submitted. Paraquat was applied prior to sowing of wheat over two seasons each at rates corresponding to 1.02 kg ai/ha. The article indicated that they found paraquat in wheat grains ranging between 21.6 and 49.02 mg/kg with residues also found in the control crop (3.1 mg/kg).

4.11.1 APVMA response

This is inconsistent with the cereal residue trials presented to the review where pre-emergence trials on wheat, barley and oats did not detect residues above the Limit of Quantification (LOQ) (0.01 to 0.05 mg/kg) in grain after application at 1.12 – 5.6 kg ai/ha (up to 9× the current rate). The non-GLP journal article is not considered to be a reliable measure of potential residues in wheat grain from the registered uses of paraquat.

4.12 Wheat and oats – diquat

Relevant comment(s)
148

In response to the proposed regulatory decisions recommending a diquat MRL of 2 for wheat and oats, Syngenta have submitted additional diquat data for wheat and oats.

4.12.1 APVMA response

The submitted diquat residue studies have been assessed and included in the Paraquat Final Review Technical Report.

5 Human Health

The APVMA received 49 written submissions related to human health in response to the publication of the proposed regulatory decisions on the reconsideration of paraquat and diquat. The included 26 submissions without supporting references calling on a ban of paraquat due to links to Parkinson's Disease and 23 submissions that provided further information that has been considered by the APVMA.

5.1 Paraquat should be banned

Relevant comment(s)
7, 18, 19, 22, 23, 28, 29, 32, 38, 52, 54, 62, 67, 68, 76, 77, 88, 90, 91, 93, 94, 96, 99, 104, 112, 117, 133, 134, 153, 157, 158, 159, 160, 161, 163, 164, 166, 167, 168, 169, 170, 171

43 Submissions argued that paraquat should be "banned" because of links to Parkinson's disease. Of these, 17 submissions cited 156 references consisting of 134 peer reviewed papers, 22 additional documents (including reports, guidance documents, news articles) and one submission from industry which were screened for relevance to the human health risk assessment of paraquat used as a herbicide. Of the 156 cited references, those initially identified as potentially relevant to the HHRA were read and considered in their entirety. Of these papers, 17 were identified as published after completion of the 2016 APVMA review and were therefore considered in detail for this report. A further 4 relevant papers were identified in a literature search and were also considered in detail for this report.

5.1.1 APVMA response

The submissions received by the APVMA in relation to Parkinson's disease have been considered carefully by the APVMA. The details of these assessments are published separately: briefly, the conclusion of the assessments is that there is no convincing evidence for a causal link between paraquat exposure when used as a herbicide and Parkinson's disease.

5.2 Worker safety – gloves

Relevant comment(s)
30

The Australian Pesticide Reduction Network raised concerns about the suitability and efficacy of chemical resistant gloves as specified in the proposed safety directions for paraquat.

5.2.1 APVMA response

The issues raised are not specific to paraquat but address the broader issue of efficacy of chemical resistant glove types to specific pesticides. Chemical resistant gloves in Australia are covered by AS/NZS 2161.10:2005 standard, which aligns with the European EN 374 standard. In respect of paraquat specifically this is a highly ionised and highly water-soluble chemical that will not readily penetrate any otherwise chemical resistant glove material.

The APVMA does not recommend specifications for gloves. The recommendation is to use appropriate personal protective equipment (PPE) including elbow-length chemical resistant gloves. The onus is on the user to ensure compliance with WHS regulations when handling chemicals and pesticides.

5.3 Worker safety – area treated

Relevant comment(s)
103

Apple and Pear Australia Ltd state that it would be highly uncommon for a single operator in a pome fruit orchard to be treating 60-600 ha/day and suggests repeating modelling for 6-59 ha as a more reasonable area range to be treated in a single day.

5.3.1 APVMA response

In the proposed regulatory decisions, the use of paraquat and combination products containing both paraquat and diquat was not supported in orchards above 54 g paraquat/ha, while products containing diquat were not supported above 88 g diquat/ha due to risks to terrestrial vertebrates. In the final regulatory decisions, following revisions of risk assessment these maximum acceptable rates are 45 g ac/ha for paraquat and 188 g ac/ha for diquat.

The APVMA has assessed medium scale groundboom application (> 6 to < 60 ha/d) and considers the existing minimum personal protective equipment for broad scale use suitable for medium scale use.

