Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
REASSESSMENT

Application Form: HS8 Application for whether there are Grounds for a Reassessment of a Hazardous Substance

under section 62 of the Hazardous Substances and New Organisms Act 1996

Send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: HSApplications@epa.govt.nz
Payment must accompany application; see our fees and charges schedule for details.

Applicant:

Environmental Protection Authority

Date:

18 June 2020

APPLICANT CHECKLIST	
Mandatory sections filled out	Y
Appendices enclosed	Included at the end of this document
Fees enclosed	N/A
Signed and dated	Y

OFFICE USE ONLY	
Application code	**Date received**
EPA contact	**Fees paid $**
Application version no.	

Important

1. Before you fill in this application form, please talk to the EPA. We can help you scope and prepare your request.
2. We need all relevant information early on in the process. Quality information up front will speed up the process.
3. Any extra material that does not fit in the form should be clearly labelled and cross-referenced. If there is commercially sensitive information, it should be collated in a separate document.
4. All applicants must sign the form at the end of Part A and enclose the correct application fee. Please check the EPA's current pricing policy: http://www.epa.govt.nz/about-us/fees/Pages/Hazardous-Substances-fees-schedule.aspx. We are unable to process applications that do not contain the correct fee.
5. Copies of all our application forms are available on our website: http://www.epa.govt.nz.
6. If you have any suggestions for improvements to this form, please contact our operations staff at the address below.
7. You can get more information at any time by telephoning, writing to, or calling in at our Wellington office. One of our staff members will be able to help you.

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1. Applicant details

This should be the organisation or person formally responsible for this application, and be located within New Zealand.

Name: [redacted]

Address: [redacted]

Phone: [redacted]

Fax: -

Email: [redacted]

Service Address (if different from above): [redacted]

1.2. Contact's details (if different from above).

Name: [redacted]

Address:

Phone:

Fax:

Email: [redacted]

2. Hazardous substance details

2.1. Name of substance (identify the substance as fully as possible).

If more than one substance is involved – for example, the active ingredient and the products – they should all be listed.

Chlorpyrifos, and all chlorpyrifos-containing substances (see Appendix 1 for indicative list)

Chlorpyrifos-methyl, and all chlorpyrifos-methyl-containing substances (see Appendix 1 for indicative list)

2.2. If the substance has been assessed by the authority, list the reference number(s) of the existing approval (from the authority's register).

If more than one substance is involved, for example, the active ingredient and the products, they should all be listed.

Chlorpyrifos – HSR002942

Chlorpyrifos-methyl – HSR004064

Chlorpyrifos-containing substances – see Appendix 1 for indicative list

Chlorpyrifos-methyl-containing substances – see Appendix 1 for indicative list

2.3. If the substance is covered by Parts XI to XV, list any reference numbers of registrations, licenses etc under the Explosives Act, Pesticides Act, Toxic Substances Act, Dangerous Goods Act or Animal Remedies Act.

N/A

3. Grounds for reassessment

3.1. Please indicate which category applies.

More than one may be relevant.

Has significant new information relating to the effects of the substance become available?

☒ Yes (go to question 3.2)

Has another substance with similar or improved beneficial effects and reduced adverse effects become available?

☐ Yes (go to question 3.3)

Has information showing a significant change of use of the substance become available?

☐ Yes (go to question 3.4)

Has information showing a significant change in the quantity of the substance manufactured or imported become available?

☐ Yes (go to question 3.5)

Other?

☐ Yes (go to question 3.6)

3.2. Provide details of the significant new information relating to the effects of the substance. (Include the date and some of the information.)

Further information?	☐ Yes	☒ No
Commercially sensitive information?	☐ Yes	☒ No

Chlorpyrifos

New Zealand background

Chlorpyrifos has been an approved hazardous substance since 2006, with chlorpyrifos-containing formulations been approved hazardous substances since 2004, when they were transferred into the Hazardous Substances and New Organisms (HSNO) Act (in the Hazardous Substances (Chemicals) Transfer Notice 2006 and Hazardous

Substances (Pesticides) Transfer Notice 2004, respectively). Chlorpyrifos-containing substances were approved prior to the introduction of the Hazardous Substances and New Organisms Act (and the associated transfer notices), with products having had Agricultural Compounds and Veterinary Medicines (ACVM) Act approvals since 1972.

Chlorpyrifos is used across a number of different crops, including but not limited to grasses (such as pasture, ryegrass), orchard fruits (for example, grapes, kiwifruit), and vegetables (eg, squash, brassicas).

Chlorpyrifos-containing substances have been the subject to a number of previous reassessments.

