Australian Government
Department of Health
Therapeutic Goods Administration

Notice of final decisions to amend (or not amend) the current Poisons Standard

25 November 2020

TGA Health Safety Regulation

Contents

1 Notice of final decisions to amend (or not amend) the current Poisons Standard

This web publication constitutes a notice for the purposes of regulation 42ZCZS and regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS and 42ZCZX, this notice publishes:

- the decisions made by a delegate of the Secretary pursuant to regulations 42ZCZR and 42ZCZU
- the reasons for those final decisions; and
- the date of effect of those decisions.

2 Final decisions in relation to nicotine and cannabidiol (private application and delegate initiated)

Note that the final decisions on nicotine and cannabidiol (private application and delegate initiated) are not published in this notice. Publication is expected in mid December and late December 2020, respectively.

3 Final decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZR

3.1 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #31, June 2020)

3.1.1 Final decision in relation to oxymetazoline

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to oxymetazoline.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to oxymetazoline;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #31);
- The ten public submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to oxymetazoline. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submissions received before the second closing date in response to the call for further submissions published on 13 October 2020 under regulation 42ZCZP of the Regulations. I note that nine public submissions were in support of the interim decision. I acknowledge the one opposing submission, which makes reference to the global Adverse Event data provided in the application, however as stated in the interim decision, I consider that the risks associated with prolonged use and self-diagnosis indicate the requirement for pharmacist input.

3.1.2 Final decision in relation to eletriptan

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to eletriptan as follows:

Schedule 4 - Amend Entry

ELETRIPTAN except when included in Schedule 3.

Schedule 3 - New Entry

ELETRIPTAN for oral use in tablets containing 40 mg or less per tablet and when in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.

Appendix H - New Entry

ELETRIPTAN

Index - Amend Entry

ELETRIPTAN

Schedule 4
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Appendix H

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to eletriptan;
- The two public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #31);
- The eight public submissions received, in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to eletriptan. My reasons for making the final decision are those set out in

the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submission received before the second closing date in response to the call for further submissions published on 13 October 2020 under regulation 42ZCZP of the Regulations. I note that seven of the eight public submissions were in support of my interim decision.

Date of effect of the decision

1 February 2021

3.1.3 Final decision in relation to clotrimazole

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to clotrimazole:

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to clotrimazole;
- The seven public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #31);
- The eight public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to clotrimazole. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submissions received before the second closing date in response to the call for further submissions published on 13 October 2020 under regulation 42ZCZP of the Regulations. I note the public submissions were in support of my interim decision.

3.1.4 Final decision in relation to sildenafil

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to sildenafil:

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to sildenafil;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #31);
- The nine public submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to not amend the current Poisons Standard with respect to sildenafil. My reasons for making the final decision are those set out in the interim decision.

In making my final decision, I have taken into account the material detailed in the interim decision and the public submissions received before the second closing date in response to the call for further submissions published on 13 October 2020 under regulation 42ZCZP of the Regulations.

I note the public submission on the interim decision from the Pharmaceutical Society of Australia, which reiterates their earlier submission, supporting the applicant's down-scheduling proposal. However, no new information has been provided to mitigate my concern that the down-scheduling of sildenafil may lead to risk for consumers accessing sildenafil without medical intervention and lack of follow up. I remain of the firm view that the medical practitioner oversight is required and the current scheduling of sildenafil under Schedule 4 is appropriate.

3.1.5 Final decision in relation to ibuprofen

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to Ibuprofen as follows:

Schedule 2 - Amend Entry

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

a. in liquid preparations when sold in the manufacturer's original pack containing 8 g or less of ibuprofen; or

b. in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units except when:

   i. as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent);

   ii. packed in blister or strip packaging or in a container with a child-resistant closure;

   iii. in a primary pack containing not more than 25 dosage units;

   iv. compliant with the requirements of the Required Advisory Statements for Medicine Labels;

   v. not labelled for the treatment of children 6 years of age or less; and

   vi. not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

c. in divided immediate release preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 12 dosage units, when labelled:

   i. not for the treatment of children under 12 years of age.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to ibuprofen;
- The five public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #31);
- The eleven public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;

- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to ibuprofen. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submissions received before the second closing date in response to the call for further submissions published on 13 October 2020 under regulation 42ZCZP of the Regulations.

I have considered the public submission that opposes the amendment due to the risks of NSAIDs. I remain of the view that the net benefits of broadening the availability of immediate release ibuprofen with restrictions placed on age, dosage form and pack size, combined with warning labels, outweighs the potential risks associated with improper use.