To minimise the likelihood of decanting into unacceptable containers which may lead to consequential accidental exposure, a closed mixing/loading system is required for all paraquat and diquat uses, including medium scale groundboom application.

5.4 Worker safety – daily work rates (ha/day)

Relevant comment(s)
64, 121, 148

Commentors questioned the assumptions in Table 9 of the Paraquat Review Technical Report which states that the value for ground boom field application to cotton is 600 hectares per day. They note that this figure seems high and conflicts with the value of 400 hectares per day that was used in the recent regulatory review of chlorpyrifos. The basis for the number of hectares treated per day should be reviewed and reconsidered. If appropriate the worker exposure assessment should be revised accordingly.

5.4.1 APVMA response

Instead of modelling exposure for a pre-determined work rate, the APVMA used a reverse exposure modelling approach to determine the maximum quantity of active constituent that can be safely handled each day (determined as 337 kg paraquat/day). For example, when using a 250 g/L paraquat product, a single operator must not mix, load and apply more than 1348L of neat product per day, which would be sufficient to treat approximately 1,450 ha at the maximum rate supported by the environment risk assessment of 231 g ac/ha. As it is not feasible that a single user could treat this area, no restrictions on area treated or quantity of product used will be applied.

5.5 Retain 20 litre containers – closed mixing and loading is feasible

Relevant comment(s)
64, 113, 121, 148

Several commenters advised the APVMA that 20 L containers compatible with closed mixing and loading systems are commercially available and that these should remain an approved pack size.

5.5.1 APVMA response

It is a condition of continued registration that products containing paraquat, diquat or both active constituents in combination must be supplied in a container sealed with a fitting compatible with closed mixing and loading systems to prevent decanting of the products into unapproved secondary containers and to mitigate risks of worker exposure during mixing and loading. Provided that the container meets this condition, it would be acceptable to retain 20L containers.

The APVMA considers the restriction that a closed mixing/loading system MUST be used is suitable for all diquat containing products regardless of the container size. The use of drum tap lids is not considered sufficient to mitigate risks associated with decanting into unacceptable containers, noting that risk of accidental exposure is not restricted to splash-back risks.

5.6 Clarity and presentation of re-entry instructions

Relevant comment(s)
64, 71, 121, 148

Several submissions commented that the proposed re-entry period statements are confusing and argue that it does not make sense to have different re-entry period statements for paraquat only products as opposed to paraquat plus diquat formulations.

5.6.1 APVMA response

The re-entry period considers the active application rate used when performing post application activities. The differences in re-entry periods between paraquat only and paraquat plus diquat products were determined based on a higher paraquat application rate being modelled for paraquat only products compared to paraquat plus diquat products, and a higher diquat application rate modelled for diquat only product compared to paraquat + diquat products.

For paraquat, low exposure activities, including scouting and irrigation, are acceptable once the spray is dried. High exposure activities, including ploughing, tilling, levelling, planting, and mechanical harvesting, are acceptable using closed cab equipment at any time, or if using open cab equipment, on day 3 after application.

For diquat a similar meaning applies, low exposure activities including scouting and non-hand-set irrigation are acceptable 1 day after application and hand-set irrigation is acceptable 3 days after application. High exposure activities including ploughing, tilling, levelling, planting and mechanical harvesting are acceptable using closed cab equipment at any time, or if using open cab equipment, 12 days after application.

6 Appendix – Environment – background information

6.1 Mammalian allometric equations and daily energy expenditure

Daily energy expenditure (DEE) is predicted to be lower for non-eutherian mammals compared to eutherian mammals. Therefore, the default equation for mammals in EFSA (2009) will overestimate the DEE for marsupials/monotremes. This is a known issue in the context of risk assessment for mammals in Australia. Historically the APVMA has used equations from the study Nagy (1999) to refine risk assessments when needed.

During the consultation period alternate allometric equations were proposed for non-eutherian mammals (i.e. marsupials/monotremes), to replace the allometric equation for eutherian mammals used in EFSA (2009). Given the newly proposed equations include more data than existing approaches they have been considered further. Table 912 summarises the allometric equations for calculating DEE[84]. The resulting DEE estimates for body weights up to 5000 g are illustrated in Figure 1 (natural scale) and Figure 2 (log scale) – body weight is plotted up to 5000 g, this being an arbitrary choice with no specific significance. The percentage difference between the results from the different equations is illustrated in Figure 3; where 0% on the y axis indicates that an alternate equation would calculate the same result as the proposed AEA (2024) equation for all non-eutherian mammals at that body weight – only body weights up to 100 g are presented, as smaller animals are typically more critical to risk assessment. Discussion of the equation used in risk assessment is included in the response *Risks to terrestrial vertebrates – paraquat/diquat – mammalian daily energy expenditure for marsupials/monotremes*.

