Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

6 June 2019

Overview

Substance	Sprinter 700DS and monomethylamine
Application code	APP203776
Application type	To modify an existing approval for a hazardous substance under section 63A of the Hazardous Substances and New Organisms Act (HSNO Act; "the Act")
Applicant	Nufarm Limited
Purpose of the application	To reassess the hazard classification of both the formulated substance Sprinter 700DS (HSR100806) and the substance monomethylamine (HSR001008) which currently have the 6.8B classification – suspected human reproductive or developmental toxicant.
Submissions received	One (1) submission - Lynne Clapham.
Considered by	A Decision-Making Committee of the Environmental Protection Authority (EPA) Dr Derek Belton (Chair) Dr John Taylor
Decision	Modified reassessment approved
Approval code	Sprinter 700DS: **HSR100806** Methanamine (methylamine): **HSR001008** Methylamine, >25% in a non hazardous gaseous diluent: **HSR006444**
Hazard classifications	Sprinter 700DS: 6.1D (O), 6.5B, 6.9A (O), 6.9B (I), 8.3A, 9.1B, 9.2A, 9.3B Methanamine (methylamine): 2.1.1A, 6.1C (I), 6.1C (O), 6.9B (I), 8.2B, 8.3A, 9.2D, 9.3B Methylamine, >25% in a non hazardous gaseous diluent: 6.1C (I), 6.1C (O), 6.9B (I), 8.2B, 8.3A, 9.2D, 9.3B

Application dates	
Date application formally received	20 December 2018
Submission period	29 January 2019 – 13 March 2019
Consideration date	28 May 2019
Date decision signed	6 June 2019

Executive summary

Nufarm Limited (“Nufarm”) applied for the reassessment of Sprinter 700DS and monomethylamine under section 63 of the Hazardous Substances and New Organisms Act (HSNO Act; “the Act”).

Nufarm asked for the original approvals of both the formulated substance Sprinter 700DS (HSR100806) and the substance monomethylamine (HSR001008) to be reassessed to make changes to the hazard classifications set in the existing approvals. The related substance methylamine, >25% in a non hazardous gaseous diluent (HSR006444) was also included in the reassessment application. All of these substances were classified as 6.8B suspected human reproductive or developmental toxicants, and Nufarm requested that the Environmental Protection Authority (‘the EPA’) review this hazard classification.

Their reassessment application was formally received on 20 December 2018, and the EPA decided that the application would be progressed as a publicly notified, modified reassessment in accordance with section 63A of the Act.

The only aspect of the approvals being considered in this modified reassessment is the reproductive/developmental hazard classification of the substances.

The notification period for members of the public and other interested parties to provide written submissions was open from 29 January 2019 to 13 March 2019. One submission was received: this submission was opposed to the application. The submitter advocated that the application be declined based on insufficient data being provided in the application to justify removal of the 6.8B hazard classification. The submitter indicated a wish to be heard if a hearing was held to decide the application, but subsequently withdrew this request after noting that there were no other submissions and that the applicant had not requested a hearing.

Additional information was sought from the applicant to enable the EPA to conduct a thorough review, and further information to support the application was received on 10 April 2019.

The EPA reviewed the available information relating to the reproductive/developmental hazard classification of methylamine, and determined the appropriate hazard classifications for the affected substances. The amended hazard classifications of the three substances trigger no changes to the default or additional controls.

Nufarm provided an assessment of the effects relating to the proposed change to the reproductive/developmental hazard classification of the substances. The EPA reviewed this assessment and considered that there was an overall positive effect in making the proposed changes to the approvals and no significant adverse effects.

After considering all relevant information available, the Decision-Making Committee (‘the Committee’) decided that it had sufficient information for making a decision.

The Committee assessed all the effects associated with the reassessment in accordance with section 63A(6) of the Act. The Committee considered that the positive effects associated with the reassessment outweigh the adverse effects and decided to approve the modified reassessment application and implement the change to the reproductive/developmental hazard classification of the substances.

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1 Background

1.1 Monomethylamine is an industrial chemical which is used predominantly by professional workers as a chemical intermediate in a number of different industries. The chemical has a number of different common names including monomethylamine, methylamine, methanamine, and MMA.

