

**FORM section 63A
(Chief Executive-Initiated Modified Reassessment)**

Application for a Modified Reassessment
under section 63A of the
Hazardous Substances and New Organisms Act 1996

2009 Yearly Chemical Review
ERMA200067

Applicant: Chief Executive of ERMA New Zealand

Signed: _____

Date: _____

SECTION ONE – APPLICANT DETAILS

1.1 Name and postal address in New Zealand of the organisation making the application

Name: R Forlong, Chief Executive
Address: ERMA New Zealand (the Agency)
PO Box 131
Wellington
Phone: 04 916 2426
Fax: 04 914 0433

1.2 The applicant's location address in New Zealand (if different from above)

Address: Level 1, BP House
20 Customhouse Quay
Wellington

1.3 Name of the contact person for the application

Name: Susan Collier
Position: Senior Advisor, Hazardous Substances
Phone: 04 918 4869
Fax: 04 914 0433
Email: susan.collier@erманz.govt.nz

SECTION TWO – APPLICATION TYPE

2.1 The approvals being reassessed

2.2 The substances which are the subject of this application are listed in **Appendix 3** and **Appendix 4**.

2.3 Grounds for the reassessment

2.3.1 In July 2009, the Environmental Risk Management Authority ('the Authority') considered whether or not there were grounds for reassessing the approvals, under section 62 of the Act.

2.3.2 The Authority concluded that the new information relating to the effects of the substances listed in **Appendix 3** was such as to justify a reassessment of these substances under section 62(2)(b).

2.3.3 This application for a 'modified' reassessment under section 63A of the Act has been prepared by the Chief Executive of the Agency following the Authority's decision on grounds.

2.4 Specific aspect of the approval being reassessed

2.4.1 The reassessment considers only the specific aspect of each approval that is outlined in **Appendix 3** and **Appendix 4**.

2.4.2 HSNO approvals and associated classifications for 5-6000 chemicals were published in the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (and its amendments) and the Hazardous Substances (Chemicals) Transfer Notice 2006.

2.4.3 From time to time, the Agency discovers, or has brought to its attention, errors or inconsistencies in the transferred classifications. The purpose of this reassessment is to correct inconsistencies and omissions in the classifications of the substances set out in **Appendix 3** and **Appendix 4**, to reflect new information or data, or to align with internationally accepted data. In order to avoid industry having to deal with a constant flow of such changes throughout the year, the Agency intends that this process will be by way of 'modified' reassessment, at least once a year, under section 63A of the HSNO Act for the changes which are more than "minor" and so not able to be made under section 67A of the Act.

2.4.4 The proposed changes are considered to be more than "minor in effect" for the following reasons:

- a) all the proposed changes may result in some costs for industry particularly for companies which have many products affected by the change;
- b) there is no requirement for industry to register products covered by individual approvals or group standard approvals with the Agency. Therefore, the Agency does not know who the affected parties with respect to amendment of classifications for chemical substances are. It should be noted that a number of the substances with proposed changes are widely used and are found in many products (for example, ethanol);
- c) some changes of classification result in the need for changes to safety data sheets and often labelling requirements. Amendment of classifications by section 67A does not allow for time to implement these changes. As part of this reassessment the Agency proposes a phase in period for implementing any resulting control and information changes.
- d) some of the changes are to remove controls. It is important that this is done using a public process.

2.5 Public notification and consultation

- 2.5.1 Section 63A(4) allows the Authority to reassess substances under section 63A without publicly notifying the reassessment in accordance with section 53 providing the Authority does everything reasonably practicable on its part to consult with all persons who, in its opinion, may be affected by the reassessment (section 63A(5)).
- 2.5.2 In its decision on the 'grounds' application, the Authority was of the view that the reassessment application should be widely consulted on with as many hazardous substance stakeholders as possible being notified. The Agency therefore intends to ensure that as many hazardous substances stakeholders are notified of the application and are given a reasonable opportunity to make submissions or comments. The application will therefore be notified in the usual way, by notice on ERMA New Zealand's website and in the four main national newspapers.
- 2.5.3 Submissions received as a result of the consultation will, together with the application, be used by the Authority in considering the application. The Authority will hold a public hearing, if required by any submitter, and then consider the application in accordance with the Act.
- 2.5.4 The period for consultation and submissions is 30 working days and closes on 20 November 2009. Submissions on this proposal should be sent to:

Applications Administrator HS
ERMA New Zealand
PO Box 131

Wellington

Or by e-mail:

submissions@ermanz.govt.nz

SECTION THREE – INFORMATION ON THE SUBSTANCES

3.1 The unequivocal identification of the substance

3.1.1 Refer to **Appendix 3** and **Appendix 4**.

3.2 Information on the chemical, physical and hazardous properties of the substance

Not applicable

3.3 Identification of the controls on the substances

3.3.1 The changes to controls for each substance based on the proposed change are listed in **Appendix 3** and **Appendix 4**.

3.4 The proposal to modify the approval of the substances

3.4.1 The change proposed for each substance is listed in **Appendix 3** and **Appendix 4**.

3.4.2 For products containing substances listed in **Appendix 3** and **Appendix 4**, the Agency recognises that a reasonable period of time should be allowed in which to comply with the proposed new classifications and controls. The Agency therefore proposes that a transitional (phase-in) period of 1 year should be allowed in which to implement any changes approved by the Authority.

3.5 Commercial sensitivity

3.5.1 Where the mixtures (products) affected by the proposed classification changes are confidential, a summary of the known substances that are affected is listed in **Appendix 4**. This includes any product that has been approved under Part 5 of the Act and any product that has been assessed by the Agency's "status of substance" (SOS) process and requires a legal change to the classification.

3.5.2 Substances that do not require a legal change to the classification, because they are approved under group standards, are not listed in **Appendix 4**. ERMA New Zealand will contact the applicants of products affected that have been through the SOS process to make them aware of the proposed changes.

- 3.5.3 Products approved under group standards, that have not been through the SOS process and may be affected by the proposed classification changes, will need to be assessed by the importer/manufacture of the product to determine whether or not the product classification should be changed.

SECTION FOUR: RISKS, COSTS AND BENEFITS

4.1 Identification of all the effects associated with the reassessment proposal (section 63A(6)(a))

- 4.1.1 The proposed modified reassessment of these substances seeks to amend classifications and controls to better manage the hazards/risks of the substances listed in **Appendix 3** and **Appendix 4**.
- 4.1.2 Each proposed change will have different costs and benefits associated with the change. The addition of a hazard that is considered a dangerous good (DG) (as prescribed in the UN Model Regulations for the Transportation of Dangerous Goods¹) may have a significant effect on the management of the substance. In most cases, where the proposed change will result in the substance becoming regulated as a DG, the substance will already be handled as a DG internationally. Where the proposed change is to remove an irritant classification where the substance has other toxicity classifications, no change in controls other than labelling and documentation is required.
- 4.1.3 In some cases the removal of a classification will result in the removal of controls. This may result in a significant reduction in compliance costs.
- 4.1.4 The main benefit of making the changes listed in **Appendix 3** and **Appendix 4** is to ensure consistency within the HSNO classification system and with internationally accepted classifications and data.
- 4.1.5 Ensuring that the regulation of hazardous substances in New Zealand is consistent with best international practice will reduce compliance cost and make the substances easier to manage on an international level.

4.2 Assessment of the risks associated with the reassessment proposal

- 4.2.1 Where the proposed change for a substance is to add a classification new controls or labelling will apply. If these changes are not made the risks associated with the added hazard classification will not be managed by the existing controls. By not managing the risks a harm may result that could have been avoided.
- 4.2.2 Maintaining HSNO classifications that are not aligned with internationally accepted classifications may lead to increased cost to importers and manufacturers who will need to re label and produce New Zealand specific safety data sheets.

¹ http://www.unece.org/trans/danger/publi/unrec/rev15/English/03E_Part3.pdf

4.3 Assessment of the costs associated with the reassessment proposal

- 4.3.1 The proposed changes may result in some costs for industry particularly for companies which have many products affected by the change. All changes of classification result in the need for changes to safety data sheets and often labelling requirements. In some cases these costs may be significant. However, these should be short term costs.
- 4.3.2 A number of the proposed changes will result in the removal of controls which could lead to significant reduction in compliance costs.
- 4.3.3 In the long term, better alignment of classifications internationally should reduce the costs to industry as documentation and re-labelling to New Zealand-specific requirements would not be required.

4.4 Assessment of the benefits associated with the reassessment proposal

- 4.4.1 The proposed amendments will allow better management of the hazards and risks of the listed substances and also better alignment with internationally accepted classifications which should reduce compliance costs in the long term
- 4.4.2 Where classifications are proposed to be added to substances the risks associated with the substances will be better managed by the addition of new controls related to the properties of the substance.

SECTION FIVE – INTERNATIONAL CONSIDERATIONS

5.1 The best international practices and standards for the safe management of the substance (section 63A(6)(b))

- 5.1.1 Alignment of the HSNO classification with internationally accepted classifications will aid in the implementation of the Globally Harmonised System for Classification and Labelling of Chemicals (GHS) GHS worldwide. Implementation of GHS is aligned with best international practice.
- 5.1.2 Amending approvals to remove regulatory inconsistencies between the controls applying to HSNO substances is also best practice for the safe management of the relevant substances.

5.2 International obligations and treaties

- 5.2.1 New Zealand has an obligation to contribute to the establishment of the Globally Harmonised System for Classification and Labelling of Chemical (GHS). The HSNO classification system is based on GHS. However, while this provides a system of “rules” for classification it does not provide an international classification for a chemical. By aligning its classifications with internationally accepted classifications, ERMA New Zealand and New Zealand will be contributing to the success of GHS.