Table 9: Mammalian allometric equation parameters for determining DEE

Mammalian group	Reference/ source	Allometric equation parameters			Data set	
		Log(a)	b	r^2	Total observations	No. species
Eutherian[85]	EFSA 2009	0.814	0.715	0.968	NR	46
All non-eutherian[86]	DEFRA 2007	0.957	0.593	0.958	NR	32
	AEA 2024	**1.011**	**0.589**	**0.968**	**91**	**39**
Herbivorous non-eutherian	AEA 2024	0.774	0.653	0.945	47	21
Insectivorous non-eutherian	AEA 2024	1.000	0.619	0.916	26	8
Omnivorous non-eutherian	AEA 2024	1.112	0.531	0.886	14	7

NR = not reported

Allometric equation parameters calculate daily energy expenditure (DEE) as: DEE (KJ/d) = 10^(Log(a) + b × Log(bw))

[84] Equations from Nagy 1999 are not reproduced as that data is included in both the AEA and DEFRA equations for non-eutherian mammals.

[85] Placental mammals, excludes non placental mammals (marsupials and monotremes) and desert dwelling and marine placental mammals

[86] Non-placental mammals, i.e. marsupials and monotremes

Figure 1: Mammalian daily energy expenditure (natural scale)

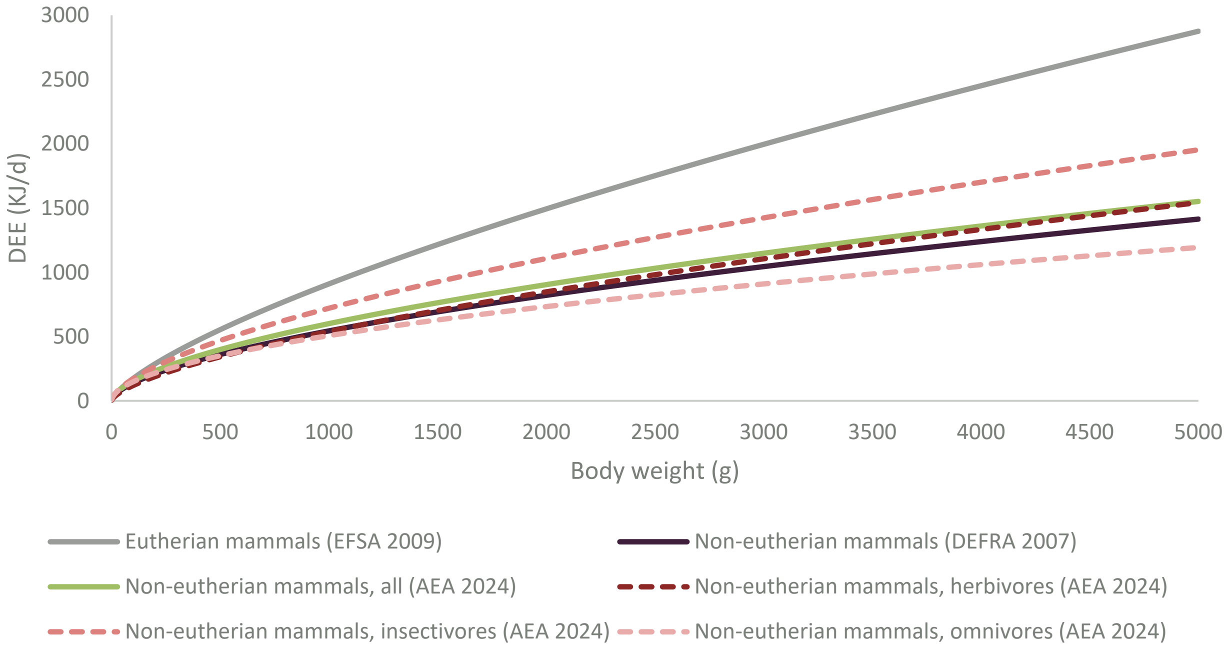


Figure 2: Mammalian daily energy expenditure (log scale)

