Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013

Select Legislative Instrument No. 108, 2013

I, Professor Marie Bashir AC CVO, Administrator of the Government of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation under the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

Dated 13 June 2013

Marie Bashir
Administrator

By Her Excellency's Command

Peter Douglas Sidebottom
Parliamentary Secretary for Agriculture, Fisheries and Forestry

OPC60056 - A

Contents

Federal Register of Legislative Instruments F2013L01016

1 Name of regulation

This regulation is the *Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013*.

2 Commencement

This regulation commences on 1 July 2013.

3 Authority

This regulation is made under the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

4 Schedule(s)

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995

1 Regulations 4, 5 and 6

Repeal the regulations.

2 Subregulation 6A(1)

Repeal the subregulation.

3 Subregulation 6A(2) (heading)

Repeal the heading, substitute:

2006-2007 financial year to 2012-2013 financial year

4 Subregulation 6A(2)

After "succeeding financial year", insert "up to and including the 2012-2013 financial year".

5 At the end of regulation 6A

Insert:

2013-2014 financial year and subsequent years

(3) For section 12C of the Act, the following rates are prescribed in respect of the 2013-2014 financial year and each succeeding financial year:

(a) for the part of leviable disposals not exceeding $1 000 000—0.70%;

(b) for the part of leviable disposals exceeding $1 000 000 but not exceeding $5 000 000—0.40%;

(c) for the part of leviable disposals exceeding $5 000 000—0.28%.

Agricultural and Veterinary Chemicals Code Regulations 1995

6 Subregulation 3(1)

Insert:

Australian GMP Code means the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products*, published by the APVMA.

category 1 licence means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product that is:

(a) registered as being, represented to be, or required to be sterile; or

(b) an immunobiological product;

whether or not the licence also authorises the carrying out of steps in the manufacture of other chemical products.

category 2 licence means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product, other than a veterinary chemical product mentioned in the definition of:

(a) category 1 licence; or

(b) category 3 licence; or

(c) category 4 licence; or

(d) category 6 licence.

category 3 licence means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product that is an externally applied ectoparasiticide.

category 4 licence means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product that is a premix or stockfood supplement.

category 6 licence means a licence issued under Part 8 of the Code to carry out only one or more of the following steps in the manufacture of a veterinary chemical product:

(a) processing;

(b) assembling;
(c) packaging;
(d) labelling;
(e) storage;
(f) sterilising;
(g) testing;
(h) releasing for supply.

multi-category licence means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product mentioned in the definition of one of the following terms:

(a) category 2 licence;
(b) category 3 licence;
(c) category 4 licence;

at the same premises as are used to carry out steps in the manufacture of veterinary chemical products mentioned in the definition of at least one other of those terms.

7 Regulation 5

Repeal the regulation.

8 At the end of Subdivision 2.1.2

Add:

14A Assessment of chemical products manufactured outside Australia

(1) Subregulation (2) applies if:
(a) a step in the manufacture of a chemical product occurs outside Australia; and
(b) the product is not an exempt product within the meaning given by regulation 59; and
(c) the product is not a listable chemical product; and
(d) the product is not a reserved chemical product.

(2) For paragraph 14(5)(i) of the Code, a prescribed matter is whether the step complies with a standard that the APVMA has determined

is comparable to the manufacturing principles and the Australian GMP Code.

Note: Under paragraph 14(5)(i) of the Code, the regulations may prescribe matters to which the APVMA must have regard when deciding whether to register a chemical product.

9 After regulation 59D

Insert:

59E Requirements for issue of licence

It is a requirement for the issue of a licence that, if directed to do so by the APVMA CEO, the applicant for the licence:

(a) undergoes an audit by an APVMA inspector, or another person authorised in writing by the APVMA, of the facilities, equipment, systems, processes, procedures and personnel to be used in the manufacture of the chemical products; and

(b) demonstrates to the satisfaction of the APVMA that the applicant will comply with the conditions to be imposed on the licence if the licence is issued.

10 At the end of paragraph 61(3)(d)

Add:

; (e) any complaint or product failure in relation to the chemical products, and the investigations and actions undertaken in relation to the complaint or product failure.

11 After subregulation 61(3)

Insert:

(3A) The holder of a licence must manufacture the chemical products in accordance with:

(a) the manufacturing principles; and

(b) the Australian GMP Code.

12 After subregulation 61(7)

Insert:

(7A) The holder of a licence may sub-contract the manufacture of the chemical products only to:

(a) a manufacturer, or laboratory, licensed by the APVMA to perform a step in the manufacture of the chemical products; or

(b) a manufacturer or laboratory located outside Australia that the APVMA has determined complies with a standard of manufacture comparable to the manufacturing principles and the Australian GMP Code.

