EXPLANATORY STATEMENT

Issued by Authority of the Minister for Agriculture, Fisheries and Forestry

Agricultural and Veterinary Chemicals Code Act 1994

Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2022

Legislative Authority

The *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act), in part, sets out the regulatory framework for the evaluation, registration, control and manufacture of agricultural and veterinary (agvet) chemicals.

Subsection 6(1) of the Code Act, in part, specifies that the Governor- General may make regulations prescribing matters required or permitted by the Agricultural and Veterinary Chemicals Code set out in the Schedule to the Code Act (Code) to be prescribed by regulations within the meaning of the Code.

Specifically, regulations can be made pursuant to, or for the purposes of, the provisions listed at Attachment A.

Purpose

The purpose of the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2022* (Amendment Regulations) is to amend the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Code Regulations) to give effect to changes in the Cost Recovery Implementation Statement (2022 CRIS) of the Australian Pesticides and Veterinary Medicines Authority (APVMA), including to adjust certain fees. The Amendment Regulations also strengthens the operation, and makes clearer the policy objective of, certain provisions.

Background

Agvet chemicals are regulated through a cooperative 'National Registration Scheme for Agricultural and Veterinary Chemicals' (the NRS). The NRS is a partnership between the Commonwealth and the states and territories, with an agreed division of responsibilities.

The NRS is implemented, in part, through the Code Act, including the Code. The Code, in part, provides for the APVMA to assess, approve, register and reconsider active constituents, and agvet chemical products and their associated labels. The states and territories apply the Commonwealth law (the Code) as a law of their own jurisdiction, supported by an intergovernmental agreement.

The APVMA was established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. The APVMA is responsible for regulating agvet chemicals up to and including the point of supply, i.e., retail sale.

The operations of the APVMA are funded almost entirely through cost-recovery via fees and levies from industry. The 2022 CRIS for the period between 1 February 2023 and 30 June 2025 outlines how the APVMA will implement cost recovery arrangements relating to the agency fulfilling its statutory function to ensure that agvet chemicals sold within Australia are safe and effective and do not unduly prejudice trade.

In particular, the 2022 CRIS informs that:

- The APVMA will introduce new modules to capture assessment types where a reduced timeframe and fee is considered appropriate.
- The modules relating to toxicology and to work health and safety are consolidated into 'health' modules. The terminology for Module 4 and 4.1 is changing from 'toxicology requiring poison schedule classification' to 'poison scheduling'.
- Applications made under section 27 of the Code (applications to vary the relevant particulars or conditions of an approved active constituent, label or registered chemical product) will be included in the 'catch all' application type at table item 24 under clause 2.1 in Schedule 6 to the Code Regulations.

Impact and Effect

The Amendment Regulations enable the APVMA to consider certain assessments under reduced period of completion timeframes and at reduced fees that are more appropriate for those assessments and as such will have a positive effect on applications made to the APVMA. The Amendment Regulations improves the efficiency and effectiveness of Code Regulations, while maintaining human, environmental, plant and animal health and trade safeguards through clearer policy objectives of certain provisions and improved the financial stability of the APVMA.

Consultation

The Amendment Regulations were developed in consultation with the APVMA.

The APVMA consulted widely about the 2022 CRIS through targeted consultation with key stakeholders and public consultation via the APVMA's website between 11 August 2022 and 8 September 2022. Relevant state and territory agencies were also consulted and provided with the opportunity to comment and make suggestions about all measures set out in the Amendment Regulations.

The APVMA was consulted on the minor clarification of the term mould inhibitor. This clarification does not change the intent of the regulation and therefore further consultation was not required.

Overall, stakeholders continue to support the need for a robust, effective, and efficient agvet chemical regulatory scheme and the need for cost recovery arrangements to underpin this scheme.

The Office of Best Practice Regulation (OBPR) was consulted in the preparation of the Amendment Regulations (ID OBPR22-02952). The OBPR advised a Regulation Impact Statement was not required as the measures are unlikely to have no more than minor regulatory impact.

Details/ Operation

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003* (Legislation Act).

Sunsetting does not apply to the Code Regulations due to subsection 54(1) of the Legislation Act. This is because the enabling legislation for the Code Regulations (which also authorises the creation of the Code Regulations) facilitates the establishment or operation of an intergovernmental body or scheme (being the NRS) and authorises the Code Regulations to be made for the purposes of the NRS.

The Amendment Regulations commence on 1 February 2023.