SECTION SIX – MISCELLANEOUS

6.1 A glossary of scientific and technical terms used in the application

6.1.1 Not applicable.

6.2 Other information considered relevant to this application not already included

6.2.1 None.

SECTION SEVEN – SUMMARY OF PUBLIC INFORMATION

7.1 Name of the substance for the public register

7.1.1 2009 Yearly Chemical Review.

7.2 Purpose of the application for the public register

7.2.1 From time to time, the Agency discovers, or has brought to its attention, errors or inconsistencies in substance classifications. The purpose of this reassessment is to correct inconsistencies and omissions in the classifications of the substances set out in Schedules of the application, to reflect new information or data, or to align with internationally accepted data.

7.3 Executive summary

7.3.1 The reassessment is confined to the issues listed in **Appendix 3** and **Appendix 4** of the application.

Appendix 1 Submission Form

Making a Submission

Name of person or organisation
making submission (required):

Postal address (required):

Town (required):

Country (required):

Phone:

Fax:

Contact E-mail:

Are you submitting this as (tick one box only in this section):

An individual (not on behalf of an organisation)

On behalf of a group or organisation

Other (please specify) _____

Please return your submission no later than **20 November 2009** by post to:

ERMA New Zealand
PO Box 131
Wellington
New Zealand

or to
submissions@emanz.govt.nz

Name of Consultation: **2009 Yearly Chemical Review**

Reason for submission (required):

What decision do you seek?

Do you wish to speak in support of your submission at a public hearing? (required – choose only one):

Yes

No

All submissions will be acknowledged by ERMA New Zealand and a summary of submissions will be sent to all those who request a copy. The summary will include the names of all those who made a submission. In the case of those who withhold permission to release personal details, the name of the organisation will be given if supplied.

Do you wish to receive a copy of the summary of submissions?

Yes

No

Your submission may be requested under the Official Information Act 1982. If this happens, ERMA New Zealand may be required to release your submission to the person who requested it. If you are an individual, and we are required to release your submission, we will remove your personal details from the submission if you check the following box.

I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

Note:

In the case that a submitter **does not** tick the box, this does not mean that their personal information will necessarily be released in response to a request for information. Rather, objective consideration of all the facts and circumstances of that particular case will have to be undertaken (including Official Information Act and Privacy Act requirements) to determine whether a submission is to be released with their personal details included.

Submissions on individual Substances (please supply supporting data)

Approval Number	
Substance Name	
CAS Number (if applicable)	
Issue/Comments	
Supporting Information	

Approval Number	
Substance Name	
CAS Number (if applicable)	
Issue/Comments	
Supporting Information	

Repeat as many times as necessary.

Appendix 2

DRAFT

Application Form (HS??)

Request for Classification/Controls Review

Send by post to: ERMA New Zealand, PO Box 131, Wellington OR

email to reassessments@ermanz.govt.nz

Company name:		
Company address:		
Postal address [if different to company address]		
Contact name:		
Job title		
Contact person phone / e-mail:		

Please tick which type of review is requested

Classification

Controls

HSNO Approval Number	
Chemical/Product Name	
CAS number (if applicable)	
Change Requested	
Supporting information	

Instructions to complete form

You need to ensure that you provided supporting information for the change requested. If the form is received incomplete, we will be unable to process your application and will need to contact you to fill in the missing information.

Appendix 3

Substances for reassessment

This appendix lists all the non confidential substances which are proposed for reassessment under this application.

Substances that are mixtures affected by the proposed classification changes where formulation information is confidential are listed in **Appendix 4**.

Current classifications and proposed classifications are given. The schedule also includes the justification for the proposed changes and an indication of the controls affected by these changes.

For more detailed information on the control code please refer to the following document

<http://www.ermanz.govt.nz/resources/publications/pdfs/TheMatrix.pdf>

Bold lettering indicates affected classifications.

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Pyrantel pamoate CAS 22204-24-6	HSR003679	6.9B		<p>Remove 6.9B The 6.9B classification for pyrantel pamoate was based on the tartrate salt. The 6.9B classification of pyrantel pamoate was based on a NOAEL of 3 mg/kg bw/day with effects on liver weights and serum alanine aminotransferase values. This was incorrect since the classification should be based on a LOAEL vale.</p> <p>The LOAEL was 30 mg/kg bw/day and considering the duration of the study (2 years), pyrantel tartrate should not trigger the 6.9 classification. Also noted was that the tartrate salt is 10 times more toxic than the pamoate salt. The 6.9B classification for pyrantel pamoate should therefore be removed. Pyrantel pamoate no longer triggers any HSNO classifications.</p>	<p>All controls will be removed as these substances no longer trigger a HSNO classification.</p>
Solid containing 8 - 70% oxantel pamoate, 0.5 - 7% praziquantel and 2 - 20% pyrantel pamoate	HSR001940	6.9B			
Solid containing 60 - 80% oxantel pamoate and 15 - 23% pyrantel pamoate	HSR001902	6.9B			
Solid containing 50 - 70 g/kg praziquantel and 640 - 720 g/kg pyrantel pamoate	HSR001947	6.9B			
Solid containing 50 - 90% pyrantel pamoate	HSR001956	6.9B			
Liquid containing 10 - 20 g/litre pyrantel pamoate	HSR001966	6.9B			
Paste containing 18 - 32 g/litre praziquantel and 250 - 350 g/litre pyrantel pamoate	HSR001877	6.9B			
Paste containing 16 - 20% niclosamide and 2 - 4% pyrantel pamoate	HSR002371	6.3B, 6.4A, 6.5B, 6.9B , 9.1A, 9.3C	6.3B, 6.4A, 6.5B, 9.1A, 9.3C		No change to controls.

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Paste containing 26 - 29% niclosamide and 8 - 12% pyrantel pamoate	HSR001957	6.4A, 6.5B, 6.9B , 9.1A, 9.3B	6.4A, 6.5B, 9.1A, 9.3B		
Paste containing 26 - 29% niclosamide and 8 - 12% pyrantel pamoate	HSR001957	6.4A, 6.5B, 6.9B , 9.1A, 9.3B	6.4A, 6.5B, 9.1A, 9.3B		
Aluminium sulphate CAS 10043-01-3	HSR003958	6.1D, 6.3A, 8.3A , 9.1B, 9.3C	6.1D, 6.3A, 6.4A , 9.1B, 9.3C	Change 8.3A to 6.4A For CAS 16828-11-8 change name to Aluminium sulphate hexadecahydrate, >25% in a non hazardous diluent Aluminium sulphate should be classified 6.4A (eye irritant), rather than 8.3A (eye corrosive) based on the following data: Acute Exposure to Hydrated aluminium sulphate (Al ₂ (SO ₄) ₃ , 14.3H ₂ O): Moderately irritating to rabbit eyes (European Chemicals Bureau; IUCLID Dataset, Aluminium sulphate (10043-01-3) (2000 CD-ROM edition). Available from, as of June 15, 2004: http://ecb.jrc.ec.europa.eu/iuclid-datasheet/10043013.pdf)	Controls to be removed as they are triggered by 8.3A EM2, I2, I10, I22 and P14
Aluminium sulphate 18-hydrate CAS 7784-31-8	HSR004337	6.1D, 6.3A, 8.3A , 9.1B, 9.3C	6.1D, 6.3A, 6.4A , 9.1B, 9.3C		
Aluminium sulphate, >25% in a non hazardous diluent CAS 16828-11-8	HSR004338	6.1D, 6.3A, 8.3A , 9.1B, 9.3C	6.1D, 6.3A, 6.4A , 9.1B, 9.3C		
Aluminium sulphate, >25% in a non hazardous diluent CAS 10043-01-3	HSR005743	6.1D, 6.3A, 8.3A , 9.1B, 9.3C	6.1D, 6.3A, 6.4A , 9.1B, 9.3C		
Sodium carbonate CAS 497-19-8	HSR003265	6.1B , 6.3A, 6.4A, 6.9B, 6.9B	6.1D (inhalation), 6.1E(oral), 6.3A, 6.4A	Remove 6.9B classification Change 6.1B to 6.1D Sodium Carbonate - 6.9B classification should be removed because the target organ toxicity is a result of primarily or secondary effects on the gastro-intestinal tract due to irritation and thus not due to systemic toxicity. Target organ toxicity should be mediated through a systemic not local effect. Sodium carbonate – 6.1B (inhalation) classification should be lowered to 6.1D. The 6.1B classification was based on a Guinea pig study however the Guinea pig is not a preferred species for inhalation studies. The LC50 rat study, whole body, 2 hours with a dust (combustion products) is 2300 mg/m ³ . Converting this to a 4 hour exposure and to mg/L gives a value of 1.15 mg/L 6.1D classification. This 6.1D classification	Controls to be removed as they are triggered by 6.1B EM2, I2, I10, I22 and P14 T3, T6. TR1, AH1
Sodium carbonate, >10 - 44% in a non hazardous diluent CAS 497-19-8	HSR006706	6.3A, 6.4A	6.3A, 6.4A (no change)		No change to controls

