



NEW ZEALAND
LAW SOCIETY

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AGRICULTURAL COMPOUNDS AND VETERINARY MEDICINES AMENDMENT BILL

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THE AGRICULTURAL COMPOUNDS AND VETERINARY MEDICINES AMENDMENT BILL

Summary

1. The New Zealand Law Society (Law Society) welcomes the opportunity to comment on the Agricultural Compounds and Veterinary Medicines Amendment Bill (Bill). The Law Society notes that as New Zealand has concluded negotiations on the Trans-Pacific Partnership (TPP), further amending legislation in relation to data protection periods is likely to be required. Parliament may consider it more efficient to defer progress of the Bill pending the implementation of the TPP.
2. If the Bill is to proceed in its current form, the submission also makes technical comments on other aspects of the Bill relating to registration provisions and the Bill's interface with the Hazardous Substances and New Organisms Act 1996 (HSNO Act).

Introduction

3. New Zealand's current regulatory regime in respect of data protection for agricultural compounds – Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997 (Act) – complies with obligations under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Article 39.3 of that Agreement requires signatories to provide some form of data protection for agricultural chemicals that involve new chemical entities, although it does not set a minimum period of protection. The New Zealand regime provides 5 years' data protection for applications to register innovative agricultural compounds (i.e. those containing an active chemical ingredient that has not previously been registered in New Zealand).
4. The Minister for Primary Industries stated in the first reading debate on the Bill that after a review, "the Government decided that modest extensions to data protection provisions are warranted".¹ In addition to the current 5 year basic protection period, the Bill provides an extended period of protection for new uses of registered innovative trade name products (TNP) of 1 year for each new use, up to a maximum of 3 years, so that the total period of protection would be 8 years maximum (clause 6: proposed section 74B(5) – (7)). The Bill also introduces 3 years' data protection for applications to register non-innovative TNP or new uses for non-innovative TNP (proposed sections 74C – 74F).

Interface with TPP

5. The TPP requires a minimum 10 year data protection period for a new agricultural product.² The Law Society expects that the data protection regime proposed in this Bill will therefore need to be

¹ 15 September 2015. Hansard Volume: 708; Page: 6619, http://www.parliament.nz/en-nz/pb/debates/debates/speeches/51HansS_20150915_00001275/guy-nathan-agricultural-compounds-and-veterinary-medicines.

² Article 18.47 of the TPP text released by the Ministry of Foreign Affairs and Trade on 5 November reads:

Article 18.47: Protection of Undisclosed Test or Other Data for Agricultural Chemical Products

1. *If a Party requires, as a condition for granting marketing approval² for a new agricultural chemical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product,² that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar² product on the basis of that information or the marketing approval granted to the person that submitted such test or other data for at least ten years² from the date of marketing approval of the new agricultural chemical product in the territory of the Party.*
2. *If a Party permits, as a condition of granting marketing approval for a new agricultural chemical product, the submission of evidence of a prior marketing approval of the product in another territory, that Party shall*

amended in the near future when Parliament implements the TPP. Accordingly, the Law Society proposes that Parliament should consider deferring the Bill until Parliament is implementing the TPP.

That is because:

- a. it is not a sensible use of Parliamentary time and resources to deal with the Bill at this time; and
- b. enacting the Bill may create an expectation that the 3 year extended period of protection will be included in the amendments to give effect to the TPP, thereby creating a total protected period of 13 years; and
- c. there is a risk of creating regulatory confusion.

Use of resources

6. To comply with article 18.47.1 of the TPP, the basic protected period of 5 years will need to be replaced with a 10 year basic protected period.
7. The Bill's Regulatory Impact Statement (RIS) states that the policy was developed from an analysis of an independent study of the effects of New Zealand's protection rules on the market for agricultural compounds (the "Covec Study").
8. The Covec Study and the RIS are both predicated on the basic term of data protection for agricultural compounds being 5 years (not 10). The Bill provides additional terms of data protection for new uses of registered agricultural chemicals, to a maximum total of 8 years. When the TPP is implemented creating a 10 year basic protected period, there will need to be a reconsideration of the need for extended periods of protection.

Creating an expectation of a 13 year protected period

9. The introduction of extended periods of protection now may create an expectation that extended periods will also be included in the regime after the implementation of the TPP. It may be difficult to take away extended periods for new uses once extended periods are in force. So if the Bill is enacted and TPP later implemented, the possible outcome is a 10 year basic protected period and an extended protected period of up to 13 years.

