AGRICULTURAL, VETERINARY AND DOMESTIC CHEMICALS

Buprofezin – Schedule required

Amendment and Reasons

The decision below was based on buprofezin’s toxicological profile, in particular its acute oral toxicity. A cut-off to exempt at a concentration of 40% was agreed because of the reduced oral toxicity at this concentration and the ability of safety directions and warning statements applied through the registration system for agricultural and veterinary chemicals to adequately address the slight eye irritation which was attributed to the product formulation.

Schedule 5 – New entry

Buprofezin except in preparations containing 40 per cent or less of buprofezin.

Copper hydroxide - progression of foreshadowed decision to include copper hydroxide in Schedule 6 with cut-off to Schedule 5 at 50 per cent and to exempt at 12.5 per cent.

Amendment and Reasons

The amendment below was based on the acute oral toxicity of copper hydroxide, its severe eye irritancy / corrosivity, and the possibility of products containing copper hydroxide being accessible in domestic situations and therefore presenting a risk of accidental ingestion.

Schedule 6 – New entry

Copper Hydroxide except:

(a) when included in Schedule 5; or

(b) in preparations containing 12.5 per cent or less of copper hydroxide.

Schedule 5 – New entry

Copper Hydroxide in preparations containing 50 per cent or less of copper hydroxide except in preparations containing 12.5 per cent or less of copper hydroxide.

Cyhexatin - Review of Appendix F warning statements and Appendix J rider.
Amendment and Reasons

The NDPSC agreed that Warning Statement 47 concerning teratogenicity and the Appendix J rider relating to availability should continue to apply to cyhexatin.

Deletion of the Appendix F, Part 3 entry for cyhexatin was an administrative action based on warning statements for agricultural and veterinary chemicals being applied through the FAISD Handbook rather than through the SUSDP, and the fact that cyhexatin already appears in the FAISD as requiring warning statement 47.

APPENDIX F, Part 3 – Amendment

Cyhexatin – delete entry

Eltenac – Schedule required

Amendment and Reasons

The decision below was based on the toxicological profile of eltenac as identified in the evaluation report, together with its indications for use and proposed route of administration requiring direct management by a veterinary surgeon.

Schedule 4 – New entry

ELTENAC.

Eucalyptus oil and cineole- progression of foreshadowed decision to increase to 2 litres the nominal capacity of containers which require child-resistant closures.

Amendment and Reasons

The NDPSC agreed to proceed with the foreshadowed proposal to ensure that such products when available for domestic use are packaged in such a way that they do not present a hazard in the home.

PART 2 – RECOMMENDED STANDARDS FOR LABELS AND CONTAINERS – CONTAINERS – Amendments

Child-resistant Closures - Paragraph 55

Amend nominal capacity for eucalyptus given in Column 2 of the TABLE to read: 2 litres or less.

Amend nominal capacity for cineole given in Column 2 of the TABLE to read: 2 litres or less.
Fludioxonil – Schedule 5 to exempt for preparations containing 15 per cent or less of fludioxonil.

Amendment and Reasons

The decision below was based on the expected toxicological profile of a product containing 10% fludioxonil, based on the toxicological profile of the active and other products containing the active. Eye irritancy is anticipated to be slight at most and able to be addressed by the application of appropriate safety directions through the registration process.

Schedule 5 – Amendment

FLUDIOXONIL – amend entry to read:
FLUDIOXONIL except in preparations containing 10 per cent or less of fludioxonil.

Melegestrol Acetate – Schedule required

Amendment and Reasons

The decision below was based on the toxicological profile of melegestrol acetate, in particular its teratogenic effects and low NOEL, and the use pattern of the proposed product. While melegestrol acetate when used as an animal feed additive would be re-scheduled from Schedule 4 to Schedule 6, all other uses of melegestrol would remain as currently classified, that is, as Schedule 4. For clarity however, a specific Schedule 4 entry for melegestrol would be made.

Schedule 6 – New entry

MELENGESTROL ACETATE when used as an animal feed additive.

Schedule 4 – New entry

MELENGESTROL except when included in Schedule 6.

Moxidectin – Proposal to reschedule from Schedule 7 to Schedule 4 preparations for injection containing 10% or less of moxidectin.

