# Strategic and Operational Management

## NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS

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ISSN 1036-7632

ISBN 0 644 39088 3

Canberra ACT
18 December 1997

Dear Madam President
Dear Mr Speaker

In accordance with the authority contained in the *Audit Act 1901*, the Australian National Audit Office has undertaken a performance audit of the National Registration Authority for Agricultural and Veterinary Chemicals and I present this report and the accompanying brochure to the Parliament. The report is titled *Strategic and Operational Management - National Registration Authority for Agricultural and Veterinary Chemicals.*

Yours sincerely

P. J. Barrett
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

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# Abbreviations / Glossary

| | |
|---|---|
| AERP | Adverse Experience Reporting Program |
| agvet | agricultural and veterinary |
| ANAO | Australian National Audit Office |
| ANZFA | Australia New Zealand Food Authority |
| ARMCANZ | Agriculture and Resource Management Council of Australia and New Zealand |
| Clock Time | The length of time an application is under active management by the NRA (including when an outside agency is evaluating an application for the NRA), but does not include periods when the application has been referred back to the applicant |
| AS/NZS ISO | Australian Standard/New Zealand Standard International Standards Organisation |
| EA | Environment Australia |
| ECRP | Existing Chemical Review Program |
| Efficacy Review | Review to ascertain the effectiveness of agvet chemical products against their intended use |
| Elapsed Time | The full length of time taken for an application for registration of a chemical product |
| GMP | Good Manufacturing Practice |
| IC | Industries Commission |
| ISLA | Interim Service Level Agreement |
| MAB/MIAC | Management Advisory Board/Management Improvement Advisory Committee |
| MLS | Manufacturers' Licensing Scheme - to ensure that quality is built into products at the time of manufacture |

| | |
|---|---|
| MOU | Memorandum of Understanding |
| MRL | Maximum Residue Limit |
| NCRIS | National Chemicals Registration and Information System |
| NDPSC | National Drugs and Poisons Schedule Committee |
| NRA | National Registration Authority for Agricultural and Veterinary Chemicals |
| NRS | National Registration Scheme |
| OECD | Organisation for Economic Cooperation and Development |
| PSA | Prices Surveillance Authority |
| SORO | Submit Once Review Once |
| TGA | Therapeutic Goods Administration |
| TGAC | Technical Grade Active Constituent - related program is designed to ensure that active constituents in formulated products pass NRA evaluation for quality and standard of manufacture |
| Worksafe | Worksafe Australia |

# Summary and Recommendations

# Summary

## The National Registration Scheme

**1.** The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) was established to undertake the Commonwealth's responsibilities under the National Registration Scheme (NRS) for agricultural and veterinary activities. The NRS grew out of the 1990 Special Premiers' Conference as an element of the micro-economic reform package. Under the scheme the NRA is responsible for the evaluation, registration and review of agricultural and veterinary chemicals and their control up to the point of sale. The States and Territories retain responsibility for control-of-use activities, including licensing of pest control operations and aerial spraying, and for carrying out reviews and providing advice on the effectiveness of agvet chemical products against their intended use.

**2.** The Therapeutic Goods Administration, Environment Australia and Worksafe Australia are also involved in providing specialist advice to the NRA for the more complex applications for registration.

**3.** The NRA commenced operation in June 1993 but did not assume its full responsibilities until March 1995. The NRA is a Commonwealth statutory authority and, under the *Agricultural and Veterinary Chemicals (Administration) Act 1992,* responsibility for the strategic direction of the Authority is vested in a Board of Directors.

**4.** The principal program area of the NRA is the registration of agricultural and veterinary products. Other NRA programs relate to existing and special chemical review; ensuring that products sold comply with registration; the quality of active constituents in formulated products; the Manufacturers' Licensing Scheme; and the reporting of adverse experiences.

**5.** The NRA funds its operations almost completely through a system of statutory charges, with revenue from application and renewal fees and levies for 1996-97 being $14.1 million. At 30 June 1997 the NRA's total staff was 102.

## Audit objective and criteria

**6.** The objective of the audit was to assess the efficiency and effectiveness of the NRA's strategic and operational management, particularly the assessment and registration activities. The audit criteria took into account the scope for the application of risk management principles which are integral to strategic and operational management. The audit did not seek to form judgements on scientific matters related to chemical product and safety outcomes.

## Audit conclusion

**7.** The NRA has had the challenge of integrating State-based regulatory schemes into one national scheme while dealing with a complex operating environment involving various stakeholder groups with differing expectations. The NRA has taken a number of initiatives to improve its processes. However, in the ANAO's opinion, risk management has not yet been applied in a sufficiently comprehensive and integrated manner to the management of the NRA's operations to produce more cost effective outcomes. The use of risk management principles needs to develop from the NRA's corporate and strategic planning and link directly into its operations, particularly its consideration of applications for registration. The results of the NRA's risk management planning also need to be reflected in resource allocation decisions. The ANAO noted that applications for registration are often not approved within statutory timeframes.

**8.** The ANAO also considers that efficiencies would result from applying business re-engineering principles to the assessment procedures. Improvements proposed by the ANAO to the agreements between the NRA and those agencies providing expert services should provide a useful indication of the additional scope available to the NRA to ensure that it is receiving value for money and that service providers are properly held accountable.

**9.** This report makes 12 recommendations covering key management issues including planning, risk management, process administration and cost recovery.

## NRA response

**10.** Overall, the NRA accepts the thrust of the conclusions and recommendations contained within the audit report. The general approach of applying risk management principles to the NRA's activities is endorsed, and the recommendations generally appear logical and appropriate for this stage of the NRA's development. Indeed they are consistent with many of the initiatives the NRA has already implemented and is continuing to develop.

**11.** At the same time the NRA has noted that the application of risk management principles to its process management must be done in the context of its overall legislative responsibilities to ensure that agricultural and veterinary chemicals which are registered for use in Australia do not pose unacceptable risks to human health, the environment and trade. In refining its processes to date, the NRA has therefore been careful to ensure that efficiency gains could be achieved, without jeopardising its legislative responsibilities.

# Key findings

## Strategic direction and corporate planning

**12.** The ANAO considers that linkages between the NRA's corporate objectives and its statutory responsibilities are not sufficiently clear for effective management. The NRA needs to ensure that as part of its corporate planning framework, the corporate objectives are carried through into operational action and are supported by an effective performance information framework.

**13.** The ANAO noted the concerns expressed by some groups regularly involved with the NRA consultative processes who did not feel that their inputs were having an impact. At the same time, it is recognised that it may not always be possible for the NRA to reconcile the competing views of its diverse range of stakeholders. In conjunction with the establishment of its corporate planning framework, the ANAO suggests that a more structured and systematic approach to risk management would help ensure that stakeholders' views are incorporated directly into the NRA's operations as part of good corporate governance and result in better outcomes.