Details of the Amendment Regulations are set out in Attachment B.

Other

The Amendment Regulations are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full Statement of Compatibility with Human Rights is set out in Attachment C.

Attachment A

Authorising provisions

Subsection 6(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) specifies that Governor- General may make regulations prescribing matters required or permitted by the Agricultural and Veterinary Chemicals Code set out in the Schedule to the Code Act (Code) to be prescribed by regulations within the meaning of the Code. This subsection also specifies that the Governor-General may make regulations prescribing matters necessary or convenient to be prescribed by such regulations for carrying out or giving effect to the Code.

For assessment fees and assessment periods, the following provisions are relevant:

- Subsection 164(1) of the Code specifies, in part, that the regulations may prescribe, or prescribe a method of working out, the fees to be paid in respect of the making of an application to the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the Code.
- Subsection 165(1) of the Code specifies that, when an application is made under the Code to the APVMA, the APVMA must determine the application within a period stated in, or determined in, accordance with the regulations.

For agricultural chemical products, paragraph 4(4)(b) of the Code specifies that an agricultural chemical product does not include a substance or mixture of substances declared by the regulations not to be an agricultural chemical product.

The *Agricultural and Veterinary Chemicals Code Regulations 1995* is made under the Code Act and, in part, prescribes fees and charges, and related matters for applications made to the APVMA.

Attachment B

Details of the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2022*

Section 1 – Name

This section specifies that the name of the instrument is the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2022* (Amendment Regulations).

Section 2 – Commencement

This section has effect that the whole of the Amendment Regulations commence on 1 February 2023.

Section 3 – Authority

This section specifies that the Amendment Regulations are made under the authority of the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act).

Section 4 – Schedules

This section is the formal enabling provision for the Schedule to the Amendment Regulations and specifies that each instrument that is specified in a Schedule is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in the Schedule has effect according to its terms.

The *Agricultural and Veterinary Chemicals Code Regulations 1995* (Code Regulations) is amended.

Schedule 1–Amendments

Schedule 1 to the Amendment Regulations deals with two matters:

- changes to give effect to the Cost Recovery Implementation Statement (2022 CRIS) of the Australian Pesticides and Veterinary Medicines Authority (APVMA) (including to adjust certain fees, amend module types and descriptions, and deal with a consequential update to a formula that references the modules); and
- changes to clarify the operation of provisions related to the exclusion of certain uses of substances from being considered agricultural chemical products.

Agricultural and Veterinary Chemicals Code Regulations 1995

Item 1 Subsection 78B(5) (definition of *A*)

This item amends the definition of *A* to the formula under sub-regulation 78B(5) of the Code Regulations to make amendments consequential to the amendments made by items 9, 14 and 15 of the Amendment Regulations.

Sub-regulation 78B(5) of the Code Regulations sets out a formula for determining the period in which a reconsideration of an approval or registration under Division 4 of Part 2 of the Code must be concluded by the APVMA.

The meaning of *A* and *B* of the formula are defined to consider the periods, in months, mentioned in column 2 of specified table items in Schedule 7 to the Code Regulations.

The 2022 CRIS:

- sets out updates to application item descriptions, module descriptions, and period of completion and fee for certain assessment modules, including in some cases new modules to capture assessment types where a reduced timeframe and fee is considered appropriate;
- sets out the fee and period of completion for new assessment modules relating to health; assessment modules of which are a combination of assessment modules relating to toxicology (not requiring poison schedule classification) and to work health and safety;
- as a consequence of the above updates, provides for the formula, for working out the period in which the APVMA must conclude a reconsideration of an approval or registration, to be updated to include the new modules where relevant.

Consistent with the 2022 CRIS, item 9 of the Amendment Regulations amends Schedule 7 to the Code Regulations to insert new modules for assessment relating to health and their fee and period of completion. The new modules reflect a merger of the assessment modules relating to toxicology (not requiring poison schedule classification) and work health and safety into new modules for health and, as such, the previous assessment modules set out in Schedule 7 to the Code Regulations (to be merged) are repealed. See the notes for items 9 and 14 of the Amendment Regulations for the inclusion of the assessment modules relating to health and the repeal of the assessment modules relating to toxicology (not requiring poison schedule classification) and work health and safety.