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Sodium carbonate, >2 - 10% in a non hazardous diluent CAS 497-19-8	HSR006548	6.3B	6.3B (no change)	adopts a cautious approach; the SIDS Initial assessment form, October 2002 indicates that the particle size for the rat inhalation study was in the region of 1um aerodynamic equivalent diameter (there was however no details how this was measured) whilst the average particle size diameter expected to occur in dust to which humans will be exposed will range from 90 to 500 um. In humans, due to the higher particle size much of the dust would be expected to be deposited in the upper respiratory airways and then proceed to the stomach via the mucocilliary escalator, however there is the potential for the smaller particles to reach the lower respiratory tract which justifies the cautious approach. Sodium Carbonate - 6.9B classification should be removed because the target organ toxicity is a result of primarily or secondary effects on the gastro-intestinal tract due to irritation and thus not due to systemic toxicity. Target organ toxicity should be mediated through a systemic not local effect. Sodium carbonate – 6.1B (inhalation) classification should be lowered to 6.1D. The 6.1B classification was based on a Guinea pig study however the Guinea pig is not a preferred species for inhalation studies. The LC50 rat study, whole body, 2 hours with a dust (combustion products) is 2300 mg/m3. Converting this to a 4 hour exposure and to mg/L gives a value of 1.15 mg/L 6.1D classification. This 6.1D classification adopts a cautious approach; the SIDS Initial assessment form, October 2002 indicates that the particle size for the rat inhalation study was in the region of 1um aerodynamic equivalent diameter (there was however no details how this was measured) whilst the average particle size diameter expected to occur in dust to which humans will be exposed will range from 90 to 500 um. In humans, due to the higher particle size much of the dust would be expected to be deposited in the upper respiratory airways and then proceed to the stomach via the mucocilliary escalator, however there is the potential for the smaller particles to reach the lower respiratory tract which justifies the cautious approach. Sodium Carbonate - 6.9B classification should be removed because the target organ toxicity is a result of primarily or secondary effects on the gastro-intestinal tract due to irritation and thus not due to systemic toxicity. Target organ toxicity should be mediated through a systemic not local effect. Sodium carbonate – 6.1B (inhalation) classification should be lowered to 6.1D. The 6.1B classification was based on a	No change to controls
Sodium carbonate, >44% in a non hazardous diluent CAS 497-19-8	HSR006547	6.1E, 6.3A, 6.4A	6.1D (inhalation), 6.1E(oral), 6.3A, 6.4A		Controls to add based on the addition of 6.1D EM11, EM12, EM13, I17, I18, I20, I29
Sodium carbonate, decahydrate CAS 6132-02-1	HSR005703	6.4A	6.4A (no change)		No change to controls
Sodium carbonate, monohydrate CAS 5968-11-6	HSR005702	6.4A	6.1D (inhalation), 6.1E (oral), 6.3A , 6.4A		Controls to add based on the addition of 6.1D and 6.3A EM11, EM12, EM13, I8, I17, I18, I20, I29, I30, T5, T8

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				<p>Guinea pig study however the Guinea pig is not a preferred species for inhalation studies. The LC50 rat study, whole body, 2 hours with a dust (combustion products) is 2300 mg/m³. Converting this to a 4 hour exposure and to mg/L gives a value of 1.15 mg/L 6.1D classification. This 6.1D classification adopts a cautious approach; the SIDS Initial assessment form, October 2002 indicates that the particle size for the rat inhalation study was in the region of 1µm aerodynamic equivalent diameter (there was however no details how this was measured) whilst the average particle size diameter expected to occur in dust to which humans will be exposed will range from 90 to 500 µm. In humans, due to the higher particle size much of the dust would be expected to be deposited in the upper respiratory airways and then proceed to the stomach via the mucociliary escalator, however there is the potential for the smaller particles to reach the lower respiratory tract which justifies the cautious approach. References: National Library of Medicine "Sodium carbonate" http://toxnet.nlm.nih.gov/cgi-bin/sis/search. Sodium Carbonate, OECD SIDS Initial Assessment Report for SIAM 15 (22-25 October 2002)</p>	
<p>Coumatetralyl CAS 5836-29-3</p>	<p>HSR002777</p>	<p>6.1A, 6.9A, 9.1D, 9.3A</p>	<p>6.1B, 6.9A, 9.1D, 9.3A</p>	<p>6.1A change to 6.1B</p> <p>The following 6.1 inhalation data was present at the time of the original classification:</p> <ul style="list-style-type: none"> • 4h LC40 rat inhalation 39 mg/m³ = 0.039 mg/L • 4h LC50 mice inhalation 54 mg/m³ [The Pesticide Manual 11th Edition, British Crop Protection Council] <p>The 6.1A inhalation classification was given based on the LC40 value in rats (6.1A given if value <0.05 mg/L) rather than a LC50 value. It would be expected that the LC50 would be higher than LC40 and thus the LC50 value may not trigger 6.1A classification. There is a LC50 value in mice, which is 0.054 mg/L which would trigger 6.1B rather than 6.1A. In the absence of a LC50 value in rats it is acceptable to take the LC50 value in mice, also if the LC40 value in rats was extrapolated to a LC50 value it is likely that this value would lie around 0.05 mg/L. It is therefore considered that the weight of evidence is such that the LC50 for this chemical is in the region of 0.05 mg/L, triggering a 6.1B classification rather than 6.1A.</p>	<p>Control PG1 change to PG2</p>

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				The following 6.1 inhalation data was present at the time of the original classification: <ul style="list-style-type: none"> • 4h LC40 rat inhalation 39 mg/m3 = 0.039 mg/L • 4h LC50 mice inhalation 54 mg/m3 [The Pesticide Manual 11th Edition, British Crop Protection Council] 	
Iron (III) Chloride CAS 7705-08-0	HSR004016	6.1D, 6.3A , 8.3A, 9.1C, 9.3B	6.1D, 8.2C , 8.3A, 9.1C, 9.3B	Change 6.3A to 8.2C Iron (III) chloride has an individual UN number 1773 Class 8 PGIII. Therefore it should have an 8.2C rather than 6.3A classification.	No change to controls.
Iron (III) chloride, anhydrous, >25% in a non hazardous diluent CAS 7705-08-0	HSR004519	6.1D, 6.3A , 8.3A, 9.3C	6.1D, 8.2C , 8.3A, 9.3C		
alpha-Cypermethrin CAS 67375-30-8	HSR003293	6.1B, 6.9B, 9.1A, 9.3B , 9.4A	6.1B, 6.9B, 9.1A, 9.3A , 9.4A	Change 9.3B to 9.3A The 6.1B classification is derived from a mouse LD50 of 35 mg/kg whereas the 9.3B classification is derived from an LD50 of 474 mg tech./kg. These values should be consistent, and so the lowest LD50 should be used. With a LD50 of 35 mg/kg the 9.3A classification is triggered. The lowest LD50 in the rat is given as 40 mg/kg. The oral LD50 values do vary with vehicle, with the highest values being associated with the use of corn oil (EHC 142, 1992). Corn oil is a commonly used vehicle for oral LD50 type studies and in the absence of information to indicate that the corn oil studies are invalid the lowest LD50 value in the rat should be used. Therefore the 9.3B classification should be changed to 9.3A.	No change to controls.
FLP 200	HSR002699	3.1D, 6.1D, 6.3A, 6.4A, 6.8 , 6.9B, 9.1A, 9.3C , 9.4A	3.1D, 6.1D, 6.3A, 6.4A, 6.8A, 6.9B, 9.1A, 9.3B , 9.4A		
Alpha cypermethrin EC 10%	HSR001754	6.1D, 6.3B, 6.9B, 9.1A, 9.3C , 9.4A	6.1D, 6.3B, 6.9B, 9.1A, 9.3B , 9.4A		
Emulsifiable concentrate containing 100 g/litre alpha-cypermethrin. Also contains xylene	HSR000290	3.1B, 6.1C, 6.3A, 6.4A, 6.8B, 6.9B, 9.1A, 9.3C , 9.4A	3.1B, 6.1C, 6.3A, 6.4A, 6.8B, 6.9B, 9.1A, 9.3B , 9.4A		
Liquid containing 0.5 - 0.9% alpha-cypermethrin, 6 - 9% piperonyl butoxide and 1.4 - 2.6% tetrachlorvinphos	HSR001776	6.1E, 6.3B, 6.4A, 6.5B, 6.8A, 9.1A, 9.4B	6.1E, 6.3B, 6.4A, 6.5B, 6.8A, 9.1A, 9.3C , 9.4B		Controls to add based on addition of 9.3B E4
Liquid containing 20 - 50 g/litre alpha-cypermethrin	HSR001765	6.5B, 6.9B, 9.1A, 9.4A	6.5B, 6.9B, 9.1A, 9.3C , 9.4A		
Suspension concentrate containing 15 g/litre alpha-	HSR000286	6.1E, 6.5B, 6.9B, 9.1A, 9.4B	6.1E, 6.5B, 6.9B, 9.1A, 9.3C , 9.4B		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
cypermethrin					
Alpha Cypermethrin 50SC	HSR001710	6.9B, 9.1A 9.4A	6.9B, 9.1A, 9.3B , 9.4A		
Hydroxylamine sulphate CAS 10039-54-0	HSR004057	6.1D, 6.3A, 6.4A , 6.5B, 6.9A, 9.1A	6.1D, 6.5B, 6.9A, 8.2C, 8.3A , 9.1A	Change 6.3A to 8.2C and 6.4A to 8.3A Change the substance description of Hydroxylammonium sulphate, >3 - 9%in a non hazardous diluent to Hydroxylammonium sulphate, ≥5 - 9%in a non hazardous diluent Add 6.9 classification to dilutions. This substance has a specific UN number 2865 Class 8 PG III We should not have a classification in conflict with internationally accepted information. An 8.2C classification is therefore recommended. If a 8.2C is applied then it is logical to also apply a 8.3A. Mixtures containing hydroxylamine sulphate will be 8.2C at 5% and greater and 8.3A above 3 %.	Controls to add based on addition of 8.2C and 8.3A I2, I10, I22, , P14, EM2
Hydroxylammonium sulphate, >26% in a non hazardous diluent CAS 10039-54-0	HSR006830	6.1D, 6.3A, 6.4A , 6.5B, 9.1A, 9.3B	6.1D, 6.5B, 6.9A, 8.2C, 8.3A , 9.1A, 9.3B		Controls to add based on addition of 8.2C 8.3A and 6.9A T3, I2, I10, I22, P14, EM2,
Hydroxylammonium sulphate, >10 - 24% in a non hazardous diluent CAS 10039-54-0	HSR006838	6.1E, 6.3A, 6.4A , 6.5B, 9.1B	6.1E, 6.5B, 6.9A, 8.2C, 8.3A , 9.1B		
Hydroxylammonium sulphate, >3 - 9%in a non hazardous diluentCAS 10039-54-0	HSR006843	6.3A , 6.5B, 9.1B	6.1E, 6.5B, 6.9B, 8.2C, 8.3A , 9.1B	The dilution classifications are not consistent with the parent 6.9A classification. The 6.9 classification should also apply to the dilutions.	Controls to add based on addition of 8.2C , 8.3A and 6.9B I2,I8, I10, I22, I30, P14,EM2
Mancozeb CAS 8018-01-7	HSR002904	4.2C, 4.3C , 6.4A , 6.5B, 6.9B, 9.1A	6.4A, 6.5B, 6.9B, 9.1A	Change name to Mancozeb (stabilised) Remove 4.2C, 4.3C There is no such thing a mancozeb technical as it is an unstable material. Mancozeb is made as a 800 g/kg product (i.e. mancozeb plus a stabiliser) and never as a technical. The 800g/kg product is used to make other mancozeb products. There is no 4.2, 4.3 UN number applicable to mancozeb.	Controls to be removed as they are triggered by 4.2C and 4.2C F1,F2,F3,F7,F11,F12,F13 ,F15,F16, I 5. I13, I25, P9, P10, D2, EM4, EM9, EM10
2-Bromopyridine CAS 109-04-6	HSR006014	6.3A, 6.4A	3.1C, 6.1C (oral), 6.1B (dermal), 6.3A, 6.4A	Add 3.1C, 6.1C(oral), 6.1B(inhalation) The reported flashpoint in a number of SDS's for this substance was 54oC which would give a 3.1C classification. The weight of evidence indicates a flashpoint of 54oC. It is recommended that a 3.1C classification is added to this substance. There is no specific UN number for this substance. The most common UN number assigned in the references was 2929 Class 6.1 PGII Subrisk: 3 Recommendations of 6.1B and 3.1C are in line with this UN number. LD50 data (company data): oral (rat)= 92mg/kg,	Controls to add as they are triggered by 3.1C and or 6.1B AH1, D2, EM9,10,11,12,13; F1,2,3,5,6,11,12,14,16; GN35A; I5,8,13,17, 18, 20,25,29,30; P5, PG2,3; T3,6,8; TR1.