1.2 Methylamine was approved under the HSNO Act on 1 July 2004 via the Hazardous Substances (Dangerous Goods and Schedules Toxic Substances) Transfer Notice 2004 under the HSNO Approval Number HSR001008 and the approval uses the substance name: methanamine (methylamine). The substance is classified as follows: 2.1.1A, 6.1C (O), 6.1C (I), 6.8B, 6.9B (I), 8.2B, 8.3A, 9.2D, 9.3B.

1.3 Eastman Chemical Asia Pacific Pte Ltd ("Eastman") applied for grounds to reassess methylamine in 2017 so that the hazard classification of the substance could be reviewed and potentially revised. The Committee considered that there was significant new information relating to the reproductive/developmental hazard classification of the substance. In their decision, it was noted that any changes to the classification of methylamine would also affect the classification of the substance "methylamine, >25% in a non hazardous gaseous diluent", a dilution of methylamine that was approved under the HSNO Act on 1 July 2006 via the Hazardous Substances (Chemicals) Transfer Notice 2006 under the HSNO Approval Number HSR006444. It was decided that grounds exist for the reassessment of methanamine (methylamine) (HSR001008) and the related substance methylamine, >25% in a non hazardous gaseous diluent (HSR006444).

1.4 Sprinter 700DS is a soluble concentrate liquid containing 700g/L 2,4-D as dimethylamine and monomethylamine salts. It is intended to be used as a herbicide for control of broadleaf weeds in pasture and cereal crops.

1.5 Sprinter 700DS was approved under the HSNO Act on 5 March 2013 under the HSNO Approval Number HSR100806 following approval of EPA application APP201596, and is registered under the Agricultural Compounds and Veterinary Medicines ("ACVM") Act under registration number P008712. The substance is classified as follows: 6.1D (O), 6.5B, 6.8B, 6.9A (O), 6.9B (I), 8.3A, 9.1B, 9.2A, 9.3B.

1.6 Nufarm applied for grounds for a reassessment of Sprinter 700DS in 2017. Grounds were approved based on significant new information relating to the reproductive/developmental hazard classification of the substance, due to the availability of new data on the methylamine component of the substance that caused this hazard classification to be triggered when the substance was originally evaluated and approved.

1.7 Nufarm applied for the reassessment of both Sprinter 700DS and monomethylamine, and indicated that confidential supporting information for the application would be provided by a consultant for Eastman.

2 Process, consultation and notification

Lodgement and formal receipt

2.1 The Nufarm reassessment application was lodged on 6 December 2018. It was formally received on 20 December 2018. In their application to reassess Sprinter 700DS and the methylamine substances, Nufarm requested the EPA to review the reproductive/developmental

hazard classification of the approvals and proposed that the substances should not be classified as reproductive/developmental toxicants.

Scope of application

2.2 The EPA's Chief Executive considered the content of the application and decided to use the EPA's discretionary power in section 63A(1) of the Act to proceed with the application as a modified reassessment. It was decided that the scope of the modified reassessment would be limited to an assessment of the reproductive/developmental hazard classification.

Notification of application

2.3 The Ministry for the Environment, the Ministry of Health, the ACVM group of the Ministry for Primary Industries, and the Department of Conservation were advised of the application and notified of the submission period. WorkSafe New Zealand ("WorkSafe") provided email comments on this application which are included in the EPA Staff Report.

2.4 The General Manager Hazardous Substances and New Organisms decided not to use the EPA's discretionary power in section 63A(4) of the Act to target the consultation on this application, and it was publicly notified in accordance with section 53 of the Act.

2.5 The application was opened for submissions from 29 January 2019 to 13 March 2019.

Submissions received

2.6 One submission was received for this application. The submitter indicated a wish to be heard, but subsequently withdrew the request to be heard, given the circumstances that a public hearing was not requested by others.

2.7 The Committee took account of this submission in making its decision and noted that the EPA Staff Report responded to the issues raised in the submission.

3 The EPA Staff Report

3.1 The Staff Report is the EPA review of the application, the submission, the available information regarding the reproductive/developmental toxicity of the substances, and assessment of the effects of the proposed changes. It provides information to assist the Committee to make its decision.

3.2 The EPA reviewed and assessed the available information on the reproductive /developmental toxicity classification of methylamine against the relevant classification criteria and concluded that methylamine should not be classified as a reproductive/development toxicant. Therefore the 6.8B classification should not be applied to the affected substances: Sprinter 700DS [HSR100806], Methanamine (methylamine) [HSR001008], and Methylamine, >25% in a non hazardous gaseous diluent [HSR006444].