I have considered the public submissions that oppose the confinement to immediate release ibuprofen, stating that modified release ibuprofen has an equivalent safety profile. Ibuprofen modified release was launched as Schedule 3 in November 2019 and as noted in my interim decision, has limited clinical experience in Australia. It is my view that this is a matter for a separate scheduling application. Therefore, I have not relied on the material in the public submissions in making my final decision.

Date of effect of the decision

1 February 2021

3.1.6 Final decision in relation to cumyl-pegaclone

Final decision

Pursuant to regulation 42ZCZR of the Regulations, a Delegate of the Secretary has made a final decision to confirm the interim decision and amend the current Poisons Standard in relation to cumyl-pegaclone as follows:

Schedule 9 - New Entry

2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDOL-1-ONE (SGT-151)

Index - New Entry

2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDOL-1-ONE (SGT-151)
cross reference: SGT-151, CUMYL-PEGACLONE.

Schedule 9

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to cumyl-pegaclone;

- The three public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations;
- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #31);
- The six public submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my interim decision to amend the current Poisons Standard with respect to cumyl-pegaclone. My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the public submissions received before the second closing date in response to the call for further submissions published on 13 October 2020 under regulation 42ZCZP of the Regulations.

Date of effect of the decision

1 February 2021

4 Final decisions on proposed amendments to the current Poisons Standard under regulation 42ZCZU

In my capacity as a delegate of the Secretary for the purpose of regulation 42ZCZU of the *Therapeutic Goods Regulations 1990* (**Regulations**), I have made final decisions under regulation 42ZCZU with respect to the following substances:

- Bupivacaine
- Lidocaine
- BEF vaccine
- Fluazaindolizine
- Florylpicoxamid

4.1 Final decision in relation to bupivacaine

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to bupivacaine as follows:

> **Schedule 5 - Amend Entry**
>
> BUPIVACAINE in aqueous gel preparations containing 0.5 per cent or less of bupivacaine, for the dermal spray-on administration to the wounds of animals ~~post-surgical wounds associated with 'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves~~.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to bupivacaine;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- Australian Animal Welfare Standards and Guidelines.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined

under Section 52E of *the Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular I note that:

- The proposed amendment to the Poisons Standard entry for bupivacaine, from its limited indication for the "'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves", to the more expansive indication for the "dermal spray-on administration to the wounds of animals", increases potential benefits to the farming and veterinary industry from the broader use of the substance. The exposure of humans to bupivacaine-containing preparations to the active constituent is expected to be no greater than currently approved uses. The regulator (APVMA) has concluded that the human health risk posed by the product is acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994) (52E(1)(a)).

  The purpose and extent for which the substance is to be used has been adequately outlined by the Applicant. I have taken into account that surgical procedures and treatment of significant injuries are adequately covered in the Australian Animal Welfare Standards and Guidelines. These standards provide animal age-related and developmental stage-related standards and guidance on when a non-veterinarian can and cannot perform such procedures (52E(1)(b)).

- I have taken into account the broader uses of bupivacaine and note that it is currently used for therapeutic uses in humans. I find that my decision would not affect such use in humans because the amendment will continue to limit use to animals when in aqueous gel preparations for dermal spray-on administration (52E(1)(b)).

- There has been no substantive change in the information available regarding the toxicity of the substance since it was last considered for Scheduling that would warrant a change to its Scheduling Classification in Schedule 5 in the Poisons Standard based on the criteria set out in the SPF (2018) under the scheduling factors for Schedule 5 substances (52E(1)(c)).

- The packaging of the preparation containing the substance will not change as a result of its broader use in animals. However, the Applicant has demonstrated that appropriate risk mitigation measures, including labelling, will be put in place should the proposed product containing the substance be registered for use in Australia. As a result, no additional measures are required in the Poisons Standard. The proposed amended entry for the substance in the Poisons Standard will not affect bupivacaine-containing ingredients listed under the ARTG (52E(1)(d)).

- The potential for misuse or abuse of the substance is unchanged from previous considerations (52E(1)(e)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 February 2021

4.2 Final decision in relation to lidocaine (lignocaine)

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to lidocaine as follows:

Schedule 5 – Amend Entry

LIDOCAINE in aqueous gel preparations containing 4.5 per cent or less of lidocaine, for the dermal spray-on administration to the wounds of animals ~~post-surgical wounds associated with 'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves.~~

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to lidocaine;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance.
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018);
- The Scheduling handbook: Guidance for amending the Poisons Standard; and
- Australian Animal Welfare Standards and Guidelines.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of *the Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular I note that:

- The proposed amendment to the Poisons Standard entry for lidocaine, from its limited indication for the "'mulesing' of sheep; tail docking and castration of lambs; or castration and disbudding/dehorning in calves", to the more expansive indication for the "dermal spray-on administration to the wounds of animals", increases potential benefits to the farming and veterinary industry from the broader use of the substance. The exposure of humans to lidocaine-containing preparations to the active constituent is expected to be no greater than currently approved uses. The regulator (APVMA) has concluded that the human health risk posed by the product is acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994)(52E(1)(a)).
- The purpose and extent for which the substance is to be used has been adequately outlined by the Applicant. I have taken into account that surgical procedures and treatment of significant injuries are adequately covered in the Australian Animal Welfare Standards and Guidelines. These standards provide animal age-related and developmental stage-related

standards and guidance on when a non-veterinarian can and cannot perform such procedures 52E(1)(b)).