## Assessment procedures

**14.** The NRA has implemented a number of initiatives in response to concerns of agvet manufacturers about the time taken to process applications. However, the ANAO considers that the evidence suggests the NRA's performance could be significantly improved. For example, only 65% of applications have been completed within statutory timeframes. Performance for agricultural product assessments is poorer than for veterinary, with only approximately half of agricultural product assessments being finalised within statutory timeframes.

**15.** The ANAO found that elapsed time to complete applications for registration was often between 100% and 400% in excess of the time the application was under active management by the NRA. For some types of applications the excess has been of the order of one to two years. The ANAO considers that using elapsed time as a secondary performance indicator would help improve overall timeliness performance and provide a greater focus on service to customers. The ANAO considers that scope exists using business re-engineering techniques to make improvements to the assessment

processes, and has suggested several areas for improvement. In addition, tailoring the NRA's overall approach to deal with lower risk chemicals in a way that incorporates enhanced risk management has considerable potential to achieve improvements in the NRA's efficiency and effectiveness.

## External service provision

**16.** Memoranda of Understanding (MOUs) and Agreements between the NRA and service providers do not include sufficient detail of how the professional assistance is to be provided, the performance and quality standards required and the actual timing of delivery of assistance. Without clear indications of how the agencies are to carry out their contractual obligations, it is difficult to establish performance specifications and measure success.

**17.** The ANAO also considers that including levels of fees for services provided in agreement with service providers would permit greater assurance about value for money and provide benchmarks to facilitate contestability. It would also be of benefit for the NRA to examine the possible use of alternative sources of professional assistance to achieve more cost effective outcomes.

**18.** The ANAO found that although there are guidelines for reviews undertaken by the States of the effectiveness of agvet chemical products against their intended use (efficacy reviews), they are not up-to-date and are not clear on a number of aspects of the process. For example, the guidelines are not clear on the priority of this work even though the reviews are generally carried out by State/Territory officials or institutional experts in addition to their normal duties. Improved guidance for efficacy reviews should include clear parameters as to the priority of, and the time(s) required for, the reviews.

## Other NRA programs

**19.** The Existing Chemical Review Program (ECRP) was instituted to comprehensively review existing chemicals on a priority basis. As currently managed, the ECRP will not be able to review a significant proportion of active ingredients registered prior to the establishment of the National Registration Scheme for a number of years.

**20.** The Manufacturers' Licensing Scheme aims to ensure that quality is built into products at manufacture, and assesses manufacturers against a good manufacturing practice (GMP) code. There has been a high initial level of non-

compliance with the GMP code for this scheme, of the order of 60%. The NRA has indicated that a high failure rate is to be expected in the initial stages of the scheme. It has identified lack of industry awareness and knowledge of the GMP as key factors. The ANAO considers that it is important that the NRA extend its analysis of the reasons for the failures to include the adequacy of industry practices, the relevance and appropriateness of GMP codes and the auditing process.

**21.** In addition to the evaluation of applications for registration and the programs discussed above, the NRA is responsible for programs covering compliance, technical grade active constituents and adverse experience reporting. The ANAO considers that a comprehensive risk-based approach to the NRA's range of programs is critical to the success of the National Registration Scheme. The ANAO concludes that there would be benefits in the NRA adopting a structured, comprehensive risk management approach which would involve the NRA addressing issues related to all its program activities in an integrated manner, including its approach to chemical product registration.

## Resource allocation and fee implications

**22.** One of the challenges for the NRA has been to match resources to the application workload to address the need to improve registration performance. The NRA has the basis for a more structured approach than adopted so far to workload matching through its work on ISO accreditation. Using a more quantitative approach, building on the process mapping already undertaken, should provide the basis for enhanced approaches to, and greater efficiency of, resource allocation. In addressing this, it is important that resource allocation decisions are made consistent with outcomes of the risk management process.

**23.** The ANAO considers that the NRA's cost recovery model, with income largely driven by manufacturers' sales and re-registration of products, does not impose any pressure for improvements in efficiency and effectiveness by maintaining downward pressure on the NRA's costs. This view was reflected in a 1993 Prices Surveillance Authority report.

# Recommendations

*Set out below are the ANAO's recommendations and the NRA's responses. The ANAO considers that the NRA should give priority to Recommendation Nos 1, 5, 10 and 11.*

| | |
|---|---|
| Recommendation No. 1 Para. 2.14 | The ANAO *recommends* that the NRA develops a corporate planning framework, drawing on a systematic risk assessment process, that directly links statutory responsibilities to corporate objectives and then into operational plans through strategies and targets based on appropriate quantitative and qualitative performance indicators.<br><br>Agency response: Agreed. |
| Recommendation No. 2 Para. 2.22 | In conjunction with the establishment of its corporate planning framework, the ANAO *recommends* that the NRA reviews existing consultative arrangements with its key stakeholders to ensure that their perspectives are reflected in the NRA's strategic assessments.<br><br>Agency response: Agreed. |
| Recommendation No. 3 Para. 3.26 | The ANAO *recommends* that the NRA investigates the use of 'elapsed time' as a secondary indicator in managing the assessment of all applications for the registration of agvet chemical products.<br><br>Agency response: Agreed. |
| Recommendation No. 4 Para. 3.45 | The ANAO *recommends* that the NRA employs business re-engineering procedures to achieve further efficiencies in the assessment processes, including through:<br>• using fewer registration categories;<br>• examining processes associated with difficulties in meeting statutory timeframes;<br>• maximising the use of overseas assessments; and<br>• commencing aspects of the public comment process earlier.<br><br>Agency response: Agreed. |