3.3 The Staff Report stated that no changes to the default or additional controls were triggered by this proposed change to the reproductive/developmental toxicity classifications.

3.4 The EPA assessed the effects of the proposed changes and concluded that there was an overall positive effect in making the proposed changes to the approvals in that the classifications would more accurately represent the hazards of the substances compared to those identified in the original approvals. No significant adverse effects to the proposed changes were identified.

4 Approval reissue

4.1 A section 63A modified reassessment of an approval is subject to sections 77, 77A and 77B of the Act. Therefore, the EPA Notice controls will apply to the modified approvals with transitional periods for some. Approvals subject to a modified reassessment need to be reissued, under clause 4(3) of Schedule 7 of the Act, to ensure that the approvals are updated to replace the existing prescribed controls (controls set previously under the former HSNO Regulations) with new controls under the EPA Notices.

4.2 The approvals for the substances affected by this modified reassessment were reissued on 3 May 2019 prior to the consideration of this modified reassessment. From this date, the EPA Notice controls apply, with a transitional period that ends on 30 November 2021 for the following EPA Notices:

- Hazardous Substances (Labelling) Notice 2017
- Hazardous Substances (Packaging) Notice 2017
- Hazardous Substances (Safety Data Sheet) Notice 2017.

5 Consideration

Information available for consideration

5.1 The information available to the Committee for consideration of this application consisted of:

- the application form
- confidential appendix submitted by the applicant with the application form
- the submission
- additional information provided in support of the application, including both confidential study information and non-confidential documents
- information received from WorkSafe
- EPA Staff Report.

5.2 After considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application.

Hazard classifications

5.3 The Committee considered the information provided in the application, the supporting information, and the review by the EPA presented in the EPA Staff Report, and was satisfied that methylamine should not be classified as a reproductive/development toxicant, and the 6.8B classification should not apply to the substance.

5.4 The Committee was satisfied that the revised hazard classifications of methylamine identified in the Staff Report should apply. The hazard classifications are summarised in Table 1 below.

Table 1 Hazard classifications of Methanamine (methylamine)

Hazard	Classification
Flammability	2.1.1A
Acute toxicity (oral)	6.1C (oral)

Hazard	Classification
Skin corrosivity	8.2B
Eye corrosivity	8.3A
Target organ or systemic toxicity	6.9B (inhalation)
Soil ecotoxicity	9.2D
Terrestrial vertebrate ecotoxicity	9.3B

5.5 The Committee was satisfied that the revised hazard classifications of the formulated substance methylamine, >25% in a non hazardous diluent as identified in the Staff Report should apply. The hazard classifications are summarised in Table 2 below.

Table 2 Hazard classifications of Methylamine, >25% in a non hazardous diluent

Hazard	Classification
Acute toxicity (oral)	6.1C (oral)
Skin corrosivity	8.2B
Eye corrosivity	8.3A
Target organ or systemic toxicity	6.9B (inhalation)
Soil ecotoxicity	9.2D
Terrestrial vertebrate ecotoxicity	9.3B

5.6 The Committee was also satisfied that the revised hazard classifications of the formulated substance Sprinter 700DS as identified in the Staff Report should apply. The hazard classifications are summarised in Table 3 below.

Table 3 Hazard classifications of Sprinter 700DS

Hazard	Classification
Acute toxicity (oral)	6.1D (oral)
Eye corrosivity	8.3A
Contact sensitisation	6.5B
Target organ or systemic toxicity	6.9A (oral); 6.9B (inhalation)
Aquatic ecotoxicity	9.1B
Soil ecotoxicity	9.2A
Terrestrial vertebrate ecotoxicity	9.3B

Controls

5.7 The Committee noted that the approvals for the substances affected by this modified reassessment were reissued on 3 May 2019. The reissued approvals set out the suite of controls and requirements that apply to the substances.

5.8 The Committee noted that no changes to the controls are triggered by the change to the reproductive/developmental toxicity classifications of the substances. Therefore the same suite of controls and requirements as set out in the reissued approvals will continue to apply. These are detailed in Appendix A of this document.

Assessment of effects associated with the reassessment

5.9 The Committee took into account the EPA assessment of the effects of the proposed change, as detailed in the Staff Report. The key points are summarised below.

5.10 The Committee considered that the change in hazard classifications of the substances will have no effect on the overall risks to human health for workers, bystanders, and the public compared to those identified when the substances were originally approved.