- I have taken into account the broader uses of lidocaine and note that it is currently used for therapeutic uses in humans. I find that my decision would not affect such use in humans because the amendment will continue to limit use to animals when in aqueous gel preparations for dermal spray-on administration (52E(1)(b)).
- The product under consideration contains 40.6 g/L lidocaine (4.1%, as hydrochloride) and has low acute toxicity in rats by the oral and dermal routes, is a slight skin and eye irritant, and may be a skin sensitiser. The toxicity of the substance to humans will not be increased as similar quantities and administrative routes of the product are proposed (52E(1)(c)).
- There has been no substantive change in the information available regarding the toxicity of the substance since it was last considered for Scheduling that would warrant a change to its Scheduling Classification in Schedule 5 in the Poisons Standard based on the criteria set out in the SPF (2018) under the scheduling factors for Schedule 5 substances (52E(1)(c)).
- The packaging of the preparation containing the substance will not change as a result of its broader use in animals. However, the Applicant has demonstrated that appropriate risk mitigation measures, including labelling, will be put in place should the proposed product containing the substance be registered for use in Australia. As a result, no additional measures are required in the Poisons Standard. The proposed amended entry for the substance in the Poisons Standard will not affect lidocaine-containing ingredients listed under the ARTG (52E(1)(d)).
- The potential for misuse or abuse of the substance is unchanged from previous considerations (52E(1)(e)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 February 2021

4.3 Final decision in relation to Bovine Ephemeral Fever vaccine

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to bovine ephemeral fever vaccine as follows:

Schedule 4 – Amend Entry

VACCINES, veterinary live virus **except**:

a) poultry vaccines;

b) pigeon pox vaccine; or

c) scabby mouth vaccine; or

d) bovine ephemeral fever.

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to bovine ephemeral fever vaccine;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of *the Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular I note that:

- The proposed amendment to the Poisons Standard entry is to exempt from scheduling the bovine ephemeral fever (BEF) vaccine used for treatment of bovine ephemeral fever in beef and dairy cattle. The regulator (APVMA) has concluded that the human health risk posed by bovine ephemeral fever live vaccines is acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994)(52E(1)(a)).
- The purpose and extent for which the substance is to be used has been adequately outlined by Applicant (52E(1)(b)).
- Safety concerns may arise during preparation, administration and storage of the vaccine. The risks that may arise during vaccine reconstitution of the vaccine are comparable with that of unscheduled vaccines for cattle, and risks arising during administration can be managed through the provision of appropriate training programs for rural resellers by manufacturers. A number of other live-virus vaccines for use in animals are currently unscheduled, and present similar risk to the BEF vaccine (52E(1)(c)).
- Producers have safely administered approximately 180,000 doses of the BEF vaccine. There are no known reports of vaccine interactions in treated animals that would require the monitoring or intervention of a veterinarian. Between 2009 and 2019, human adverse events reported to the APVMA include four incidences of accidental exposure, either needle-stick or squirting towards the face, with no documentation of toxicity (52E(1)(c)).
- There is also no evidence of communal harm from the BEF Vaccine. The APVMA considers, that based on the data, no foreseeable communal harm from the use of this product is likely (52E(1)(c)).
- The dosage, formulation, labelling, packaging and presentation of the product under consideration will remain unchanged (52E(1)(d)).
- The current BEF live virus vaccine has no ability to produce dependency and no propensity for misuse, abuse or illicit use (52E(1)(e)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 February 2021

4.4 Final decision in relation to fluazaindolizine

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to Fluazaindolizine as follows:

Schedule 5 – New entry

FLUAZAINDOLIZINE in preparations containing 50 per cent or less fluazaindolizine

Schedule 6 – New entry

FLUAZAINDOLIZINE **except** when included in Schedule 5.

Index – New entry

FLUAZAINDOLIZINE.