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| Recommendation No. 5 Para. 3.63 | The ANAO *recommends* that the NRA adopts a comprehensive risk management approach to the overall assessment arrangements applying to applications for registration, including categorising applications based on an assessment and analysis of risk and determining treatment regimes that are consistent with any risk assessments and analyses.<br><br>Agency response: Agreed. |
| Recommendation No. 6 Para. 4.16 | The ANAO *recommends* that the NRA ensures that service agreements are established with all significant service providers which include:<br>• clear documentation of professional assistance to be provided, including appropriate performance standards, technical and quality standards and specific timeframes for the delivery of such assistance; and<br>• establishing appropriate fees for service based on providing value for money.<br><br>Agency response: Agreed. |
| Recommendation No. 7 Para. 4.21 | The ANAO *recommends* that the NRA assesses the possibility of using alternative sources of advice, in place of either any one or all of the existing agencies, in order to provide a more informed and contestable framework for the delivery of services to the NRA.<br><br>Agency response: Agreed. |
| Recommendation No. 8 Para. 4.28 | The ANAO *recommends* that the NRA, in conjunction with the States and Territories, updates guidelines to establish clearly the purpose, parameters and priority of the efficacy reviews undertaken by States and Territories of the effectiveness of agvet chemical products against their intended use. The new guidelines should cover the duties and responsibilities of reviewers.<br><br>Agency response: Agreed. |

| | |
|---|---|
| Recommendation No. 9 Para. 5.27 | The ANAO *recommends* that the NRA reviews the outcomes of the administration of the Manufacturers' Licensing Scheme in order to develop appropriate strategies to achieve a higher level of compliance. This should include examining the codes and guidelines, auditing standards and manufacturer liaison and education practices.<br><br>Agency response: Agreed. |
| Recommendation No. 10 Para. 5.36 | The ANAO *recommends* that all NRA programs be incorporated into a structured risk management plan to assist in fulfilling the NRA's objectives. The risk treatment regime identified in the plan would guide the development and priorities of, and balance between, each of the programs.<br><br>Agency response: Agreed. |
| Recommendation No. 11 Para. 6.9 | The ANAO *recommends* that, as part of its resource management, the NRA:<br>• undertakes as far as possible an appropriate quantitative analysis of its operations to provide a structured approach to determining staffing levels; and<br>• reflects the outcomes of risk assessment and analysis activities in the allocation of resources to individual programs.<br><br>Agency response: Agreed. |
| Recommendation No. 12 Para. 6.24 | The ANAO *recommends* that there be a review of the NRA's cost recovery model. The review should be undertaken following the implementation of formal risk management processes and should address appropriate means of ensuring pricing or review mechanisms to provide downward pressure on NRA costs.<br><br>Agency response: Agreed with qualifications. |

# Audit Findings and Conclusions

# 1. BACKGROUND

*This chapter describes the National Registration Scheme and the role of the NRA and its programs. The objectives and conduct of the audit are also described.*

## The National Registration Scheme

**1.1** The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) was established to undertake the Commonwealth's responsibilities under the National Registration Scheme for agricultural and veterinary chemicals that places registration activities under one national umbrella. The National Registration Scheme (NRS) grew out of the 1990 Special Premiers' Conference as an element of the micro-economic reform package, although the Commonwealth has been involved in the evaluation of chemicals to ensure their human and environmental safety and effectiveness for many years. Prior to the NRS, the States and Territories exercised the full range of responsibilities, including registration, in relation to agvet chemicals. The NRS is a partnership between the Commonwealth and the States and Territories. Under the scheme the NRA is responsible for the evaluation, registration and review of agricultural and veterinary (agvet) chemicals and their control up to the point of sale. The States and Territories retain responsibility for control-of-use activities, including licensing of pest control operations and aerial spraying. The benefits expected from the NRS were:

- one national regulatory system;
- a more uniform and predictable regulatory environment for the agvet chemical industry; and
- an improved capability to take into account environmental and public health issues on a national basis.

**1.2** The NRA commenced operation in June 1993. However, it did not assume its full powers and responsibilities until March 1995 with the passing of the final piece of NRS enabling legislation. In the interim, the NRA assumed progressively the assessment and registration functions although each State and Territory issued formal registration certificates.

## The National Registration legislation

**1.3** The National Registration legislation comprises the following seven Acts:

- the Agricultural and Veterinary Chemicals Act 1994 [No. 36 of 1994];
- the Agricultural and Veterinary Chemicals Code Act 1994 [No. 47 of 1994];
- the Agricultural and Veterinary Chemicals (Consequential Amendments) Act 1994 [No. 37 of 1994];
- the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 [No. 41 of 1994];
- the Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994 [No. 39 of 1994];
- the Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994 [No. 38 of 1994]; and
- the Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994 [No. 40 of 1994].

**1.4** In the preamble to one of the key pieces of legislation, the *Agricultural and Veterinary Chemicals Code Act 1994* (the Act), it is recognised that:

- the protection of human health and safety is essential to the well being of society and can be enhanced by putting in place a system for the regulation of agricultural and veterinary chemical products;
- the principle of ecologically sustainable development requires a regulatory system that ensures that the use of such products today will not impair the prospects of future generations;
- the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products are essential for the well being of the economy and require a system for regulating such products that is efficient, predictable, adaptive and responsive; and
- it is desirable to establish a regulatory system that is open and accountable and provides opportunity for public input with respect to the regulation of such products.

**1.5** The legislative package provides the NRA with a full range of powers, including detailed operational provisions for evaluating, registering and reviewing agricultural and veterinary (agvet) chemical products; control over

the importation, manufacture and export of chemical products; and compliance and enforcement.

**1.6** In broad terms an agvet chemical product is a substance or mixture of substances that directly or indirectly:

- destroys or repells pests, including those on animals;
- destroys plants;
- prevents, cures or alleviates diseases/injuries in animals;
- modifies the physiology of a plant or animal; or
- modifies the effect of other agvet chemical products.

## NRA's programs

**1.7** The principal program of the NRA is the registration of agricultural and veterinary products. Other programs relate to existing and special chemical review, compliance, technical grade active constituents, Manufacturers' Licensing Scheme and adverse experience reporting programs as listed in Table 1.

### Table 1

**NRA's programs**

| Program | Function |
|---|---|
| Registration of Agricultural and Veterinary Chemical Products | Responsible for assessing and registering chemicals, and their control up until the point of sale. |
| Compliance Program | Aims to ensure that only those products that have been registered are sold, and that labels and advertising do not lead to improper or unsafe use. |
| Existing Chemical Review Program | Systematic review of older chemicals to determine whether they meet contemporary standards. |
| Technical Grade Active Constituents (TGAC) Program | Aims to ensure that TGAC in formulated products pass NRA evaluation for quality and standard of manufacture. |
| Manufacturers' Licensing Scheme and Good Manufacturing Practices (GMP) | Aims to ensure that quality is built into products at the time of manufacture. |
| Adverse Experience Reporting Program | Requires manufacturers to report adverse effects of veterinary products to NRA, and allows voluntary |

| | |
|---|---|
| | notification of adverse effects by product users. |

## NRA's structure

**1.8** The NRA is a Commonwealth statutory authority within the Primary Industries and Energy portfolio. Under the provisions of the *Agricultural and Veterinary Chemicals (Administration) Act 1992,* responsibility for the strategic direction of the Authority is vested in a Board of Directors. The Board comprises an independent chairman and seven other directors who have been selected on the basis of their experience in the agricultural and veterinary chemical industry, the rural sector, occupational health and safety and consumer groups.