5.11 The Committee considered that there will be no change to the environmental effects of the substances, including potential impacts on native or valued species and/or ecosystems, associated with the change in hazard classifications of the substances.

5.12 The Committee considered that there are some economic benefits associated with the change to the hazard classifications of the substances.

5.13 The Committee considered that any potential costs to industry of making changes to their labelling, packaging and Safety Data Sheets to reflect the classification change could be mitigated by providing a sufficient period of time to update documentation related to the substances, including labelling, packaging and Safety Data Sheets. The Committee noted that the reissued approvals already set a transitional period ending on 30 November 2021 to comply with controls set in EPA Notices for labelling, packaging and Safety Data Sheets. In view of this, the Committee considered that an implementation period ending on 30 November 2021 should also be provided to allow industry to update documentation to reflect the new hazard classifications.

5.14 The Committee did not identify any further effects on society, the community, or the market economy associated with the change to the hazard classifications of the substances. The Committee therefore did not consider this further.

5.15 The Committee considered that there will be no change to the effects of the substances on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga, and therefore these risks will be unchanged from those identified when the substances were originally approved.

5.16 The Committee considered that there are some positive effects on New Zealand's international obligations associated with the proposed change to the hazard classifications of the substances in terms of harmonising chemical classifications with other major jurisdictions. No other effects on any international obligations were identified.

5.17 Taking into account the effects identified above, the Committee considered that there was an overall positive effect in making the change to the hazard classifications of the approvals, and noted that the classifications will more accurately represent the hazards of the substances compared to those identified in the original approvals.

6 Conclusion and decision

6.1 Pursuant to sections 63A(6) of the Act and section 32 of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology"), the Committee considered this application to modify an approval. In doing so, the Committee applied all the relevant sections of the Act and clauses of the Methodology.

6.2 The Committee considered all the effects associated with the reassessment. They considered that the positive effects of implementing the change to the hazard classifications of the approvals outweigh the adverse effects.

6.3 In making its decision, the Committee took into account best international practices and standards for the safe management of hazardous substances.

6.4 Consequently, the Committee confirmed the change to the hazard classifications of the substances and **approved** the modified reassessment application.

Signed by: **Dr Derek Belton**	**Date: 6 June 2019**
Chair, Decision Making Committee **Environmental Protection Authority**	

Appendix A: Controls

Controls applying to Methanamine (methylamine)

The controls in Table A-1 are prescribed by the EPA Notices. The additional controls set under section 77A are in Table A-2.

The controls in Table A-3 are requirements under the HSW legislation. Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW legislation according to the classification of the substance. They are listed here for information purposes only.

Table A-1 EPA Controls for Methanamine (methylamine)

Control code	EPA Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
SDS	EPA Safety Data Sheets Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-2	EPA Hazardous Property Controls Notice 2017 Part 2	Certain substances restricted to workplaces only
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances

Table A-2 Additional controls and modifications to controls for Methanamine (methylamine)

Control code	HSNO Act	Control
Use restriction	Section 77A	A use restriction is applied to this substance. No person may use this substance described as a pesticide or a veterinary medicine. However, this substance may be used in the formulation of a pesticide or a veterinary medicine. For the purpose of this control— (a) **pesticide** includes, but is not limited to, a product intended for use as an acaricide, antifouling paint, avicide, fumigant, fungicide, insecticide, herbicide, miticide, molluscicide, piscicide, timber treatment preservative or vertebrate toxic agent (b) **veterinary medicine** has the same meaning given to it in the Agricultural Compounds and Veterinary Medicines Act 1997.

Table A-3 HSW Requirements for Methanamine (methylamine)

Code	Regulation	Description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-2	Reg 2.5 - 2.10	Signage
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12 - 2.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances
HSW4-2	Reg 4.5 - 4.6	Information, instruction, training and supervision
HSW5-1	Reg 5.2 - 5.5	Fire extinguishers
HSW5-2	Reg 5.6 - 5.13	Emergency response plans
HSW8-1	Reg 8.1 - 8.2	Compliance certification
HSW8-2	Reg 8.3 - 8.4	Requirements for public transportation of class 1 to 5 substances
HSW10-1	Reg 10.3	General controls on class 2, 3, and 4 substances
HSW10-2	Reg 10.4	Substances that must be secured
HSW10-3	Reg 10.5	Requirement to segregate class 2, 3, and 4 substances