Schedule 6

Schedule 5

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to fluazaindolizine;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

In determining, that this matter will be a delegate-only decision I have taken into account the information provided in the application from the Applicant (APVMA), and the matters outlined under Section 52E of *the Therapeutic Goods Act 1989* and the Scheduling Policy Framework (2018). In particular I note that:

- The proposed amendment to the Poisons Standard entry is to include a new entry for fluazaindolizine in Schedule 6, and for preparations containing 50 per cent or less fluazaindolizine in Schedule 5, based upon benefits to the agricultural industry from the introduction of this new nematicidal active constituent. The risks to human health and safety from fluazaindolizine have been addressed by the pesticide regulator (APVMA) in its application that concluded that the human health risk posed by the product is acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994) 52E(1)(a)(b)).
- The applicant provided data for a product containing 500 g/L of the active constituent fluazaindolizine, which indicated that the toxicity profile was consistent with a Schedule 5 entry, i.e. low acute toxicity by the oral (LD_{50} >2000 mg/kg bw), dermal (LD_{50} >5000 mg/kg bw) and inhalational (LC_{50} >5100 mg/m^3) routes. The product was a slight eye and skin irritant and was not a skin sensitiser. The skin and eye irritation potential of this product can be adequately managed with safety directions. Overall, the substance was found to be non-carcinogenic, non-genotoxic and did not exhibit any developmental or reproductive toxicities (52E(1)(c)(d)).
- I find that the risks to human health and safety from exposure to fluazaindolizine at a concentration of 50% or less, during use, re-entering treated areas or handling treated material, and the general public coming into contact with the product have been adequately qualified in the APVMA's Human Health Risk Assessment (HHRA) technical report (52E(1)(a)).
- Products containing 50% or less fluazaindolizine, are intended only for professional use, and will not be available to the general public. Therefore, the potential for misuse or abuse of the substance as contained in the proposed products is limited. The substance has no established therapeutic value in humans that would indicate that there is a risk of dependency, abuse, misuse or diversion into illicit use (52E(1)(e)).

Therefore, based on the information provided in the application, I have decided to amend the current Poisons Standard in the manner set out in the application. The proposed amendment was not referred to an expert advisory committee.

Date of effect of the decision

1 February 2021

4.5 Final decision in relation to florylpicoxamid

Final decision

Pursuant to regulation 42ZCZU of the Regulations, a Delegate of the Secretary has made a final decision to amend the current Poisons Standard in relation to florylpicoxamid as follows:

Appendix B, Part 3 – New entry

Substance	Date of entry	Reasons for listing	Area of use
FLORYLPICOXAMID	1 February 2021	a	1.3

Index – New entry

FLORYLPICOXAMID.

Appendix B, Part 3

Materials considered

In making this final decision, the Delegate considered the following material:

- The application to amend the current Poisons Standard with respect to florylpicoxamid;
- Subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health;
- The Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- The Scheduling handbook: Guidance for amending the Poisons Standard.

Reasons for the final decision (including findings on material questions of fact)

The proposed amendment was not referred to an expert advisory committee. In not referring this matter to either the ACCS or the Joint ACCS-ACMS, I am satisfied that sufficient information has been provided by the Applicant for me to exercise my delegation.

In determining that this matter will be a delegate-only decision, I note that:

- Florylpicoxamid is a pesticide used in emulsifiable concentrate formulations for the treatment of wheat and bananas. Products containing florylpicoxamid are intended only for professional use, and will not be available to the general public. The potential for misuse or abuse of the substance as contained in the proposed products is limited. The substance has no established therapeutic value in humans that would indicate that there is a risk of dependency, abuse, misuse or diversion into illicit use (52E(1)(a)(b)(e)).
- The APVMA has concluded that the human health risk posed by the product is acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994) 52E(1)(a)).

- Products containing florylpicoxamid (100g/L) have shown a very low toxicity profile with the weight of evidence from the toxicological database indicating that it does not appear to present any substantial risk from acute, short term or long term exposure. The data indicate that florylpicoxamid has very low toxicity by oral, dermal and inhalation routes. It is a slight eye irritant in rabbits, but is not a skin irritant, or skin sensitiser in the local lymph node assay (LLNA) test in mice. There is no evidence of neurotoxicity, immunotoxicity, endocrine disruption, genotoxicity, carcinogenicity, effects on reproduction or teratogenicity (52E(1)(a)(c)(f)).
- The applicant has demonstrated that appropriate risk mitigation measures will be put in place for use of a registered product in Australia, accounting for the dosage (application rate), formulation, labelling, packaging and presentation of florylpicoxamid. As a result, no additional measures are required in the Poisons Standard. Further use of florylpicoxamid in other pesticide products will be addressed by the pesticide regulator (APVMA) in any future applications to the regulator (52E(1)(d)).

Therefore, based on the information provided in the application, it is considered that florylpicoxamid does not meet the factors for inclusion in the Schedules of the Poisons Standard. Florylpicoxamid should be listed in Appendix B due to its low toxicity (Part 1, a; Part 2, 1.1).

Date of effect of the decision

1 February 2021