THE OUTLOOK FOR REGULATORY CONTROL OF AGRICULTURAL COMPOUNDS

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ABSTRACT

The Pesticides Act will be repealed once the hazardous substances part of the Hazardous Substances and New Organisms Act 1996 commences. When this new Act commences, the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, which is administered by the Ministry of Agriculture and Forestry, will also commence. With the delay in the commencement of the new legislation, the ACVM Group of MAF Food has introduced over the last two years a number of operational changes in the administration of the Pesticides Act. These changes, which will continue until the new legislation commences, have been made to align the Pesticides Act where possible with the administration of the ACVM Act. This paper discusses the changes that have occurred and the new direction in regulatory control of agricultural compounds to be undertaken by the ACVM Act.

Keywords: pesticides, agricultural compounds, regulatory, government.

INTRODUCTION

The Pesticides Act 1979 has been in operation for over 15 years. Over this period, the regulatory environment both here and internationally has changed significantly. In the mid-eighties, a number of Government Departments were involved in a review of legislation in this and other related areas.

The outcome of this review was the development of the Hazardous Substances and New Organisms (HSNO) Act 1996 by the Ministry for the Environment and the Agricultural Compounds and Veterinary Medicines (ACVM) Act by the Ministry of Agriculture and Forestry. Both these Acts replace a number of existing Acts such as the Pesticides, Animal Remedies, Fertilisers, and Toxic Substances Acts. The HSNO Act manages hazardous substances in relation to human health and environment, while the ACVM Act manages agricultural compounds in relation to risks to trade, agricultural security, animal welfare and compliance with domestic residue standards. The two Acts are complementary to each other. The ACVM Act provides a more flexible system in dealing with agricultural compounds compared with the prescriptive nature of the Pesticides Act.

Although the new organism part of the HSNO Act has commenced, its hazardous substances part has not, due to delays in the development of regulations. The ACVM Act cannot commence as it is linked to the HSNO Act in a number of areas. One of the main linkages is that if the agricultural compound is also a hazardous substance then its approval under the ACVM Act is subject to its approval under the HSNO Act.

This delay in implementation has caused a number of problems. One of these is the expectation by industry that certain agricultural compounds will have less regulatory oversight because their risks are low, bearing in mind both Acts are risk based. Therefore, the ACVM Group has made a commitment to align the Pesticides Act as much as possible with the ACVM Act.

REALIGNMENT OF THE PESTICIDES ACT

The ACVM Group has made a number of changes to processing of applications for registration under the Pesticides Act. The first step was to update our information requirements package. This involved categorising the various application types and

the associated data requirements for each. For example, applications for registration have been split between applications involving new or generic active ingredients and variations to existing registered pesticides, such as additional claims, changes in formulations, etc. Another important feature was the introduction of a pre-screen stage. This means that applications submitted to us, are first reviewed to see whether the applicant has submitted the appropriate data sets with their application. While not an in-depth review, it enables the identification of obviously deficient applications. Such applications can then be removed from the system. The benefit to applicants is that these applications no longer clog the system and cause delays in processing applications that do meet our data requirements.

This was followed by development of standards and guidelines in chemistry and manufacturing, residue, toxicology and environment areas. Relevant parties were consulted before their introduction. There was no development in the area of efficacy because under the ACVM Act there is no requirement, in the majority of cases, for an applicant to prove the efficacy of their pesticide. This does not mean applicants do not have to submit efficacy data in relation to the Pesticides Act, but rather that there is no standard for applicants to meet in this area. The exceptions to this (under the ACVM Act) are where the ACVM Group require efficacy data to determine good agricultural practice to establish maximum residue limits (MRLs) or a company wishes to have such data for their own use in defence under the Fair Trading Act.

These standards facilitated the development of a discretionary data assessment service. The purpose of this service is to separate data assessment from regulatory review of pesticides, an approach which is based on the process proposed under the ACVM Act. This means independent risk assessors (persons that are accredited by ACVM Group) would undertake the data assessment, identify the risks and produce a report. When the application is received by the ACVM Group, it would review the report, and data where necessary, and place appropriate controls on the pesticide to manage its risks to an acceptable level. At this stage, there are no independent risk assessors accredited. Until such time as there are, the ACVM Group will temporarily undertake this role, along with its regulatory function. Therefore, from the applicant's point-of-view there is little change to the system.