HSW10-4	Reg 10.6 - 10.7	Duty of PCBU to establish a hazardous area
HSW10-5	Reg 10.8 - 10.20	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances
HSW10-10	Reg 10.26	Duty of PCBU to establish hazardous substance location
HSW10-13	Reg 10.34 - 10.35	Requirement to have compliance certificate if class 2.1.1, 2.1.2, or 3.1 substance present at hazardous substance location
HSW10-15	Reg 10.37	Requirement for transit depot
HSW11-1	Part 11	Controls relating to adverse effects of unintended ignition of class 2 and 3.1 substances
HSW13-1	Reg 13.3 - 13.4	Records of application for class 6 substances
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used
HSW13-5	Reg 13.10	Substances not requiring a certified handler to be secured
HSW13-7	Reg 13.14 - 13.16	Transportation of certain class 6 and 8 substances
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-13	Reg 13.26 - 13.29, 13.35 - 13.37	Storage and segregation of certain class 6 or 8 substances
HSW13-15	Reg 13.34, 13.38 - 13.39	Duty of PCBU to establish hazardous substance location and compliance certificate requirements where certain class 6 or 8 substances present
HSW13-16	Reg 13.40 - 13.44	Separation of hazardous substance locations holding class 6 and 8 substances
HSW13-17	Reg 13.45	Additional emergency management requirements for certain class 6 or 8 substances
HSW15-1	Part 15	Requirements for gases under pressure
HSW16-1	Part 16	Requirements for tank wagons and transportable containers
HSW17-1	Part 17	Requirements for stationary container systems

Controls applying to Methylamine >25% in a non hazardous gaseous diluent

The controls in Table A-4 are prescribed by the EPA Notices. The additional controls set under section 77A are in Table A-5.

The controls in Table A-6 are requirements under the HSW legislation. Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW legislation according to the classification of the substance. They are listed here for information purposes only.

Table A-4 EPA Controls for Methylamine >25% in a non hazardous gaseous diluent

Control code	EPA Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
SDS	EPA Safety Data Sheets Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-2	EPA Hazardous Property Controls Notice 2017 Part 2	Certain substances restricted to workplaces only
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances

Table A-5 HSNO Additional controls and modifications to controls for Methylamine >25% in a non hazardous gaseous diluent

Control code	HSNO Act	Control
Use restriction	Section 77A	A use restriction is applied to this substance. No person may use this substance as a pesticide, or veterinary medicine; however, this substance may be used in the formulation of a pesticide or veterinary medicine.

Table A-6 HSW Requirements for Methylamine >25% in a non hazardous gaseous diluent

Code	Regulation	Description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-2	Reg 2.5 - 2.10	Signage
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12 - 2.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances
HSW4-2	Reg 4.5 - 4.6	Information, instruction, training and supervision
HSW5-2	Reg 5.6 - 5.13	Emergency response plans
HSW13-1	Reg 13.3 - 13.4	Records of application for class 6 substances
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used
HSW13-5	Reg 13.10	Substances not requiring a certified handler to be secured
HSW13-7	Reg 13.14 - 13.16	Transportation of certain class 6 and 8 substances
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-13	Reg 13.26 -13.29, 13.35 - 13.37	Storage and segregation of certain class 6 or 8 substances
HSW13-15	Reg 13.34, 13.38 - 13.39	Duty of PCBU to establish hazardous substance location and compliance certificate requirements where certain class 6 or 8 substances present
HSW13-16	Reg 13.40 - 13.44	Separation of hazardous substance locations holding class 6 and 8 substances
HSW13-17	Reg 13.45	Additional emergency management requirements for certain class 6 or 8 substances
HSW15-1	Part 15	Requirements for gases under pressure
HSW16-1	Part 16	Requirements for tank wagons and transportable containers

HSW17-1	Part 17	Requirements for stationary container systems

Controls applying to Sprinter 700DS

The controls in Table A-7 are prescribed by the EPA Notices. The additional controls set under section 77A are in Table A-8.

The controls in Table A-9 are requirements under the HSW legislation. Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW legislation according to the classification of the substance. They are listed here for information purposes only.