Amendment and Reasons

The decision below was based on the presentation of moxidectin as a high concentration injectable which has a long-term effect achieved through a sustained release mechanism.

Schedule 4 – New entry

MOXIDECTIN in preparations for injection containing 10 per cent or less of moxidectin except when included in Schedule 5.
Schedule 7 – Amendment

MOXIDECTIN – amend entry to read:
MOXIDECTIN except when included in Schedule 4, 5, or 6.

Paraformaldehyde / Formaldehyde - Review of first aid instructions for formaldehyde concentrations between 5 and 10%, and all concentrations of paraformaldehyde.

Amendment and Reasons

The decision below to create a separate SUSDP entry for paraformaldehyde was made in order to clarify the current scheduling of paraformaldehyde.

Schedule 6 – New entry

PARAFORMALDEHYDE (excluding its derivatives) except in preparations containing 5 per cent or less of formaldehyde.

Schedule 6 – Amendment

FORMALDEHYDE – amend entry to read:
FORMALDEHYDE (excluding its derivatives) except in preparations containing 5 per cent or less of formaldehyde.

Selenium – Schedule 4 to Schedule 5 for veterinary preparations (supplements for dogs & cats) with a daily dose not exceeding 2 µg/kg body weight.

Amendment and Reasons

The amendment below was based on the conclusion that the risk of serious acute toxicity from the accidental ingestion of veterinary preparations containing selenium in doses up to 30 µg per dosage unit is low. Exemption from scheduling for these low dose veterinary preparations was considered to be consistent with the exemption allowed for low dose preparations for human use.

Schedule 4 – Amendment

SELENIUM – amend entry to read:

SELENIUM for therapeutic use except:

(a) when included in Schedule 3, 6 or 7;

(b) in preparations for oral human use with a recommended daily dose of:

   (i) 26 micrograms or less of selenium in organic form; or

   (ii) 52 micrograms or less of selenium in organic form; or
(c) for the treatment of animals:

(i) in solid, slow release bolus preparations each weighing 100 g or more and containing 300 mg or less of selenium;

(ii) in other divided preparations containing 30 micrograms or less of selenium per dosage unit;

(iii) as elemental selenium, in pellets containing 100 g/kg or less of selenium; or

(iv) in feeds containing 1 g/tonne or less of selenium; or

(d) in preparations for topical use containing 2.5 per cent or less of selenium sulphide.

**Sodium laureth-6 carboxylate** – Schedule required.

*Amendment and Reasons*

The decision below was based on the toxicity profile of sodium laureth-6 carboxylate, and in particular its severe eye irritancy potential. The cut-off to exempt at 1% was based on the information provided on irritancy.

**Schedule 5 – New entry**

SODIUM LAURETH-6 CARBOXYLATE except in preparations containing 1 per cent or less of sodium laureth-6 carboxylate.

**Appendix E, Part 2 – New entry**

Sodium laureth-6 carboxylate  

Standard statement a

**Appendix F, Part 3 – New entry**

Sodium laureth-6 carboxylate

Warning statement 79  

Safety direction 1

**Sodium sulfide / 2-mercaptoethanol / butyric acid:**

- sodium sulfide - Schedule 6 with cut-off to Schedule 5 for insect lures and metal treatment
- 2-mercaptoethanol – Schedule required;
- butyric acid – Schedule required.
Amendment and Reasons

The decision below was based on the toxicological profiles identified in the evaluation report, particularly the acute oral toxicity of sodium sulfide and 2-mercaptoethanol, and the severe eye irritation potential of all three substances. Limitation of the Schedule entries to preparations for use as insect lures resulted from anticipation of the regulatory impact of unqualified entries in the absence of safety concerns at this time, in other uses.

Schedule 6 – New entries

BUTYRIC ACID in preparations for use as insect lures.

2-MERCAPTOETHANOL in preparations for use as insect lures.

SODIUM SULFIDE in preparations for use as insect lures.

Schedule 5 – Amendment

SODIUM SULFIDE – amend entry to read:

SODIUM SULFIDE in preparations for metal treatment in containers each containing 50 g or less of sodium sulfide.

3,6,9-Trioxaundecanedioic acid - progression of foreshadowed decisions for Schedule 6 entry and Appendix F warning statements and safety directions.

