



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:

29/11/2019

APPLICANT CHECKLIST

Mandatory sections filled out

Appendices enclosed

Fees enclosed

Signed and dated

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: Dr Allan L Freeth, Chief Executive

Address: Environmental Protection Authority, Private Bag 63002, Waterloo Quay, Wellington, 6140

Phone: 04 916 2426

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Email: reassessments@epa.govt.nz

Service Address (if different from above):

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

Name: Gayle Holmes, Acting General Manager – Hazardous Substances and New Organisms

Address: Environmental Protection Authority, Private Bag 63002, Waterloo Quay, Wellington, 6140

Phone: 04 916 2426

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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.

The neonicotinoid active ingredients clothianidin, thiamethoxam, imidacloprid, thiacloprid, and acetamiprid. Full details are provided in Table 1.

The names of all currently approved substances that contain clothianidin, thiamethoxam, imidacloprid, thiacloprid, or acetamiprid as the active ingredient are listed in Table 2 for information purposes only. The list of substances includes agricultural and home garden insecticides, veterinary medicines, timber treatments and wood preservatives, and insecticidal pest control products such as ant baits and fly sprays.

Any future reassessment application will include full details of the scope of the reassessment and which substances are included. The reassessment may cover all or some of the substances listed in Table 2, as well as any substances containing any of the five neonicotinoid active ingredients that are approved in the interim period between this grounds application and receipt of the reassessment application.

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.

- Clothianidin – no individual approval – active ingredient is listed on the New Zealand Inventory of Chemicals (NZIoC) and there are approvals for clothianidin-containing substances
- Thiamethoxam – HSR002755
- Imidacloprid – HSR003302
- Thiacloprid – HSR100091
- Acetamiprid – HSR004088
- Approval numbers of all approved substances that contain clothianidin, thiamethoxam, imidacloprid, thiacloprid, or acetamiprid as the active ingredient are listed in Table 2 for information purposes only.

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.

Not applicable as Parts 11 to 15 of the Hazardous Substances and New Organisms Act have expired.

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

Key details of the information considered to be significant new information for the neonicotinoids for which grounds are being applied for are included in Table 1. This information includes publicly available regulatory reports from a number of key international regulatory agencies, as well as information gathered during EPA evaluation of recent applications for approval of neonicotinoid-containing substances. It has been identified that this information was not available/taken into account at the time the HSNO approvals for the active ingredients and/or many of the earlier neonicotinoid-containing substances were issued.

Other information gathered during the EPA's recent open call for information has identified significant overlaps between current New Zealand use patterns and those assessed in the regulatory reports identified in Table 1. Initial environmental monitoring data from New Zealand streams and soil has also been provided, as well as scientific literature on New Zealand species, data on amounts of different products used or different crop types grown in New Zealand, and information on environmental exposure mitigation measures. These information sources may also be factored in to any assessment of the risks and benefits of the neonicotinoids.

