ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

12 April 2010

Application code	ERMA200067
Application type	Application for the amendment of various approvals under section 63A of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Chief Executive of ERMA New Zealand
Date application received	7 October 2009
Submission period	8 October 2009 to 20 November 2009
Considered by	A committee of the Authority ("the Committee")
Purpose of the application	To amend the classifications and controls of the substances listed in the application as part of the 2009 Yearly Chemical Review.

1 Summary of Application

1.1 From time to time, the Agency discovers, or has brought to its attention, errors, or inconsistencies in substance classifications or new information that requires classifications or controls to be amended

1.2 In order to assist industry in avoiding a constant flow of changes throughout the year and with an aim of improving communication with stakeholders over changes proposed under this application, the Agency intends that this process will be by way of "modified" reassessment, at least once a year, under section 63A for the changes which are more than "minor" and so not able to be made under section 67A.

1.3 The purpose of this reassessment is to correct inconsistencies and omissions in the classifications of or reclassify, the substances set out in **Appendix 2** and **Appendix 3**, to reflect new information or data, or to align with internationally accepted data.

2 Decision

2.1 The Authority gives the substances new hazard classifications under section 77(1), as specified in **Appendix 2** and **Appendix 3**.

2.2 Subject to paragraph 2.3 in accordance with section 77(2), the controls prescribed for each hazard classification shall attach to the substance.

2.3 In accordance with section 77A(1), a stationary container system, secondary containment system, tank wagon, place of storage, or place of use that immediately before the date of this decision was:

(a) being used to contain, transport or store a substance described in **Appendix 2** or **3**, or for products containing substances listed in **Appendix 2**; or

(b) designed to be used to contain, transport or store the substance and construction of the stationary container system, secondary containment system, tank wagon, place of storage or place of use to that design had commenced;

is not required to comply with a control prescribed for a hazard classification that attaches to a substance if:

(i) it meets the requirements of a compliance plan approved by the Authority for that stationary container system, secondary containment system, tank wagon, place of storage, or place of use; and

(ii) the stationary container system, secondary containment system, tank wagon, place of storage, or place of use has a current test certificate certifying that it meets the requirements of (i) above.

2.4 These requirements will come into effect one year after the date of this decision.

3 Process

3.1 The application for a "modified" reassessment under section 63A has been prepared by the Chief Executive of the Agency following grounds for reassessment having been established under section 62 by the Authority in its decision dated 23 July 2009.

3.2 The application has been considered in accordance with section 63A as:

3.2.1 The reassessment considers only the specific aspect of each approval that is outlined in **Appendix 2** and **Appendix 3**; and

3.2.2 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 changes;

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 is noted that a number of the substances (for example, ethanol) with proposed changes are widely used and are found in many products;

c) some changes of classification result in the need for changes to safety data sheets and 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; and

d) some of the changes are to remove controls. It is important that this is done using a public process.

3.3 Section 63A(6) allows the Authority to approve or decline an application for reassessment under section 63A as it considers appropriate after taking into account:

(a) all the effects associated with the reassessment; and

(b) the best international practices and standards for the safe management of hazardous substances.

3.4 Under section 63A(3), the application for reassessment was deemed to be an application made under section 29. Section 29 requires the Authority to consider adverse and positive effects of a substance and to make a decision based on whether or not the positive effects of the substance outweigh the adverse effects of the substance.

3.5 In making this decision the Committee has applied the relevant sections of the Act and followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology") as detailed in the decision path set out in **Appendix 1** to this decision.

3.6 Reference made to a section in this document means that section of the Act, reference to a clause refers to the relevant clause in the Methodology.

4 Consideration

Evaluation of the risks costs and benefits

4.1 The modified reassessment seeks to amend classifications and controls to better manage the hazards/risks of the substances listed in **Appendix 2** and **Appendix 3.**

4.2 Each change will have different costs and benefits associated with the change. For instance, the addition of a hazard that makes the substance a dangerous good (DG) (as prescribed in the UN Model Regulations for the Transportation of Dangerous Goods[1]) 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.

4.3 However, where the proposed change is to remove a minor classification, such as irritancy, where the substance has other toxicity classifications, no change in controls other than labelling and documentation is required.