Amendment and Reasons

The decision below was based on the potential of TDA to cause irritant effects in the eyes. On balance a Schedule 5 classification combined with warning statements was considered to provide adequate control. As the potential for irritant effects on the eyes is reduced by low concentration and pH values of 3.5 or greater, the Committee agreed it would be appropriate to exempt products meeting those criteria.

Schedule 5 – New entry

3,6,9-TRIOXAUNDECANEDIIOIC ACID except in preparations containing 5 per cent or less of 3,6,9-trioxaundecanedioic acid, the pH of which is 3.5 or greater.

APPENDIX F, Part 3 – New entry

3,6,9-Trioxaundecanedioic acid

Warning statement 5

Safety direction 1

Uniconazole –p – Schedule required
The decision below was based on the toxicological profile of uniconazole-p as identified in the evaluation report, in particular its acute oral toxicity and slight eye irritancy. Exemption from scheduling at a concentration of 5% was based on the greatly reduced acute oral toxicity at this concentration and the capacity of the registration system for agricultural and veterinary chemicals to address the potential for slight eye irritation through appropriate label warnings.

**Schedule 6 – New entry**

UNICONAZOLE-P except in preparations containing 5 per cent of less of uniconazole-p.

**PHARMACEUTICALS**

**Becaplermin – New drug – Schedule required**

*Amendment and Reasons*

The NDPSC agreed a Schedule 4 classification was appropriate for becaplermin on the grounds of the need for professional diagnosis and management.

**Schedule 4 - New Entry**

BECAPLERMIN.

**Benzoyl peroxide – Review of safety to assess the appropriate scheduling under the general principles of harmonisation.**

*Amendment and Reasons*

The NDPSC agreed that benzoyl peroxide be rescheduled on the grounds of harmonisation and that previous public health concerns had been resolved.

**Schedule 4 – Amendment**

BENZOYL PEROXIDE – amend entry to read:

BENZOYL PEROXIDE except:

(a) when included in Schedule 2; or

(b) in preparations for human external therapeutic use containing 5 per cent or less of benzoyl peroxide.

**Schedule 3 – Amendment**

BENZOYL PEROXIDE – delete entry
Schedule 2 – Amendment

BENZOYL PEROXIDE – amend entry to read:

BENZOYL PEROXIDE in preparations for human external therapeutic use containing 10 per cent or less of benzoyl peroxide **except** in preparations containing 5 per cent or less of benzoyl peroxide.

Schedule 5 – Amendment

BENZOYL PEROXIDE – amend entry to read:

BENZOYL PEROXIDE **except**:

(a) when included in Schedule 2 or 4; or

(b) in preparations containing 5 per cent or less of benzoyl peroxide.

Appendix F, Part 3 - Amendment

Benzoyl peroxide when included in Schedule 2 or 3 – amend to read:

Benzoyl peroxide when included in Schedule 2

Warning statement 55

**Dalfoprostin and Quinuprostin** - New drugs – Schedule required

*Amendment and Reasons*

The NDPSC agreed a Schedule 4 classification for dalfopristin and quinupristin on the grounds of the need for medical management in use.

**Schedule 4 – New entries**

DALFOPRISTIN.
QUINUPRISTIN.

**Dofelitide** – New Drug – Schedule required

*Amendment and Reasons*

The NDPSC considered that on the grounds of the need for medical management a schedule 4 classification for dofetilide was appropriate.

**Schedule 4 - New entry**

DOFETILIDE.
Etonogestrol – New drug – Schedule required

Amendment and Reasons

The NDPSC considered that on the grounds of the need for medical management a schedule 4 classification for etonogestrol was appropriate.

Schedule 4 - New Entry

ETONOGESTREL.

Mometasone - Proposal for a Schedule 3 entry for mometasone in aqueous nasal sprays delivering 50 micrograms or less per actuation when the recommended maximum daily dose is no greater than 200 micrograms.

Decision and Reasons

The NDPSC supported the rescheduling of mometasone to Schedule 3 for use in aqueous nasal sprays for the treatment of seasonal allergic rhinitis. The committee considered the rescheduling was appropriate on the grounds of safety in use, safety based on its pharmacokinetic parameters, and that preparations for the treatment of seasonal allergic rhinitis have a place in schedule 3.

