Australian Government
Australian Pesticides and
Veterinary Medicines Authority

Our reference: LEX 4661

5 February 2016

Concerned
Concerned foi+request-1426-d827623e@righttoknow.org.au

By email: foi+request-1426-d827623e@righttoknow.org.au

Dear Concerned

Freedom of Information Request
Notice of Decision on Access
Details of companies subject to compliance action referred to in Regulatory Update 220

I refer to your request under the *Freedom of Information Act 1982* (**FOI Act**) received in this office on 10 December 2015.

2. You requested access to:

   '...the company name(s), the product (s) concerned and more detail regarding the compliance offences mentioned in your recent regulatory update nos 220'

3. On 23 December 2015, the Australian Pesticides and Veterinary Medicines Authority (**APVMA**) acknowledged receipt of your request.

4. On 24 December 2015, the APVMA advised that it had commenced consultation with third parties to your request pursuant to section 27 of the FDI Act.

5. On 27 January 2016, you clarified that the scope of your request was limited to the notices referred to in Regulatory Update 220.

6. I am an officer of the APVMA authorised under section 23 of the FOI Act to make a decision in relation to an access request. I am also authorised to make a decision about the publication of information released in response to an access request.

Decision

7. This letter sets out my decision in relation to your request for access. I have identified five documents relevant to your request. I have decided to:

   a. release all five documents in part.

8. I have decided that details of the request will be published on the APVMA's Disclosure Log and the documents will be made available to the public on request.

9. A statement of reasons in support of my decision is provided at **Attachment A.**

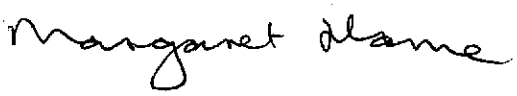
10. Review rights

11. You may seek review of this decision if you are not satisfied with it. If you wish to seek internal review of this decision, you need to expressly request in writing that the APVMA do this. If you wish to seek external review from the Office of the Australian Information Commissioner (OAIC) you need to follow the steps at http://www.oaic.gov.au/freedom-of-information/requesting-a-review. Please be aware that if you wish to seek review of this decision you have 30 days from receiving this letter to seek internal review from the APVMA, or 60 days to seek external review from the OAIC.

12. If you are concerned about the way your FOI request was handled you may formally lodge a complaint with the Commonwealth Ombudsman.

13. If you have any questions, please contact the FOI Team at foi@apvma.gov.au or on (02) 6210 4794.

Yours sincerely



Margaret Horne
Principal Legal Officer
Legal Program

Tel: (02) 6210 4782
Fax: (02) 6210 4787
Email: foi@apvma.gov.au

Attachment A

STATEMENT OF REASONS

Findings on material questions of fact

Scope of request

1. The initial scope of your request was:

   '...the company name(s), the product (s) concerned and more detail regarding the compliance offences mentioned in your recent regulatory update nos 220'

2. One of the objects of the FOI Act is to provide a right of access to documents of an agency, not merely or only to 'information'. In that context, confirmation was sought that you sought access to the relevant 'notices' referred to in Regulatory Update 220. This confirmation was provided by you on 27 January 2016.

Searches

3. As a result of the clarification or narrowing of the scope of your request on 27 January 2016, five documents were identified as satisfying the scope of your request.

Those documents are:

a. Infringement Notice number IN-2014/096-01, dated 3 November 2015 (**Document 1**);

b. Infringement Notice number IN-2014/096-02, dated 3 November 2015 (**Document 2**);

c. Formal Warning notice dated 26 October 2015 (**Document 3**);

d. Formal Warning notice dated 30 September 2014 (**Document 4**);

e. Formal Warning notice dated 26 November 2015 (**Document 5**).

Material relied on

4. In making my decision and preparing this statement of reasons, I have taken into account and relied on, the following material:

   a. the terms of the request dated 10 December 2015;

   b. the revised terms of the request dated 27 January 2016;

   c. the documents relevant to the request (identified above);

   d. responses of the third parties consulted in accordance with the FOI Act;

e. advice from APVMA officers within the Legal and Compliance Program with responsibility for matters relating to the documents to which you seek access;

f. the *Agricultural and Veterinary Chemicals Code* scheduled to *the Agricultural and Veterinary Chemicals Code Act 1994*;

g. the APVMA's Confidential Commercial Information Guideline;

h. the FOI Act, including the objects provision; and

i. the Guidelines issued under section 93A of the FOI Act by the Office of the Australian Information Commissioner (the Guidelines).