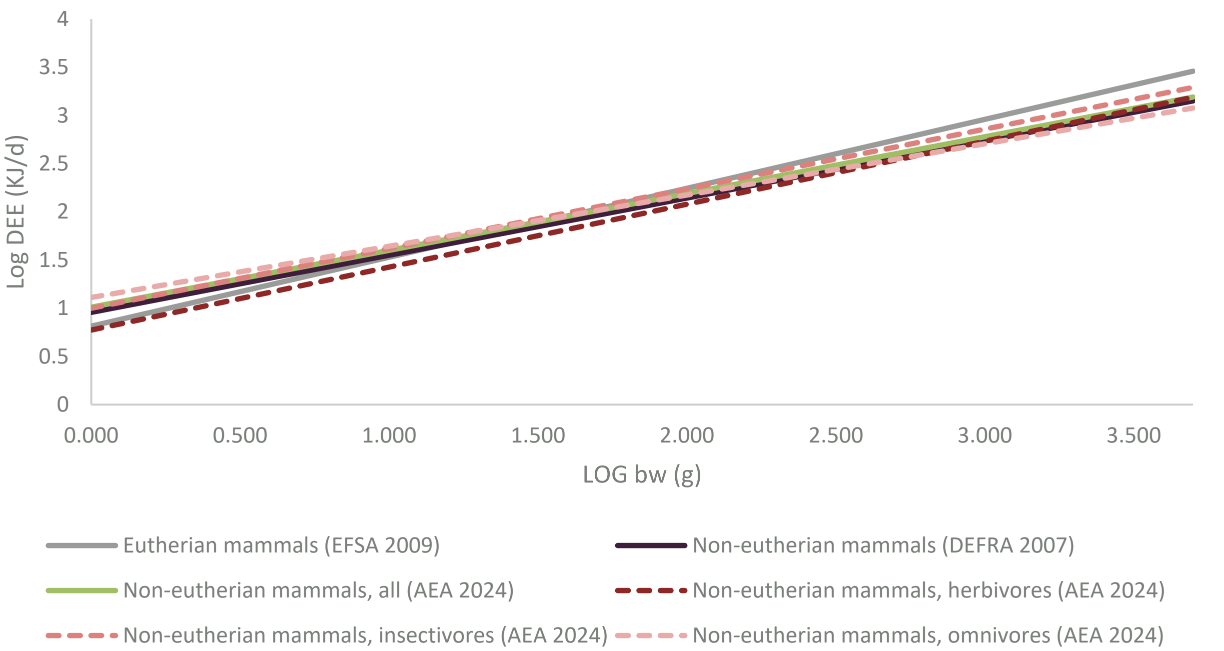
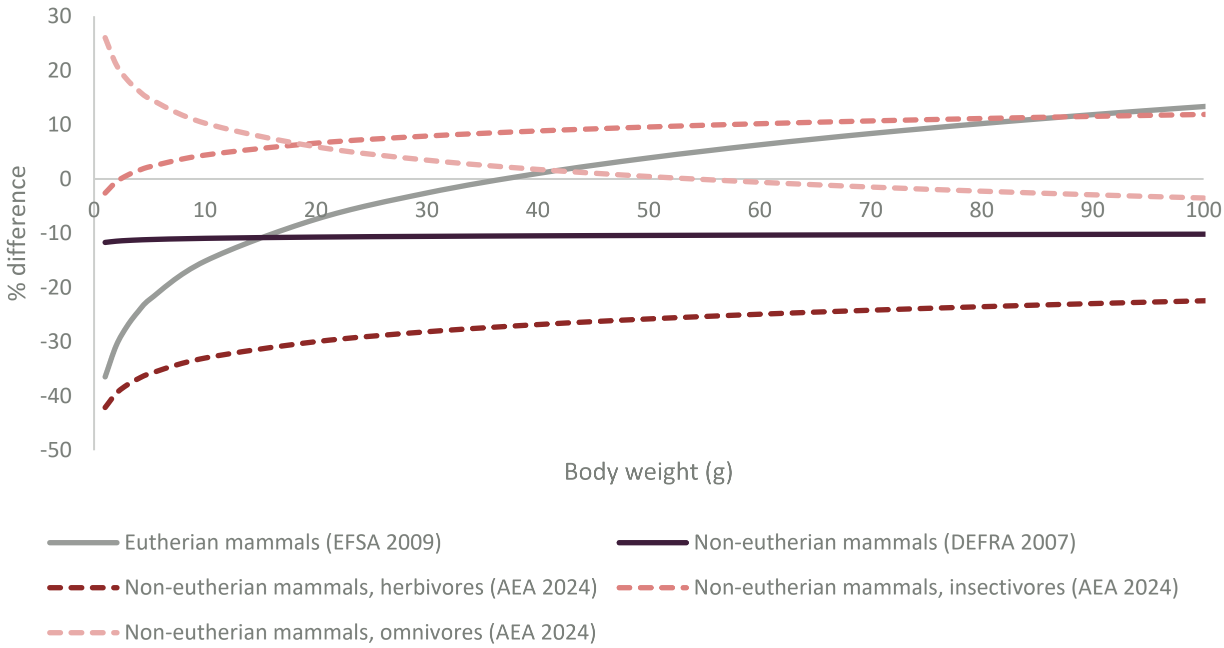