**1.9** Day to day management is in the hands of a Chief Executive Officer (CEO) who is responsible to the Board.

## Resourcing

**1.10** The NRA funds its operations almost completely through a system of statutory charges, set by regulation. These include fees on the initial request for registration of agvet chemical products, annual re-registration charges and a levy on the sale of registered agvet chemicals that have annual sales in excess of $100 000. Total revenue from application and renewal fees and levies for 1996-97 was $14.1 million and parliamentary appropriations accounted for $0.077 million.[1] Interest and other fees and revenue brought total revenue for 1996-97 to $15.1 million. Total operating expenses for 1996-97 were $13.2 million.[2]

**1.11** The distribution of NRA staff resources, totalling 102 staff at 30 June 1997, is shown below, with more detail at Appendix A. The majority of staff are

[1] Only one NRA program, the Minor Use Program, is funded by the Commonwealth. Its purpose is to encourage the development of specific agvet chemicals that otherwise would not be economically viable to produce.

[2] Source: NRA data.

devoted to registration activities. (Policy includes, *inter alia*, staff engaged in chemical review, compliance and the Manufacturers' Licensing Scheme).

## NRA stakeholders and external service providers

**1.12** The NRA seeks to take into account a number of interests in fulfilling its responsibilities, including those of:

- *Commonwealth Government*, represented primarily by the Department of Primary Industries and Energy, responsible for the implementation of government policy in the area of agriculture and agricultural trade;
- *agvet chemical manufacturers*, ranging from large multi-national companies to small enterprises, and covering a wide range of chemicals suitable for broad acreage agriculture, animal production, pet care and some household chemicals such as pesticides;
- *end users*, including primary producers, agricultural workers and other groups such as pet owners, pest control operators and veterinarians;
- *community groups*, including consumer groups, the medical profession and the environmental movement concerned with the public health or environmental issues associated with the wide use of agricultural chemicals; and
- *State Governments* which have a partnership with the Commonwealth Government and have passed complementary legislation to implement the NRS. They carry out efficacy reviews and provide advice on the effectiveness of the product for its intended use. They also provide expert advice to the NRA based on detailed knowledge of local soil, climatic, and other relevant conditions and agricultural practices.

**1.13** In carrying out its responsibilities, the NRA has relationships with certain Commonwealth agencies. The main organisations are:

- *Therapeutic Goods Administration* - provides advice on toxicology data used to assess the risk to public health posed by products;
- *Environment Australia* - provides advice concerning possible adverse environmental effects associated with products;
- *Worksafe Australia* - provides advice on occupational health implications of a product's end use to minimise risks to workers using the products; and
- *Australia and New Zealand Food Authority (ANZFA)* - the NRA assists the ANZFA in respect of its responsibilities for food standards by providing information on chemical residues.

## Audit objective

**1.14** The objective of the audit was to assess the efficiency and effectiveness of the NRA's strategic and operational management, particularly the assessment and registration activities. The audit took into account the scope for the application of risk management principles which are integral to strategic and operational management, but it did not seek to form judgments on scientific matters related to chemical product and safety outcomes.

## Audit methodology and criteria

**1.15** The responsibilities of the NRA are well suited to the application of risk management principles. These principles can help guide the development of strategic and corporate directions, bearing in mind the NRA's legislative framework, and assist at the operational level in the management of functions such as assessment, chemical review and compliance.

**1.16** Appendix B provides a fuller statement of the risk management process, including the six steps of establishing the context, identifying risk, analysing risks, setting priorities, identifying treatments and monitoring and review. These guided the criteria applied in the audit.

**1.17** The ANAO interviewed NRA staff and gathered evidence from NRA files, records, policies and information systems. The ANAO also interviewed a number of NRA's external stakeholders, including:

- chemical manufacturers and their industry associations;
- relevant Commonwealth and State agencies;
- primary producer representatives; and
- certain consumer and environmental interest groups.

**1.18** A list of the organisations and associations interviewed during the audit is at Appendix C.

**1.19** The audit was conducted in accordance with ANAO Auditing Standards, with fieldwork being undertaken between November 1996 and June 1997. It cost about $320 000.

## Report outline

**1.20** Chapter 2 addresses the NRA's approach to determining its strategic direction and corporate plan and examines how client perspectives are best taken into account in this process.

**1.21** Chapter 3 considers the procedures that the NRA has in place for assessing applications for registration and examines the scope for improvement, including the use of risk management.

**1.22** Chapter 4 considers the relationship between the NRA and those agencies which provide it with services, and indicates ways in which management of these relationships could be improved.

**1.23** Chapter 5 discusses the NRA programs other than registration.

**1.24** Chapter 6 examines the resource management of the NRA, and canvasses issues that have fee implications for the NRA.

# 2. Strategic Direction and Corporate Planning

*This chapter examines the NRA's approach to strategic direction and corporate planning and suggests that the use of a risk management process would help link statutory obligations to corporate objectives and operational plans.*

## Introduction

**2.1** An effective risk management process requires an organisation first to establish its strategic/organisational context. This includes determining its capabilities and the relationship with its operating environment, including the financial, operational, competitive, public image, cultural, client and legal parameters within which the organisation functions.

**2.2** An effective risk management process will enable the NRA to identify and deal with any risks that may impede it achieving its statutory objectives.

## Relationship between strategic direction and corporate planning

**2.3** The NRA's Corporate Plan for 1996-97 to 1998-99 describes its mission as:

*to establish an efficient and cost-effective national registration regime for agricultural and veterinary chemicals that will protect the health and safety of people and the environment, and enhance the domestic and export market potential of Australia's agricultural and animal industries.*

**2.4** The corporate objectives given in the Corporate Plan are shown below.

| **Corporate objectives** |
|---|
| Develop the NRA as a respected, professional, innovative, credible and well managed organisation. |
| Operate a cost-effective registration system which ensures that safe and effective chemical products are available to users. |

| |
|---|
| Review and strengthen programs which ensure that safe and effective chemical products are fit to use. |
| Ensure that Australia contributes to and benefits from international harmonisation initiatives. |

**2.5** In the best performing organisations, a planning and performance framework provides links between the highest level of strategic planning and the performance of individual operating procedures, based on:

- objectives derived from the statutory responsibilities or stated role of an organisation that provide the corporate direction or goals for the organisation to strive for;
- strategies derived from the objectives that direct planning and activity towards the achievement of the objectives;
- targets derived from the strategies that ensure that all action undertaken within the organisation is consistent with the strategies;
- subordinate operational plans that are designed to deliver the outcomes specified by the corporate strategies; and
- performance measures as to whether objectives are being achieved and/or require reassessing.