Reasons for decision

5. Pursuant to section 11A of the FOI Act, an agency must grant access to a document unless the agency is not required to grant access because the document is either an exempt document, or the document is a conditionally exempt document, and access to the document would be contrary to the public interest.

6. For the reasons set out below, I have decided to release the documents in part under sections 47G of the FOI Act and made relevant redactions pursuant to section 22(1) of the FOI Act.

Public interest conditional exemption - Business 47G(1)(a)

7. Section 47G (1)(a) of the FOI Act provides:

Public interest conditional exemptions—business

(1) A document is conditionally exempt if its disclosure under this Act would disclose information concerning a person in respect or his or her business or professional affairs or concerning the business, commercial or financial affairs of an organisation or undertaking, in a case in which the disclosure of the information:

(a) would or could reasonably be expected to, unreasonably affect that person adversely in respect of his or her lawful business or professional affairs or that organisation or undertaking in respect of its lawful business, commercial or financial affairs; or

(b) could reasonably be expected to prejudice the future supply of information to the Commonwealth, Norfolk Island or an agency for the purpose of the administration of a law of the Commonwealth or of a Territory or the administration of matters administered by an agency.

8. In relation to this exemption, the Guidelines explain:

Unreasonable adverse effect of disclosure

The presence of 'unreasonably' in s 47G(1) implies a need to balance public and private interests, but this does not amount to the public interest test of s 11A(5) which follows later in the decision process. It is possible that the decision maker may need to consider one or more factors twice, once to determine if a projected effect is unreasonable and again in assessing the public interest balance. This is inherent in the structure of the business information exemption.

The test of reasonableness applies not to the claim of harm but to the objective assessment of the expected adverse effect. For example, the disclosure of information that a business's activities pose a threat to public safety may have a substantial adverse effect on that business but it may be reasonable in the circumstances to disclose it. Similarly, it would not be unreasonable to disclose information about a business that revealed serious criminality. These considerations necessitate a weighing of a public interest (public safety) against a private interest (preserving the profitability of a business) but at this stage it bears only on the threshold question of whether the disclosure would be unreasonable.

...

Business or professional affairs

The use of the term 'business or professional affairs' distinguishes an individual's personal or private affairs and an organisation's internal affairs. The term 'business affairs' has been interpreted to mean 'the totality of the money-making affairs of an organisation or undertaking as distinct from its private or internal affairs'.

Are the documents conditionally exempt?

9. The Guidelines explain at paragraph 6.16 that for each of the conditional exemptions (except the deliberative process exemption), the harm threshold that must be reached is specified in the provision.

10. The 'harm threshold' in the business exemption in this case involves the notion that disclosure must reasonably be expected to have an unreasonable and adverse effect on the business affairs of the organisations concerned.

Could reasonably be expected

11. The Guidelines at paragraph 6.164 explain that mere assertion or speculative possibility is not enough. The third party submissions argue that disclosure could reasonably be expected to result in damage to product brand, discontinued use of the product and ultimately a reduction in sales and revenue.

12. I am required to assess the likelihood of the third parties' predicted or forecasted outcomes by the 'test' in the business exemption. The Guidelines explain at paragraph 5.14 that the use of the word 'could' rather than 'would' is less stringent and requires analysis of the reasonable expectation as opposed to the certainty of an event occurring.

13. I consider that in the circumstances disclosure of the documents could reasonably be expected to cause commercial and reputational harm to the products and companies concerned. I consider that there is a reasonable expectation that customers and clients would interpret the Formal Warnings and Infringement Notices as findings of guilt, and subsequently base their commercial decisions in relation to the products and companies on that presumption. I consider these forecast events to be clearly adverse to the interests of the companies concerned.

Unreasonable adverse effect of disclosure

14. I am required to consider whether disclosure would still be reasonable in the circumstances, given the projected adverse effects considered above. This involves determining if the public

interest benefit in disclosing the information justifies the adverse effect to the companies' commercial activities.