The Environmental Risk Management Authority (ERMA, the EPA's predecessor organisation) started conducting reviews into organophosphate and carbamates (OPC) chemicals in 2007 because a large number of substances on the then Chief Executive Initiated Reassessment List (based on pesticides known to be present in Aotearoa New Zealand in high volumes in 2004, and the predecessor to the current Priority Chemicals List) were OPCs. Chlorpyrifos is a member of the OPC family.

As part of the OPC review, in June 2013 (application APP201045), plant protection products containing chlorpyrifos (and a number of other OPCs) were reassessed (any products with dual uses were deferred to a later reassessment). The risk assessment looking at chlorpyrifos used data from the European Food Standards Agency (EFSA) from 2005 (EPA, unpublished). Following the reassessment, chlorpyrifos-containing substances continued to be approved, though a number of controls were altered. The decision in the 2013 reassessment has been amended (using section 67A of the HSNO Act) twice. It was modified via a further reassessment (using s63A) in 2015 to update the wording of the bee control. (EPA, 2015)

Continuing the review of OPCs, in January 2016 (application APP202098), several substances containing chlorpyrifos used for non-plant protection uses, such as veterinary medicines and in urban pest management, were reassessed. These substances were revoked (that is, their approvals were declined), because it was considered they were not being used in New Zealand at that time. As such, it was considered that there was no benefit from the substances, and that the adverse effects of the hazardous substances outweighed any positive effects.

One chlorpyrifos-containing substance ('Water dispersible granule containing 750 g/litre chlorpyrifos', approval number HSR000167) was excluded from the 2013 reassessment because it was thought to have dual plant protection and non-plant protection uses. Further information prior to the 2016 reassessment indicated that it only had plant protection uses. It was therefore excluded from the 2016 reassessment also. This substance, therefore, has not been reassessed, it has current HSNO and ACVM approvals, and is currently in use in New Zealand.

Chlorpyrifos was screened by the EPA in 2018 as part of its new reassessment programme, where it was considered to be a Priority Group B substance and, consequently, added to the EPA's Priority Chemicals List. (EPA, 2020)

New human health information

Since the above 2013 reassessment in New Zealand, EFSA, the United States Environmental Protection Agency (US EPA), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and Canada's Pest Management

Regulatory Authority (PMRA) have all issued new risk assessments and/or decisions on chlorpyrifos and chlorpyrifos-containing substances.

A new human health risk assessment from EFSA in 2014 considered the risks from the use of chlorpyrifos in table and wine grapes as representative uses of the wide range of crops treated with chlorpyrifos. EFSA identified that the risks to re-entry workers (that is, those going back in to a treated field, orchard or vineyard) were a concern. The toxicological data that EFSA used in this assessment resulted in an Acceptable Operator Exposure Level (AOEL) that was an order of magnitude lower than previously used (see Table 1). (EFSA, 2014)

Consequently, in January 2020, the European Union did not renew the approval for chlorpyrifos. This was based on critical areas of concern to human health, including that EFSA could not exclude that chlorpyrifos has a genotoxic potential, and that EFSA's peer review experts considered it appropriate for chlorpyrifos to be classified as toxic for reproduction, category 1B (equivalent to the HSNO classification 6.8A). (European Commission, 2020a)

The US EPA has published several updated risk assessments on chlorpyrifos since 2013, the latest published in 2016. This latest human health risk assessment used updated physio-kinetic (PBPK) modelling to understand how chlorpyrifos affects the body. The US EPA uses a different approach to EFSA (and the NZ EPA), in that they use the lowest observed adverse effect level (LOAEL) to generate a point of departure (POD); the POD is then used to calculate a margin of exposure (MOE), which is then compared to a predetermined level of concern value. The results of this risk assessment indicate that the US EPA had concerns for users and bystanders of chlorpyrifos-containing substances, including ultra-low volume mosquito applications. The US EPA had introduced buffer zones in 2012 to help manage the risks to children and other bystanders, which are not included in the new controls set in 2013 in New Zealand. (US EPA, 2012, 2016, 2019)

The APVMA cancelled all domestic and home uses of chlorpyrifos-containing substances in September 2019. They considered that there were detectable inhibition of a group of hormones called chlolinesterases, from which they had concerns regarding serious neurodevelopment and neuro-behavioural toxicity. The Acceptable Daily Intake (ADI) value they used in their risk assessment is provided in Table 1. Due to labelling requirements, a permit for people and organisations to possess these substances was granted for a year, ending in July 2020. (APVMA, 2019)

Table 1 Toxicological values used by different international agencies

Year	Jurisdiction	Agency	AOEL ($mg/kg_{bw}/d$)	ADI ($mg/kg_{bw}/d$)	ARfD[1] (mg/kg_{bw})	Reference
2013	New Zealand	EPA	0.01	-	-	EPA (unpublished)
2014	Europe	EFSA	0.001	0.001	0.005	EFSA, 2014
2019	Australia	APVMA	-	0.001	0.03	APVMA, 2019