For the period, in months, for modules relating to toxicology (not requiring poison schedule classification), the period is necessary for the formula where an assessment relating to

toxicology is required for the purposes of the reconsideration. The 2022 CRIS informs that the new modules 3.1 to 3.5 for Health Levels–1 to 5 replace previous modules 3.1 to 3.3 for Toxicology (not requiring poison schedule classification) levels–1 to 3. As such, new modules 3.1 to 3.5 for Health are modules where an assessment relating to toxicology may be applicable and required.

Furthermore, item 15 of the Amendment Regulations inserts a new item 7.4 into Schedule 7 to the Code Regulations for a new module for assessments relating to environment. The new assessment module specifies the period of completion for that module.

This item repeals and substitutes the previous definition of *A* of the formula under sub-regulation 78B(5) of the Code Regulations such that *A* means:

(a) if an assessment relating to toxicology is required for the purposes of the reconsideration—the longest of the periods, in months, mentioned in column 2 of Schedule 7 to the Code Regulations for whichever of items 3.1 to 3.5, 4.1 and 7.1 to 7.4 of Schedule 7 to the Code Regulations that the APVMA determines are necessary for the reconsideration; or

(b) in any other case—the longest of the periods, in months, mentioned in column 2 of Schedule 7 to the Code Regulations for whichever of items 4.1 and 7.1 to 7.4 of Schedule 7 to the Code Regulations that the APVMA determines are necessary for the reconsideration.

The new example under the new definition of *A* explains that, if the APVMA determines that items 3.1 and 7.3 of Schedule 7 are necessary for the reconsideration, *A* is the longest of the periods in column 2 for those items, which is 13 months (the period for item 3.1).

The purpose of this amendments is to ensure that the amendments made by items 9 and 14 of the Amendment Regulations do not affect the consideration under the definition of *A* of the formula under sub-regulation 78B(5) of the Code Regulations and as such, has the effect of maintaining the status quo for the period, in months, to be considered.

The amendment also has the effect of ensuring that the period of completion in new table item 7.4 of Schedule 7 to the Code Regulations is included for the purposes of working out the period in which the APVMA must conclude a reconsideration.

Item 2 Subsection 78B(5) (definition of *B*)

Like item 1 of the Amendment Regulations, item 2 of the Amendment Regulations amends the definition of *B* to the formula under sub-regulation 78B(5) of the Code Regulations to make amendments consequential to the amendments made by items 8, 9, 12, 13 and 14 of the Amendment Regulations.

Item 2 repeals and substitutes the previous definition of *B* of the formula under sub-regulation 78B(5) of the Code Regulations such that *B* means:

(a) if an assessment relating to work health and safety is required for the purposes of the reconsideration—the longest of the periods, in months, mentioned in column 2 of Schedule 7 to the Code Regulations for whichever of items 2.1 to 2.5, 3.1, 3.3 to 3.5, 5.1 to 5.5, 9 and 10.1 to 10.3 of Schedule 7 to the Code Regulations that the APVMA determines are necessary for the reconsideration; or

(b) in any other case—the longest of the periods, in months, mentioned in column 2 of Schedule 7 to the Code Regulations for whichever of items 2.1 to 2.5, 5.1 to 5.5, 9 and 10.1 to 10.3 of Schedule 7 to the Code Regulations that the APVMA determines are necessary for the reconsideration.

In line with the notes for item 1 of the Amendment Regulations, the amendments made by items 9 and 14 of the Amendment Regulations replaces the assessment modules relating to work health and safety, and the associated period of completion, that are to be considered for the definition of *B* of the formula under sub-regulation 78B(5), with new relevant assessment modules relating to health.

For the period, in months, for modules relating to work health and safety, the period is necessary for the formula where an assessment relating to work health and safety assessment is required for the purposes of the reconsideration. The 2022 CRIS informs that the new modules 3.1, 3.3, 3.4 and 3.5 for Health Levels–1, 3, 4 and 5 replace previous modules 6.1, 6.2 and 6.3 for Work health and safety levels–1 to 3. As such, new modules 3.1, 3.3, 3.4 and 3.5 for Health are also modules where an assessment relating to work health and safety may be applicable and required.

Furthermore, items 8, 12 and 13 insert new table items 2.4 and 2.5, and amend table items 5.3 and 5.5, of Schedule 7 to the Code Regulations. See the notes for items 8, 12 and 13 of the Amendment Regulations.

The purpose of this amendment is to ensure that the amendments made by items 9 and 14 do not affect the consideration under the definition of *B* of the formula under sub-regulation 78B(5) of the Code Regulations and as such, has the effect of maintaining the status quo for the period, in months, is considered.