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				<p>dermal(rabbit)= 81.5mg/kg supports the addition of a 6.1 classification. For a substance to hold a 6.1C classification, oral LD50 values must be above 50mg/kg and less than or equal to 300mg/kg. For a substance to hold a 6.1B classification, dermal LD50 values must be above 50mg/kg but less than or equal to 200mg/kg. Since a substance must carry the highest classification, this substance should have a 6.1B classification.</p>	
<p>2-Aminopyridine CAS 504-29-0</p>	<p>HSR006044</p>	<p>6.3A, 6.4A</p>	<p>6.1C, 6.3A, 6.4A, 9.3A</p>	<p>Add 6.1C, 9.3A RTECS data (US180858) Oral mouse LD50 145 mg/kg = 6.1C Oral rat LD50 200 mg/kg = 6.1C Oral Quail LD50 133 mg/kg = 9.3B Oral Wild bird LD50 33 mg/kg = 9.3A Skin guinea pig LD50 500 mg/kg = 6.1C</p> <p>This substance has a specific UN number 2671 Class 6.1 PG II Generally a 6.1 PGII would have a 6.1B classification in this case all the data indicated a 6.1C classification even though all MSDS's assign the UN number 2671.</p> <p>In assigning a packing group to UN class 6 the following directions are given in the orange book: "Substances of Division 6.1, including pesticides, are allocated among the three packing groups according to their degree of toxic hazard in transport as follows: (a) Packing group I: Substances and preparations presenting a very severe toxicity risk; (b) Packing group II: Substances and preparations presenting a serious toxicity risk; (c) Packing group III: Substances and preparations presenting a relatively low toxicity risk. 2.6.2.2.2 In making this grouping, account shall be taken of human experience in instances of accidental poisoning and of special properties possessed by any individual substance, such as liquid state, high volatility, any special likelihood of penetration, and special biological effects." RTECS and http://www.cdc.gov/NIOSH/pdfs/0026-rev.pdf has inhalation data for humans listed.</p>	<p>Controls to add as they are triggered by 6.1C and 9.3A: AH1, D5, E1, E2, E4, E5, E6, E7, EM7, EM11, EM12, EM13, I3, I8, I11, I17, I18, I20, I23, I29, I30, T3, T6, T8, PG3, TR1</p>

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				<p>http://www.cdc.gov/NIOSH/pdfs/0026-rev.pdf also gives a mouse oral LD50 value of 50 mg/kg. National exposure standards/limits exist for this chemical also suggesting exposure to humans is an issue.</p> <p>The ICSC:0214 has a statement under inhalation risk saying "A harmful contamination of the air can be reached very quickly on evaporation of the substance at 20oC."</p> <p>Although for this substance it does not seem justified to classify as 6.1B on LD50 values considering there is human experience evidence and a UN PGII has been cited based on expert judgment it is recommended that there should be a 6.1B classification</p> <p>A 9.3A classification should also be added based on the RTECS data for wild bird LD5033 mg/kg.</p>	
1-Octen-3-ol CAS 3391-86-4	HSR003548	6.1C , 6.3B, 6.4A	3.1D, 6.1D , 6.3B, 6.4A	<p>Add 3.1D 6.1C change to 6.1D</p> <p>Data indicates this substance has a flashpoint of 68°C which triggers 3.1D classification. New data indicates LD50 (oral), rat = 340mg/kg which triggers 6.1D rather than 6.1C.</p>	<p>Controls to be removed as they are triggered by 6.1C AH1, PG3, T3, T6, TR1.</p> <p>Controls to add as they are triggered by 3.1D D2, EM10, EM9, F11, F2, F6, GN35A, I13, I25, I5, P5.</p>
Doxycycline CAS 17086-28-1	HSR007003	6.5A, 6.5B, 6.9B	6.1D, 6.3B, 6.4A , 6.5A, 6.5B, 6.9B, 9.1A, 9.2A, 9.3C	<p>CAS 17086-28-1 Change name to doxycycline monohydrate Add 6.1D, 6.3B, 6.4A, 9.1A, 9.1A, 9.2A, 9.3C</p> <p>CAS 564-25-0 Add 6.5A, 9.2A</p> <p>The only difference between these substances is that one is anhydrous and the other is a monohydrate. Therefore, the classifications for both records should match. The proposed classifications are to make the substance classifications consistent with each other.</p>	<p>Controls to add based on the classification changes AH1, D5, E1, E2, E4, E5, E6, E7, EM7, EM13,I3, I11, I20, I23, I219, I30, P15, TR1</p>
Doxycycline CAS 564-25-0	HSR003876	6.1D, 6.3B, 6.4A, 6.5B, 6.9B, 9.1A, 9.3C	6.1D, 6.3B, 6.4A, 6.5A , 6.5B, 6.9B, 9.1A, 9.2A , 9.3C	<p>The only difference between these substances is that one is anhydrous and the other is a monohydrate. Therefore, the classifications for both records should match. The proposed classifications are to make the substance classifications consistent with each other.</p>	No change to controls.
Solid containing 30 - 48% doxycycline	HSR002114	6.1E, 6.3B, 6.4A, 6.5B, 6.9B, 9.1A, 9.3C	6.1E, 6.3B, 6.4A, 6.5B, 6.9B, 9.1A, 9.2A , 9.3C	<p>The 9.2A classification should be applied to all antimicrobials/antibiotics where there is not data to the contrary. There is no data for doxycycline therefore a 9.2A classification should apply.</p>	
Paste containing 10 - 18% doxycycline	HSR002227	6.3B, 6.4A, 6.5B, 6.9B, 9.1B	6.3B , 6.4A , 6.5B , 6.9B, 9.2B , 9.1B		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Solid containing 2.6 - 8% doxycycline	HSR002373	6.3B, 6.5B, 6.9B, 9.1B	6.3B, 6.5B, 6.9B, 9.1B, 9.2B	6.5A classifications are not generally applied to veterinary medicines as the route of exposure is not relevant.	
Chlorine dioxide, >26% in a non hazardous gaseous diluent CAS 10049-04-4	HSR007152	6.1B , 8.2C, 8.3A, 9.1A, 9.3A	5.1.2A, 6.1A , 8.2C, 8.3A, 6.9A , 9.1A, 9.2A, 9.3B	<p>Add 5.1.2A, 6.9A, 9.2A Change 6.1B to 6.1A Change 9.3A to 9.3B</p> <p>Chlorine dioxide is classified as a 5.1.2A oxidizing gas converted from the R8. When the dilution was classified it was assumed that all the dilutions were in water, therefore, a gas classification was not appropriate for a liquid and was not applied. Consultation with industry informed ERMA New Zealand that chlorine dioxide is not that soluble so it was not possible to get a dilution of this concentration. The name was changed to Chlorine dioxide >26% in a non hazardous gaseous diluents. However, the classification was not reconsidered when the name was changed. A gas at >26% in a gas mixture will still be oxidizing therefore the 5.1.2A classification should be applied to the substance. The 6.1A (inhalation) and 6.9A (inhalation) were also determined for a solution not a gas mix these inhalation classifications are relevant for the substance in gaseous form and should therefore be applied to this substance.</p> <p>Based on the following information 9.2A should be added (expert judgement) USEPA: Chlorine dioxide and sodium chlorite are active ingredients in numerous products used in the control of bacteria, fungi, and algal slimes. In addition, chlorine dioxide and sodium chlorite are used as material preservatives and as disinfectants. At this time, products containing chlorine dioxide and sodium chlorite are intended for agricultural, commercial, industrial, medical and residential use. The agricultural premises and equipment uses include the disinfection of hard surfaces and equipment (such as hatching facilities and mushroom houses). US Department of Agriculture: Chlorine dioxide gas was also demonstrated to reduce pests in soil, such as nematodes, fungi and weeds that are detrimental to plants, and could be a potential alternative for methyl bromide, a widely used soil fumigant.</p> <p>Based on the following information the 9.3A should be</p>	Controls to add based on the classification changes CG, D3, EM5, EM9, EM10, I7, I15, I27, O1, O2, O3, O4, O5, O6, O8, O9, O10, O11, PG1