13 Subregulation 61(8)

Repeal the subregulation, substitute:

(8) If directed by the APVMA CEO, the holder of a licence must:

(a) undergo an audit by an APVMA inspector, or another person authorised in writing by the APVMA (an ***auditor***), of the facilities, equipment, systems, processes, procedures and personnel used in the manufacture of the chemical products (a ***GMP audit***); and

(b) demonstrate to the satisfaction of the APVMA that the holder is complying with the following conditions of the licence:

(i) any conditions imposed on the licence under subsections 126(1) and (2) of the Code;

(ii) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition;

(iii) any of the conditions mentioned in subregulations (3) to (7A) to which the licence is subject.

(8A) For the purposes of a GMP audit, the holder of the licence:

(a) must give the auditor access to all facilities, equipment, systems, processes, procedures and personnel used in the manufacture of the chemical products, and any information relevant to the GMP audit; and

(b) must not conceal or withhold relevant information from the auditor.

(8B) If the audit identifies a non-conformance by the holder of the licence that, in the auditor's opinion, is a critical non-conformance, the holder must notify the APVMA in writing of the critical

non-conformance within 3 working days of being told of the critical non-conformance by the auditor.

(8C) Following a GMP audit of the holder of a licence, the holder must:

(a) within the period determined by the APVMA, give to the APVMA:

(i) the original audit report, signed by the auditor, and any associated audit report supplements; and

(ii) details of the corrective action the holder proposes to take in relation to any non-conformance identified in the audit report; and

(iii) a proposed period for taking the corrective action; and

(b) implement the corrective action within the period agreed to or specified by the APVMA; and

(c) give to the APVMA evidence demonstrating that the holder is complying with the following conditions of the licence:

(i) any conditions imposed on the licence under subsections 126(1) and (2) of the Code;

(ii) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition;

(iii) any of the conditions mentioned in subregulations (3) to (7A) to which the licence is subject.

14 After regulation 61

Insert:

61A Determination following GMP audit

(1) For paragraph 6(2)(c) of the Act, this regulation applies if the holder of a licence is directed by the APVMA CEO to undergo a GMP audit under subregulation 61(8).

(2) On receipt of the information mentioned in subregulation 61(8C), the APVMA must:

(a) assess the information, having regard to the following:

(i) whether the audit report identified any non-conformances;

(ii) whether any non-conformances identified in the audit report have been rectified following corrective action;

(iii) any other matters the APVMA considers relevant; and

(b) determine whether the APVMA is satisfied that the holder is complying with the following conditions of the licence:

(i) any conditions imposed on the licence under subsections 126(1) and (2) of the Code;

(ii) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition;

(iii) any of the conditions mentioned in subregulations 61(3) to (7A) to which the licence is subject.

15 Subregulations 70(4) and (5)

Omit "$505" (wherever occurring), substitute "$535".

16 Subregulation 71(4) (note 2)

Omit "$505", substitute "$535".

17 Subregulation 71A(2)

Repeal the subregulation, substitute:

(2) In addition, for section 164 of the Code, an annual fee (the ***overseas GMP compliance assessment fee***) is payable by the interested person, in relation to the registration of a veterinary chemical product, for each site outside Australia at which:

(a) the product is manufactured; or

(b) a step in the manufacture of the product occurs.

(3) However, the overseas GMP compliance assessment fee is not payable:

(a) in relation to a site if the interested person has, in the financial year in respect of which the fee is payable, already paid an overseas GMP compliance assessment fee in relation to another chemical product manufactured at the same site; or

(b) in relation to a chemical product that is:

(i) an exempt product within the meaning given by regulation 59; or

(ii) a listable chemical product; or

(iii) a reserved chemical product; or

(4) The amount of the overseas GMP compliance assessment fee is $1 000 for each financial year for which the registration is in force.

(5) The overseas GMP compliance assessment fee is payable on the date on which the interested person makes an application for renewal of the registration of the chemical product.

18 After regulation 71A

Insert:

71B Overseas GMP compliance assessment

(1) This regulation applies in relation to the registration of a veterinary chemical product if:

(a) the product is manufactured outside Australia; and

(b) the product is not:

(i) an exempt product within the meaning given by regulation 59; or

(ii) a listable chemical product; or

(iii) a reserved chemical product; and

(c) the registration of the product is subject to a condition that each step in the manufacture of the product complies with any of the following:

(i) the Code;

(ii) the manufacturing principles;

(iii) the Australian GMP Code;

(iv) any standards that apply to the chemical products;

(v) any standard determined by the APVMA to be comparable to the manufacturing principles or the Australian GMP Code; and

(d) the registration of the product is subject to a condition that the interested person in relation to the registration must, if directed by the APVMA CEO, give to the APVMA, or arrange for the manufacturer of the product to give to the APVMA, evidence of compliance with the condition mentioned in paragraph (c).