**2.6** The NRA's mission statement is consistent with the overall intent of the national registration legislation. However, linkages between the corporate objectives and the intent of the legislation are not clear. The corporate objectives are expressed in general terms that lack the precision and focus needed to form the basis of an effective strategic planning framework. In addition, the objectives tend to describe activities rather than outcomes, and do not provide a focus for performance measurement. It is difficult to see how some of the requirements indicated by the legislation - such as public input and responsiveness - are captured in the corporate objectives.

**2.7** For corporate objectives to be effective there must first be a clear relationship between the objectives and the overall responsibilities or role of an organisation, and second, the objectives need to be expressed in a concise manner that communicates clearly what is to be achieved, measured and assessed.

**2.8** The ANAO notes that the NRA's stated corporate objectives have changed from year to year. Each of the NRA's annual reports since its inception in 1993 has differently stated objectives, although they cover similar themes. The ANAO recognises that the NRA is a relatively new agency that has had to amalgamate disparate State-based registration schemes into one national scheme and that some level of development and refinement is to be

expected in these circumstances. In the ANAO's view, however, these changes have not flowed from fundamental changes to the NRA's responsibilities. The number and the nature of the changes to objectives is not conducive to articulating and maintaining a consistent corporate direction, which is clearly aligned with statutory requirements.

**2.9** The Corporate Plan lists a series of strategies to achieve each of the objectives. For example, in relation to the first objective, it lists items such as:

- develop highly motivated and effective staff;
- strengthen communication and customer service; or
- monitor changes in operating environment.

**2.10** However, the Corporate Plan provides little detail of how these strategies are to be implemented, how the performance is to be measured, or how to tell when they have been successful.

**2.11** The NRA's Operational Plan includes specific output targets for various actions. However, in many cases it is difficult to relate the actions set out in the operational plan back to any specific strategy in the Corporate Plan or to strategic objectives. In other words, the relationship between the Operational Plan and the Corporate Plan is not sufficiently clear.

**2.12** It is important for effective management that there be a performance information framework, containing both quantitative and qualitative indicators, which links the Operational Plan and the Corporate Plan and provides reporting of results against targets.

### *Conclusion*

**2.13** The NRA has sought to meet the challenge of successfully integrating different State-based regulatory schemes into one national scheme while dealing with a complex operating environment involving various stakeholder groups with differing expectations. However, the ANAO considers that linkages between the NRA's corporate objectives and its statutory responsibilities are not sufficiently clear for effective management and that it has not developed sufficiently a corporate planning framework. The NRA needs to ensure that as part of its corporate planning framework, the corporate objectives are carried through into operational action and are supported by an effective performance information framework. In the ANAO's view, this suggests that the NRA has not been able to elucidate clearly how to approach the many tasks that make up its statutory responsibilities. The ANAO also

considers that a systematic risk assessment process would help inform the NRA's corporate planning.

## Recommendation No. 1

**2.14** The ANAO *recommends* that the NRA develops a corporate planning framework, drawing on a systematic risk assessment process, that directly links statutory responsibilities to corporate objectives and then into operational plans through strategies and targets based on appropriate quantitative and qualitative performance indicators.

### *Agency response*

**2.15** Agreed. The need to align the NRA's objectives closely with its legislative responsibilities is agreed. The NRA already has clearly defined and measurable objectives, strategies and targets for some functions, but we accept that further improvements can be made. Implementation of this recommendation is seen as a further refinement of current NRA planning, noting that the conduct of a systematic risk assessment process will have resource implications for the NRA. The NRA considers that corporate planning also needs visionary elements to supplement the problem solving/avoidance matters covered by risk assessment.

## Client aspects

**2.16** An important step in the risk management process is to identify relevant external groups or stakeholders and their interests. This provides key information when determining an organisation's strengths, weaknesses, opportunities and threats.

**2.17** The NRA fully recognises that it has a diverse range of stakeholders to consult. To meet this need the NRA has developed a communications strategy involving some five consultative committees, various working groups on registration, a newsletter, and other publications to seek the views of, and otherwise communicate with, various stakeholders.

**2.18** For consultative arrangements to be effective, it is important that the contribution that they make to the NRA's overall strategic objectives is well understood both by the NRA and the relevant stakeholders. The ANAO interviewed a range of stakeholder organisations and stakeholders to ascertain, among other things, to what extent they saw the consultative

arrangements as effective in determining the direction of the NRA. The main needs of the clients were identified as timeliness, predictability and consistency, and responsiveness. Some of the reactions of particular external groups are set out in Table 2.

**Table 2**
**Reactions of external groups**

| External groups | Interests/comments |
|---|---|
| Agvet chemical manufacturers | • seek value for money from regulatory system<br>• timeliness and predictability for assessments are a key need<br>• mix of views over the fairness of existing funding regime |
| End users (diverse group ranging from primary producers to veterinarians and the general consumer) | • need agvet chemicals that are effective<br>• clear instructions on safety and application<br>• residues that will not impede trade<br>• chemical review is important, but too slow<br>• registration is too slow<br>• use overseas assessments more<br>• need more up to date information on MRLs and withholding periods<br>• insufficient emphasis on public health, especially cumulative effects |
| Environmentalists | • seek more emphasis on the environmental and public health effects<br>• considered NRA to be placing undue emphasis on the interests of chemical manufacturers |

### *ANAO comments on stakeholder views*

**2.19** The comments made to the ANAO reflect the understandably different viewpoints of external groups, and the complexity of the environment in which

the NRA operates. It would be difficult to respond always in a way to satisfy all viewpoints. Whilst recognising this diversity and the legislative responsibilities of the NRA, the ANAO noted the concerns expressed by some groups involved regularly with the NRA consultative processes who did not feel that their inputs were having an impact.

**2.20** Although individual decisions affecting specific groups will sometimes result in tension between the NRA and the groups, it is important that external input is considered, particularly in determining the context for the NRA's strategic risk assessment. Over time, effective communication with stakeholders should help improve stakeholders' understanding of the NRA's corporate direction.

**2.21** In conjunction with the establishment of the NRA's corporate planning framework, the ANAO suggests that a more structured and systematic approach to risk management would help ensure that stakeholders' views are incorporated directly into the NRA's operations as part of good corporate governance and result in better outcomes.

## Recommendation No. 2

**2.22** In conjunction with the establishment of its corporate planning framework, the ANAO *recommends* that the NRA reviews existing consultative arrangements with its key stakeholders to ensure that their perspectives are reflected in the NRA's strategic assessments.