4.4 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.

4.5 The main benefit of making the changes listed in **Appendix 2** and **Appendix 3** is to ensure consistency within the HSNO classification system and secondly where appropriate (i.e where there are sufficient data to support), with internationally accepted classifications.

4.6 The Committee has taken into account the effects associated with the reassessment and best international practices and standards. The Committee considers the revised classifications to more accurately represent the hazards of the substances and the

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

controls are more appropriate to manage the risks of the substances. Thus, the listed changes will improve the effective management of the substances. These changes also represent an attempt at alignment with internationally accepted classification.

Revised classifications and controls

4.7 Having considered the risks, costs and benefits of the amendment proposals, the Committee has given the substances the hazard classifications specified in **Appendix 2** and **Appendix 3**.

4.8 Subject to paragraph 5.2 the controls prescribed for each hazard classification shall attach to the substance.

4.9 For the substances listed in **Appendix 2** and **Appendix 3**, and for products containing substances listed in **Appendix 2**, the Committee recognises that a reasonable period of time should be allowed in which to comply with the proposed new classifications and controls. The Committee therefore has decided that a transitional (phase-in) period of 1 year should be allowed in which to implement any changes.

4.10 The submission form asked whether or not a 1 year phase in for compliance with new classifications/controls is reasonable. Generally, submitters thought this was reasonable; however, the extent of the required changes was an issue. Where changes result in the need for major infrastructure upgrades or investments (e.g. building new storage facilities) a one year phase in period was thought to be too short.

4.11 The Committee has decided that where major infrastructure upgrades or investments are required as a consequence of this application a compliance plan may be submitted to extend the phase in period. The compliance plan is to be submitted within 1 year of the changes being approved.

4.12 Under section 77A, the Committee may add additional controls but must be satisfied that the criteria set out in section 77A(4) are met. By allowing a phase in period and the option for submission of a compliance plan the Committee considers it more likely that compliance with the new controls will be met and that consistency with the controls on existing substances will occur. As the new controls are more likely to achieve compliance this will lead to the more effective management of the listed substances.

4.13 Accordingly, the Committee considers that a compliance plan that allows for a period of non-compliance with one or more of the following prescribed controls may be approved by the Authority, where appropriate:

- Stationary container systems (Schedule 8, Gazette Notice 35 2004);
- Secondary containment (Regulations 38, 39 and 40 of the Hazardous Substances (Emergency Management) Regulations 2001; Clauses 1 and 2 of Schedule 9 Gazette Notice 35 2004; the variation made in Schedule 7, Gazette Notice 35 2004 to the regulation 38 of the Hazardous Substances (Emergency Management) Regulations 2001);
- Tank wagons (Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004);

- Schedule 10, Gazette Notice 35 2004; Regulations 71-106 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001; and
- Site and storage group standard conditions of any of the above.

4.14 A compliance plan submitted for approval by the Authority should set out:

(1) a proposed programme for extending the time by which the controls listed in paragraph 4.13 will be complied with; and/or

(2) proposed variations to the requirements of the controls listed in paragraph 4.13.

5 Conclusions

5.1 Pursuant to section 63A(6) the Committee determines that in accordance with section 29 and clause 27,

5.1.1 the substances are given the hazard classifications under section 77(1), as specified in **Appendix 2** and **Appendix 3**; and

5.1.2 subject to paragraph 5.2 in accordance with section 77(2), the controls prescribed for each hazard classification shall attach to the substance.

5.2 In accordance with section 77A(1), a stationary container system, secondary containment system, tank wagon, place of storage, or place of use that immediately before the date of this decision was:

(a) being used to contain, transport or store a substance described in **Appendix 2** or **Appendix 3**, or for products containing substances listed in **Appendix 2**; or

(b) designed to be used to contain, transport or store the substance and construction of the stationary container system, secondary containment system, tank wagon, place of storage or place of use to that design had commenced;

is not required to comply with a control prescribed for a hazard classification that attaches to a substance if:

(i) it meets the requirements of a compliance plan approved by the Authority for that stationary container system, secondary containment system, tank wagon, place of storage, or place of use; and

(ii) the stationary container system, secondary containment system, tank wagon, place of storage, or place of use has a current test certificate certifying that it meets the requirements of (i) above.