For working out the period in which the APVMA must conclude a reconsideration of an approval or registration, the amendment also has the effect of ensuring that the period of completion in new table items 2.4, 2.5, 5.3 and 5.5 of Schedule 7 to the Code Regulations are included.

Item 3 In the appropriate position in Part 10

This item inserts new regulation 95 into Part 10 of the Code Regulations.

The effect of new sub-regulation 95(1) is that the amendments of regulation 78B of the Code Regulations made by Schedule 1 to the Amendment Regulations apply in relation to reconsiderations of approvals and registrations under Division 4 of Part 2 of the Code that are started on or after 1 February 2023.

The effect of new sub-regulation 95(2) is that the amendments of Schedules 6 and 7 to the Code Regulations made by Schedule 1 to the Amendment Regulations apply in relation to applications made on or after 1 February 2023.

Items 4 and 5

Part 3 of Schedule 3 of the Code Regulations sets out classes of substances or mixtures of substances and the circumstances that must be met in order for the classes of substances or

mixture of substances to be declared under the Code Regulations to not be agricultural chemical products.

Table item 1 in Part 3 of Schedule 3 of the Code Regulations specifies a certain substance for use in the manufacture of paper, paper pulp, glue, plywood, carpets, plastics, glass, fabrics, domestic items, bedding material, leather goods or surface coatings (including paint but excluding antifouling paint) would be declared under the Code Regulations to not be agricultural chemical products, if the circumstances specified in that item are satisfied.

The substance referred to as mould inhibitor in table item 1 in Part 3 to Schedule 3 to the Code Regulations is a substance that stops any small growths (including bacteria or algae) in the listed manufactured products and, as such, is a biocide.

These items amend the chapeau and paragraph (a) of table item 1 in Part 3 to Schedule 3 to the Code Regulations to substitute 'mould inhibitor' with the clearer term 'biocide'.

The purpose of these amendments is to better identify the substance to which table item 1 in Part 3 to Schedule 3 to the Code Regulations applies. These amendments do not change the scope of table item 1 in Part 3 to Schedule 3 to the Code Regulations.

Item 6 Part 3 of Schedule 3 (paragraph (b) of table item 1)

Under table item 1 in Part 3 of Schedule 3 to Code Regulations, a circumstance that must be satisfied under previous paragraph (b) for any mould inhibitor (biocide) for use in the manufacture of paper, paper pulp, glue, plywood, carpets, plastics, glass, fabrics, domestic items, bedding material, leather goods or surface coatings (including paint but excluding antifouling paint) to be declared under the Code Regulations to not be an agricultural chemical product was that the substance is not released into the environment from the manufactured product.

The circumstance under previous paragraph (b) of table item 1 in Part 3 of Schedule 3 to the Code Regulations does not exclude any mould inhibitor (biocide) in manufactured products that is unintentionally released as the product gradually breaks down over time.

This item repeals and substitutes paragraph (b) of table item 1 in Part 3 of Schedule 3 to the Code Regulations. New paragraph (b) specifies that the biocide is not incorporated into the product for the purpose of that product releasing the biocide into the environment.

The purpose of this amendment is to clarify that the unintended gradual breakdown of manufactured products that contain mould inhibitor (biocide) does not make the substance an agricultural chemical product.

Item 7 Schedule 6 (cell at table item 24, column 1)

The table under clause 2.1 of Schedule 6 to the Code Regulations specifies the assessment period, extended assessment period, maximum pre-application assistance rebate and fees for an application identified by column 1 of an item of that table.

Previously, column 1 of table item 24 under clause 2.1 provides for an application made under section 10 of the Code; these particular applications being applications for registration,

or approval of an active constituent or label requiring assessment of a technical nature (other than those of the kinds described in any of table items 1 to 10, 15, 16 or 17 in clause 2.1 of Schedule 6 to the Code Regulations).

Previous table item 24 operated as a 'catch all' application type for applications made under section 10 of the Code that might, for some reason or other, not be caught by any of the other more specific application descriptions in the table.

Previous table item 24 did not capture applications made under section 27 of the Code, being applications to vary the relevant particulars or conditions of an approved active constituent, label or registered chemical product. The 2022 CRIS seeks to extend the operation of table item 24 to capture applications made under section 27 of the Code.

Consistent with the 2022 CRIS, item 7 of the Amendment Regulations amends column 1 of table item 24 to enable applications covered by table item 24 to also cover applications made under section 27 of the Code.