Figure 3: Percentage difference in daily energy expenditure, compared to AEA (2024) equation for all non-eutherian mammals (0% indicates no difference, positive values indicate a larger DEE, negative values indicate lower DEE)



6.2 Australian rodent species and implications for generic focal species

Australian rodent species are summarised in Table 10. This is the group of mammal species expected to be represented by the small omnivorous and small herbivorous mammal generic focal species.

A selection of dietary assumptions for small omnivorous mammals are included in Table 11. This is intended to illustrate the impact of different dietary assumptions in relation to the discussion in *Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species*, it does not imply any statement about the validity or relevance of the alternate diets.

A selection of dietary/body-weight assumptions for small herbivorous mammals are included in Table 12. This is intended to illustrate the impact of different body weights on the shortcut values that would be used for risk assessment. In *Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species* it has been proposed to use a body weight of 50 g for the small herbivorous mammal generic focal species. The shortcut values quoted in the table with the 'grass + cereals' RUD are the relevant values for use in risk assessment. For brevity only shortcut values where the interception factor is 0 have been presented. Where necessary for risk assessment the shortcut values have been adjusted to reflect appropriate interception factors (based on EFSA 2020), situations where this is the case have been identified in the refined assessments in the paraquat and diquat final RTRs.

Table 10: Australian rodent species

Order	Family	Species[87]	Extant/extinct
Rodentia	Muridae	*Conilurus albipes*	Extinct
		Conilurus capricornensis	Extinct
		Conilurus penicillatus	Extant
		Hydromys chrysogaster	Extant
		Leggadina forresti	Extant
		Leggadina lakedownensis	Extant
		Leporillus apicalis	Extinct
		Leporillus conditor	Extant
		Mastacomys fuscus	Extant
		Melomys burtoni	Extant
		Melomys capensis	Extant
		Melomys cervinipes	Extant
		Melomys rubicola	Extinct
		Mesembriomys gouldii	Extant
		Mesembriomys macrurus	Extant
		Mus musculus	Extant
		Notomys alexis	Extant
		Notomys amplus	Extinct
		Notomys aquilo	Extant
		Notomys cervinus	Extant
		Notomys fuscus	Extant
		Notomys longicaudatus	Extinct
		Notomys macrotis	Extinct
		Notomys mitchellii	Extant
		Notomys mordax	Extinct
		Notomys robustus	Extinct
		Pogonomys mollipilosus	Extant
		Pseudomys albocinereus	Extant
		Pseudomys apodemoides	Extant
		Pseudomys auritus	Extinct
		Pseudomys australis	Extant
		Pseudomys bolami	Extant
		Pseudomys calabyi	Extant
		Pseudomys chapmani	Extant
		Pseudomys delicatulus	Extant
		Pseudomys desertor	Extant
		Pseudomys fumeus	Extant
		Pseudomys glaucus	Extinct
		Pseudomys gouldii	Extant
		Pseudomys gracilicaudatus	Extant
		Pseudomys hermannsburgensis	Extant
		Pseudomys higginsi	Extant
		Pseudomys johnsoni	Extant
		Pseudomys mimulus	Extant
		Pseudomys nanus	Extant
		Pseudomys novaehollandiae	Extant
		Pseudomys occidentalis	Extant
		Pseudomys oralis	Extant
		Pseudomys patrius	Extant
		Pseudomys pilbarensis	Extant
		Pseudomys shortridgei	Extant
		Rattus colletti	Extant
		Rattus exulans	Extant
		Rattus fuscipes	Extant

[87] Taxonomy based on the Australian Faunal Directory (https://biodiversity.org.au/afd/home)