Schedule 4 - Amendment

MOMETASONE - amend entry to read: MOMETASONE except when included in Schedule 3.

Schedule 3 - New Entry

MOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the treatment of seasonal allergic rhinitis in adults and children 12 years and over.

Naproxen - Proposal to amend the Schedule 2 entry to include naproxen in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 24 or less dosage units.

Decision and Reasons

The NDPSC agreed that in view of the evidence of safety, naproxen in dosage units of 250 mg or less and in pack sizes of 30 or less be rescheduled from Schedule 3 to Schedule 2.
Schedule 4 – Amendment

NAPROXEN – amend entry to read:
NAPROXEN except when included in Schedule 2.

Schedule 3 – Amendment

NAPROXEN – delete entry

Schedule 2 – Amendment

NAPROXEN – amend entry to read:
NAPROXEN in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 30 or less dosage units.

Appendix F, Part 3 - Amendment

Naproxen – amend entry to read:

Naproxen when included in Schedule 2

   (a) in preparations for the treatment of dysmenorrhoea

       Warning statements 34 or 35

   (b) in other preparations

       Warning Statements 34 or 35,71
RECORD OF REASONS WHEN NO AMENDMENT TO THE STANDARD FOR
THE UNIFORM SCHEDULING OF DRUGS AND POISONS WAS MADE

AGRICULTURAL, VETERINARY AND DOMESTIC CHEMICALS

Sodium dichloroisocyanurate - review of warning statements, safety directions and application of the "FIRE AND EXPLOSION HAZARD" cautionary statement for formulations which have modified reactivity and fire hazard profile.

Reasons

The Committee deferred consideration of the proposal pending the receipt of further information.

Bismuth subnitrate in preparations for therapeutic use in animals – Schedule required.

Reasons

The NDPSC agreed that the proposed product containing bismuth subnitrate for animal use should be exempt from scheduling. The decision below was based on the toxicity profile of bismuth subnitrate as presented in the toxicological evaluation, the use pattern of the proposed product and its specific presentation.

Copper oxides - progression of foreshadowed decision to include copper oxides in Schedule 6 with cut-off to Schedule 5 at 25 per cent and to exempt at 5 per cent.

Reasons

Having considered the impact that scheduling would have on the marine paint industry, and the range of other products in which copper oxide is contained or used, the Committee agreed not to proceed with the foreshadowed scheduling of copper oxides. In agreeing not to proceed, the NDPSC noted that if concerns in other uses for copper oxides become apparent in the future scheduling could be reconsidered at that time.

Glycolic acid – consideration of NICNAS Priority Existing Chemical No. 18 draft Report.

Reasons

The NDPSC agreed that although the draft PEC report indicates that, on toxicological grounds, glycolic acid may require poisons scheduling, further information first should be sought on the use of glycolic acid in products other than cosmetics.

Isostearyl alcohol ethoxylate – Schedule required.
Reasons

The NDPSC agreed that isostearyl alcohol ethoxylate should be exempt from poisons scheduling. The decision was based on the low toxicity of isostearyl alcohol ethoxylate as presented in the toxicological evaluation, the widespread use of chemically related compound without apparent adverse consequences, and the ability of the registration system for agricultural and veterinary chemicals to address the potential for slight eye irritation through appropriate label warnings.

PHARMACEUTICALS

Diphenhydramine - Proposal to amend the Schedule 2 entry for diphenhydramine to include oral preparations containing 10 doses or less when in combination with paracetamol.

Decision and Reasons

The NDPSC did not support the rescheduling of diphenhydramine from Schedule 3 to Schedule 2 for use in combination with paracetamol. The Committee considered Schedule 2 was not appropriate for diphenhydramine and paracetamol in combination because of the potential for abuse and misuse if available without mandatory professional advice.

Radiographic Contrast Media – Progression of foreshadowed decision to remove the exemption from scheduling for injectable radiographic contrast media, and include the preparations in Schedule 4.

Decision and Reasons

The NDPSC decided that on the basis of radiographic contrast media being diagnostic agents with no other therapeutic use, their use under direct medical supervision, and the lack of availability to the general public, the media should not be included in schedule 4.