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

Not applicable

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

Not applicable

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

Not applicable

3.6. Provide details of other reasons requesting a reassessment.

Further information? Yes No

Commercially sensitive information? Yes No

Not applicable

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

Further information? Yes No

Commercially sensitive information? Yes No

Not applicable

Table 1 Neonicotinoid active ingredients

Neonicotinoid active ingredient		Supporting information	Factors for grounds that apply
Name	Approval number		
Clothianidin (CAS# 210880-92-5)	-	<p>All outdoor uses of clothianidin were banned in Europe in May 2018, so that only the use in permanent greenhouses remained permissible. Approval of clothianidin for these remaining greenhouse uses expired in January 2019 following non-renewal by the applicant. The restriction was based on concerns identified by the European Food Safety Authority (EFSA) in terms of risks to bees in their 2018 updated pesticide risk assessment of uses of clothianidin as seed treatments or granules (EFSA, 2018a). Previous restrictions on the use of clothianidin-containing plant protection products in Europe were based on an earlier EFSA pesticide risk assessment for bees which identified concerns (EFSA, 2013a).</p> <p>The Health Canada Pest Management Regulatory Agency (PMRA) cancelled the registration of clothianidin for some uses due to unacceptable risks to pollinators. Many of the remaining uses were registered with new mitigation measures, including changes to use patterns and label statements (PMRA, 2019a).</p> <p>Canada is proposing to cancel all outdoor uses of clothianidin on food and feed crops including seed treatments and on turf, over three to five years, based on unacceptable risks of chronic adverse effects on aquatic invertebrates (PMRA, 2018a). A final decision on the aquatic invertebrate special review for clothianidin is anticipated to be published in January 2020.</p>	Significant new information relating to the effects
Thiamethoxam (CAS# 153719-23-4)	HSR002755	<p>All outdoor uses of thiamethoxam were banned in Europe in May 2018, so that only the use in permanent greenhouses remained permissible. Approval of thiamethoxam for these remaining greenhouse uses expired in April 2019 following non-renewal by the applicant. The restriction was based on concerns identified by the EFSA in terms of risks to bees in their 2018 updated pesticide risk assessment of uses of thiamethoxam as seed treatments or granules (EFSA, 2018b). Previous restrictions on the use of thiamethoxam-containing plant protection products in Europe were based on an earlier EFSA pesticide risk assessment for bees which identified concerns (EFSA, 2013b).</p> <p>Canada cancelled the registration of thiamethoxam for some uses due to unacceptable risks to pollinators. Many of the remaining uses were registered with new mitigation measures, including changes to use patterns and label statements (PMRA, 2019b).</p> <p>Canada is proposing to cancel all outdoor uses of thiamethoxam on food and feed crops including seed treatments and outdoor ornamentals, over three to five years, based on unacceptable risks of</p>	Significant new information relating to the effects

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		<p>chronic adverse effects on aquatic invertebrates. Continued registration of greenhouse uses is proposed (PMRA, 2018b). A final decision on the aquatic invertebrate special review for thiamethoxam is anticipated to be published in January 2020.</p> <p>The EPA declined a thiamethoxam-containing seed treatment in 2014 (application APP201609) because of risks to terrestrial invertebrates, particularly bees, which outweighed potential benefits (EPA, 2014). Another application for a thiamethoxam-containing foliar spray and soil treatment was withdrawn by the applicant in 2016 (application APP202892) following the identification of risks to bees in the EPA's quantitative environmental risk assessment (EPA, 2016a).</p>	
<p>Imidacloprid (CAS# 138261-41-3)</p>	HSR003302	<p>All outdoor uses of imidacloprid were banned in Europe in May 2018, so that only the use in permanent greenhouses remains permissible. The restriction was based on concerns identified by the EFSA in terms of risks to bees in their 2018 updated pesticide risk assessment of uses of imidacloprid as seed treatments or granules (EFSA, 2018c). Previous restrictions on the use of imidacloprid-containing plant protection products in Europe were based on an earlier EFSA pesticide risk assessment for bees which identified concerns (EFSA, 2013c).</p> <p>Canada cancelled the registration of imidacloprid for certain uses to address potential risks of concern to pollinators. Many of the remaining uses were registered with new mitigation measures, including changes to use patterns and label statements (PMRA, 2019c).</p> <p>Canada is proposing to phase-out all the agricultural and a majority of other outdoor uses of imidacloprid over three to five years, based on risks of concern to aquatic invertebrates, and potential risks to birds and small mammals (PMRA, 2016). A final decision on the general re-evaluation of imidacloprid is anticipated to be published in January 2020.</p> <p>The EPA declined an imidacloprid-containing foliar spray and soil drench in 2018 (application APP203422) due to risks posed by the substance to soil-dwelling organisms, potential groundwater contamination risks, and non-negligible risks to pollinator species, which outweighed the benefits (EPA, 2018). Another application for a combination insecticide including imidacloprid was declined in 2016 (application APP202093) due to risks which exceeded the benefits (EPA, 2016b). These risks included chronic effects on soil organisms, oral and contact risks to bees specifically from the imidacloprid active ingredient component, as well as potential impacts on Māori culture or traditional relationships with ancestral lands, water, sites, wāhi tapu, valued flora and fauna or other taonga,</p>	Significant new information relating to the effects
<p>Thiacloprid (CAS# 111988-49-9)</p>	HSR100091	<p>There has been a recent vote not to renew the approval for thiacloprid in Europe, which will likely result in expiry of the approval in April 2020. The non-renewal proposal was based on concerns in terms of potential human health risks due to the substance's reproductive toxicity and potential risks</p>	Significant new information relating to the effects