Another significant change is that the Pesticides Board has agreed to alter the structure of the decision making committee. Previously, the Board delegated its decision making on applications to the Executive Committee, comprised of Board members and outside personnel. The Board has now delegated this responsibility to a smaller decision making committee comprised of ACVM Group personnel. This allows for more frequent meetings and means applications can be processed more quickly.

This change in decision making was linked to the setting up by the ACVM Group of a Technical Consultative Committee, whose membership is comprised of individuals with relevant experience and expertise in a range of areas. Its purpose is to consider significant applications, such as those associated with new active ingredients or novel uses, as part of the regulatory review process. Therefore, when the application is considered by the decision making committee, it has confidence that the application has had a rigorous review. This committee also meets on a frequent basis.

The certificate of registration can now be issued without the requirement of approving the final label, a change that is in line with the ACVM Act. A low risk standard has also been introduced, which means that data sets are significantly reduced for any product that meets the definition and criteria for a low risk product as outlined in the standard.

ACVM ACT

The purpose of the ACVM Act is to manage specific risks related to trade in primary produce, agricultural security and animal welfare, to ensure the use of agricultural compounds does not result in breaches in domestic food residue standards and to ensure the provision of sufficient consumer information about agricultural compounds.

The Act defines an agricultural compound, (paraphrasing the definition relevant to pesticides from the Act) as:

Any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which plants and animals are managed, for the purposes of:

- a) managing or eradicating pests, including vertebrate pests; or
- b) maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
- c) fulfilling special nutritional requirements;

.....

- g) enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or

... and

includes any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfection of raw primary produce, and any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of (the ACVM Act) by Order in Council.

It also defines the sub-group of compounds used to manage animals as **veterinary medicines**, but does not define the subgroup used to manage plants in any of the ways specified in the definition of an agricultural compound.

The definition of an agricultural compound is very wide ranging and will include products that are not presently regulated, such as surfactants and marker dyes. An important aspect of the ACVM Act is the ability to exempt agricultural compounds with or without conditions from registration. This exemption relates to groups of agricultural compounds and not trade name products. Exemptions are managed by regulation and will be considered for agricultural compounds for which risks can be managed without registration. This mechanism allows for an appropriate level of regulatory control without imposing the costs of registration.

Agricultural compounds not exempt must be registered as trade name products with or without conditions. The types of conditions that can be imposed on a trade name product are wide. However, any conditions set must be consistent with the purpose of the Act in relation to the trade name product.

Because conditions are used to manage the risks, there is no need to approve labels under the Act, bearing in mind that a number of conditions will require certain information to be stated on the label, e.g. use rates and withholding periods. It is illegal under the Act to breach any condition. Conditions will also be applied to manage the risks associated with 'off-label' use so that the obligation falls on the user to comply with domestic residue requirements. Other legislation, such as the Fair Trading Act, will cover consumer protection aspects of products and labels.

The Act also allows for public notification of certain application types, and specifies time frames for assessing applications under the Act. As assessment of data is the major component of assessment time, this has led to the development of the data assessment service, which will operate outside the Act. The process will be similar to that alluded to above.

Therefore, the ACVM Act is a significant departure from how regulation of pesticides is currently managed. It provides a more flexible system to ensure the risks of pesticides are only managed where necessary, thus ensuring minimal regulatory intervention.

CONCLUSION

The delay in the implementation of the ACVM Act has led to the ACVM Group to review its modus operandi. A number of operational changes have been made to align, where possible, the Pesticides Act with the proposed operation of the ACVM Act.

The introduction of the ACVM Act will move regulation of pesticides from a prescriptive regime to an enabling one. There are a number of significant differences between the ACVM Act and Pesticides Act.

REFERENCES

Agricultural Compounds and Veterinary Medicines Act 1997.

Agricultural Compounds and Veterinary Medicines Group, 1999. Regulatory Control

Methodology Under the Agricultural Compounds and Veterinary Medicines Act

1997. ACVM Group, MAF Food, Wellington.

Pesticides Act 1979.