

ERMA NEW ZEALAND

INFORMATION SHEET

NUMBER 12
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Confidential Information

Introduction

To ensure proper consideration of the risks, costs and benefits associated with hazardous substances and new organisms, adequate information must be available. However, the innovative nature of many new organisms and hazardous substances considered by the Authority means that specific information about them is likely to be highly confidential because of commercial sensitivity.

The HSNO Act provides for public participation in the approval process. There is likely to be conflict between the commercial sensitivity of some information and the requirement to provide for effective public participation.

This information sheet describes how confidential information will be managed under the HSNO Act processes.

What is confidential information?

Generally, information which can be withheld under the Official Information Act 1982 (OIA) can be confidential information under HSNO. The most likely grounds for withholding information – specifically referred to in the HSNO Act – is spelled out in the OIA. It applies where withholding the information is necessary to 'protect information where the making available of the information would disclose a trade secret or would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information'. (OIA, s9 (2)(b)).

While ERMA New Zealand must make the decision whether information is released, we rely on the person providing such information to identify it as confidential, and to justify this position.

Protection of confidential information

Information supplied by a prospective applicant at the pre-application stage is held by ERMA New Zealand on behalf of that person and the Official Information Act does not apply to it. This information will not be released without the permission of the provider and will be returned on request.

Confidential information is securely stored, and is not released when any application is publicly notified.

If we receive a request under the Official Information Act to release information identified as being confidential, we must advise the person who provided the information. The provider has ten working days to advise whether the information should be withheld under the OIA (and why) before ERMA New Zealand decides to release or withhold the information.

Any decision to withhold information under the OIA is subject to review by the Ombudsman.

Providing the action is in accordance with our statutory obligations, we will treat it as confidential for as long as is specified by the applicant or submitter. All information provided by an applicant or submitter classified as such by that person remains commercially confidential.

Where we believe that information identified as confidential by the person who supplied it does not fall within the statutory criteria for withholding such information, we will advise the person supplying the information. We will give them the opportunity to further justify why the information should be withheld.

If an evaluation and review report or a decision document includes confidential information, this will be contained in a confidential appendix not publicly available. Where confidential information is to be presented at a hearing, the hearing can go into closed session for this purpose. At the conclusion of the closed session, the Chairman will report back to the full hearing, in terms which do not disclose the matters canvassed in the closed session.

How to handle confidential information when making an application

Confidential information should be clearly identified as such. We urge applicants to separate out confidential information into an appendix to the application that we can then place in secure storage.

Applicants should include in their publicly accessible application enough information to enable submissions to be made on an informal basis and, more generally, for the Authority to be able to give reasons for its decisions. Thus, while confidential information should be excised into an appendix, this main application should include a non-confidential summary of the information. This should make it clear what the application is about, likely risks, costs and benefits, and likely effects of the hazardous substance or new organism.

Please resist the temptation to identify whole documents as confidential where only certain information is truly commercially sensitive.

In some instances, submissions on notified applications may contain confidential information. The above principles apply to such submissions.

Applications for innovative agricultural compounds and innovative medicines

Along with the general provision for confidential information, the HSNO Act also makes special provision for confidential supporting information. This affects applications which are also the subject of applications for approval as an innovative agricultural compound (under the Agricultural Compounds and Veterinary Medicine Act 1997) or an innovative medicines application (under the Medicines Act 1981).

Where such a substance is the subject of an application under HSNO and under either of these Acts, confidential supporting information cannot be disclosed (with certain limited exceptions). Neither can the information be used by the Authority to determine whether to approve another application.

Confidentiality of notifications submitted under the Toxic Substances Act

The processing of notifications under section 32 of the Toxic Substances Act was carried out by ERMA New Zealand, on behalf of the Ministry of Health. ERMA New Zealand is responsible for assessing these substances under the Transitional Provisions of the HSNO Act.

The confidentiality of the information provided through the notification process will be maintained by ERMA New Zealand under the same conditions applied by the Ministry of Health. There is no public access to the information supplied with notifications. Technically, requests for information can be made under the Official Information Act but there are provisions for withholding information that is considered commercially sensitive. No information would be released without first checking with the notifier.

Conclusion

Robust mechanisms are in place for protecting confidential information. For these mechanisms to operate within the public HSNO approvals process:

- confidential information should be clearly identified as such and be included in a separate document
- the public documents should include a non-confidential description of the information and its significance
- only information which is truly confidential should be classified as such.

If you have any queries, please contact one of our application officers.

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ERMA NEW ZEALAND INFORMATION SHEETS:

ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issues or proposals being dealt with by the Authority.

Please feel free to photocopy this material. Acknowledgement of ERMA New Zealand would be appreciated.

The information sheets are available from

ERMA New Zealand, PO Box 131 Wellington. Phone: 64 4 473 8426. Fax: 64 4 473 8433. Email: info@ermanız.govt.nz

The information sheets can also be viewed and downloaded on our website at www.ermanız.govt.nz