New column 1 of table item 24 covers applications made under:

- section 10 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 1 to 10, 15, 16 or 17); and
- section 27 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 11 to 14 or 18).

The purpose of the amendment is to enable a catch all for applications made under section 27 of the Code and, as such, has the effect of ensuring any unintended gaps in the previous application types are closed and allowing full use of the new modules where the modules might not fit into the previous item structure.

This is particularly important for applications to vary an approved active constituent as the previous table item 18 under clause 2.1 in Schedule 6 to the Code Regulations did not allow for modular assessment and, as such, did not allow for use of the chemistry modules as may be appropriate.

Item 8 Schedule 7 (after table item 2.3)

Schedule 7 to the Code Regulations sets out the assessment modules that may be necessary to determine an application for which a fee (the fee in column 3 of Schedule 7) and period (the period of completion in column 2 of Schedule 7) applies.

The 2022 CRIS informs that the APVMA will introduce new modules to capture assessment types where a reduced timeframe and fee is considered appropriate.

Consistent with the 2022 CRIS, this item amends Schedule 7 to the Code Regulations to insert table items 2.4 and 2.5 into Schedule 7 to the Code Regulations for assessment modules relating to chemistry.

The period of completion and fee in new table item 2.4 for the new assessment module, referred to as 'Chemistry–level 4', is 3 months and $970, respectively. The period of completion and fee in table item 2.5 for the new assessment module, referred to as 'Chemistry–level 5', is 2 months and $480, respectively.

The purpose of these amendments is to give effect to the changes as set out in the 2022 CRIS. As a result of these amendments, item 2 of the Amendment Regulations amends the definition of *B* of the formula under sub-regulation 78B(5) of the Code Regulations such that the period of completion in these new assessment modules may be considered under the formula, as necessary.

The new modules has the effect of enabling the APVMA to recover the lower costs for assessments relating to chemistry requiring less time to complete that would not otherwise be available to the APVMA.

Items 9, 10, 11 and 14

The 2022 CRIS specifies new assessment modules relating to health, which is a combination of the assessment modules relating to toxicology (not requiring poison schedule classification) and to work health and safety. The new assessment modules are items 3, 3.1, 3.2, 3.3, 3.4, 3.5 and 3.6.

As a result, the 2022 CRIS sets out changes:

- to the name of assessment modules relating to toxicology (requiring poison schedule classification) such that they are assessment modules relating to Poison schedule classifications; and
- removing assessment modules relating to work health and safety.

For the 2022 CRIS changes with respect to the merger of the assessments relating to toxicology (requiring poison schedule classification) and to work health and safety, items 9 and 14 of the Amendment Regulations repeals and substitutes previous table items 3, 3.1, 3.2, and 3.3 of Schedule 7 to the Code Regulations with new table items 3, 3.1, 3.2, 3.3, 3.4, 3.5 and 3.6, and repeals table items 6, 6.1, 6.2, and 6.3 in Schedule 7 to the Code Regulations, respectively.

The new assessment levels for health, and their period for completion and fee are as follows:

Item	Module, level or type	Period for completion	Fee ($)
3	**Health**		
3.1	Health—level 1	13 months	36,740
3.2	Health—level 2	11 months	27,920
3.3	Health—level 3	9 months	18,980
3.4	Health—level 4	5 months	7,963
3.5	Health—level 5	4 months	4,000
3.6	Health—level 6	2 months	2,000

The new health modules offer more flexibility when a reduced timeframe and fee is considered appropriate by the APVMA and enable assessments relating to toxicology, and to work health and safety, to be considered as a single assessment as necessary.

Items 10 and 11 of the Amendment Regulations repeal and substitute the cell at table item 1 under column 1, and the cell at table item 4.1 under column 1, of Schedule 7 to the Code Regulations such that:

- item 4 refers to assessment modules relating to Poison schedule classification and as such, sets out the type of assessment to which a table item 4 item within that type of assessment relate; and
- item 4.1 provides for assessments relating to Poison schedule classification.

The purpose of the amendments is to give effect to the changes set out in the 2022 CRIS. As a result of these amendments, items 1 and 2 of the Amendment Regulations amend the definition of *A* and *B* of the formula under sub-regulation 78B(5) of the Code Regulations such that the period of completion in these new assessment modules may be considered under the formula, as necessary.

Items 12 and 13

The 2022 CRIS informs that the APVMA will introduce new modules to capture assessment types where a reduced timeframe and fee is considered appropriate.