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				changed to 9.3B. IUCLID SPECIES: Rat ENDPOINT: LD50 VALUE: 292 mg/kg bw REFERENCE SOURCE: IUCLID	
Ethyl fluoroacetate CAS 459-72-3	HSR006123	3.1B	3.1C, 6.1B	Change 3.1B to 3.1C Add 6.1B The 3.1B classification was based on an R phrase. Data indicates the flashpoint for this substance is 30°C which supports a 3.1C rather than 3.1B classification. Based on several data sheets indicating R phases equivalent to 6.1B classification, based on a weight of evidence approach a 6.1B (all) classification should be assigned based on a precautionary approach.	Controls to be removed as they are triggered by 3.1B F4, Controls to add as they are triggered by 6.1B D4, EM6, I8, I16, I17, I18, I20, I28, I30, P13, T1, T2, T3, T4, T5, T6, T7, T8, TR1
1,3-Cyclohexadiene CAS 592-57-4	HSR006773	3.1B , 6.1E	3.1C , 6.1E	Change 3.1B to 3.1C The 3.1B classification was based on an R phrase. Data indicates the flashpoint for this substance is between 26°C - 26.67°C which supports a 3.1C rather than 3.1B classification.	Controls to be removed as they are triggered by 3.1B F4, AH1, PG2 Add PG3
3-HexanoneCAS 589-38-8	HSR006769	3.1B , 6.1E	3.1C , 6.1E	Change 3.1B to 3.1C The 3.1B classification was based on an R phrase. Data indicates the flashpoint for this substance is 35°C which supports a 3.1C rather than 3.1B classification.	Controls to be removed as they are triggered by 3.1B AH1, F4, PG2 Add PG3
Triisobutylamine CAS 1116-40-1	HSR006349	3.1B , 8.2C, 8.3A	3.1C , 8.2C, 8.3A	Change 3.1B to 3.1C The 3.1B classification was based on an R phrase. Data indicates the flashpoint for this substance is 57°C which supports a 3.1C rather than 3.1B classification.	Controls to be removed as they are triggered by 3.1B AH1, F4, PG2 Add PG3
1-Chloroethyl chloroformate CAS 50893-53-3	HSR006172	3.1C, 8.2C, 8.3A	3.1C, 6.1D , 8.2C, 8.3A	Add 6.1D(oral) Based on company data of oral LD50 of 470 mg/kg a 6.1D classification should be added.	Controls to add as they are triggered by 6.1D EM6, I8, I16, I20, I28, P13, T1, T2
3-(chloropropyl)-trimethoxysilane	HSR005506	3.1C	3.1D	3.1C change to 3.1D The 3.1C classification was based on a R10 risk phrase. Based	Controls to be removed as they are

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
CAS 2530-87-2				on the manufactures SDS giving a flashpoint of 85oC the classification should be 3.1D. There is only one manufacture of this substance that notified this chemical.	triggered by 3.1C F1, F12, F14, F16, F3, F5, P5, PG3 Add PS4
Chlorophenylacetyl chloride CAS 2912-62-1	HSR004325	3.1C, 6.1E , 8.2C, 8.3A	3.1C, 8.2C, 8.3A	Remove 6.1E classification The 6.1E classification is based on a R37 irritating to the respiratory system. There are no other data available in support of this classification and no indication that this chemical triggers R65 may cause lung damage if swallowed. On this basis it is recommended that the 6.1E classification is removed	Controls to be removed as they are triggered by 6.1E EM6, I8, I16, I28, P13, T1, T2, T8
1,4-Dimethylpiperazine CAS 106-58-1	HSR004152	3.1C , 6.1D, 8.2C, 8.3A, 9.3C	3.1B , 6.1D, 8.2C, 8.3A, 9.3C	Change 3.1C to 3.1B The 3.1C classification was based on an R phrase. Data indicates the flashpoint for this substance is 18°C with an IPB of 130-133°C which supports a 3.1B rather than 3.1C classification.	Controls to add as they are triggered by 3.1B AH1, F4, PG2
Propyl propionate CAS 106-36-5	HSR004959	3.1C , 6.1D, 9.3C	3.1B , 6.1D, 9.3C	Change 3.1C to 3.1B The 3.1C classification was based on an R phrase. Data indicates the flashpoint for this substance is 19.4°C with an IPB of 120-124°C which supports a 3.1B rather than 3.1C classification.	Controls to add as they are triggered by 3.1B AH1, F4, PG2
Bromotrimethylsilane CAS 2857-97-8	HSR004379	3.1B , 6.1E, 8.2C, 8.3A	3.1C , 6.1E, 8.2C, 8.3A	Change 3.1B to 3.1C The 3.1B classification was based on an R phrase. Data indicates the flashpoint for this substance is in the range 25-32°C which supports a 3.1C rather than 3.1B classification.	Controls to be removed as they are triggered by 3.1B AH1, F4, PG2
Perboric acid, sodium salt, monohydrate CAS 10332-33-9	HSR003633	5.1.1C, 6.1D, 6.3B, 6.4A, 6.6A, 6.9A , 9.1C	5.1.1C, 6.1D, 6.3B, 6.4A, 6.6A, 6.8B , 6.9B , 9.1C, 9.3C	Perboric acid, sodium salt, monohydrate CAS 10332-33-9 Add 6.8B, 9.3C Change 6.9A to 6.9B Sodium perborate, tetrahydrate CAS 10486-00-7 and >25% dilution Add 5.1.1C, 6.3B, 6.4A, 6.6A, 6.8B, 6.9B Change 6.1D to 6.1E to be consistent with CAS 10332-33-9 Both the monohydrate and tetrahydrate forms of sodium perborate are degraded in vivo to boric acid and H2O2. The acid is excreted via the urine whilst the hydrogen peroxide is broken down to water by catalase (European Chemicals Bureau, 2007; Agency for Toxic Substances and Disease Registry, 2007). Therefore, borates should have a similar toxicity profile; due to the higher water content in the tetrahydrate form this form may be slightly less toxic than the monohydrate.	Controls to add based on the classification changes E4

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Sodium perborate, tetrahydrate CAS 10486-00-7	HSR004017	6.1D	5.1.1C, 6.1E, 6.3B, 6.4A, 6.6A, 6.8B, 6.9B	Acute toxicity – Review by the European Chemicals Bureau, 2007 Sodium perborate monohydrate oral LD50 in rats = 1,800	Sodium perborate, tetrahydrate controls should be consistent with CAS 10332-33-9 Controls to add based

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Sodium perborate, tetrahydrate, >25% in a non hazardous diluent CAS 10486-00-7	HSR004782	6.1D	5.1.1C , 6.1E, 6.3B, 6.4A, 6.6A, 6.8B , 6.9B	<p>mg/kg bw è implies 6.1D. Sodium perborate tetrahydrate oral LD50 in rats = 2,567 mg/kg bw è implies 6.1E. Sodium perborate monohydrate dermal LD50 > 2,000 mg/kg bw è unlikely to trigger classification as dermal absorption very poor. The same is considered to apply to the tetrahydrate form.</p> <p>Skin irritation: In some studies with the monohydrate after prolonged exposure very mild irritating effects were observed (European Chemicals Bureau, 2007). However, this is not sufficient justification for 6.3 classification.</p> <p>Eye irritation Sodium perborate caused strong eye irritation in animal studies, the effects being not reversible in most of the animals tested. Both sodium perborate monohydrate and tetrahydrate are proposed to be classified with Xi; R41, "Risk of serious damage to eyes" (European Chemicals Bureau, 2007). This implies a 8.3A classification.</p> <p>Repeated dose toxicity No data was located to support 6.9 classification for borates.</p> <p>Mutagenicity In vitro studies without metabolic activation show a genotoxic potential of sodium perborate, which may be due to the generation of H2O2. Since the effects of H2O2 are reduced in the presence of catalase, the genotoxic potential of sodium perborate may not be relevant in vivo. Furthermore and in contrast to H2O2, due to its ionisation sodium perborate should be taken up less easily by cells than H2O2 (European Chemicals Bureau, 2007). These findings suggest that the 6.6 classification for perborates is not justified.</p> <p>Carcinogenicity No animal data on carcinogenicity of sodium perborate is available. In the 28-day test discussed previously, 1,000 mg/kg bw sodium perborate tetrahydrate led to hyperplasia of the fundic mucosa of the stomach in rats. It may be speculated that, in analogy to H2O2, prolonged exposure to high irritating concentrations of sodium perborate may cause</p>	<p>on the classification changes AH1, D1, D3, EM3, EM5, EM9, EM10, I4, I7, I12, I15, I20, I24, I27, O1, O2, O3, O4, O5, O6, O7, O8, O9, O10, O11, P4, P11, PG2, TR1</p>