5.3 The Authority will consider approval of a compliance plan that allows for a period of non-compliance with one or more of the following prescribed controls:

- Stationary container systems (Schedule 8, Gazette Notice 35 2004);
- Secondary containment (Regulations 38, 39 and 40 of the Hazardous Substances (Emergency Management) Regulations 2001; Clauses 1 and 2 of Schedule 9 Gazette Notice 35 2004; the variation made in Schedule 7, Gazette Notice 35 2004

to the regulation 38 of the Hazardous Substances (Emergency Management) Regulations 2001);

- Tank wagons (Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004);
- Schedule 10, Gazette Notice 35 2004; Regulations 71-106 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001; and
- Site and storage group standard conditions of any of the above.

5.4 These requirements will come into effect one year after the date of this decision.

5.5 In accordance with clause 36(2)(b), the Committee records that, in reaching these conclusions, it has applied the balancing tests in section 29 and clauses 26 and 27 and has also applied the relevant criteria in the decision path set out in the **Appendix 1** to this decision.

Helen Atkins Date: 12 April 2010

Chair

Appendix 1: Decision path for reassessment of hazardous substances

Context

This decision path describes the decision-making process for the application. This application is made under section 63 (Reassessment) of the HSNO Act, and determined under section 29 of the Act.

Introduction

The purpose of the decision path is to provide the Authority with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the Authority may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the ERMA New Zealand Methodology.

The decision path has two parts –

- **Flowchart** (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- **Explanatory notes** (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory notes provide a comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

Decision path for applications to import or manufacture a hazardous substance, application made under section 28 of the Act and determined under section 29.