Consistent with the 2022 CRIS, these items amend Schedule 7 to the Code Regulations to amend table items 5.3 and 5.5 of Schedule 7 to the Code Regulations for assessment modules relating to residues. These amendments introduce a reduced timeframe and fee for assessment modules relating to residues.

Item 12 of the Amendment Regulations repeals and substitutes table item 5.3 of Schedule 7 to the Code Regulations such that:

- the period of completion is reduced from 8 months to 6 months; and
- the fee is reduced from $16,400 to $9,000.

Item 13 of the Amendment Regulations repeals and substitutes table item 5.5 of Schedule 7 to the Code Regulations such that:

- the period for completion is reduced from 4 months to 3 months; and
- the fee is reduced from $4,00 to $2,000.

The purpose of these amendments is to give effect to the changes as set out in the 2022 CRIS and to better reflect the time necessary to complete assessments relating to residues and revised costs incurred by the APVMA. As a result of these amendments, item 2 of the Amendment Regulations amends the definition of *B* of the formula under sub-regulation 78B(5) of the Code Regulations such that the period for completion in these table items may be considered under the formula, as necessary.

Item 15 Schedule 7 (after table item 7.3)

The 2022 CRIS informs that the APVMA will introduce new modules to capture assessment types where a reduced timeframe and fee is considered appropriate.

Consistent with the 2022 CRIS, like items 8, 12 and 13 of the Amendment Regulations, item 15 amends Schedule 7 to the Code Regulations to insert table item 7.4 into Schedule 7 to the Code Regulations for assessment modules relating to environment. These amendments introduce a reduced timeframe and fee for assessment modules relating to environment.

The period of completion and fee in new table item 7.4 for the new assessment module referred to as ‘Environment–level 4’ is 3 months and $1,490.

The purpose of this amendment is to give effect to changes as set out in the 2022 CRIS. As a result of this amendment, item 1 of the Amendment Regulations amends the definition of *A* of the formula under sub-regulation 78B(5) of the Code Regulations such that the period for completion in the new assessment module may be considered under the formula, as necessary.

The new module has the effect of enabling the APVMA to recover costs for assessments relating to environment requiring less time to complete that would not otherwise be available to the APVMA.

Attachment C

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2022

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The Australian Pesticides and Veterinary Medicines Authority (APVMA), established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, assesses, registers, and approves agricultural and veterinary (agvet) chemicals for use in Australia.

The *Agricultural and Veterinary Chemicals Code Act 1994* sets out in its Schedule the Agricultural and Veterinary Chemicals Code (the Code), as it applies as a law for the government of the participating Territories. The object of the Code is to make provision for and in relation to:

- the evaluation, approval, and control of the supply, of active constituents for proposed or existing agricultural chemical products or veterinary chemical products; and
- the evaluation, registration, and control of the manufacture and supply, of agricultural chemical products and veterinary chemical products.

The APVMA is responsible for regulating agvet chemicals up to and including the point of supply, i.e., retail sale. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The operations of the APVMA are funded almost entirely through cost-recovery via fees and levies from industry. The Cost Recovery Implementation Statement (2022 CRIS) outlines how the APVMA implements cost recovery arrangements relating to the agency fulfilling its statutory function to ensure that agvet chemicals sold within Australia are safe and effective and do not unduly prejudice trade.

The 2022 CRIS:

- sets out updates to application item descriptions, module descriptions, and period of completion and fee for certain assessment modules, including in some cases new modules to capture assessment types where a reduced timeframe and fee is considered appropriate;
- sets out the fee and period of completion for new assessment modules relating to health; assessment modules of which are a combination of assessment modules relating to toxicology (not requiring poison schedule classification) and to work health and safety;
- as a consequence of the above updates, provides for the formula, for working out the period in which the APVMA must conclude a reconsideration of an approval or registration, to be updated to include the new modules where relevant;

- informs that applications made under section 27 of the Code (applications to vary the relevant particulars or conditions of an approved active constituent, label or registered chemical product) will be included in the 'catch all' application type at table item 24 under clause 2.1 in Schedule 6 to the Code Regulations.

The amendments made in Schedule 1 to the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2022* (Legislative Instrument) amends the *Agricultural and Veterinary Chemicals Code Regulations 1995* to give effect to the afore-mentioned changes specified in the 2022 CRIS, and to strengthen the operation of provisions and make the related the policy objectives clearer.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Senator the Hon. Murray Watt
Minister for Agriculture, Fisheries and Forestry