### *Agency response*

**2.23** Agreed. The NRA believes that it is timely to evaluate its current, extensive consultative arrangements to ensure stakeholder views are considered effectively in the NRA's activities. As noted by the ANAO, the divergence of views of different interest groups means that there is likely to be elements of disagreement with many NRA decisions, and that where there is disagreement, the affected party will often claim they have not been heard. It is important, however, for the NRA to take into account all relevant views, but then to make the responsible regulatory decision.

# 3. Assessment Procedures

*This chapter examines the management and performance outcomes of the NRA's major program under which it evaluates applications for the registration of agvet products. It identifies the scope for more cost effective outcomes.*

## Assessment categories and timeframes

**3.1** The NRA is responsible for the evaluation and registration of agvet chemical products. Each application is assigned to one of 63 assessment categories, detailed in the Regulations under the Act. The categories cover a range of situations including:

- registration of chemical products with active constituents not previously approved;
- formulation changes to chemical products already registered;
- registration of new chemical products similar to products already registered; and
- label changes, including safety and use instructions.

**3.2** Section 165(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* provides that when an application is made to the NRA, the NRA must determine the application within a period stated in, or determined in accordance with, the regulations. For each assessment category there is an assessment period, determined under the Agricultural and Veterinary Chemicals Code Regulations (Statutory Rules 1995, No. 27), within which applications are to be processed. The range of timeframes for assessments is shown in Table 3.

**3.3** The NRA engages the services of a number of Commonwealth and State Government agencies for advice on certain categories of assessments. These applications are the more complex ones and have statutory timeframes of between eight and 15 months.

**Table 3**
**Assessment timeframes**

| Timeframe | Category |
|---|---|
| 15 months | New products with active constituents not previously approved that are to be used on food producing species. |
| 13 months | New products involving already approved active constituents for use on different food producing species. |
| 8 months | New combinations of approved constituents. |
| 6 months | Certain new veterinary chemical products that are orally administered. |
| 5 months | Range of agvet chemical products, including new products similar to those already registered where bioequivalence data is required. This also includes minor extensions to label claims. |
| 3 months | Range of minor technical and administrative changes, including instructions for use and safety information on labels where limited technical data is required. |

## Information requirements

**3.4** The assessment and registration of agvet chemical products is a complex process, requiring the analysis of a range of highly technical issues. Applicants have to supply technical data in support of the more complex applications which is generally several volumes and addresses:

- *chemistry and manufacture* - the general chemical and physical properties of the product, including formulation, active constituent(s) and their concentration, and manufacturing details of the active constituent(s) and the final product;
- *toxicology* - toxicological details of active constituent(s) and product including studies that may have been undertaken;
- *metabolism and toxicokinetics* - studies of how the chemical product is absorbed in the target plant or animal, its impact and possible residues;

- *residues and trade* - studies of the residue levels in crops and animals as well as the setting of maximum residue levels and their trade implications;
- *occupational health and safety* - data on the nature of occupational exposure, health conditions that would preclude use and general health and safety information;
- *environment* - assessment of the product's environmental impact including such characteristics as its rate of degradation, possible accumulation in animals, soils etc and its toxicological impact on animals, birds and fish; and
- *efficacy and safety* - studies of the effectiveness of the product under field conditions.

**3.5** The more straightforward assessment categories (eg minor technical changes to products) require the supply of far less information.

## Developments and improvements in the assessment processes

**3.6** The NRA has introduced a number of initiatives to improve the processing of applications for registration.

### *AS/NZS ISO 9002 accreditation*

**3.7** The NRA considered that the task of integrating the somewhat disparate State and Territory-based regulatory systems into one national regulatory system, as well as taking on a range of new responsibilities, highlighted the importance of fully documenting procedures to ensure a consistent and defensible approach to all decision-making.

**3.8** The NRA believed that this could be best achieved through accreditation under the international quality standard, AS/NZS ISO 9002. This involved extensive assessment, documenting and mapping of the NRA's key processes, and accreditation was achieved in July 1996. The NRA has estimated that the establishment of the ISO process increased the organisation's workload by 10% during implementation.

**3.9** The NRA regards accreditation as the first step in a process of continuous improvement in its assessment and policy functions. The ANAO acknowledges that ISO accreditation, by defining and documenting an organisation's operations, can provide a foundation from which benchmarking or continuous improvement processes can commence. However, ISO accreditation does not ensure that existing procedures are the most efficient

and effective procedures, and the ANAO notes that the decision to pursue accreditation does not appear to have been based on an organisational risk assessment that identified ISO accreditation as a key risk treatment. It will be important that NRA realises some of the benefits from this considerable investment through further process improvements.

### *Submit Once Review Once Initiative*

**3.10** The aim of the Submit Once Review Once (SORO) initiative is to reduce the delays in processing by minimising the number of applications returned to applicants because of incomplete information. Details of this and other initiatives are at Appendix D. As part of the SORO initiative, in late 1996 the NRA began to issue a series of registration manuals aimed at giving applicants a much better indication of registration requirements. The new manuals give a much clearer indication of the general registration process and the range of technical data required for registration.

**3.11** Nevertheless, applicants are still asked to refer to 'interim documents', dated February 1995, for advice on the detailed technical information that must be supplied. The ANAO acknowledges the complexity involved in preparing these technical guidelines, but, given their importance to clients, the NRA should give high priority to their finalisation.

**3.12** Application pre-screening is another element of the SORO initiative. There are three levels of pre-screening which aim to identify deficient applications within days of arrival, and which single out the less complex applications for immediate action. There has been a high deficiency rate - of the order of 50% - although many are minor deficiencies. The NRA has held registration seminars for registrants and registration consultants (used by many chemical manufacturers in preparing applications) to help improve the quality of applications.

### *Streamlining of assessment procedures*

**3.13** The NRA has also undertaken a number of initiatives aimed at improving the efficiency and effectiveness of the assessment procedures. These include:

- approving labels at the text and format stage rather than at the final printed stage, provided they meet the NRA labelling code;
- handling minor administrative changes to records and labels by notification rather than formal application;

- setting up a Registration Process Section to manage the registration process, freeing individual product evaluators to concentrate on the technical aspects of the process; and
- trialing the management of major applications on the basis of elapsed time, using milestones to measure performance against set timeframes. This is a departure from the NRA's normal 'clock time' approach to the management of the assessment process.

**3.14** The NRA's current assessment processes, following these changes, are detailed in Figure 2 below.

## Performance

### *Application flow*

**3.15** The NRA processes approximately twice as many applications for agricultural products than for veterinary products. The numbers of applications received and finalised, and the number in progress, are summarised in Figures 3 and 4 (for agricultural and veterinary chemicals respectively).

**3.16** Between April 1995 and September 1996, the number of applications received for agricultural products consistently exceeded the number finalised. It was not until October 1996, 18 months after the NRA assumed full operational responsibilities, that the total number of applications in progress began to fall.