Regulatory confusion

10. Enacting the Bill and then subsequently implementing TPP could lead to regulatory confusion. The current regime will be replaced by the one proposed in this Bill, and that regime is likely to be replaced shortly thereafter by one that is compliant with TPP.

not permit third persons, without the consent of the person that previously submitted undisclosed test or other data concerning the safety and efficacy of the product in support of that prior marketing approval, to market the same or a similar product based on that undisclosed test or other data, or other evidence of the prior marketing approval in the other territory, for at least ten years from the date of marketing approval of the new agricultural chemical product in the territory of the Party.

3. *For the purposes of this Article, a new agricultural chemical product is one that contains² a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product. [citations omitted]*

Recommendation:

11. That consideration be given to deferring progress of the Bill pending the implementation of the Trans-Pacific Partnership.

Deferring registration

12. The following remarks are relevant if the Bill does continue.
13. The policy of the Bill is to encourage registration for as many uses as justifiable from as early a stage as possible. But the Bill may have the unintended consequence that rather than having several uses registered from the outset, second, third and fourth uses might not be registered until sometime after the first use.
14. Clause 74B of the Bill allows for an extended protected period for each new use authorised by the granting of a variation application. The Law Society is concerned that an applicant for registration of a trade name product will be encouraged by the Bill to base the original application on a single use rather than listing all uses from the outset. Then, when the original application is registered, the applicant will file one or a series of variations to introduce the other uses. In that way the applicant extends the protected period.
15. The issue can be demonstrated by adapting the example from clause 74B of the Bill. At present an applicant with data to establish use on species A, B and C will apply for use on species A, B and C. The applicant will get a 5 year protected period. Under the Bill the applicant could decide to apply only for species A. When that use is granted the applicant separately applies for species B and C. The applicant then gets a data protection period extended from 5 to 7 years. The unintended consequence is that approval for use on species B and C is delayed.
16. The Law Society considers the intended policy of the Bill and avoiding gaming the system could be achieved by allowing for a basic protected period that is five years for one use, six years for two uses et cetera, up to a maximum of eight years. To encourage registration of further new uses there should still be an extended protected period for each new use authorised by the granting of a variation application, but up to a maximum of eight years in total.
17. The Law Society recognises that such a proposal may encourage applicants to specify several narrow uses in their original application. But that encouragement will already exist if the Bill is enacted to grant extended protected periods based on new uses.

Recommendation:

18. That consideration be given to amending the basic protected period to five years for one use, six years for two uses et cetera, up to a maximum of eight years.

Relationship with HSNO Act

19. Some innovative trade name products may also be new organisms or hazardous substances subject to approval under the HSNO Act 1996. In such cases, for data protection to be effective, the Environmental Protection Agency (EPA) must be subject to the same obligations of confidentiality and noncross-referencing as the Director-General of the Ministry for Primary Industries (MPI).
20. New subsections 55(3) to (7) of the HSNO Act (in Schedule 2 of this Bill) meet this obligation. The new wording is clearer than the wording it replaces in spelling out the obligations on the EPA because of the overlap of regulatory requirements.

21. However, section 57 of the HSNO Act could be interpreted as an exception to the obligations of the EPA under amended section 55. Section 57 provides that:
- where the EPA holds supplied information that has been classified by the supplier as commercially sensitive; and
 - an Official Information Act request has been made to release that information; and
 - the person who supplied the information does not respond to a notice from the EPA stating “whether the person believes that the information should be withheld”; then
 - the EPA may release the information.

Recommendation:

22. In view of the fact that the Act and the HSNO Act are administered by different agencies, that consideration be given to amending section 57(1) of the HSNO Act by inserting: “other than confidential information subject to the provisions of Sections 23A to 23C of the Medicines Act 1981³ or Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997” after “application” in line 2.

Minor technical correction

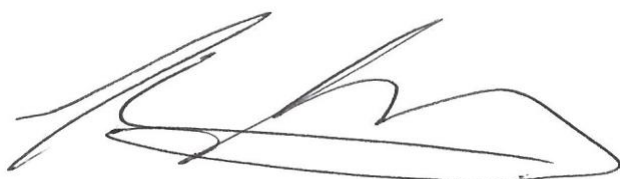
23. Clause 74B(6)(b) seems to be an alternative to clause 74B(6)(a), yet clause 74B(6)(a) ends with a colon. It appears this clause should end with “; or”.

Recommendation:

24. That the colon in clause 74B(6)(a) be replaced with “; or”.

Conclusion

25. The Law Society does not wish to be heard, but is available to meet with the officials advising on the Bill if the Committee considers that this would be of assistance.



Kathryn Beck
President-elect
29 January 2016

³ Although the Medicines Act 1981 is not being amended by this Bill, new section 55(3) of the HSNO Act (which refers to the Medicines Act 1981) is.