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

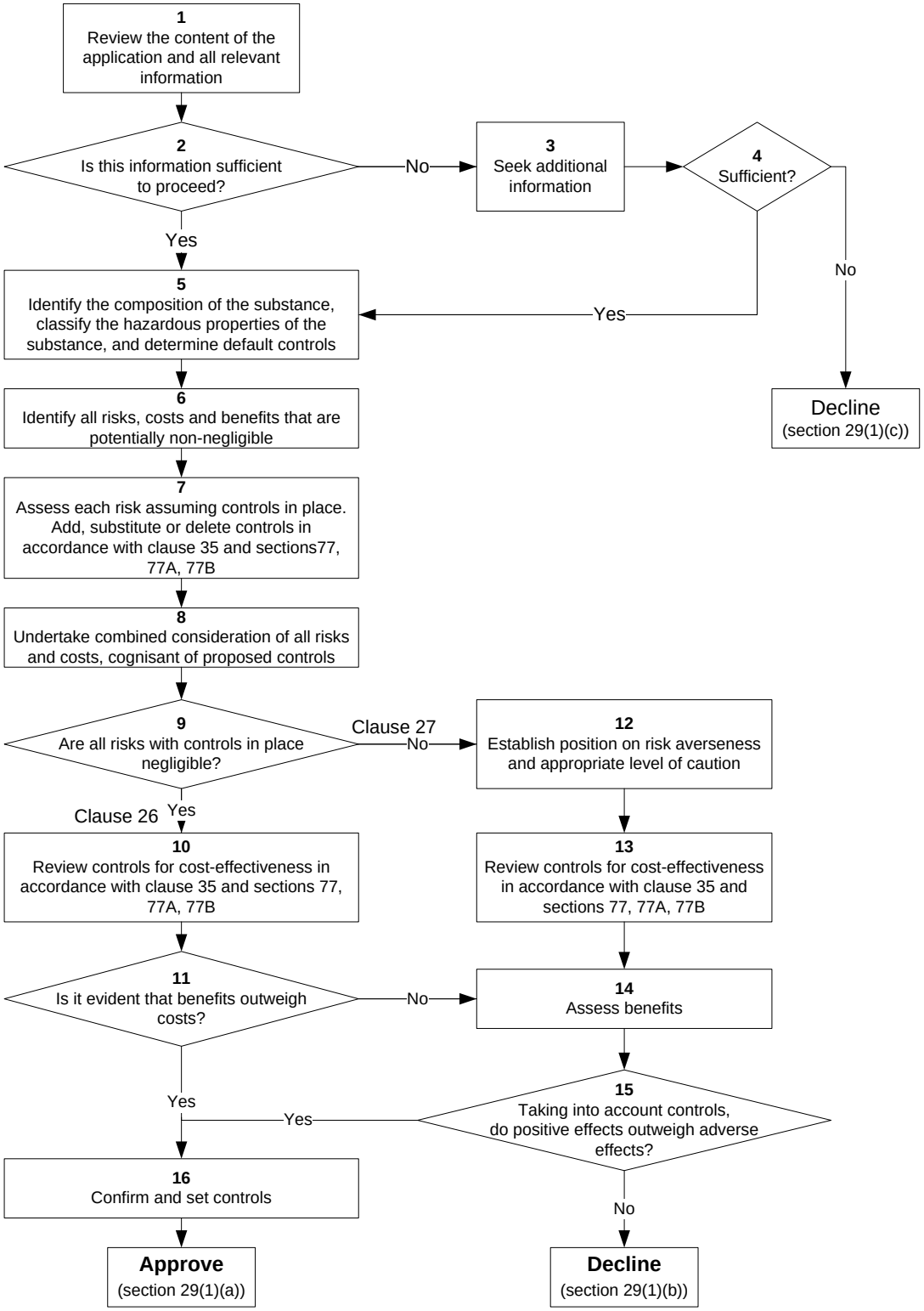

Figure updated: April 2008

Figure 1 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.

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.

The Methodology (clause 8) states that the information used by the Authority in evaluating applications shall be that which is appropriate and relevant to the application. While the Authority will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.

Item 3: (if no) Seek additional information
If there is not sufficient information then additional information may need to be sought from the applicant, the Agency or other parties/experts under section 58 of the Act (clause 23 of the Methodology).

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 Authority is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).

Item 5: (If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls
Identify the composition of the substance, and establish the hazard classifications for the identified substance.

Determine the default controls for the specified hazardous properties using the regulations 'toolbox'.

Item 6: Identify all risks, costs and benefits that are potentially non-negligible[2]
Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11).

[2] 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.

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[3]. 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[4], 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 it 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.

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[3] 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.

[4] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significant 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 Authority 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 Authority's approach to risk (clause 33 of the Methodology) or how risk averse the Authority should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls.
See ERMA New Zealand report 'Approach to Risk' for further guidance[5].

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 10 and 13

If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.

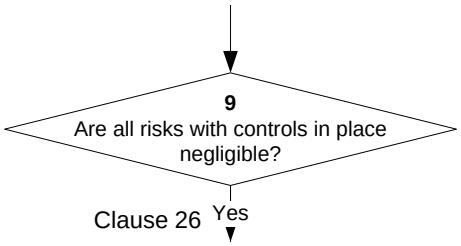
Item 8: Undertake combined consideration of all risks and costs, cognisant of proposed controls

Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.

Item 9: Are all risks with controls in place negligible?

Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible.

Item 10:



(from item 9 - if 'yes') 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 practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or

[5] http://www.ermanz.govt.nz/resources/publications/pdfs/ER-OP-03-02.pdf

delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.

Item 11: **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.

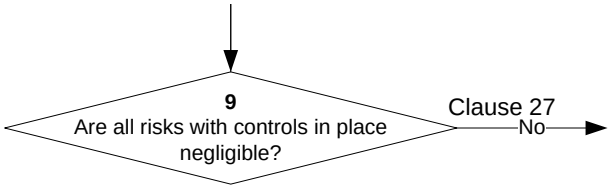
Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community.

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[6]. 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 Authority 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 14).

Item 12:



(from item 9 - if 'no') Establish Authority'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 are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7)

Item 13: **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 9 and 12).

Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)).

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[6] Technical Guide 'Risks, Costs and Benefits' page 6 - Note that, where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the Authority 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'.

Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result.

As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.

