

6 Confidential Information

6.1 Summary

The Royal Commission on Genetic Modification recommended that the HSNO Act and the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.

As a result, the Government has directed officials to undertake consultation with key stakeholders to determine the level of protection that is appropriate for commercially sensitive or confidential supporting information provided with applications for approval, with a view to amending the HSNO and ACVM Acts.

Two main areas are addressed: the notification requirements in the HSNO and ACVM Acts relating to requests to release confidential information under the Official Information Act 1981 (OIA), and the special protection against release provided in accordance with the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

The HSNO and ACVM Acts require that suppliers of confidential information be notified when a request is received for that information under the OIA. If no response is received from that person, the Act allows for the information to be released without further reference to that person. Four options are presented for amending the notification provisions.

It is proposed that the special protection afforded in accordance with the TRIPs agreement be extended to confidential information supplied with all hazardous substances and new organisms that are the subject of innovative agricultural compound or medicine applications. We are seeking comment on the further extension of such protection to other innovative hazardous substance and new organism applications, and what the criteria for those applications might be. Additional comment is sought on related matters such as the cross-referencing of data and the length of the period of protection.

6.2 Confidential information: the issues

The concern is with the confidentiality of information (including confidential supporting information) provided to ERMA and the ACVM Group⁶ with applications under the HSNO and ACVM Acts, respectively.

In general, such information is subject to both the New Zealand Bill of Rights Act 1990 and the OIA. Rights under the Bill of Rights Act include the right to seek, receive and impart information of any kind and in any form. The OIA presumes that information will be disclosed unless there are grounds for withholding the information. There are also other considerations favouring disclosure. For example, the HSNO Act (but not the ACVM Act nor the Medicines Act) has a strong emphasis on public participation. Sufficient information therefore has to be provided with applications for a submitter to adequately understand and comment on the effects of the organism.

Further, the general philosophy of the HSNO Act is that an approval relates to the substance or organism – not the applicant. This contrasts with the approach under the ACVM Act, where trade named products are registered to applicants. Under the HSNO Act anyone can do what the substance or organism has been approved for, provided they comply with the controls and conditions of the approval (published in the public register of applications). Section 29A of the HSNO Act (approval for innovative agricultural compounds and medicines) is an exception to that philosophy.

Release of confidential information may occur as part of agencies' general dealing with information submitted with applications or through a request under the OIA. The concern is that information might be accidentally divulged or made available through an OIA request to a third person, including an applicant's competitors, because of miscommunication or delays in an applicant responding under the current notification procedures specified in the HSNO and ACVM Acts.

6.2.1 Patents Act

One of the requirements of the granting of a patent is that the invention be novel. If information about an invention is released before a patent application is filed, then this may prejudice the grant of the patent, both in New Zealand and overseas, as the invention would no longer be considered novel.

Under section 60(1) of the Patents Act 1953, the novelty of an invention would not be destroyed if the invention is disclosed to a government department or to a person authorised by a government department to investigate the invention. If confidential information about an invention was inadvertently made public by a government department (or anyone else), then this would destroy the novelty of the invention.

⁶ The ACVM Group is responsible for the regulatory control of agricultural compounds (veterinary medicines/plant compounds), and their importation, manufacture, sale and use on behalf of the Director-General, Ministry of Agriculture and Forestry, under the ACVM Act 1997.

An amendment to the Patents Act proposed as part of the current review⁷ of that Act would provide that disclosure of an invention by way of a breach of confidence would *not* destroy the novelty of an invention. This provision would, however, only apply in relation to the grant of a patent in New Zealand. The accidental release of confidential information could still prevent the grant of a patent in other countries that do not have similar provisions in their patents legislation.

6.2.2 Special protection

New Zealand has certain obligations in relation to protection of confidential supporting information through the fact that it is party to the WTO TRIPs agreement.

Article 39.3 of the TRIPs agreement provides:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The rationale behind this provision is that protecting confidential data supports the aim of fostering innovation. To obtain regulatory approval, people are required to disclose to government authorities commercially valuable information that would otherwise remain secret. To encourage full and frank disclosure of such information as is necessary for regulatory approval to be given, people need to be certain that the information they provide is properly protected. It is also in the public health interest for there to be regulatory control of dealings with products that could harm public health.

Section 55 of the HSNO Act and Part 6 of the ACVM Act include the provision of protection to confidential supporting information in recognition of these objectives. Under the HSNO Act such protection is provided for hazardous substances that are also the subject of innovative agricultural compound or innovative medicine applications under the ACVM and Medicines Acts. In submissions to the Royal Commission there were, however, concerns as to whether the extent of that protection is more limited than under the previous regulatory regime.

⁷ For further information on the Patents Act review, visit www.med.govt.nz/buslit/int_prop/patentsreview/index.html.