Table A-7 EPA Controls for Sprinter 700DS

Control code	EPA Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheets Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of class 9 pesticides

Table A-8 HSNO Additional Controls and Modifications to Controls for Sprinter 700DS

<table>
<tr><th>Control code</th><th>HSNO Act</th><th>Control</th></tr>
<tr><td>Application rate</td><td>Section 77 variation to HPC Notice clause 50</td><td>A maximum application rate is set for this substance.
Sprinter 700DS shall be applied at a maximum application rate of 3.6 L/ha (2.52 kg 2,4-D/ha) with a maximum application frequency of once per season.</td></tr>
<tr><td>Label</td><td>Section 77 variation to Labelling Notice</td><td>Additional label information has been specified.
The label must have a statement saying “if re-entry work is required within 24 hours of application, eye protection, waterproof gloves, boots and overalls must be worn’.</td></tr>
<tr><td>Label</td><td>Section 77 variation to Labelling Notice</td><td>Additional label information has been specified.
The label must contain a statement specifying the minimum droplet size:
<table>
<tr><th>Method</th><th>Droplet size</th><th>Reference</th></tr>
<tr><td>Aerial</td><td>No finer than coarse</td><td>BCPC or ASABE S572</td></tr>
<tr><td>Boom</td><td>No finer than medium</td><td>BCPC or ASABE S572</td></tr>
</table></td></tr>
<tr><td>Max impurity</td><td>Section 77A</td><td>The maximum level of an impurity in the technical grade active material for this substance is set.
The maximum content of dioxin TEQ shall be less than 0.1 ppb (ng/g).
The concentration of 2,3,7,8 tetrachlorodibenzo-para-dioxin (2,3,7,8 TCDD) congener must be undetectable at a detection limit of 0.01 ppb (ng/g) or lower.</td></tr>
</table>

Table A-9 HSW Requirements for Sprinter 700DS

Code	Regulation	Description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-2	Reg 2.5 - 2.10	Signage
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12 - 2.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances
HSW4-2	Reg 4.5 - 4.6	Information, instruction, training and supervision
HSW5-2	Reg 5.6 - 5.13	Emergency response plans

HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used
HSW13-7	Reg 13.14 - 13.16	Transportation of certain class 6 and 8 substances
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-14	Reg 13.30 - 33	Secondary containment requirements for class 6 and 8 pooling substances
HSW16-1	Part 16	Requirements for tank wagons and transportable containers
HSW17-1	Part 17	Requirements for stationary container systems