**3.17** The reduction in applications in progress stemmed from increases in NRA assessment staff resources and in the number of applications finalised per staff member. This was particularly evident in the area of agricultural chemical products, where output increased from 4.6 to 8.8 applications per person per month over the 12 month period to June 1997.

### *Statutory assessment timeframes exceeded*

**3.18** Notwithstanding the increase in output, a high proportion of assessments are not completed within the statutory timeframes.

**3.19** On average only 65% of applications were assessed within their assessment timeframes over the seven quarters between October 1995 and June 1997 (see Appendix E). Performance is poorer for agricultural chemical products than for veterinary products, with an average of 49% of assessments completed outside the statutory time. For veterinary chemical products an

average of 16% of assessments were completed outside the statutory time. Figure 5 summarises the trends.

**3.20** The ANAO has considered whether the involvement of outside agencies to provide evaluation services has affected performance against assessment timeframes. However the ANAO has found that this factor is limited in the above data since only about 10% of applications finalised involved outside agencies.

**3.21** The ANAO concludes that the bulk of the scope for improvement lies within the NRA's management of its own assessment procedures.

## Elapsed time

**3.22** The statutory assessment timeframes are set on the basis of 'clock time' as opposed to 'elapsed time'. 'Clock time' is the length of time an application is under active management by the NRA (including when an outside agency is evaluating an application for the NRA). If, for any reason, the application is referred back to the applicant, the time that the application is with the applicant is not counted in the NRA's statutory obligations, or 'clock time'. 'Clock time', therefore, will be equal to or shorter than the total 'elapsed time' for dealing with the application.

**3.23** Table 4 shows the percentage by which average 'elapsed time' exceeds average 'clock time' for the quarters from 1 October 1995 to 30 June 1997. It shows that average 'elapsed time' was often substantially in excess of average 'clock time' - often of the order of 100% to 400%. The percentage excess tends to be less for assessments where outside agencies assisted the NRA through the supply of evaluation services.

**Table 4**

**Percentage by which average 'elapsed time' exceeds average 'clock time'**

| Three month period end | Application type[(1)] | Ag % | Vet % |
|---|---|---|---|
| Dec 1995 | E | 60 | 178 |
| | I | 96 | 318 |
| Mar 1996 | E | 97 | 127 |
| | I | 158 | 207 |

| | | | |
|---|---|---|---|
| Jun 1996 | E | 118 | 180 |
| | I | 161 | 376 |
| Sept 1996 | E | 35 | 138 |
| | I | 106 | 357 |
| Dec 1996 | E | 48 | 167 |
| | I | 140 | 382 |
| Mar 1997 | E | 77 | 79 |
| | I | 142 | 573 |
| Jun 1997 | E | 56 | 283 |
| | I | 141 | 284 |

(1) 'E' refers to applications for which the NRA uses external agencies to provide it with evaluation services, 'I' refers to assessments undertaken completely by NRA itself.

**3.24** The ANAO recognises that the NRA cannot control the time that an application is back with the applicant. However a focus on 'clock time' risks placing insufficient emphasis on the overall effectiveness of the assessment process. For example, the extent to which 'elapsed time' exceeds 'clock time' is potentially a significant factor in customer service since it affects the time it takes to clear a product for manufacture/use. The ANAO notes that for some types of applications the excess of 'elapsed time' over 'clock time' has been of the order of one to two years.

**3.25** While recognising that the NRA cannot control 'elapsed time', the ANAO supports the recent trialing by the NRA of 'elapsed time' to aid management of the more complex applications. The ANAO considers using 'elapsed time' as a secondary indicator would help improve overall timeliness performance and may indicate areas where clients have ongoing difficulty. This could lead to a more customer service oriented approach, particularly service in terms of achieving overall outcomes for the customer, and may point to ways of reducing 'dead time'.

## Recommendation No. 3

**3.26** The ANAO *recommends* that the NRA investigates the use of 'elapsed time' as a secondary indicator in managing the assessment of all applications for the registration of agvet chemical products.

### *Agency response*

**3.27** Agreed. The NRA agrees that this is an important parameter and has actually been measuring and reporting elapsed time as well as clock time for the last two years. However, it is contended that it is not appropriate for the NRA to be responsible for the time applicants may take to respond to deficiencies in their applications, particularly when they relate to matters clearly specified in NRA guidelines and requirements.

## Further scope to improve processes

**3.28** Although the NRA has taken a number of important steps to improve assessment procedures there has been no discernible decrease to June 1997 in the number of applications that exceed statutory timeframes. The ANAO considers that there is scope to make further improvements, particularly in the area of the NRA's internal processes. This includes benchmarking against other organisations involved in caseload management and examining the scope for business re-engineering procedures to remove any unnecessary steps or otherwise streamline activities.

**3.29** The ANAO notes that a consultant's study in 1993 indicated that there was ample scope for improving the efficiency of the assessment processes.

### *Business re-engineering*

**3.30** Business re-engineering offers the NRA opportunities to review and improve processes through:

- identifying and eliminating/decreasing waste or non-value added activities;
- implementing new processes to enable significant improvements in performance; and
- encouraging continuous improvement on the basis of the initial improvements.

**3.31** The NRA's ISO accreditation, by defining and documenting the NRA's assessment procedures, should provide a firm foundation from which any benchmarking or business re-engineering exercises could commence.

**3.32** The ANAO considers that scope exists to make business re-engineering improvements. Some examples are discussed below.

### Fewer registration categories

**3.33** Business re-engineering which seeks to reduce the number of registration categories is one opportunity. At the moment, applications to register new chemical products or modify the conditions of already registered products are assigned to one of 63 registration categories covering most situations. However, this has resulted in a complex situation where applicants as well as NRA staff are a times unsure as to which category individual applications should be assigned.

**3.34** The result of this uncertainty is that applications for similar products could be allocated inappropriately to different categories and, in turn, different assessment requirements, leading to inefficient and ineffective processes, and possible inequitable outcomes.

### Review processes related to statutory timeframe difficulties

**3.35** Assessment timeframes have been set by the Agricultural and Veterinary Chemicals Code Regulations. The establishment of these timeframes followed lengthy consultations with the external agencies involved in the assessment process as well as with chemical manufacturers on such issues as workloads and customer expectations.

**3.36** However, the ANAO understands that subsequent to the setting of the timeframes, the NRA was given additional responsibilities as part of the assessment processes. These relate to enhanced public consultation on the registration of certain agvet chemical products and trade issues that arise with establishing MRLs.