6.3 What is confidential information?

Neither ‘commercially sensitive’ nor ‘confidential supporting information’ are defined directly in the HSNO Act. However, the relevant provisions of the ACVM Act and the Medicines Act apply in some circumstances. Those Acts have the following definitions:

Confidential supporting information means confidential information given –

- (a) *In, or in relation to, an innovative [agricultural compound/medicine] application; and*
- (b) *About the [agricultural compound/medicine] that is or was, as the case may be, the subject of that application:*

[Confidential information includes –

- (a) *Trade secrets; and*
- (b) *Information that has commercial value that would be, or would be likely to be, diminished by disclosure:]*

The question then arises: Is this definition of confidential information too broad? The OIA refers to situations whereby the disclosure “would be *likely unreasonably* to prejudice the commercial position of the person”. Similarly, the Australian Gene Technology Act,⁸ for example, refers to:

- (a) *a trade secret; or*
- (b) *any other information that has a commercial value or other value that would be, or **could reasonably be expected to be**, destroyed or diminished if the information were disclosed; or*
- (c) *other information that:*
 - (i) *concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and*
 - (ii) *if it were disclosed, **could unreasonably affect** the person, organisation or undertaking; ...[emphasis added]*

6a Should the definition of confidential information also include the element of reasonableness?

⁸ For further information on this Act and the Office of the Gene Technology Regulator, see www.ogtr.au/publications/legislation.htm and www.ogtr.gov.au/, respectively.

A related question is: Who decides what is confidential information? Under the HSNO and ACVM Acts, applicants are able to identify or classify information they consider to be confidential or commercially sensitive. However, where a request is received under the OIA, generally the regulator may make its own decision as to what information may be withheld under the OIA if it is satisfied that “the withholding of that information is not outweighed by other considerations which render it desirable, in the public interest, to make that information available”. In contrast, the Australian Gene Technology Act requires that a formal application be made to the Gene Technology Regulator for a declaration that the information supplied is confidential commercial information for the purposes of the Gene Technology Act. Similar to the OIA, the Gene Technology Act must be satisfied that the public interest in disclosure does not outweigh the prejudice that the disclosure would cause to any person.

6b Should there be a formal process in the HSNO and ACVM Acts for identifying what is confidential or commercially sensitive information?

6.4 OIA requests for information

In the case of an OIA request for official information, the standard OIA grounds for withholding information apply. However, when an OIA request is made, the HSNO (section 57) and ACVM (section 12) Acts require that the person who classified the information as commercially sensitive be notified of the request. If that person does not respond within 10 days, ERMA or the Director-General of MAF may release the information. There is no express obligation under the OIA to notify the person who supplied the information; although in practice natural justice and general principles of administrative law would require an agency to contact that person.

These provisions give an opportunity for the original classifier to put forward reasons why the information should not be released. However, some industry sectors have expressed concern that a lack of response (for whatever reason) may be interpreted by ERMA or the ACVM Group (in exercising their power to withhold or release the information) as indicating that the information is no longer confidential or commercially sensitive. Conversely, these sections are seen by some as increasing the emphasis on freedom of information by increasing the likelihood of release of information that might otherwise have been withheld.

The options here are to:

- **Option 1:** Retain the status quo.
- **Option 2:** Amend the HSNO and ACVM Acts:
 - (i) by deleting the notification requirement completely (therefore relying solely on the OIA); or
 - (ii) to clarify what is required by ‘notification’; for example, to ensure that direct contact is made with either the person who supplied the information (or their organisation), or at least a reasonable attempt is made; or
 - (iii) so that the reference is to the action that may be taken under the OIA (to decide whether or not non-disclosure is outweighed by the public interest in release) rather than to the action of release.

6c Which option do you prefer, and why?

6d Have you been notified of an OIA request for information you have supplied? If so, please let us know how you found the above process.

6.5 What are appropriate levels of protection?

6.5.1 Pharmaceutical or agricultural chemical products

The special protection afforded under s55 of the HSNO Act to confidential supporting information in accordance with the TRIPs agreement is only available where it relates to applications for *hazardous substances* that are *also* the subject of innovative agricultural compound or medicine applications under the ACVM and Medicines Acts, respectively.

The Royal Commission was concerned that when the HSNO Act came fully into force for hazardous substances⁹ (and, with the ACVM Act, replaced the Pesticides Act 1981 and the Animal Remedies Act 1967), confidential supporting information submitted to ERMA with GMO applications would not have the protection it has under the ACVM and Medicines Acts and had under the Pesticides and Animal Remedies Acts.

This concern arises because the definition of hazardous substance in the HSNO Act does not include certain organisms (including GMOs) that come within the definition of a medicine or an agricultural compound under the Medicines Act and the ACVM Act, respectively. Therefore, the scope of the protection available for confidential supporting information, now that the HSNO Act is fully in force, may be more limited than previously.