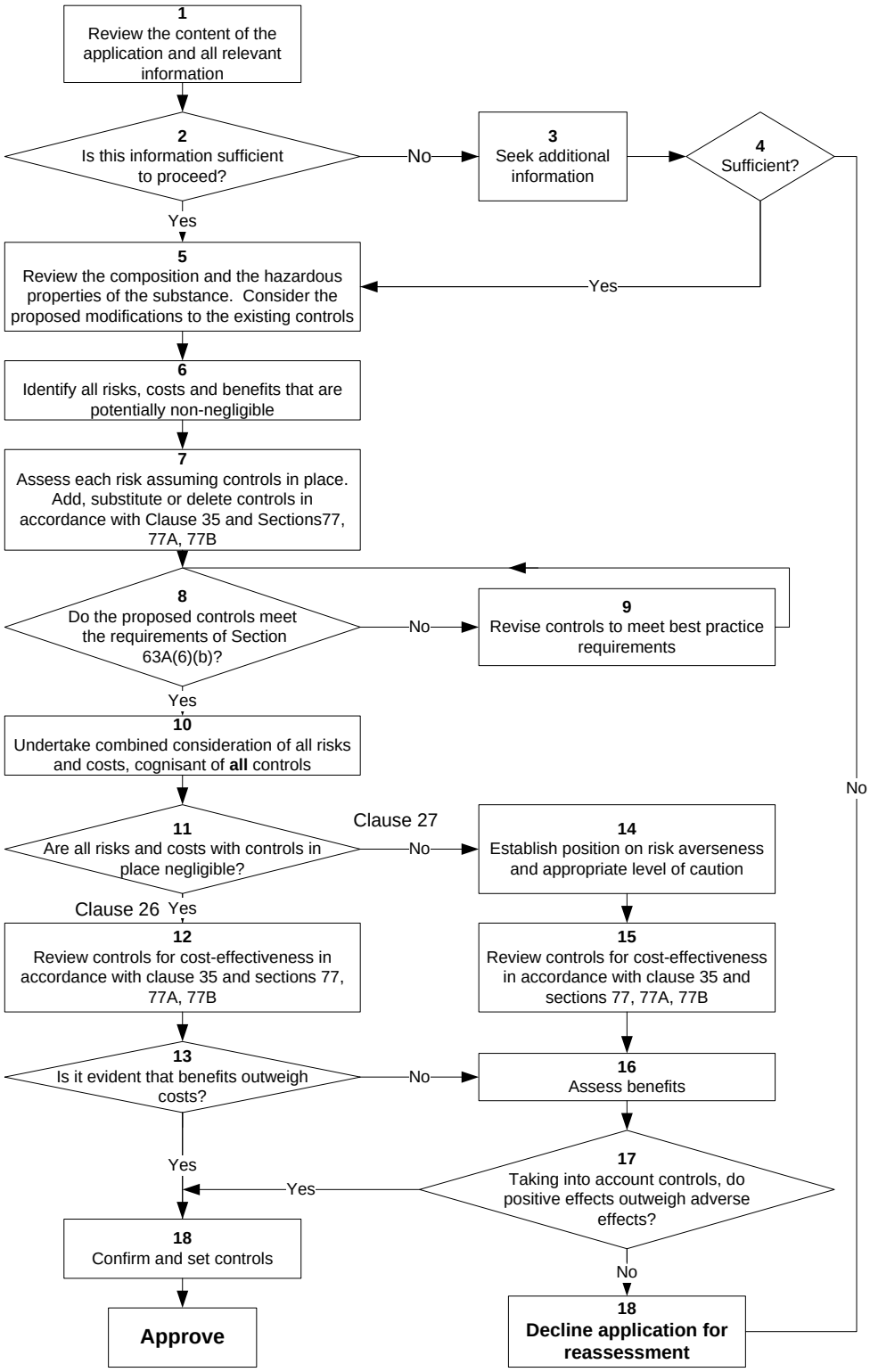
Appendix B: Decision Path

Context

This decision path describes the decision-making process for applications for a modified reassessment for amendments to hazardous substances approvals. These applications are made and determined under section 63A of the HSNO Act.

Decision path for modified reassessment for amendments to hazardous substance approvals: application made and determined under section 63A.

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.



Explanatory Notes

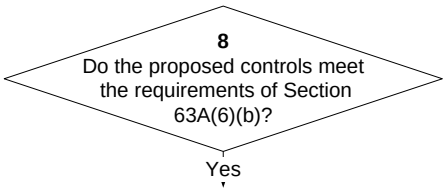
Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology. While section 63A is not mentioned in section 53 (public notification), sections 63A(4) and (5) provide discretion for the HSNO decision maker to consider public notification (cf section 53(2)) and guidance re consultation where an application is not publicly notified.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision.
Item 3:	**(if 'no') Seek additional information** If there is not sufficient information then additional information may need to be sought under section 52 or 58 of the Act. If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the HSNO decision maker may choose to decline the application, or the application may lapse.
Item 4	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application for reassessment must be declined (see item 18).
Item 5:	**(if 'yes' from item 2 or from item 4) Review the composition and the hazardous properties of the substance, and the proposed modifications to the existing controls** Review the composition of the substance, its hazardous properties, and the existing suite of controls on the substance. The level of detail for this review will depend on the nature of the application for modified reassessment. In most cases a detailed review will not be required. Consider the proposed modifications to the existing controls.
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[1]** The modified reassessment process concentrates on a specific aspect of the approval (section 63A(1)(a)). All risks, costs and benefits that are potentially non-negligible need to be identified. However, emphasis should be placed on effects that are expected to change as a result of the proposed changes to controls.

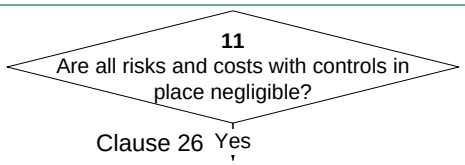
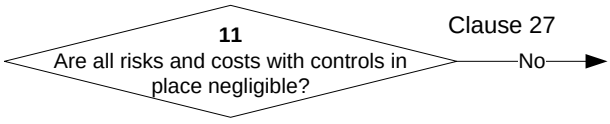
[1] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called 'sunk' costs since they are incurred whether or not the application is successful.