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				<p>tumours as a consequence of increased cell proliferation. From the reversibility of the effects on the stomach with sodium perborate as well as with H₂O₂, it can be argued, that doses, which would not lead to irritation, also would not lead to tumour formation (European Chemicals Bureau, 2007). However, this is not adequate justification to warrant 6.7 classification.</p> <p>Toxicity for reproduction Reproductive toxicity The testes are target organs of toxicity of boron compounds. In the 28-day study after oral application of 1,000 mg sodium perborate tetrahydrate/kg bw a decrease in absolute testes weights was recorded, which could be an early sign of testicular toxicity (European Chemicals Bureau, 2007). The following data were obtained from a report by the Agency for Toxic Substances and Disease Registry. Testicular atrophy, sperm abnormalities, and reduced sperm production have been observed in mice, rats and dogs after intermediate-duration ingestion of doses ≥ 26 mg boron/kg/day as boric acid. Complete sterility was observed in Sprague-Dawley rats fed boric acid or borax in the diet (101 and 116 mg boron/kg/day for males and females, respectively) for 14 weeks before mating; sterility was associated with a lack of viable sperm in atrophied testes in males and decreased ovulation in females. No pregnancies occurred, when female rats exposed to this dose level were mated with non-exposed male rats. At lower exposure levels (10 or 30 mg boron/kg/day for males and 12 or 35 mg boron/kg/day for females), no exposure-related adverse effects were found on overall fertility indices in three successive generations. The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) and the International Programme On Chemical Safety (IPCS) reports also support these findings. Therefore, perborates should be assigned a 6.8B classification.</p> <p>Developmental toxicity No studies were found on the developmental effects of boron and compounds in humans following inhalation, oral, or dermal exposure. In acute-duration oral exposure animal studies, developmentally toxic effects (including reduced fetal weight and increased skeletal variations or malformations) have been reported in CD-1 mice exposed during gestation to</p>	

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				<p>boric acid doses as low as 70 mg boron/kg (2 times/day) and in New Zealand rabbits exposed during gestation (days 6–19) to doses of 44 mg boron/kg/day. Developmental effects (including decreased fetal weight, increased incidence of skeletal variations and malformations, and increased resorptions) have been observed in offspring of rat and mouse dams exposed to 13–79 mg boron/kg/day as boric acid during gestation for intermediate durations. The reduction in fetal body weight is the most sensitive end point observed in rats. Mice given intraperitoneal doses of 175 mg boron/kg (as boric acid) on gestation day 8 exhibited hyperacetylation of embryonic somites, inhibition of histone deacetylase, and increased incidences of skeletal malformations (fused ribs and vertebra, changes in the typical number of axial segments in different axial districts). The association of these biochemical and morphological effects suggest that boric acid-induced skeletal malformations may result from inhibition of histone deacetylase. Another study reported a cranial shift in the anterior limits of the <i>hoxa6</i> and <i>hoxc6</i> genes in the foetuses of pregnant rats given two gavage doses of 88 mg/boron/kg/day (as boric acid) on gestation day 9. The control of position and development of the foetal vertebrae have been associated with the activity of these genes. Developmental effects (including decreased foetal weight, increased incidence of skeletal variations and malformations, and increased resorptions) have been observed in offspring of rat and mouse dams exposed to 13–79 mg boron/kg/day as boric acid during gestation (Agency for Toxic Substances and Disease Registry, 2007). This suggests a 6.8B classification.</p> <p>Animal-to-Human Extrapolations There is no evidence of the reproductive effects occurring in humans. This suggests a 6.8B classification rather than 6.8A.</p> <p>Conclusions on classification: Sodium perborate monohydrate – 6.1D, , 8.3A, 6.8B Sodium perborate tetrahydrate – 6.1E, , 8.3A, 6.8B Sodium perborate tetrahydrate, >25% in a non-hazardous diluent – 6.1E, 8.3A, , 6.8B</p>	

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Sulphur dioxide CAS 7446-09-5	HSR001068	6.1C, 6.3B, 6.4A , 6.5A, 6.8B, 6.9A, 8.1A, 9.1A	6.1C, 8.2B, 8.3A , 6.5A, 6.8B, 6.9A, 8.1A, 9.1A	Change 6.3A to 8.2B Change 6.4A to 8.3A Sulphur dioxide has a UN number of 1079, class 2.3, subsidiary risk 8. Based on the subsidiary risk 8, the substance must have a HSNO classification of 8.2B/8.2C and 8.3A. This is supported by the EU Risk Phrase of 34 which is also equivalent to 8.2B/8.2C and 8.3A. The packing group will determine whether it should be classified as 8.2B or 8.2C. Sulphur dioxide is a gas so packing group is not applicable. Consequently the substance classification for skin corrosivity (8.2) is equivocal. However, using the conservative approach, it is recommended that the substance is classified as 8.2B.	Controls to add as they are triggered by 8.2B and 8.3A EM2, PG2
Aminotri(methylenephosphonic acid) CAS 6419-19-8	HSR003668	8.2C, 8.3A	6.1E, 6.3A, 6.4A	Aminotri(methylenephosphonic acid) CAS 6419-19-8 Add 6.1E change 8.2C to 6.3A change 8.3A to 6.4A Aminotri(methylenephosphonic acid), >5% in a non hazardous diluents CAS 6419-19-8 Split into three approvals A: Aminotri(methylenephosphonic acid), >56% in a non hazardous diluent Add 6.1E change 8.2C to 6.3A change 8.3A to 6.4A	Controls to be removed as they are triggered by 8.2C and 8.3A I2, I10, I17, I18, I22, I29, P14, EM2, EM11, EM12, EM13, PG3 Controls to add as they are triggered by 6.1E, 6.3A, 6.4A; EM6, I16, I8, I28, P13, PS4, T1, T2
Aminotri(methylenephosphonic acid), >5% in a non hazardous diluents CAS 6419-19-8	HSR004339	8.2C, 8.3A	A: Aminotri(methylenephosphonic acid), >56% in a non hazardous diluents 6.1E, 6.3A, 6.4A B: Aminotri(methylenephosphonic acid), ≥10 to 56% in a non hazardous diluents 6.3A, 6.4A C: Aminotri(methylenephosphonic acid),	B: Aminotri(methylenephosphonic acid), ≥10 to 56% in a non hazardous diluent change 8.2C to 6.3A change 8.3A to 6.4A C: Aminotri(methylenephosphonic acid), >5 to 10% in a non hazardous diluent change 8.2C to 6.3B delete 8.3A Classification changes are based on new data from the HERA Human and Environmental risk Assessment on ingredients of European household cleaning products Phosphonates report http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf , original classifications were based on R phrases from	

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
			<p>>5to 10% in a non hazardous diluent change 8.2C to 6.3B delete 8.3A 6.3B</p>	<p>Chemwatch.</p> <p>Hera data for Aminotrimethylene phosphonic acid (ATMP) is as follows; LD50 (acid) in mg/kg/day: rat – 2910; mouse – 2790 Conclusion on classification 6.1E</p> <p>Aqueous solution of 50% ATMP acid and 1% HCl applied as a single dose of 0.5ml equivalent to 333 mg of acid under an occlusive dressing for 4 hours to the shorn intact skin of three New Zealand white rabbits. Assessments done 24, 48 and 72 hours after removal of patch and test substance. No oedema, mild erythema. Primary irritation index (PII) = 0.4. Using same method, ATMP powder and a 25% aqueous solution of ATMP acid were tested. Powder: no visible irritation. 25% acid: moderate erythema, defined oedema which resolved after 7 days. PII = 4.6. This implies either oedema or erythema average score was >2.3 è implies 6.3A classification for the acid. Conclusion on classification 6.3A</p> <p>100 mg acid powder placed in conjunctival sac of rabbit eye. Observations included oedema, lid closure, copious discharge, moderate redness of the conjunctivae and mild corneal cloudiness immediately after instillation. After 24hrs and rinsing of the eyes, observations included lid closure and iris congestion. Suggests 6.4A classification. Conclusion on classification 6.4A</p> <p>Cut offs for the >5% in a non hazardous diluents approval are affected by the proposed classification change. The 6.1E classification will apply down to 56%. The 6.3A and 6.4A classification cut- off by mixture rules is 10%. 6.3B applies between 1-10%. This approval needs to be split into 3 approvals to cover the current range.</p>	

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Etidronic acid CAS 2809-21-4	HSR003147	6.1D, 6.8B , 6.9B , 8.3A, 9.1C, 9.3C	6.1D, 6.3B, 8.3A, 9.1C, 9.3C	Remove 6.8B, 6.9B Classification changes are based on new data from the HERA Human and Environmental risk Assessment on ingredients of European household cleaning products Phosphonates report http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf , original classifications were based on limited data from the internet available at the time of classification. Hera data for HEDP Acid is as follows; Studies summarised by the applicant indicate the following: NOAEL (dog, 90 day oral) - >1746 mg/kg/day NOAEL (rat, 90 day oral) - >1724 mg/kg/day	No change to controls.
Etidronic acid, >10 - 24% in a non hazardous diluent	HSR006527	6.1D, 6.8B , 6.9B , 8.3A, 9.1C, 9.3C	6.1D, 6.3B, 8.3A, 9.1C, 9.3C This suggests HEDP acid do not trigger classification as a target organ toxicants as the dose levels are above that require to trigger a 6.9 classification. It is recommended that the 6.9B classification is removed.		
Etidronic acid, >26% in a non hazardous diluent	HSR006528	6.1E, 6.8B , 6.9B , 8.3A	6.1E, 6.3B, 8.3A Test data indicates no reproductive/developmental toxicity for the acid therefore it is recommended that the 6.8B classification be removed.		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Methylene diphenyl diisocyanate, >2 - 10% in a non hazardous diluent CAS 101-68-8	HSR006540	6.1C , 6.3B , 6.5A, 6.5B, 6.9B, 9.3C	6.3B, 6.5A, 6.5B, 6.9B	<p>Change name to Methylene diphenyl diisocyanate, >1 - 7.4% in a non hazardous diluent Remove 6.1C, 9.3C</p> <p>The substance has been approved as 6.1C (oral), but the parent substance Methylene diphenyl diisocyanate is classified as 6.1E (oral). The substance does not trigger a 6.1 (oral) classification according to the mixture rules.</p> <p>The 6.1 (inhalation classifications for this substance should be reviewed against the parent record. The upper limit of the range triggered 6.1D (inhalation) but the lower limit of the range does not; no 6.1 (inhalation classification has been applied to the range.</p> <p>Methylene diphenyl diisocyanate has the following information to support its current classifications of 6.1E(oral) SPECIES: Mouse ENDPOINT: LD50 VALUE: 2200 mg/kg REFERENCE SOURCE: 85GMAT 1982 [RTECS]</p> <p>Based on this information, the diluent will never have a 6.1E classification unless it contained 100% of the active. Therefore, it can be assumed that the diluent should not be classified as 6.1C (oral).</p> <p>However, the following data is given the 6.1B(inhalation) classification of the parent: SPECIES: Rat (M) ENDPOINT: LC50 VALUE: 369 mg/cu m/4 hr (= 0.369 mg/l) INHALATION FORM: Dust or mist REFERENCE SOURCE:[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 978]**PEER REVIEWED**[HSDB]</p> <p>The estimated range for the LC50 value of the diluent Methylene dipheyl diisocyanate > 2 – 10% in a non hazardous diluent is 3.69g/L – 19.08 g/L since: Tmix(inhalation) = 100 ÷ [2/ 0.369] = 19.08 g/L: Tmix(inhalation) = 100 ÷ [10/ 0.369] = 3.69 g/L</p>	<p>Controls to be removed as they are triggered by 6.1C and 9.3C AH1, D5, E1, E2, E4, E6, EM7, EM13, I8, I11, I20, I29, I30, T3, T6, T8, TR1 Variation codes 8, 11, 18 should be removed</p>

