CALL FOR INFORMATION REQUEST

Paraquat and paraquat-containing formulations

JULY 2017

Please note:
Please note that any information supplied to the EPA as part of this process may be the subject of a request made under the Official Information Act 1982 (OIA). The OIA allows us to withhold information from release for various reasons including on the basis of commercial sensitivity or privacy. If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be asked to provide further justification for your claim of confidentiality.
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Summary

The Environmental Protection Authority (EPA) has recently determined that there are grounds to reassess use of paraquat and paraquat-containing substances, the primary concerns being that there are unmanaged human health risks and risks to aquatic environments arising from exposure to paraquat-containing substances during use.

Consequently, we, the EPA, intends to reassess the approvals for paraquat and paraquat-containing substances. We will review the current uses of paraquat and undertake an assessment of those uses, and will work with WorkSafe New Zealand to determine if risks to workers are managed. The assessment will comprise of an analysis of risks and benefits associated with paraquat use through the entire lifecycle of paraquat-containing substances from import or manufacture, to use or disposal. In order to ensure that we are able to undertake an assessment that accurate and representative of current use of these substances, we are asking industry and users to provide us with information on current use and practice, and of the benefits and need to use paraquat. We will use this information to develop representative assessment scenarios in order to present decision makers with proposals based on the best risk and benefit information that is available to us.

There will be an opportunity for interested parties to make formal submissions on the EPA’s assessment and proposals, when the application is publicly notified in 2018.

We have put together a list of questions for that we think will help us to obtain the information that we need to complete the risk-benefits assessment. We would greatly appreciate if industry or users would support this assessment by providing information about paraquat-containing products and their current use in New Zealand. Please complete the questions as comprehensively as possible and provide additional comments where appropriate. This information will be fundamental in ensuring use scenarios are accurate and applicable to the products in the reassessment.

Feedback forms are available on our website at http://epa.govt.nz/Publications/Paraquat_response_template.doc.

Please complete and return your feedback form to reassessments@epa.govt.nz the EPA by 5pm on 4 September 2017.

If you would like to provide information but cannot meet this deadline please contact us to discuss alternative options on reassessments@epa.govt.nz.

Background information

1 http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP202788_APP202788_Grounds%20Decision_FINAL.pdf
Reassessment of paraquat and paraquat-containing substances

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The EPA regulates hazardous substances (chemicals and chemical mixtures) under the Hazardous Substances and New Organisms (HSNO) Act. All hazardous substances imported, manufactured or used in New Zealand require an approval under HSNO. From time to time, the EPA reassesses the approval of a hazardous substance, or group of hazardous substances.

Paraquat is a general purpose herbicide which has been used in New Zealand since the 1960s. It is used in forestry, ground, vine and tree crops, pasture renewal and to remove weeds in drains, waterways and along fence lines. It is unique in that it is the only non-vertebrate toxic agent active ingredient for which there are formulations approved that have the highest category of classification for acute toxicity (6.1A), meaning that paraquat and paraquat containing substances are highly acutely toxic to humans.

In February 2016 we completed a risk assessment for a new pesticide containing paraquat, Para-Ken 250 (application APP202697), which showed that the risks to human health and the environment were higher than previously anticipated and that the human health risks could not be sufficiently reduced by applying controls to the substance. The risk assessment also showed that paraquat poses high risks to aquatic organisms. The application was subsequently declined, and information obtained from this risk assessment was used to determine grounds for reassessment.

We consider that the concerns raised for Para-Ken 250 are directly relevant to the other formulations containing paraquat and regulatory action may be necessary to ensure that exposures are adequately and appropriately managed. On 30 June 2017 grounds for reassessment were granted to reassess all approvals for substances that contain paraquat or paraquat dichloride.

**Next steps**

Once we have received feedback, we will use this information to assist us to prepare the formal reassessment application. This will then be publicly notified and open for submissions. After submissions have been received and evaluated, a hearing is likely to be held. Following a hearing, a final decision will be made and released. Table 1 sets out the planned dates of the different reassessment stages, however, please note that these dates may change.

<table>
<thead>
<tr>
<th>The reassessment process</th>
<th>Indicative completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call for information document and feedback process form</td>
<td>31 August 2017</td>
</tr>
<tr>
<td>released for consultation</td>
<td></td>
</tr>
<tr>
<td>Feedback received and analysed; application drafted</td>
<td>September – December 2017</td>
</tr>
<tr>
<td>Formal reassessment application open for submissions</td>
<td>Early February 2018</td>
</tr>
<tr>
<td>Submissions close</td>
<td>Mid-March 2018</td>
</tr>
<tr>
<td>Hearing/Consideration</td>
<td>Early May 2018</td>
</tr>
<tr>
<td>Final decision</td>
<td>End June 2018</td>
</tr>
</tbody>
</table>
Reassessment of paraquat and paraquat-containing substances

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Scope of reassessment

HSNO approvals and products for paraquat-containing substances to be reassessed

The following table details the paraquat-containing substances that are approved under HSNO. Each of the approvals for paraquat-containing formulations are in use for ACVM-registered products.