1: ARfD acute reference dose

The risks to humans in Aotearoa New Zealand was considered acceptable in 2013 based on the AOEL of 0.01 mg/kg_{bw}/d, with risk quotients (RQs) from the use of chlorpyrifos containing substances in the range of <0.01 to 2.2 with PPE (or <0.01 to 0.96 with respiratory protective equipment; EPA, 2012a-y). An RQ greater than 1 is often considered of concern and requiring further work to either refine the assessment or manage the risks. As an RQ is derived from dividing the predicated exposure concentration by the acceptable concentration (in this case, the AOEL), then the use of an acceptable value by other agencies an order of magnitude lower than that previously used by the EPA (see Table 1) would be expected to result in risk quotients an order of magnitude higher than those previously calculated by the EPA. Further work would be required, as part of any future reassessment, to reconfirm the predicted concentrations, and the resulting RQs and risk mitigation measures.

New environmental information

In addition to the new human health risk assessments discussed above, in May 2019, the PMRA issued an updated environmental risk assessment in which they proposed cancelling most existing uses of chlorpyrifos. This is because they considered that the risks to beneficial insects, birds, mammals, and aquatic organisms were not acceptable. This assessment is out for consultation and is not a final decision. (Health Canada Pest Management Regulatory Authority, 2019).

The environmental chemistry journal *Chemosphere* has recently published a paper recording how chlorpyrifos and its metabolites behave in the environment from a field study in Otago, New Zealand (Das et al, 2020). Similarly, *Environmental Pollution* published a paper recording the concentration of pesticides, including chlorpyrifos, across a number of New Zealand streams (Hageman et al, 2019). The details of these papers would need to be reviewed as part of any future reassessment, for which it may provide supporting environmental fate data for any revised environmental or human health risk assessments.

Chlorpyrifos-methyl

New Zealand background

Like chlorpyrifos, chlorpyrifos-methyl and chlorpyrifos-methyl-containing substances have been approved under the HSNO Act since they were transferred in from previous regimes in the in the Hazardous Substances (Chemicals) Transfer Notice 2006 and Hazardous Substances (Pesticides) Transfer Notice 2004, respectively. There are currently no known ACVM approvals for substances containing chlorpyrifos-methyl.

Chlorpyrifos-methyl is an OPC, and was subject to the 2013 OPC reassessment described above. That reassessment updated the classification of the active ingredient and substances that contain it. Although no uses

within New Zealand were identified, an approval as an export-only substance was retained, as was an approval for use in another substance.

Chlorpyrifos-methyl was screened by the EPA in 2018 as part of its new reassessment programme, where it was considered to be a Priority Group D substance (EPA, 2020).

New information

Since the 2013 reassessment, EFSA has updated their risk assessment of chlorpyrifos-methyl. They considered that no toxicological values could be set because of unclear genotoxic effects, which meant that they were unable to conduct a human health risk assessment for the impact on workers, bystanders and residents. They considered this represented a critical area of concern for chlorpyrifos-methyl. (EFSA, 2019)

EFSA considered that the toxicological effects met the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity; EFSA, 2019). This EFSA proposal is equivalent to the HSNO classification 6.8A, which is not part of chlorpyrifos-methyl's current HSNO classification. This classification would move chlorpyrifos-methyl to Priority Group C in the EPA's screening programme.

In January 2020, for the reasons presented by EFSA (above), the European Union did not renew the approval for chlorpyrifos-methyl (European Commission, 2020b).

3.3. Provide details of the information relating to the effects of the new substance (include the date and some of the information). The beneficial and adverse effects of the new substance should be compared with those of the substance.

Further information? ☐ Yes ☐ No

Commercially sensitive information? ☐ Yes ☐ No

N/A

3.4. Provide details of the significant change of use of the substance (include the former use and information on how this change has come about).

Further information? ☐ Yes ☐ No

Commercially sensitive information? ☐ Yes ☐ No

N/A

3.5. Provide details of the significant change in the quantity of the substance manufactured or imported.

Further information? ☐ Yes ☐ No

Commercially sensitive information? ☐ Yes ☐ No

N/A

3.6. Provide details of other reasons requesting a reassessment.

Further information? ☐ Yes ☐ No

Commercially sensitive information? ☐ Yes ☐ No

N/A

3.7. Provide any other information relevant to the request for reassessment.

Further information? ☐ Yes ☐ No

Commercially sensitive information? ☐ Yes ☐ No

N/A

4. Declaration

[redacted] **2020-6-18**

Signature of applicant or person authorised on behalf of applicant **Date**

Name: [redacted]