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				<p>As the trigger level for 6.1D (inhalation) is $1 \text{ mg/L} < \text{LC50} \leq 5 \text{ mg/L}$, the upper limit triggers the classification, but the lower limit does not.</p> <p>Active must have a concentration of $> 7.4\%$ if it is to trigger the 6.1D (inhalation) classification based on the following If $T_{\text{mix}}(\text{inhalation}) > 5 \text{ g/L}$ Then $5 > 100 \div [x / 0.369]$ where $x = \text{concentration of active}$. And $x = 7.38\%$</p> <p>Based on this, it is assumed that the substance description should change to Methylene dipheyl diisocyanate $> 1 - 7.4\%$ in a non hazardous diluent as the classification will change if the active was a different concentrations.</p> <p>As for the remaining classifications, based on the application of mixture rules, the following classifications should be applied to this substance: 6.3B, 6.5A, 6.5B, 6.9B.</p> <p>It appears as if the 9.3C has been added in error as this substance has no 6.1 data to support this classification and the parent has no 9.3 classifications. This classification needs to be deleted.</p> <p>The following changes need to be made to this substance</p> <ul style="list-style-type: none"> • Remove 9.3C and 6.1C classifications as they are not triggered. • Change name to Methylene dipheyl diisocyanate $> 1 - 7.4\%$ in a non hazardous 	

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Polyethylene glycol nonylphenyl ether CAS 9016-45-9	HSR003054	6.1E, 6.3B, 6.4A, 9.1B	1. Polyethylene glycol nonylphenyl ether (1 – 7 moles of ethylene oxide): 6.1E, 6.3B, 6.4A, 9.1B. 2. Polyethylene glycol nonylphenyl ether (8 – 14 moles of ethylene oxide): 6.1E, 8.3A , 9.1B. 3. Polyethylene glycol nonylphenyl ether (> 14 moles of ethylene oxide): 6.1E, 9.1B.	Split the approval into three based on the number or EO Amend the classifications based on the CESIO document Polyethylene glycol nonylphenyl ether is a non-ionic surfactant (CAS 9016-45-9) . Skin and eye irritancy for non ionic surfactant such as polyethylene glycol nonylphenyl ether will depend on the number of moles of ethylene oxide (EO) that will react with the alkyl phenol. However polyethylene glycol nonylphenyl ether current skin and eye irritancy classifications were not based on this. The Agency usually based surfactants skin and eye irritancy classifications on the CESIO document recommendations for Anionic and Non-ionic surfactants. Based on the document, polyethylene glycol nonylphenyl ether should be classified as such: <ul style="list-style-type: none"> • EO moles (1 – 7) => classified 6.3B, 6.4A (R36, R38) • EO moles (8 – 14) => classified 8.3A (R41) • EO moles (> 14) => not classified as skin and eye irritant Reference: Classification and Labelling of Surfactants for human health hazards according to the Dangerous Substances Directive - CESIO recommendations for Anionic and Non-ionic surfactants http://www.cefic.org/files/Publications/Cesio-060501-Classification_labelling-human_health.pdf	Controls to add as they are triggered by 8.2C and 8.3A I2, I10, I22, I29, I30, P14, EM2, EM13, PS3
Polyethylene glycol nonylphenyl ether, >50% in a non hazardous diluent CAS 9016-45-9	HSR006598	6.1E, 6.3B, 6.4A, 9.1B	1. Polyethylene glycol nonylphenyl ether, >50% in a non hazardous diluent (1 – 7 moles of ethylene oxide): 6.1E, 6.3B, 6.4A, 9.1B. 2. Polyethylene glycol nonylphenyl ether, >50% in a non hazardous diluent (8 – 14 moles of ethylene oxide): 6.1E, 8.3A , 9.1B. 3. Polyethylene glycol nonylphenyl ether, >50% in a non hazardous diluent (> 14 moles of ethylene oxide): 6.1E, 9.1B.		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Ethanol CAS 64-17-5	HSR001144	3.1B, 6.4A, 9.1D	3.1B, 6.4A	Remove 9.1D The 9.1D classification to ethanol was assigned based on the following data. SPECIES: Daphnia magna (Water flea) TYPE OF EXPOSURE: DURATION: 48 hr ENDPOINT: EC50 (IMM) VALUE: 9.300 mg/L REFERENCE SOURCE: Ref No: 14533. Barera,Y. and W.J.Adams (1983) Resolving Some Practical Questions About Daphnia Acute Toxicity Tests. In W.E.Bishop (Ed.), Aquatic Toxicology and Hazard Assessment, 6th Symposium, ASTM STP 802, Philadelphia, PA:509-518 [ECOTOX]	Controls to be removed as they are triggered by 9.1D D5, E1, E2, E6, EM7, I11
Ethanol, >50% in a non hazardous diluent CAS 64-17-5	HSR006424	3.1B, 6.4A, 9.1D	3.1B, 6.4A	This is a secondary reference source. The original reference shows that the EC50 for ethanol is 9.3 g/L not 9.3 mg/L . 9.3 g/L if greater than 100 mg/L therefore ethanol should not be classed as a 9.1D and this classification should be removed. The 9.1D should also be removed from the ethanol dilutions.	
Ethanol, >24 - 50% in a non hazardous diluent CAS 64-17-5	HSR006707	3.1C, 6.4A, 9.1D	3.1C, 6.4A		
Ethanol 40-80% + Isopropanol 10-40% + Methyl ethyl ketone 5-50%	HSR001514	3.1B , 6.1E, 6.3B , 6.4A , 6.9B, 9.1D	3.1B , 6.1E, 6.3B , 6.4A , 6.9B		
Methylated spirits, denatured with between 0.1% and 2% methanol	HRC05002	3.1B, 6.1E, 6.4A, 6.8B, 6.9A, 9.1D	3.1B, 6.1E, 6.4A, 6.8B, 6.9A		
Cellulose, nitrate, > 25% ethanol, (<12.6% nitrogen by dry mass)	HSR001491	4.1.3B, 6.4A, 9.1D	4.1.3B, 6.4A		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Guazatine CAS 13516-27-3	HSR005098	6.1D, 6.3A, 6.4A, 9.1A, 9.3C	6.1B, 8.2C, 8.3A, 6.9A, 9.1A, 9.3B	<p>Change name to ininocladine Crate a new approval for Guazatine CAS 108173-90-6 with the same classifications as ininocladine CAS 13516-27-3 6.1D change to 6.1B 6.3A change to 8.2C 6.4A change to 8.3A 9.3C change to 9.3B Add 6.9A</p> <p>Guazatine acetate was transferred in the Hazardous Substance (Chemical) Transfer Notice 2006 with the following classifications 6.1B , 6.7B, 6.9A , 8.2C , 8.3A , 9.1A , 9.1A, 9.3B. The 6.7B classification was removed by s67A amendment in October 2007. The data used to classify the acetate was based on guazatine information. Guazatine, ininocladine and guazatine acetate should have consistent classifications. It is proposed that the acetate classifications be adopted for all three substances.</p> <p>Based on information from Alanwood Compendium of Pesticide Common Names for CAS 13516-27-3 "The ISO common name guazatine was originally given to this substance, but the definition of guazatine was later changed when it became known that the commercial substance was a complex reaction product containing this as well as several other active compounds."Therefore the substance description for CAS 13516-273 should be ininocladine not guazatine. This means there will not be an approval for guazatine. It is proposed that a new approval be created for guazatine with the same classifications as ininocladine and guazatine acetate. Reference: http://www.alanwood.net/pesticides/ininocladine.html</p>	Controls to add based on the classification changes EM2, I10, I2, I22, P14, PG2, T3, T6
Limonene, D- CAS 5989-27-5	HSR002725	3.1C, 6.1E, 6.3B, 6.4A, 9.1A, 9.2B	3.1C, 6.1E, 6.3B, 6.4A, 6.5B , 9.1A, 9.2B	<p>Add 6.5B</p> <p>Limonene occurs as the d and l isomers, and the racemic mixture dl-limonene known as dipentene. Both NICNAS/HSIS and ECB assign the R Phrase R43 to dl-limonene, d-limonene and l-limonene</p>	Controls to add as they are triggered by 6.5B T5, I17, I18
Cyclohexene, 1-methyl-4-(1-methylethenyl)- CAS 138-86-3 (synonym dl-limonene)	HSR001142	3.1C, 6.3B, 6.4A, 9.1A	3.1C, 6.3B, 6.4A, 6.5B , 9.1A		
Methyltrioctylammonium chloride CAS 5137-55-3	HSR005057	6.1D , 6.3A, 6.4A, 9.3C	6.1C , 6.3A, 6.4A, 9.3C	<p>Change 6.1D to 6.1C</p> <p>The 6.1D classification was based on the conversion of R22 without LD50 data. The default classification for R22 is 6.1D. A number of sources review gave the LD50 value of 223 mg/kg (rat, oral). The classification should be changed to a</p>	Controls to add as they are triggered by 6.1C PG3, T3 (T6,AH1 and TR1 were deleted in the