(2) For paragraph 6(2)(c) of the Act, subregulations (3) and (4) apply if the APVMA CEO has directed the interested person to provide

evidence of compliance with the condition mentioned in paragraph (1)(c).

(3) If a GMP audit was carried out, and a report of the audit has been given to the APVMA, the APVMA must assess the report having regard to:

(a) whether the audit report identified any non-conformances; and

(b) whether any non-conformances identified in the audit report have been rectified following corrective action; and

(c) any other matters that the APVMA considers relevant.

(4) The APVMA must:

(a) assess any evidence of compliance with the condition given to the APVMA by the interested person or on behalf of the interested person; and

(b) determine whether the APVMA is satisfied that the condition has been complied with.

(3) In this regulation:

GMP audit has the meaning given by paragraph 61(8)(a).

19 Regulation 72A

Repeal the regulation, substitute:

72A Fees for licences

(1) For section 164 of the Code, this regulation prescribes matters relating to fees payable in respect of licences issued under Part 8 of the Code.

Fee for licence application

(2) The fee payable for an application for the issue of a licence is $900.

Annual licence fee

(3) The holder of a licence must pay an annual licence fee, for each financial year in which the licence is held, as follows:

(a) for a category 1 licence—$7 500;
(b) for a category 2, 3 or 4 licence—$5 000;
(c) for a category 6 licence—$1 800;
(d) for a multi-category licence—$7 500.

(4) However, if a licence is issued on a date other than on 1 July in a financial year, the annual licence fee payable for the first financial year of the licence is a pro rata amount of the fee mentioned for the licence in subregulation (3) for the number of whole months of the financial year remaining on the date the licence is issued.

(5) The annual licence fee payable for a licence for the second financial year, and each subsequent financial year, in which the licence is held is reduced by 50% if the licence holder gives the APVMA satisfactory evidence that the total notional wholesale value of the chemical products manufactured under the licence in the previous financial year was less than $50 000.

(6) If a licence is not in force on 1 July of a financial year because the licence is suspended:
(a) an annual licence fee is not payable for the licence for that financial year unless the suspension is revoked later in the financial year; and
(b) the amount payable is a pro rata amount of the fee mentioned for the licence in subregulation (3) for the number of whole months of the financial year remaining on the date of the revocation.

(7) The annual licence fee is payable on receipt of an invoice for the fee issued by the APVMA.

Fee for variation of licence

(8) An additional fee of $1 800 is payable in respect of a licence if:
(a) the holder of the licence requests that the APVMA vary the licence; and
(b) the APVMA determines that a GMP audit is required in order to assess the request.

(9) The APVMA must waive any licence fees payable before 1 July 2013 under regulation 72A, as in force immediately on 30 June 2013, that are unpaid on 1 July 2013.

(10) In this regulation:

GMP audit has the meaning given by paragraph 61(8)(a).

notional wholesale value has the same meaning as in the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*.

(11) In subregulation (5):

(a) the notional wholesale value of a batch of a veterinary chemical product is the notional wholesale value at the time of completion of manufacture of the batch; and

(b) a reference to the chemical products manufactured does not include veterinary chemical products that are:

(i) exempt products within the meaning given by regulation 59; or

(ii) listable chemical products; or

(iii) reserved chemical products.

Note: Section 3 of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* has the following definition:

"***notional wholesale value***, in relation to a chemical product at a particular time, means the amount that the APVMA determines would have been received:

(a) if the product is an Australian product—by the manufacturer; or

(b) if the product is an imported product—by the importer;

in respect of the product if, at that time, the product had been sold by the manufacturer or importer, as the case may be, by wholesale to a person with whom the manufacturer or importer was dealing at arm's length."

20 Paragraphs 73(2)(a) and (b)

Omit "$90", substitute "$95".

21 Subregulation 78(3) (note)

Omit "$505", substitute "$535".

22 Regulation 78A (note 1)

Omit "$505", substitute "$535".