15. Section 145J of the *Agricultural and Veterinary Chemicals Code* scheduled to *the Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) provides that the APVMA may issue a formal warning in the following circumstances:

> (1) The APVMA may, by written notice, issue a formal warning to a person if the APVMA has reasonable grounds to suspect that the person may have contravened the Agvet Code of this jurisdiction.

16. The explanatory material to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act) , that introduced section 145J into the Agvet Code, explains that:

> Section 145J provides for the APVMA to issue formal warnings to a person which states the APVMA's belief that the person's specific actions may constitute non-compliance with the Agvet Code. The APVMA would use these notices in instances where it believed the non-compliant behaviour was inadvertent. The APVMA may use this option at its discretion. Warnings would be considered in the context of any future compliance and enforcement and penalty considerations. Non-compliance may result in a matter being escalated to investigation and used to support increased penalty for the same offence at a later stage. Warnings may be issued generally or to address possible breaches or contraventions against specific offence or civil penalty provisions in the Agvet Code.

17. Furthermore, the explanatory material provides that:

> The new provisions also provide the APVMA with the capacity to tailor its response to the seriousness of the non-compliance through a graduated range of compliance and enforcement measures.

18. I place particular significance on the use of Formal Warnings in circumstances of 'inadvertent' non-compliant behaviour and that these notices are issued at the lower end of the 'graduated range' of compliance powers.

19. On this basis, I have determined that disclosure of business information in the Formal Warnings would result in an *unreasonable* adverse effect on the third parties' business affairs.

20. In respect of the Infringement Notices, the Agvet Code provides that these may be given:

> **145DA When an infringement notice may be given**
>
> (1) If an inspector has reasonable grounds to believe that a person has contravened a prescribed civil penalty provision, the inspector may give the person an infringement notice for the alleged contravention.
>
> (2) The infringement notice must be given within 12 months after the day the contravention is alleged to have taken place.
>
> (3) A single infringement notice must relate only to a single contravention of a single prescribed civil penalty provision.

21. As with section 145J, the Amendment Act introduced section 145DA into the Agvet Code. The explanatory material sets out the intent of the penalty infringement notice (PIN) regime as:

> ...a means for rapid conclusion to instances of non- compliance without the expense associated with court proceedings. The ability to issue PINs would align the APVMA's regulatory control options with those of other comparable regulators. PINs provide the greatest flexibility for tailoring a proportionate response to instances of non-compliance.

22. The Infringement Notice, or the decision to issue one, is not reviewable. The only recourse available to the recipient is to write to the APVMA to consider withdrawing the notice.

23. I place particular significance on the fact that the third parties have not been the subject of any further action in the 'graduated range' of compliance actions – particularly court proceedings, and that there are limitations to the availability of merits review.

24. On this basis, I have determined that disclosure of business information in the Infringement Notices would result in an *unreasonable* adverse effect on the third parties' business affairs.

25. Accordingly, I find the documents conditionally exempt.

Applying the public interest test

26. After making a finding that documents are conditionally exempt, I am required to apply the public interest test before concluding the document is exempt from disclosure.

Factors favouring disclosure

27. The FOI Act sets out four factors favouring access, which must be considered if relevant. They are that disclosure would:

    (a) promote the objects of the Act
    (b) inform debate on a matter of public importance
    (c) promote effective oversight of public expenditure
    (d) allow a person to access his or her personal information (s 11B(3)).

28. The Guidelines provide a non-exhaustive list of factors favouring disclosure at paragraph 6.25.

29. I consider that the factors favouring disclosure include informing debate on a matter of public importance, namely the effective oversight of compliance of agricultural and veterinary products.

Factors against disclosure

30. The Guidelines provide a non-exhaustive list of factors against disclosure at paragraph 6.29.

31. I consider that the factors against disclosure include the reasonable expectation of harm to the interests of a group of individuals in the sense that disclosure could reasonably be expected to reveal commercially sensitive information that would result in a commercial disadvantage to the third parties to this request.

Balancing the factors

32. In the circumstances, I find that the factors against disclosure outweigh the factors in favour of disclosure.

33. The fact the notices have been issued demonstrates that the range of compliance measures is being used appropriately by the APVMA and that alleged contraventions of the Agvet Code are being investigated thoroughly by the APVMA.

34. I note that the descriptions of the alleged contraventions are visible in the documents. I am not persuaded that revealing the company and product names would add any value to discussions about compliance activities of the APVMA, particularly in the individual circumstances in which the notices were issued and taking into account no further compliance action has been undertaken.