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		<p>to groundwater identified by the EFSA in its pesticide risk assessment review of both foliar use and seed treatment use (EFSA, 2019).</p> <p>Thiacloprid has been identified as a candidate for substitution in Europe for several years based on its endocrine disrupting properties. Candidates for substitution are pesticides for which European national authorities need to carry out an assessment to establish whether there are more favourable alternatives to using the plant protection product. The European Chemicals Agency (ECHA) adopted a harmonised classification for thiacloprid in 2015 which updated and revised the hazard classifications of the chemical, notably to classify thiacloprid as a category 1B reproductive toxicant for its adverse effects on development (ECHA, 2015). Thiacloprid is currently classified 6.8B (which aligns with GHS category 2 reproductive toxicity) in its HSNO approval, so data supporting this classification should be reviewed and potentially updated during any future reassessment.</p>	
<p>Acetamiprid (CAS# 135410-20-7)</p>	<p>HSR004088</p>	<p>Use of acetamiprid in biocidal products was approved in Europe in 2017 subject to certain conditions (ECHA 2017a). These conditions were imposed based on unacceptable risks to surface water, sediment, groundwater, and/or soil that were identified for products with outdoor uses as well as those designed for surface application via spraying or brushing. Unacceptable risks to infants and toddlers via secondary exposure were also identified for products containing acetamiprid at concentrations >0.2%.</p> <p>A comprehensive review of study data for acetamiprid can be found in the 2017 European proposal for harmonised classification and labelling (ECHA 2017b), with an opinion on the classification expected to be adopted and published by April 2020.</p>	<p>Significant new information relating to the effects</p>

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Table 2 Neonicotinoid-containing substances

Neonicotinoid active ingredient	Substances containing active ingredient		
	Substance name	Approval number	ACVM Registered products
Clothianidin	Suspension concentrate containing 600 g/litre clothianidin	HSR000694	Poncho Clear, Agri-One, Prostrike, Patrol, Clo-Kote, NipsIT INSIDE
	Poncho	HSR100825	Poncho
	Poncho Votivo	HSR101149	Poncho Votivo
	Keyrole Pro	HSR101047	KeyRole Pro
	Endow 600SC	HSR101319	-
Thiamethoxam	Suspension concentrate containing 600 g/litre thiamethoxam	HSR000408	Cruiser 600FS
	Suspension concentrate containing 350 g/litre thiamethoxam	HSR000410	-
	Actara	HSR000099	Actara, Rockot
	Durivo	HSR100068	Durivo
	Solvigo	HSR101003	Solvigo
	Insecticidal Sand	HSR101021	-
	OPTIGARD Ant Gel Bait	HSR101077	-
Imidacloprid*	Advantage Multi	HSR000060	Advantage
	Nissanclean CI	HSR000061	-
	Pilarking	HSR000078	-
	Advantix K9	HSR000090	-
	Emulsifiable concentrate containing 25 g/litre cyfluthrin and 75 g/litre imidacloprid	HSR000342	-
	Suspension concentrate containing 600 g/litre imidacloprid	HSR000495	Gaicho
	Water dispersible granule containing 50 g/kg imidacloprid	HSR000496	Confidor Garden Insecticide
	Gel containing 21.5 g/kg imidacloprid	HSR000676	-
	Ready to use liquid containing 0.125 g/litre imidacloprid	HSR000682	Confidor Ready to Use Insecticide