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				6.1C based on the LD50 data. R22 covers part of the 6.1C range.	chemicals transfer notice so should also be deleted for this substance)
Preventol TX-CE 12	HSR007912	3.1D, 6.4A, 6.5B, 6.7B, 6.9B, 9.1B, 9.2C, 9.3C	3.1D, 6.4A, 6.5B, 6.7B, 6.9B, 9.1B, 9.2C, 9.3B	9.3 change to 9.3B for listed mixtures Base on the following new data Thiocloprid, CAS 111988-49-9, should be classified 9.3A due to avian toxicity. Species: Japanese quail* Test: Acute Oral Toxicity Endpoint: LD50 49 mg ai/kg bw Reference: Schmuck, R. (2001). Ecotoxicological profile of the insecticide thiocloprid. Pflanzenschutz-Nachrichten Bayer 54 (2), 161-184	No change to controls.
Preventol TX-CT 50	HSR007913	6.1D, 6.3B, 6.4A, 6.5B, 6.7B, 6.9B, 9.1A, 9.2B, 9.3C	6.1D, 6.3B, 6.4A, 6.5B, 6.7B, 6.9B, 9.1A, 9.2B, 9.3B		
Suspension concentrate containing 480 g/litre thiocloprid	HSR000715	6.1D, 6.7B, 6.8B, 6.9B, 9.1A, 9.2C, 9.3C , 9.4C	6.1D, 6.7B, 6.8B, 6.9B, 9.1A, 9.2C, 9.3B , 9.4C		
Proteus	HSR06012	6.1D, 6.4A, 6.7B, 6.8B, 6.9B, 9.1A, 9.3C , 9.4A	6.1D, 6.4A, 6.7B, 6.8B, 6.9B, 9.1A, 9.3B , 9.4A	Thiocloprid does not have an individual approval but the listed substances are affected by the change in classification of thiocloprid.	
Taratek	HSR000046	6.1C, 8.1A, 8.2C, 8.3A, 6.9A , 9.1A, 9.2C, 9.3C	6.1C, 8.1A, 8.2C, 8.3A, 6.6A , 6.8A , 6.9B , 9.1A, 9.2C, 9.3C	Add 6.6A, 6.8A 6.9A change to 6.9B Taratek GC was approved via Part V in 2002. Subsequent to that approval, the classification of one of the constituent components (carbendazim) was revised which resulted in the addition of 6.6A and 6.8A. Carbendazim is at a sufficient concentration in Taratek GC to confer these two classifications to the formulated product. Carbendazim was transferred in the Hazardous Substances (Chemicals) Transfer Notice 2006 with the classifications 6.1E, 6.6A, 6.8A, 6.9B, 9.1A, 9.3A and 9.4A. The mixtures affected by this change in classification were not determined at the time. There was also a shift in policy (consistent with GHS) subsequent to 2002 which related to the assignment of 6.9A/6.9B classifications in mixtures when 6.9A components were present at < 10%. This change meant that the 6.9A classification originally assigned to Taratek GC would be downgraded to a 6.9B as the concentration of each 6.9A component is < 10%.	No change to controls.
Emulsifiable concentrate containing 50 g/litre esfenvalerate	HSR000320	6.1D, 6.3B, 6.5B, 6.9B, 9.1A, 9.3C, 9.4A	3.1D , 6.1D, 6.3B, 6.5B, 6.9B, 9.1A, 9.3C, 9.4A	Add 3.1D Based on flashpoint data of 69°C for the product a 3.1D classification should be added. This product is the only mixture	Controls to add as they are triggered by 3.1D

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				covered by this approval.	D2, EM9, EM10, F2, F11, F6, GN35A, I5, I13, I25
Maxforce Fire Ant Killer Granular Bait	HSR002689		Changes to controls only	<p>In December 2007 Authority considered and approved the substances Campaign Ant Bait and Amdro Fire Ant Bait (Approval codes HSR007881 and HSR007882) through the full Part V application route. Both substances are ant baits containing hydramethylnon as the active ingredient. In the Agency's assessment, the risks of wide dispersive ground-based use, and aerial application were assessed. As a result of this assessment, the Authority has set controls to mitigate specific public health and environmental risks of the substances, particularly when aerially applied.</p> <p>When initially approved, the risks of Maxforce Fire Ant Killer and Bait containing 10g/kg hydramethylnon associated with</p>	<p>New controls added</p> <p>No person may aerially apply [substance] unless that person first obtains a permission from the Authority under section 95A of the Hazardous Substances and New Organisms Act 1996</p> <p>Any person applying [substance] by ground-</p>

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Bait containing 10g/kg hydramethylnon	HSR000693		Changes to controls only	<p>wide-dispersive and aerial use of the substances were not explicitly assessed, and did not have these controls applied to their approvals. This issue was raised by the Agency in the Evaluation and Review Report for Campaign and Amdro. In its consideration, the Authority agreed that a reassessment should be initiated to apply similar controls to the previously approved ant baits containing hydramethylnon via a reassessment under section 63A.</p> <p>The following controls have been applied to Campaign and Amdro, and their relevance should be considered for Maxforce Fire Ant Killer and Bait containing 10g/kg hydramethylnon through the reassessment process:</p> <p>No person may aerially apply [substance] unless that person first obtains a permission from the Authority under section 95A of the Hazardous Substances and New Organisms Act 1996</p> <p>Any person applying [substance] by ground-based means in a place in which the public ordinarily have access must ensure that signs are erected in accordance with section 5.3.1 and Appendix M3 of NZS 8409:2004 Management of Agrichemicals</p> <p>[Substance] shall not be applied into or onto water.</p> <p>[Substance] shall be applied at a maximum rate of 2.5kg/ha, twice per annum in any particular application area.</p> <p>In addition, ADE and PDE have been set for hydramethylnon under control T1.</p>	<p>based means in a place in which the public ordinarily have access must ensure that signs are erected in accordance with section 5.3.1 and Appendix M3 of NZS 8409:2004 Management of Agrichemicals</p> <p>[Substance] shall not be applied into or onto water.</p> <p>[Substance] shall be applied at a maximum rate of 2.5kg/ha, twice per annum in any particular application area.</p> <p>In addition, ADE and PDE have been set for hydramethylnon under control T1.</p>

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Bait containing 0.05g/kg – 0.1 g/kg bromadiolone	HSR001603	6.9B, 9.1D	6.9B, 9.3A	<p>Add 9.3A classification Remove 9.1D</p> <p>During the assessment of HSR06142 (Liquid Bromatrol and Liquid Bait containing 0.06g/L bromadiolone) data was identified which indicates that 9.3A classification should apply. Application of the additivity mixture rule using acute oral mammalian data as described under sub-class 6.1 results in a calculated LD50 which does not trigger the threshold for sub-class 9.3.</p> <p>However, the Agency has identified a number of dietary studies that report complete (or near complete) mortality in test animals (rats and mice) fed 0.005% (50 ppm) bromadiolone formulations. Noting that the criteria for a 9.3A classification is an acute avian or mammalian LC50 £ 500 ppm in the diet, these dietary studies suggest that a 9.3A classification is appropriate at much lower levels than using the LD50.</p> <p>The 9.1D classification needs to be removed as the amount of bromadiolone does not trigger this classification</p>	<p>Controls to add as they are triggered by 9.3A AH1, E4, E5, E7, I3, I23, TR1</p> <p>Controls to be removed as they are triggered by 9.1D EM11, EM12</p>

Appendix 4

Confidential substances for reassessment

This schedule lists all the confidential substances which are to be reassessed under this application.

Substances affected	Justification for Change	Effect on Controls triggered
Substance A	Remove 6.9B, Change 6.1D to 6.1E Based on the classification changes to sodium carbonate	The following controls are removed: I17, I18, I20
Substance B	Remove 6.9B, Change 6.1C and 6.1D Based on the classification changes to sodium carbonate	The following controls should be removed T3, T6
Substance C	Add 6.3B Based on the classification changes to etidronic acid	No controls added
Substance D	Remove 9.1D Based on the classification changes to ethanol	The following controls were exclusively triggered by 9.1D classification and should be removed: D5
Substance E	Remove 9.1D Based on the classification changes to ethanol	The following controls were exclusively triggered by 9.1D classification and should be removed: D5
Substance F	Remove 9.1D Based on the classification changes to ethanol	The following controls were exclusively triggered by 9.1D classification and should be removed: D5
Substance G	Remove 9.1D Based on the classification changes to ethanol	The following controls were exclusively triggered by 9.1D classification and should be removed: D5
Substance H	Add 6.5B Based on the classification changes to limonene-D	No controls added
Substance I	Add 6.5B Based on the classification changes to cyclohexene, 1-methyl-4-(1-methylethenyl)- This substance is grouped under a transferred substance. There is another product grouped under this approval that does not contain the component triggering the 6.5B classification. This approval will therefore need to be split into two to cover the existing substances.	No controls added