35. In balancing the public interest factors, I am not satisfied that the benefits of disclosing the information you have requested would outweigh the harm it would cause to the third parties, particularly in circumstances where the matters complained of are at the lower range of the compliance offence spectrum.

36. Accordingly, I find documents exempt under section 47G.

37. In accordance with section 22 of the FOI Act, I have prepared an edited version of the documents with the exempt material redacted.

Publication of information to the APVMA's Disclosure Log

38. The APVMA is required to publish details of information released under the FOI Act to its website, unless publication would be unreasonable.

39. As I have granted partial access to the documents, I am now obliged to consider whether, pursuant to section 11C of the FOI Act, the documents ought to be published.

40. I have considered section 11C of the FOI Act, the Guidelines, and the APVMA's Confidential Commercial Information Guideline.

41. I have decided to publish details of the request on the APVMA's Disclosure Log and make the documents available on request. Publication will occur within 10 days of the APVMA providing access to you.

Margaret Horne
Principal Legal Officer
Legal Program

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*
Section145DA

Infringement Notice Number **IN-2014/096-01**

INFRINGEMENT NOTICE

Date notice issued:	3 November 2015
Notice issued by:	Natasha Ackland (Inspector)
Recipient name:	s. 47G(1)(a)
Recipient address:	[redacted]

The inspector identified above has reasonable grounds to believe that you have contravened a prescribed civil penalty provision of the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*. As a result you have been issued with this infringement notice.

The details of the alleged contravention are below.

Provision allegedly contravened:	Section 83(1) of the Agricultural and Veterinary Chemicals Code Act 1994
Date of alleged contravention:	Between 2 January 2015 and 31 March 2015
Place of alleged contravention:	s. 47G(1)(a) [redacted]
Description of alleged contravention:	Between 2 January 2015 and 31 March 2015, s. 47G(1)(a) [redacted] allegedly supplied a mixture of substances in a container to which is attached a label containing the name of a registered chemical product, namely s. 47G(1)(a) [redacted] s. 47G(1)(a) [redacted] where the constituents of the mixture differed by more than the prescribed extent from the constituents of the registered chemical product that are shown in the particulars for the registered chemical product contained in the APVMA Register.
The maximum penalty that could be imposed by a court for the contravention is:	$ 1,350,000.00

The amount payable to the Commonwealth under this notice is:	**$13,500.00**

PLEASE SEE THE NEXT PAGE OF THIS NOTICE FOR FURTHER INFORMATION AND PAYMENT INSTRUCTIONS

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*
Section145DA

Infringement Notice Number **IN-2014/096-02**

INFRINGEMENT NOTICE

Date notice issued:	3 November 2015
Notice issued by:	Natasha Ackland (Inspector)
Recipient name:	s. 47G(1)(a)
Recipient address:	

The inspector identified above has reasonable grounds to believe that you have contravened a prescribed civil penalty provision of the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*. As a result you have been issued with this infringement notice.

The details of the alleged contravention are below.

Provision allegedly contravened:	Section 161(1) of the Agricultural and Veterinary Chemicals Code Act 1994
Date of alleged contravention:	Between 5 November 2014 and 17 April 2015
Place of alleged contravention:	s. 47G(1)(a)
Description of alleged contravention:	Between 5 November 2014 and 17 April 2015, s. 47G(1)(a), being the holder of a registration for a chemical product, namely s. 47G(1)(a) s. 47G(1)(a) did allegedly become aware of relevant information in relation to that product and its active constituents and did not, as soon as they became aware of the information, give that information to the APVMA.
The maximum penalty that could be imposed by a court for the contravention is:	$ 1,350,000.00

The amount payable to the Commonwealth under this notice is:	**$13,500.00**

PLEASE SEE THE NEXT PAGE OF THIS NOTICE FOR FURTHER INFORMATION AND PAYMENT INSTRUCTIONS

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Formal Warning

Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994

Subsection 145J (1) – APVMA may issue a formal warning

To: s. 47G(1)(a)

I, Drew Matthew Ward, a delegate of the Australian Pesticides and Veterinary Medicines Authority (APVMA), have reasonable grounds to suspect that s. 47G(1)(a) may have contravened the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). For this reason I am issuing [redacted] with a formal warning pursuant to subsection 145J (1) of the Agvet Code.