Item 14: **(if 'no' from item 11 or in sequence from item 13) 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 it occurring. This assessment also includes consideration of the Authority's approach to uncertainty or how cautious the Authority 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 Authority will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[7]. 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 Authority 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 15: **Taking into account controls, do positive effects outweigh adverse effects?**

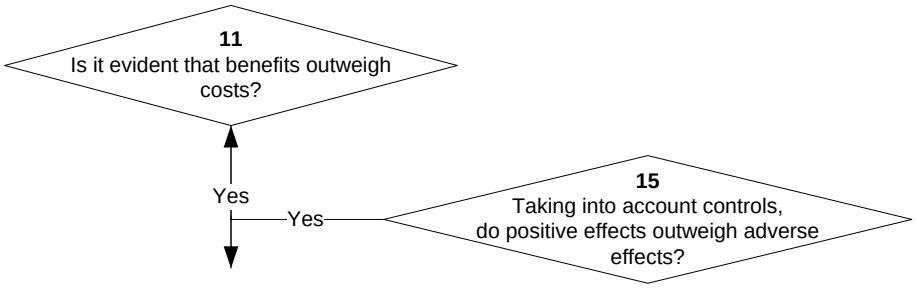
In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13.

Where this item is taken in sequence from items 12, 13 and 14 (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 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.

[7] This principle derives from Protocol Series 1, and is restated in the Technical Guide 'Risks, Costs and Benefits'.

Item 16:



(if 'yes' from items 11 or 15) Confirm and set controls

Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). 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.

Appendix 2: Substances

Current classifications and new classifications are given. The schedule also includes the justification for the changes and an indication of the controls affected by these changes.
For more detailed information on the control codes 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**		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. 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 that the pamoate salt. The 6.9B classification for pyrantel pamoate should therefore be removed. Pyrantel pamoate no longer triggers any HSNO classifications.	**All controls will be removed** as these substances no longer trigger a HSNO classification.
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.
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		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Aluminium sulphate CAS 10043-01-3	HSR003958	6.1D, 6.3A, 8.1A, **8.3A**, 9.1B, 9.3C	6.1D, 6.3A, **6.4A**, 8.1A, 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 (Al2(SO4)3, 14.3H2O): 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, 8.1A, **8.3A**, 9.1B, 9.3C	6.1D, 6.3A, **6.4A**, 8.1A, 9.1B, 9.3C		
Aluminium sulphate, >25% in a non hazardous diluent CAS 16828-11-8	HSR004338	6.1D, 6.3A, 8.1A, **8.3A**, 9.1B, 9.3C	6.1D, 6.3A, **6.4A**, 8.1A, 9.1B, 9.3C		
Aluminium sulphate, >25% in a non hazardous diluent CAS 10043-01-3	HSR005743	6.1D, 6.3A, 8.1A, **8.3A**, 9.1B, 9.3C	6.1D, 6.3A, **6.4A**, 8.1A, 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/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	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
Sodium carbonate, >2 - 10% in a non hazardous diluent CAS 497-19-8	HSR006548	6.3B	6.3B (no change)		**No change** to controls

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
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	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 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	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
				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. 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)	
Coumatetralyl CAS 5836-29-3	HSR002777	**6.1A**, 6.9A, 9.1D, 9.3A	**6.1B**, 6.9A, 9.1D, 9.3A	6.1A change to 6.1B The following 6.1 inhalation data was present at the time of the original classification: • 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] 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. The following 6.1 inhalation data was present at the time of the original classification: • 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]	Control PG1 **change** to PG2
Iron (III) Chloride CAS 7705-08-0	HSR004016	6.1D, **6.3A**, 8.3A, 9.1C, 9.3B	6.1D, **8.1A ,8.2C**, 8.3A, 9.1C, 9.3B	Change 6.3A to 8.2C Add 8.1A Iron (III) chloride has an individual UN number 1773 Class 8 PGIII. Therefore it should have an 8.2C rather than 6.3A classification. Refer to Summary of Submissions for justification for adding 8.1A 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,**8.1A**, **8.2C**, 8.3A, 9.3C		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
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-cypermethrin	HSR000286	6.1E, 6.5B, 6.9B, 9.1A, 9.4B	6.1E, 6.5B, 6.9B, 9.1A, **9.3C**, 9.4B		
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 %. 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 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		Controls to **add** based on addition of 8.2C , 8.3A and 6.9B I2,I8, I10, I22, I30, P14,EM2