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Flammable aerosol containing 0.25 g/kg imidacloprid	HSR000684	-
Granular material containing 50 g/kg imidacloprid	HSR000686	-
Suspension concentrate containing 350 g/litre imidacloprid	HSR000687	-
IFB 0.5%	HSR001679	-
Flammable liquid containing 80 - 120 g/litre imidacloprid	HSR001870	-
Raid/Baygon Fly Baits - Cube	HSR002463	-
Raid/Baygon Fly Baits - Sticker: Rose, Bouquet, Flower, Shell and Orange	HSR002464	-
Maxforce Liquid Ant Bait	HSR007635	-
Imidakote	HSR007662	Pronto, AGPRO imidacloprid, Acclaim, Punto, Kiwiagri Imidacloprid 600 SC, Sombrero 600 Seed Dressing
NTN Pour on	HSR007664	-
TNL 2189	HSR007756	-
Preventol TM-CE 25	HSR007863	-
Gaicho Clear	HSR007890	-
Boron Glycol Option 1	HSR007928	-
Boron Glycol Option 2	HSR007929	-
Boron Glycol Option 3	HSR007930	-
Boron Glycol Option 4	HSR007931	-
Boron Glycol Option 5	HSR007932	-
Maxforce Quantum	HSR100039	-
Grass Slurry Gold	HSR007996	-
NTNCS2	HSR100103	Zapp Encore
Kemiholz Ply Lik	HSR100391	-
YATES ROSE GUN ADVANCED	HSR100399	Yates Rose Gun Advanced
PNR1427	HSR100529	-

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	QuickBayt Spray Fly Bait	HSR100747	-
	Yates Complete Lawn Insect Control	HSR100711	Yates Complete Lawn Insect Control
	J57.55	HSR100582	-
	Yates Super Shield Advanced	HSR100613	-
	J57.56	HSR100617	-
	J57.59	HSR100689	-
	Joseph Lyddy Flea Control Deodorising Household Flea Spray	HSR101062	-
	FramePro Plus	HSR101074	-
	Vectothor Fly Bait	HSR101080	-
	EnviroMax Imidacloprid 200SC Termiticide & Insecticide	HSR101187	-
	Pronto	HSR100431	Savage 750 WG insecticide
	Permatek IM30	HSR100491	-
	Savage 600 Flowable Seed Dressing Insecticide	HSR100831	Radicle 600 FS Flowable Seed Dressing Insecticide
	Nuprid 350SC	HSR002691	Savage 350 Insecticide, Nuprid 350SC, Confidor
	Imidatar	HSR101008	Imidatar
	Nuprid 600ST (alternative formulation)	HSR100915	Senator 600
	Cyrus	HSR100355	Cyrus
Thiacloprid	Suspension concentrate containing 480 g/litre thiacloprid	HSR000715	Hortcare COMMEND, Alpasso, Topstar, Calypso
	Proteus	HSR007653	Proteus
	Preventol TX-CT 50	HSR007913	-
	Preventol TX-CE 12	HSR007912	-
	Insect Systemic Ready to Use	HSR100983	-
	Rose Systemic Ready to use	HSR100991	-

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Acetamiprid	Scimitar	HSR007627**	-
	SDB-1377	HSR002478	-
	Defender Maxguard RTU	HSR100662	-
	Defender Concentrate Maxguard	HSR100663	-
	Crown 225SL Systemic Insecticide	HSR100918	-
	RF-046	HSR101072	-
	RF-052	HSR101221	-
	RF-060	HSR101318	-

* There are also a number of imidacloprid-containing veterinary medicines that are registered with ACVM where the draft label information does not include a HSNO approval number (Eavance, Advantage, Neove Imidacloprid Spot-on, Advocate for cats, Advocate for dogs, Neovet for Cats, Neovet for dogs, Seresto) – it is assumed that these products use the Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard HSR100757

** Export only approval

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4. Declaration



29 November 2019

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

Date

Name: Dr Allan L Freeth

References

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