This means that information provided in relation to applications for marketing approval for agricultural or pharmaceutical products, *other than* 'hazardous substances' that use new chemical entities, are not granted any special protection from disclosure and instead are subject to the ordinary application of the OIA.

It is therefore proposed that the special protection provided to confidential supporting information by the HSNO Act be extended to all hazardous substances or new organisms that are the subject of an innovative agricultural compound or medicine application. This would ensure the same level and breadth of protection for confidential supporting information as existed prior to the HSNO Act coming fully into force.

6e Do you have any comments on this proposal?

⁹ The ACVM Act and the remaining provisions of the HSNO Act for hazardous substances came into force on 2 July 2001.

6.5.2 Other new organisms or new hazardous substances

The Royal Commission correctly identified that there is no protection for confidential supporting information provided to ERMA with applications for any new organisms (whether genetically modified or not). Such protection is not required under the TRIPs agreement unless the organism can be considered part of a pharmaceutical or agricultural chemical product that utilises new chemical entities.

A relevant point here is that the HSNO Act is unusual internationally in requiring formal regulatory approval for GMOs. Where no formal regulatory approval is required, the situation does not arise as no application and therefore no confidential supporting information is required.

The Australian Gene Technology Act is another example where regulatory approval is required. As noted above, a person making an application to the Gene Technology Regulator may seek a declaration that certain information is confidential commercial information. However, there is otherwise no special protection from disclosure and instead the information is subject to the ordinary application of the Australian Freedom of Information Act 1982 – the equivalent of the OIA. In refusing to declare that the information is confidential commercial information, the Regulator must be satisfied that the public interest in disclosure outweighs the prejudice the disclosure would cause to any person.

A similar situation to that for new organisms may arise with new hazardous substances that are not the subject of innovative agricultural compound or medicine applications, but that may be considered ‘innovative’ hazardous substances.

6f Should the TRIPs-based protection provided to confidential supporting information by the HSNO Act be extended to those applications for new organisms or new hazardous substances that are not the subject of an innovative agricultural compound or medicine application (i.e. that do not also require parallel approval under the ACVM or Medicines Act) or is the protection under the OIA sufficient?

If it is considered that the protection should be extended, then the question arises as to what new organism or new hazardous substance applications should be covered; or, alternatively, what is an ‘innovative’ organism or hazardous substance application? In effect, this raises the question of whether all special protection should be made specific to the HSNO Act and not dependent on provisions in the ACVM or Medicines Acts.

In the cases of hazardous substances or new organisms that are the subject of an innovative agricultural compound or medicine application, the requirement is driven by the requirement for approval (and their status) under the ACVM and Medicines Acts. Innovative agricultural compound and medicine applications under those Acts refer to the active ingredient of the trade-named agricultural compound or of the medicine, for which no prior application has been made (other than for provisional consent). Article 39.3 of the TRIPs agreement refers to a “new chemical entity”. On that basis, a pragmatic approach may be to consider a chemical or biological (new organism) entity as new when it has not been previously submitted for regulatory approval in New Zealand.

6g Do you agree that the special protection be specific to the HSNO Act?

6h For what applications should such protection be available?

Please illustrate your comments with examples and refer to the relevant provisions of the HSNO Act where necessary.

6.5.3 Cross-referencing data

Consideration needs to be given to the situation where confidential supporting information provided as part of one application is used in the assessment of another application (for example, one made by a competitor).

For hazardous substances that are the subject of innovative agricultural compound or medicine applications, the HSNO Act refers to the ACVM Act and Medicines Act:

If [the] information [held by ERMA] ... in respect of [those] substances includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure, –

the provisions of ... with the necessary modifications, apply to that information as if the information were confidential supporting information as defined in ... that Act.

These provisions require, during the protected period, that reasonable steps be taken to ensure that the confidential supporting information is kept confidential and that the information must not be used for the purposes of determining whether to grant any other application. There are exceptions for disclosure: on the consent of the applicant, or (on condition that reasonable steps are taken to ensure that the information is kept confidential) where necessary to protect the health and safety of members of the public, and for the purposes of a government department or statutory body or international regulatory agency.

As noted above, the Act provides an exception to the general philosophy of the HSNO Act – where an approval relates to the substance or organism, not the applicant – for hazardous substances that are the subject of an innovative agricultural compound or medicine application. These provisions support that exemption.

6i If the special protection is extended to other applications, as above, should the prohibition on cross-referencing data be extended also?

Please give your reasons.

6.5.4 Length of protected period

The HSNO Act refers to both the ACVM Act and the Medicines Act. These Acts provide a five-year protection period while the agricultural compound or medicine is being developed; for example, while under a provisional registration or consent. If a decision to register occurs within that five-year period, a second five-year period is provided.

6j Do you agree or disagree that this period be changed?

Please give your reasons.