<table>
<thead>
<tr>
<th>Approval number</th>
<th>HSNO Substance Name / product name</th>
<th>Use status</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSR003041</td>
<td>Paraquat (active ingredient)</td>
<td>Manufacturing and analysis</td>
</tr>
<tr>
<td>HSR000447</td>
<td>Soluble concentrate containing 115 g/litre diquat as the dibromide salt and 135 g/litre paraquat as the dichloride salt</td>
<td>In use</td>
</tr>
<tr>
<td></td>
<td>Speedy Herbicide</td>
<td>ACVM registered</td>
</tr>
<tr>
<td>HSR000828</td>
<td>Soluble concentrate containing 200 - 250 g/litre paraquat as the dichloride salt</td>
<td>In use</td>
</tr>
<tr>
<td></td>
<td>AGPRO Paraquat 200; Paraquat 200SL; PQ 200; Gramoxone 250; Flash Herbicide; Parable, Genfarm Paraquat 250 Herbicide</td>
<td>ACVM registered</td>
</tr>
<tr>
<td>HSR100443</td>
<td>Uniquat 250</td>
<td>In use</td>
</tr>
<tr>
<td></td>
<td>Uniquat 250</td>
<td>ACVM registered</td>
</tr>
<tr>
<td>HSR100572</td>
<td>Parable 250</td>
<td>In use</td>
</tr>
<tr>
<td></td>
<td>Parable 250</td>
<td>ACVM registered</td>
</tr>
<tr>
<td>HSR007854</td>
<td>Preeglone Inteon</td>
<td>In use</td>
</tr>
<tr>
<td></td>
<td>Preeglone</td>
<td>ACVM registered</td>
</tr>
<tr>
<td>HSR007847</td>
<td>Gramoxone Inteon</td>
<td>In use</td>
</tr>
<tr>
<td></td>
<td>Gramoxone Inteon</td>
<td>ACVM registered</td>
</tr>
</tbody>
</table>

Notes:

This list includes all approved substances that contain paraquat or its salts, including paraquat as a single substance. There is no separate approval for paraquat dichloride, or its manufacturing concentrate.
Lifecycle stages assessed

Under HSNO a substance is regulated throughout its entire lifecycle, from import/manufacture through to disposal. The risk assessment to be undertaken will focus on the life cycle stages of the substance that presents the greatest risks to the environment and human health.

General information requested

For all substances the EPA request information as outlined below. We have prepared a response template that you can use to provide the requested information if you wish. The template can be found here: http://epa.govt.nz/Publications/Paraquat_response_template.doc.

A. Substance information (for importers and manufacturers only)
The following information is requested to ensure that we have up-to-date information on the composition of substances and any associated toxicologically significant impurities that may be present. Furthermore, we are requesting product volume information to allow us to get the most complete picture of paraquat use in New Zealand and produce an accurate New Zealand risk profile.

1. Full composition of the formulation and HSNO approval number for each paraquat-containing product
2. Source of active ingredient used for each paraquat-containing product
3. Information about all impurities of toxicological and/or ecotoxicological concern in the formulation for each paraquat-containing product
4. Information on typical annual sales/use volumes for each paraquat-containing product
5. Toxicological or ecotoxicological study reports on paraquat or any paraquat-containing products.

B. Use and application information (for importers, manufacturers, applicators and growers)
The following data is requested to allow us to create representative use scenarios for paraquat-containing substances. Much of this information can be provided in GAP table format, which also includes space for providing comments and reasoning.

1. Target pest and crop treated
2. Timing of application, including details on season length and relevant crop cycles
3. Who is the user (e.g. landowner/grower/contract applicator)
4. Application rate (e.g. g/ha or g/m²)
5. Dilution rate

6. Identification of common tank-mixed additives

7. Amount of diluted substance needed to treat a certain area (e.g. x litres per 100 m² or x litres per hectare)

8. Application equipment used (e.g. sprayer type, size of tank, droplet size), with reasons for equipment/method selection

9. Typical area treated per day (e.g. 20 ha) – can be provided as a range if appropriate

10. Typical time taken for application

11. Typical amount of product handed by an individual

12. Anticipated frequency of use (e.g. number of applications per season / year / crop cycle)

13. Any known off label uses

14. Level of Personal Protective Equipment (PPE) worn to protect users, including Respiratory Protective Equipment (RPE)

15. Are any re-entry or restricted entry intervals (i.e. period after application where people are excluded from the application area) used?

16. Any relevant withholding periods

17. Disposal of any unused material

18. Any other safety precautions which are implemented protect human health or the environment (e.g. biological monitoring, use of signage, notification/communication processes)

C. Benefits and alternatives information (for importers, manufacturers, applicators and growers)

The following information is requested to provide context and evidence for selection of use of paraquat-containing substances.

1. Benefits of the substance and possible effects of the substance becoming unavailable

2. Availability of alternatives and reasons for choosing to use paraquat-containing substances over alternatives

D. Incident or injury information (for importers, manufacturers, applicators and growers)

The following information is requested to provide information on incidence or injury that may have resulted as a consequence of use of, or exposure to, paraquat-containing substances.

1. Any incidences, or injuries that you or your staff have experienced from, or attributed to, the use of paraquat or from exposure to paraquat.
2. Any information on the cause of any identified incident or injury (e.g. incorrect or inappropriate use, inadequate levels of protective equipment used).

E. Other relevant information (for importers, manufacturers, applicators and growers)
Please provide any other information that you consider to be relevant to our reassessment of paraquat-containing substances.