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
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, 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.	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, Schedule 8,9 and 10 of GN35
2-Aminopyridine CAS 504-29-0	HSR006044	6.3A, 6.4A	**6.1C**, 6.3A, 6.4A, **9.3A**	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 This substance has a specific UN number2671 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. 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	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, Schedule 8 of GN35

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				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. 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. 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." 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 A 9.3A classification should also be added based on the RTECS data for wild bird LD5033 mg/kg.	
1-Octen-3-ol CAS 3391-86-4	HSR003548	**6.1C**, 6.3B, 6.4A	**3.1D, 6.1D**, 6.3B, 6.4A	Add 3.1D 6.1C change to 6.1D 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.	Controls to be **removed** as they are triggered by 6.1C AH1, PG3, T3, T6, TR1. Controls **to add** as they are triggered by 3.1D D2, EM10, EM9, F11, F2, F6, GN35A, I13, I25, I5, P5, Schedule 9 and 10 of GN35
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**	CAS 17086-28-1 Change name to doxycycline monohydrate Add 6.1D, 6.3B, 6.4A, 9.1A, 9.1A, 9.2A, 9.3C CAS 564-25-0	Controls **to add** based on the classification changes AH1, D5, E1, E2, E4, E5, E6, E7, EM7, EM13,I3,

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				Add 6.5A, 9.2A The only difference between these substances is that one in 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. 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. 6.5A classifications are not generally applied to veterinary medicines as the route of exposure is not relevant.	I11, I20, I23, I219, I30, P15, TR1
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		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		
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		
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**		
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**	Add 5.1.2A, 6.9A, 9.2A Change 6.1B to 6.1A Change 9.3A to 9.3B 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. 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	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
				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. Based on the following information the 9.3A should be changed to 9.3B. IUCLID SPECIES: Rat ENDPOINT: LD50 VALUE: 292 mg/kg bw REFERENCE SOURCE: IUCLID	
Ethyl fluroacetate 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

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
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 CAS 2530-87-2	HSR005506	**3.1C**	**3.1D**	3.1C change to 3.1D The 3.1C classification was based on a R10 risk phrase. Based 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.	Controls to be **removed** as they are 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

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
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. Acute toxicity – Review by the European Chemicals Bureau, 2007 Sodium perborate monohydrate oral LD50 in rats = 1,800	Controls **to add** based on the classification changes E4
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**		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**	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. 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. 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. Repeated dose toxicity No data was located to support 6.9 classification for borates. 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. 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 tumours as a consequence of increased cell proliferation. From	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

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				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 6.7classification. 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. 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 boric acid doses as low as 70 mg boron/kg (2 times/day) and in New Zealand rabbits exposed during gestation (days 6–19)	

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				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 hoxa6 and hoxc6 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. 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. 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	

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
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 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), >5to 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 Chemwatch.	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), >5to 10% in a non hazardous diluent		

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
			change 8.2C to 6.3B delete 8.3A **6.3B**	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 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 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 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 64A 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.	
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.	**No change** to controls.

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
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	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 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. Test data indicates no reproductive/developmental toxicity for the acid therefore it is recommended that the 6.8B classification be removed.	
Etidronic acid, >26% in a non hazardous diluent	HSR006528	6.1E, **6.8B**, **6.9B**, 8.3A	6.1E, 6.3B, 8.3A		

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	Change name to Methylene diphenyl diisocyanate, >1 - 7.4% in a non hazardous diluent Remove 6.1C, 9.3C 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. 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. 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] 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). 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] The estimated range for the LC50 value of the diluent Methylene diphenyl 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 As the trigger level for 6.1D (inhalation) is 1 mg/L < LC50 ≤ 5	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