Provision allegedly contravened: Section 78: Supply of chemical products that are not registered products or reserved products.

Date of suspected contravention: Between 5 August 2014 and 28 August 2014.

Details of suspected contravention: s. 47G(1)(a) supplied the chemical products: s. 47G(1)(a) s. 47G(1)(a), that were not registered chemical products at the time.

The APVMA has issued this formal warning to draw s. 47G(1)(a) attention to this matter and provide s. 47G(1)(a) with a reasonable opportunity to ensure future conduct complies with the relevant requirements under the Agricultural and Veterinary Chemicals Code.

When deciding whether to issue s. 47G(1)(a) with any warnings in the future, the APVMA will give reference to your actions in the context of relevant compliance, enforcement and penalty considerations. The APVMA will also give weight to the fact that s. 47G(1)(a) has been previously issued with this formal warning.

Signed: .....

Name: Drew Ward

Position: Director, Compliance & Monitoring

Date: 26 October 2015

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Formal Warning

Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994

Subsection 145J (1) – APVMA may issue a formal warning

To: s. 47G(1)(a)

I, Phil Rohan, a delegate of the Australian Pesticides and Veterinary Medicines Authority (APVMA), have reasonable grounds to suspect that s. 47G(1)(a) may have contravened the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). For this reason I am issuing s. 47G(1)(a) with a formal warning pursuant to subsection 145J (1) of the Agvet Code.

Provision allegedly contravened:	Section 83: Supply of substances whose constituents differ from constituents of a registered chemical product.
Date of suspected contravention:	Between November 2014 and March 2015.
Details of suspected contravention:	s. 47G(1)(a) s. 47G(1)(a) supplied a registered chemical product, s. 47G(1)(a) s. 47G(1)(a), in a container to which was attached a label containing the name of the registered chemical product, the constituents of which differed by more than the prescribed extent from the constituents of the registered chemical product shown in the Register.

The APVMA has issued this formal warning to draw s. 47G(1)(a) attention to this matter and provide s. 47G(1)(a) with a reasonable opportunity to ensure future conduct complies with the relevant requirements under the *Agricultural and Veterinary Chemicals Code*.

When deciding whether to issue s. 47G(1)(a) with any warnings in the future, the APVMA will give reference to your actions in the context of relevant compliance, enforcement and penalty considerations. The APVMA will also give weight to the fact that s. 47G(1)(a) has been issued with this formal warning.

Signed: .....
Name: Phil Rohan
Position: A/g Director, Compliance & Monitoring
Date: 30 September 2015

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Formal Warning

Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994

Subsection 145J (1) – APVMA may issue a formal warning

To: s. 47G(1)(a)

I, Drew Matthew Ward, a delegate of the Australian Pesticides and Veterinary Medicines Authority (APVMA), have reasonable grounds to suspect that s. 47G(1)(a) may have contravened the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). For this reason, I am issuing s. 47G(1)(a) with a formal warning pursuant to subsection 145J (1) of the Agvet Code.

Provision/s allegedly contravened:	Section 79: Supply of registered chemical products in contravention of conditions of registration Section 83: Supply of substances whose constituents differ from constituents of registered chemical product Section 161: Notification of New Information to APVMA
Date/s of suspected contravention/s:	Between 14 April 2015 and 15 September 2015
Details of suspected contravention/s:	s. 47G(1)(a) manufactured and supplied a registered chemical product, s. 47G(1)(a) s. 47G(1)(a) in a container to which was attached a label containing the name of the registered chemical product, the constituents of which differed by more than the prescribed extent from the constituents of the registered chemical product shown in the Register

The APVMA has issued this formal warning to draw s. 47G(1)(a)'s attention to this matter and provide s. 47G(1)(a) with a reasonable opportunity to ensure that future conduct complies with the relevant requirements under the Agvet Code.

When deciding whether to issue s. 47G(1)(a) with any warnings in the future, the APVMA will give reference to your actions in the context of relevant compliance, enforcement and penalty considerations. The APVMA will also give consideration to having previously issued s. 47G(1)(a) with this formal warning.

Signed: .....

Name: Drew Matthew Ward

Position: Director, Compliance & Monitoring (0065)

Date: 26 November 2015