	Costs and benefits are defined in the Methodology as the value of particular effects. However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally synonymous and may be addressed together. Examples of costs that cannot be considered as risks are one-off direct financial costs incurred by applicants that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise they will considered in the same way as risks, but their likelihood of occurrence will be more certain. Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).	
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[2]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)). Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[3], and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 7:	**Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.** The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place. Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of its occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account. The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost.	

[2] Effects on the natural environment, effects on human health and safety, effects on Maori culture and traditions, effects on society and community, effects on the market economy.

[3] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits.

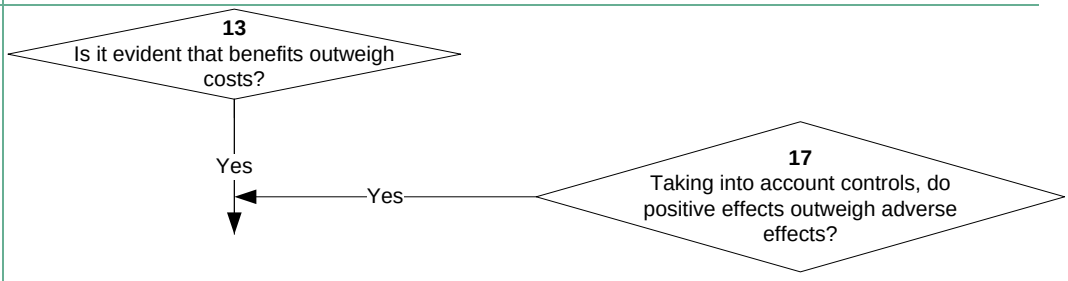
	This assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)). Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls. See EPA report 'Approach to Risk' for further guidance. Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 12 and 15. If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.
Item 8:	**Do the proposed controls meet the requirements of Section 63A(6)(b)?** Consider whether the proposed controls meet best international practices and standards for the safe management of hazardous substances. This includes the full suite of proposed controls including existing controls and modified controls.
Item 9:	**(if 'no' from item 8) Revise controls to meet best practice requirements** If the controls do not meet the best international practice criteria, then modify the controls so that they do meet them.
Item 10:	 **(if 'yes' from item 8) Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually consider all risks and costs together as a 'basket' of risks/costs. If it is feasible and/or appropriate, this may involve combining groups of risks and costs as for Clause 34 of the Methodology. The purpose of this step is to consider synergistic effects and determine whether these may change the level of individual risks.
Item 11:	**Are all risks and costs with controls in place negligible?** Looking at individual risks in the context of the 'basket' of risks, consider whether any of the residual risks (costs) are negligible.

Item 12:	 **(if 'yes' from item 11) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the cost-effectiveness of the proposed individual controls and exposure limits. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.
Item 13:	**Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[4]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 16).
Item 14:	 **(if 'no' from item 10) Establish HSNO decision maker's position on risk averseness and appropriate level of caution** Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks

[4]Technical Guide 'Decision making' section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 'General requirements for the Identification and Assessment of Risks, Costs, and Benefits'

	are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 15:	**Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 10, 13, 14 and 15). Consider (a) whether any of the non-negligible risks can be reduced by varying the controls in accordance with section 77 and 77A of the Act, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and making sure that the benefits of doing so outweigh the costs. As for item 6, If the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 16:	**(if 'no' from item 13, or in sequence from item 15) Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of its occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect. An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[5]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs the assessment is carried out with the default controls in place.
Item 17:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7 (9), 12 and/or 15. Where this item is taken in sequence from items 14, 15 and 16 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 11, 12 and 13 (i.e. risks are negligible, and there are external or public costs) it constitutes a decision made under clause 26 of the Methodology.

[5] Clause 13 of the Methodology

Item 18:	**(if 'no' from item 4 or item 17) Decline application for reassessment** (from item 4) The Act is silent on the situation if there is insufficient information to consider the application. However, sections 55-61 (section 63A(3)) are deemed to hold, therefore the HSNO decision maker concludes that the application for reassessment may be declined if there is insufficient information. (from item 17) The HSNO decision maker may decline the application under section 63A(6) after taking into account the effects of the substance and best international practices and standards. Section 63A(2)(b) notes that this modified reassessment process cannot result in an approval to import or manufacture the substance being revoked. Therefore, if the process results in a 'decline' decision, then the result is that the modified reassessment of the substance is not approved, and the existing controls remain in force.
Item 19:	 **(if 'yes' from items 13 or 17) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7 (9), 12 and/or 15). The final step in the decision-making process brings together all the proposed controls, and reviews them for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.