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
				mg/L, the upper limit triggers the classification, but the lower limit does not. Active must have a concentration of > 7.4% if it is to trigger the 6.1D (inhalation) classification based on the following If Tmix(inhalation) > 5 g/L Then 5 > 100 ÷ [x / 0.369] where x = concentration of active. And x = 7.38% Based on this, it is assumed that the substance description should change to Methylene diphenyl diisocyanate > 1 – 7.4 % in a non hazardous diluent as the classification will change if the active was a different concentrations. 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. 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. The following changes need to be made to this substance • Remove 9.3C and 6.1C classifications as they are not triggered. • Change name to Methylene diphenyl diisocyanate > 1 – 7.4 % in a non hazardous	
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	Split the approval into six based on the number or EO Amend the classifications based on the CESIO documents 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	Various controls **to add** based on the addition of a 9.1 classification Controls **to add** based on the addition of 8.2C and 8.3A I2, I10, I22, I29, I30, P14, EM2, EM13, PS3

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
			glycol nonylphenyl ether (> 14 moles of ethylene oxide): 6.1E, 9.1B.	Anionic and Non-ionic surfactants. Based on both the toxicity and ecotoxicity documents, polyethylene glycol nonylphenyl ether should be classified as such: EO moles (1 – 2): R36/R38, R51/53 -> 6.4A, 6.3A, 9.1A EO moles (3-7): R36/R38, R51/53 -> 6.4A, 6.3A, 9.1B EO moles (8 – 10): R22, R41, R51/53 -> 6.1D (oral), 8.3A, 9.1B EO moles (11): R22, R41, R52/53 -> 6.1D (oral), 8.3A, 9.1C EO moles (12 – 14): R41, R52/53 -> 8.3A, 9.1C EO moles (14+): R52/53 -> 9.1C References: 1.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 2. CESIO Recommendation for the Classification and Labelling of Surfactants as 'Dangerous for the Environment http://www.cefic.be/files/Publications/classification-environment-final23042003web.doc	
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.		
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	Controls to be **removed** as they are triggered by 9.1D D5, E1, E2, E6, EM7, I11

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
Ethanol, >50% in a non hazardous diluent CAS 64-17-5	HSR006424	3.1B, 6.4A, **9.1D**	3.1B, 6.4A	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] 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 diluentCAS 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**	Change name to ininoctadine Crate a new approval for Guazatine CAS 108173-90-6 with the same classifications as ininoctadine 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 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, ininoctadine and guazatine acetate should have consistent classifications. It is proposed that the acetate classifications be adopted for all three substances. 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 iminoctadine 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 iminoctadine and guazatine acetate. Reference: http://www.alanwood.net/pesticides/iminoctadine.html	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	Add 6.5B 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	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	Change 6.1D to 6.1C 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 6.1C based on the LD50 data. R22 covers part of the 6.1C range.	Controls **to add** as they are triggered by 6.1C PG3, T3 (T6,AH1 and TR1 were deleted in the chemicals transfer notice so should also be

Substances affected	Approval Number	Current Classification	Proposed classification	Justification for Change	Effect on Controls triggered
					deleted for this substance and replace with the requirement to be kept under lock and key)
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**	9.3C change to 9.3B for listed mixtures Base on the following new data Thiacloprid, 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 thiacloprid. Planzenschutz-Nachrichten Bayer 54 (2), 161-184 Thiocloprid does not have an individual approval but the listed substances are affected by the change in classification of thiacloprid.	**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 thiacloprid	HSR000715	6.1D, 6.7B, **6.8B**, 6.9B, 9.1A, 9.2C, **9.3C**, 9.4C	6.1D, 6.7B,6.9B, 9.1A, 9.2C, **9.3B**, 9.4C		
Proteus	HSR007653	6.1D, 6.4A, 6.7B, **6.8B**, 6.9B, 9.1A, **9.3C**, 9.4A	6.1D, 6.4A, 6.7B, 6.9B, 9.1A, **9.3B**, 9.4A		
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 assignation 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 down-graded 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
Bait containing 0.05g/kg – 0.1 g/kg bromadiolone	HSR001603	6.9B, **9.1D**	6.9B, **9.3A**	Add 9.3A classification Remove 9.1D 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. 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. The 9.1D classification needs to be removed as the amount of bromadiolone does not trigger this classification	Controls **to add** as they are triggered by 9.3A AH1, E4, E5, E7, I3, I23, TR1 Controls to be **removed** as they are triggered by 9.1D EM11, EM12

Appendix 3: Confidential substances

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