Order	Family	Species[87]	Extant/extinct
		Rattus leucopus	Extant
		Rattus lutreolus	Extant
		Rattus macleari	**Extinct**
		Rattus nativitatis	**Extinct**
		Rattus norvegicus	Extant
		Rattus rattus	Extant
		Rattus sordidus	Extant
		Rattus tunneyi	Extant
		Rattus villosissimus	Extant
		Uromys caudimaculatus	Extant
		Uromys hadrourus	Extant
		Xeromys myoides	Extant
		Zyzomys argurus	Extant
		Zyzomys maini	Extant
		Zyzomys palatalis	Extant
		Zyzomys pedunculatus	Extant
		Zyzomys woodwardi	Extant
		Count (all)	71
		Count (extant)	58

Table 11: Mammalian generic focal species, small omnivorous mammals

Generic focal species	Small omnivorous mammal				
Allometric equation	Eutherian mammal (EFSA 2009)				
BW (g)	21.7	21.7	21.7	21.7	21.7
DEE (KJ/d)	59	59	59	59	59
RUD category	(1) Non-grass herbs, (2) Weed seeds, (3) Arthropods, without interception				
PD (%)	(1) 25, (2) 50, (3) 25	(1) 50, (2) 50	(1) 50, (3) 50	(1) 75, (2) 25	(1) 75, (3) 25
Interception	0	0	0	0	0
MC (%)	(1) 88.1, (2) 9.9, (3) 68.8	(1) 88.1, (2) 9.9	(1) 88.1, (3) 68.8	(1) 88.1, (2) 9.9	(1) 88.1, (3) 68.8
AE (%)	(1) 76, (2) 84, (3) 87	(1) 76, (2) 84	(1) 76, (3) 87	(1) 76, (2) 84	(1) 76, (3) 87
FE dry (KJ/g dw)	(1) 17.8, (2) 21.7, (3) 22.7	(1) 17.8, (2) 21.7	(1) 17.8, (3) 22.7	(1) 17.8, (2) 21.7	(1) 17.8, (3) 22.7
FIR (g fw/d)	5.79	6.52	15.1	11.1	21.4
FIR/BW	0.27	0.30	0.70	0.51	0.99
RUD 90^{th}	(1) 70.3, (2) 87, (3) 13.8	(1) 70.3, (2) 87	(1) 70.3, (3) 13.8	(1) 70.3, (2) 87	(1) 70.3, (3) 13.8
Acute shortcut	17.2	23.6	29.3	38.0	55.4
RUD mean	(1) 28.7, (2) 40.2, (3) 7.5	(1) 28.7, (2) 40.2	(1) 28.7, (3) 7.5	(1) 28.7, (2) 40.2	(1) 28.7, (3) 7.5
Chronic shortcut	7.8	10.4	12.6	16.1	23.1

Grey background represents the default parameters used for the generic focal species in EFSA 2009

BW = body weight

DEE = daily energy expenditure, calculated using equation for mammals from Appendix G in EFSA 2009

RUD = residue unit dose, where RUD category, RUD 90^{th} and RUD mean from Appendix F in EFSA 2009

PD = proportion of diet

MC = moisture content from Appendix G in EFSA 2009

AE = assimilation efficiency from Appendix G in EFSA 2009

FE dry = food energy from Appendix G in EFSA 2009

FIR = food ingestion rate = DEE / ∑ (PD/100 × FE × (1 – MC/100) × AE/100)

Shortcut = ∑ (RUD × PD/100 × (1 – interception)) × FIR/BW

Table 12: Mammalian generic focal species, small herbivorous mammals

Generic focal species	Small herbivorous mammal					
Allometric equation	Eutherian mammal (EFSA 2009)					
BW (g)	25	50	500	25	50	500
DEE (KJ/d)	65	107	554	65	107	554
RUD unit	Grass + cereals			Non-grass weeds		
PD (%)	100	100	100	100	100	100
Interception	0	0	0	0	0	0
MC (%)	76.4	76.4	76.4	88.1	88.1	88.1
AE (%)	47	47	47	76	76	76
FE dry (KJ/g dw)	17.6	17.6	17.6	17.8	17.8	17.8
FIR (g fw/d)	33.3	54.7	284	40.4	66.4	344
FIR/BW	1.33	1.09	0.57	1.62	1.33	0.69
RUD 90^{th}	102.3	102.3	102.3	70.3	70.3	70.3
Acute shortcut	136.4	112.0	58.1	113.7	93.3	48.4
RUD mean	54.2	54.2	54.2	28.7	28.7	28.7
Chronic shortcut	72.3	59.3	30.8	46.4	38.1	19.8