23 Part 1 of Schedule 3

Repeal the Part, substitute:

Part 1—Preliminary

1 Definitions

In this Schedule:

air conditioning means any cooling, heating or ventilation system that modifies the condition of the air.

cooling tower means:

(a) a device for lowering the temperature of water or other liquid by evaporative cooling; and

(b) an evaporative condenser that incorporates a device containing a refrigerant or heat exchanger.

open water cooling system means a water cooling system through which water flows once with no recirculation.

ore extraction and processing means the crushing and separating of ore into valuable substances or waste.

sewage means waste matter, including, but not limited to, household waste liquid from toilets, baths, showers, kitchens and sinks, that is disposed of using sewers.

sewage treatment means the physical, chemical and biological processes applied to sewage to remove physical, chemical and biological contaminants to produce wastewater, and a solid waste or sludge, suitable for disposal or re-use in the environment.

wastewater means the water remaining at the end of sewage treatment that may be released into the environment for re-use.

water cooling system means a cooling tower and its associated equipment and pipe work.

24 Part 2 of Schedule 3 (at the end of the table)

Add:

6	Parts of a vertebrate animal, material produced from a vertebrate animal or matter the production of which involves the use of a vertebrate animal, if represented supplied or used for a purpose mentioned in subsection 4(2) of the Code

25 Part 3 of Schedule 3 (at the end of the table)

Add:

20	Biocides used to control organisms in air conditioning or water-cooling systems, other than open water-cooling systems through which water flows once with no recirculation
21	Biocides used in sewage treatment to control organisms in sewage and wastewater
22	Biocides used to control organisms in water effluent from ore extraction and processing
23	Biocides to control organisms in water, used for the purpose of maintaining equipment associated with the extraction of coal seam gas in serviceable condition
24	Whole vertebrate animals if represented, supplied or used for a purpose mentioned in subsection 4(2) of the Code

26 Part 2 of Schedule 3AA (at the end of the table)

Add:

8	Parts of a vertebrate animal, material produced from a vertebrate animal or matter the production of which involves the use of a vertebrate animal, if represented supplied or used for a purpose mentioned in subsection 5(2) of the Code

27 Part 3 of Schedule 3AA (table item 8)

Omit "blood and stem cell products", substitute "blood, blood products, stem cells or stem cell products".

28 Part 3 of Schedule 3AA (at the end of the table)

Add:

10	Any product for topical application to an animal to act as a lubricant, that: (a) is chemically inert; and (b) does not act by biochemical means; and (c) is not a teat sealant; and (d) contains no antiseptic, antimicrobial, antibiotic or other active constituent; and (e) is not claimed to have any effect other than as a lubricant
11	Semen, ova or embryos if represented, supplied or used for the purpose of reproduction
12	Whole vertebrate animals if represented, supplied or used for a purpose mentioned in subsection 5(2) of the Code

29 Amendments of listed provisions

Amendments of listed provisions

Item	Provision	Omit	Substitute
1	Schedule 6, Part 2, item 1	53 745	72 100
2	Schedule 6, Part 2, item 3	34 925	48 465
3	Schedule 6, Part 2, item 4	23 330	27 505
4	Schedule 6, Part 2, item 5	3 630	3 655
5	Schedule 6, Part 2, item 6	2 470	3 220
6	Schedule 6, Part 2, item 7	660	1 315
7	Schedule 6, Part 2, item 8	595	1 250
8	Schedule 6, Part 2, item 9	545	1 195
9	Schedule 6, Part 2,	15 685	21 460

Amendments of listed provisions			
Item	**Provision**	**Omit**	**Substitute**
	item 11		
10	Schedule 6, Part 2, item 12	615	875
11	Schedule 6, Part 2, item 16	4 430	14 105
12	Schedule 6, Part 2, item 17	1 580	2 365
13	Schedule 6, Part 2, item 18	1 005	1 850
14	Schedule 7, item 1	505	535
15	Schedule 7, item 2.1	3 255	6 915
16	Schedule 7, item 2.2	2 230	2 305
17	Schedule 7, item 2.3	1 030	1 185
18	Schedule 7, item 2.4	200	570
19	Schedule 7, item 3.1	19 490	20 940
20	Schedule 7, item 3.3	2 900	3 035
21	Schedule 7, item 4	3 720	2 435
22	Schedule 7, item 5.1	5 595	13 630
23	Schedule 7, item 5.2	4 765	7 895
24	Schedule 7, item 5.3	2 490	6 150
25	Schedule 7, item 5.4	2 230	5 600
26	Schedule 7, item 5.5	1 175	1 500
27	Schedule 7, item 6.3	1 435	2 985
28	Schedule 7, item 7.1	12 605	19 795
29	Schedule 7, item 7.2	3 255	5 485
30	Schedule 7, item 7.3	620	1 290
31	Schedule 7, item 11.1	2 230	3 040
32	Schedule 7, item 11.3	620	645
33	Schedule 7, item 11.4	160	570
34	Schedule 7, item 12	170	345