Grey background represents the default parameters used for the generic focal species in EFSA 2009

BW = body weight

DEE = daily energy expenditure, calculated using equation for mammals from Appendix G in EFSA 2009

RUD = residue unit dose, where RUD category, RUD 90^{th} and RUD mean from Appendix F in EFSA 2009

PD = proportion of diet

MC = moisture content from Appendix G in EFSA 2009

AE = assimilation efficiency from Appendix G in EFSA 2009

FE dry = food energy from Appendix G in EFSA 2009

FIR = food ingestion rate = DEE / ∑ (PD/100 × FE × (1 – MC/100) × AE/100)

Shortcut = ∑ (RUD × PD/100 × (1 – interception)) × FIR/BW

6.3 Australian herbivorous marsupials and implications for generic focal species

A selection of body weights and different allometric equations are included in Table 13. In *Risks to terrestrial vertebrates – paraquat/diquat – Australian native mammals and generic focal species* it is proposed to use a body weight of 1500 g with the AEA 2024 allometric equation to represent Australian non-eutherian species. For brevity only shortcut values where the interception factor is zero have been presented. Where necessary for risk assessment the shortcut values have been adjusted to reflect appropriate interception factors (based on EFSA 2020), situations where this is the case have been identified in the refined assessments in the paraquat and diquat final RTRs.

Table 13: Mammalian generic focal species, large herbivorous mammals

Generic focal species	Large herbivorous mammal							
Allometric equation	Eutherian mammal (EFSA 2009)		Non-eutherian mammal (AEA 2024)		Eutherian mammal (EFSA 2009)		Non-eutherian mammal (AEA 2024)	
BW (g)	1543	3800	1500	3000	1543	3800	1500	3000
DEE (KJ/d)	1241	2363	762	1146	1241	2363	762	1146
RUD unit	Grass + cereals				Non-grass weeds			
PD (%)	100	100	100	100	100	100	100	100
Interception	0	0	0	0	0	0	0	0
MC (%)	76.4	76.4	76.4	76.4	88.1	88.1	88.1	88.1
AE (%)	47	47	47	47	76	76	76	76
FE dry (KJ/g dw)	17.6	17.6	17.6	17.6	17.8	17.8	17.8	17.8
FIR (g fw/d)	636	1211	390	587	771	1468	473	712
FIR/BW	0.41	0.32	0.26	0.20	0.50	0.39	0.32	0.24
RUD 90th	102.3	102.3	102.3	102.3	70.3	70.3	70.3	70.3
Acute shortcut	42.1	32.6	26.6	20.0	35.1	27.2	22.2	16.7
RUD mean	54.2	54.2	54.2	54.2	28.7	28.7	28.7	28.7
Chronic shortcut	22.3	17.3	14.1	10.6	14.3	11.1	9.1	6.8

Grey background represents the default parameters used for the generic focal species in EFSA 2009

BW = body weight

DEE = daily energy expenditure, calculated using equation for mammals from Appendix G in EFSA 2009

RUD = residue unit dose, where RUD category, RUD 90th and RUD mean from Appendix F in EFSA 2009

PD = proportion of diet

MC = moisture content from Appendix G in EFSA 2009

AE = assimilation efficiency from Appendix G in EFSA 2009

FE dry = food energy from Appendix G in EFSA 2009

FIR = food ingestion rate = DEE / ∑ (PD/100 × FE × (1 – MC/100) × AE/100)

Shortcut = ∑ (RUD × PD/100 × (1 – interception)) × FIR/BW

6.4 Grain growing regions in Australia

During consultation, argument was provided to propose identification of non-target vertebrate species of relevance to grain growing regions in Australia, based on a claimed delineation of the latter. The comments received make reference to crop distribution information on the DAFF Land use and Management website (https://www.agriculture.gov.au/abares/aclump/publications#land-use-change), and also include a map of catchment scale land use in Australia (Figure 4). Other mapping information is available from the DAFF website which breaks down land use by simplified classifications[88] or commodities[89].

However, the crop distribution information used to support this argument has not been clearly described, nor has the nature of the parameter(s) considered to identify the putative grain growing or broadacre cropping areas.

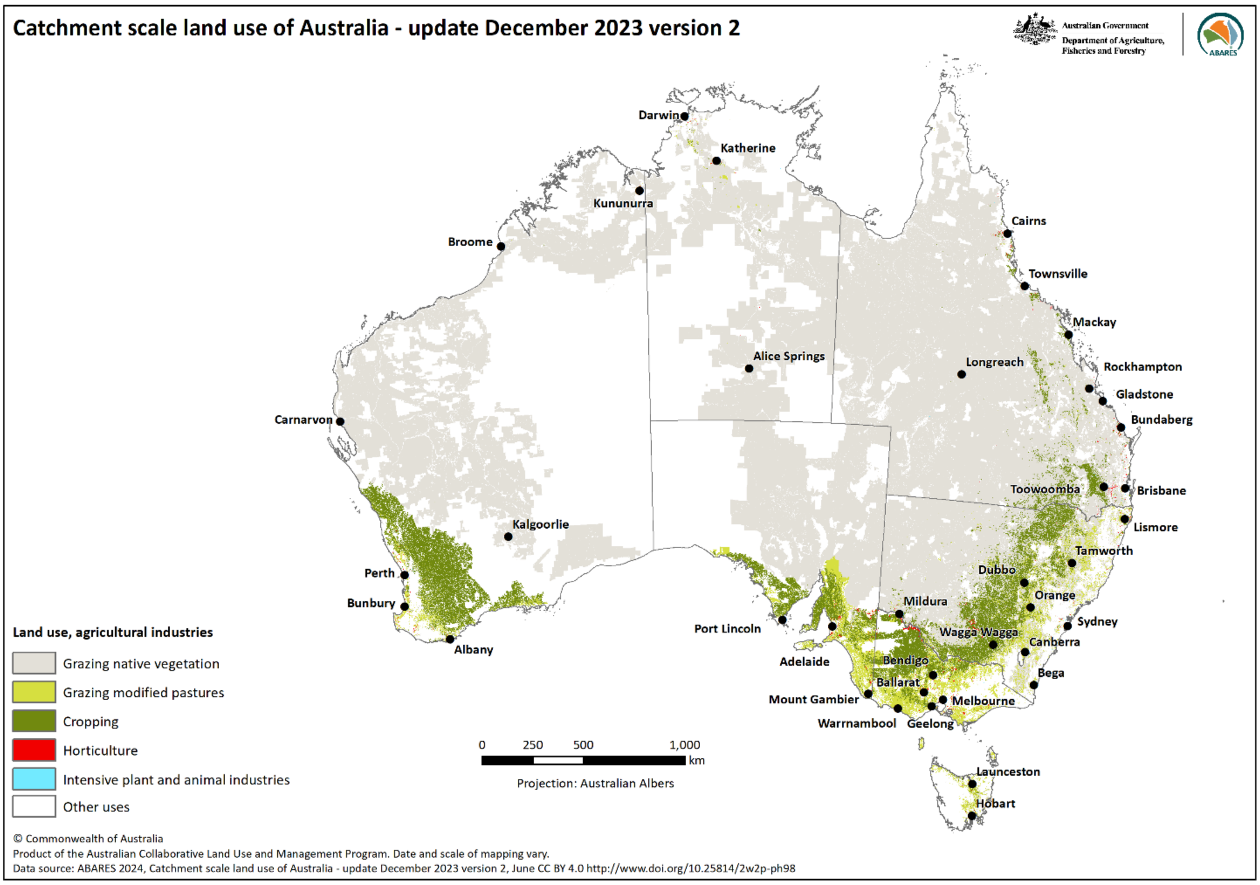
It is noted that other sources, such as Australian production data as summarised by the USDA[90], imply that depending how crop distribution information is interpreted, some regions with the capacity for grain production may not have been included in the land use analysis. For example, production data imply that sorghum is grown in northern Queensland and the Northern Territory (at relatively low quantities); it cannot be determined whether these areas have been included in the process proposed in the submitted comments.

88 https://www.agriculture.gov.au/sites/default/files/documents/NLUM_v7_250m_SIMP_2015_16.pdf

89 https://www.agriculture.gov.au/sites/default/files/documents/NLUM_v7_250m_AGCOMMOD_2020_21.pdf

90 https://ipad.fas.usda.gov/countrysummary/Default.aspx?id=AS

Figure 4: Catchment scale land use of Australia



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