**3.37** Whilst recognising this, the ANAO considers that the NRA should review those assessment processes that create most difficulty in meeting timeframes. This would help identify those areas on which business re-engineering should focus in seeking reductions in processing time.

### Overseas assessments and experience

**3.38** Maximising the use of assessments, and the experience of overseas agvet chemical regulatory schemes, is another means of streamlining processes associated with assessing agvet chemical products. The NRA has been active in developing opportunities for exchange of assessments and worksharing opportunities, either as part of OECD activities or through bilateral agreements with regulatory agencies in other countries.

**3.39** The unique Australian environmental and agricultural conditions are factors in the level of reliance that can be placed on overseas assessments. In addition, some overseas agvet chemical regulatory schemes are said not to be as comprehensive as the Australian scheme. Nevertheless, the ANAO considers that the NRA should rely as much as possible on overseas assessments, with an appropriate level of confidence, and ensure that its assessment process fully utilises such opportunities.

**3.40** The ANAO also considers that it is important to maximise monitoring of adverse effects reporting or intelligence from overseas agvet chemical registration schemes. This would be particularly valuable when considering the registration of new active ingredient(s), a new combination of actives or a major formulation change.

### Parallel processing

**3.41** Another aspect of business re-engineering processes is to maximise the number of tasks undertaken in parallel as opposed to being done sequentially. This is a typical benefit of re-engineering the components and the scheduling of tasks. An example with the assessment process is the seeking of public comment on the possible registration of chemical products containing new active ingredient(s) towards the end of the assessment process (refer to Figure 2). Scheduling the public comment stage towards the end of the assessment process has the potential to either slow up the process or leave insufficient time for adequate public comment.

**3.42** The ANAO considers that the timing of the public comment phase should be reviewed with a view to initiating it earlier; for example, as soon as an application has been accepted for assessment. This might involve the release of a public summary sheet containing information on the product's composition and intended use followed by the release of more detailed information at the end of the assessment. The earlier release of information for public comment could provide greater service to a key stakeholder group while minimising delays with the assessment process.

**3.43** The NRA could also examine the possibility of coordinating the seeking of public comment with similar activities by the Australia New Zealand Food Authority (ANZFA). This too would enhance public consultation while increasing the efficiency and effectiveness of both organisations.

**3.44** Having regard to performance against statutory timeframes, the ANAO considers that scope exists for the NRA to expand its re-engineering efforts, including in the areas identified above.

## Recommendation No. 4

**3.45** The ANAO *recommends* that the NRA employs business re-engineering procedures to achieve further efficiencies in the assessment processes, including through:

- using fewer registration categories;
- examining processes associated with difficulties in meeting statutory timeframes;
- maximising the use of overseas assessments; and
- commencing aspects of the public comment process earlier.

### *Agency response*

**3.46** Agreed. The NRA considers that a continual improvement program which incorporates such business re-engineering initiatives is essential in a rapidly changing international regulatory climate. It is also noted that the NRA is already well progressed in a number of business re-engineering activities which are designed to significantly improve the efficiency of the registration and evaluation processes. These include:

- development of the Submit Once Review Once (SORO) initiative, in consultation with industry, to both raise the quality of registration submissions and improve the efficiency with which they are processed;
- the attainment of ISO 9002 accreditation and implementation of the associated continuous improvement program;
- establishing bilateral and multilateral agreements with overseas agencies to underpin exchange of assessments and worksharing arrangements, as well as being actively involved in work developing OECD guidelines for international exchange of assessment reports;
- introduction of tiered registration, which requires different levels of submissions and assessment for applications for products with different levels of risk;
- the existence of the current system of multiple categories of registration applications which reflect the risks associated with different types of applications, and consequently the level of assessment required; and
- the initiative to establish the Registration Process Section which is aimed at streamlining the consideration of applications for registration of products

through a more effective differentiation of the administrative and technical aspects of the processes.

**3.47** It is also noted that possible moves towards earlier release of Public Release Summaries may require legislative amendments. The intent of the current legislation is for the NRA to seek comment from the public on its evaluation of an application, rather that just provide information on the product. Early release of information by the NRA would also have implications for the NRA's obligations regarding disclosure of confidential business information. Both of these factors would be likely to necessitate legislative change.

## A structured risk management approach

### *Current assessment practice*

**3.48** On receipt of an application for registration a chemical product is assigned to one of 63 application categories, depending on the required assessment procedure. Each of these application categories has a statutory timeframe and a charge or fee attached to it, and reflects a range of situations including:

- registration of chemical products with active constituents that have not previously been approved (a charge of $20 620 and an assessment timeframe of 15 months);
- formulation changes to chemical products already registered;
- registration of chemical products similar to products already registered; and
- minor changes to the labels on chemical containers (a charge of $620 and an assessment period of 3 months).

**3.49** Arguably these categories reflect to some degree differing levels of risk and of risk treatment (e.g. the need for external assessment, further data etc); nevertheless, chemical products with different risk profiles can be treated in a similar manner. The ANAO considers that greater emphasis could be placed on the inherent risk associated with each chemical product in the assessment procedures.

**3.50** The NRA has acknowledged the need to make greater use of risk management techniques and has taken some steps in this direction. For example, the notification of simple label changes is no longer subjected to formal assessment procedures. It has also begun recently to consider with

industry tiers of risk in a few categories, which may lead to exemption for some products.

**3.51** In the ANAO's view, greater use of explicit risk management techniques would enable the NRA to align its workload more closely with the inherent risk profile associated with the various classes of agvet chemical products. This would provide scope for more efficient and effective management of assessment workloads, shorter assessment timeframes in many cases and the freeing up of resources.

### *The potential for reduced assessment of chemical products submitted to the NRA for approval*

**3.52** The ANAO considers that tailoring NRA's overall approach to dealing with lower risk chemicals in an appropriate manner has considerable potential to achieve improvements in the NRA's efficiency and effectiveness.

**3.53** The risk of chemical products is a combination of the adverse effects associated with the chemical, the likely extent and nature of exposure, and impact. The risk of adverse outcomes from the assessment process is also dependent on the knowledge available about these risk parameters for particular chemicals and their use.

**3.54** In terms of identifying the potential for reduced assessment, the ANAO considered those assessment categories which broadly satisfied the criteria of:

- no new active constituent;
- no new combination of active ingredients; and
- not destined for use on a food-producing species.

**3.55** These represent about 90% of assessments. The ANAO acknowledges that within each category there is a range of risk. The precise location of a particular product's risk profile will depend on the specific chemicals used in those products and their intended use. However, there are some specific chemical products or groups of product registered by the NRA that are generally lower in risk than others due to their inherent chemical composition.

**3.56** The ANAO has not sought to obtain specialist advice to quantify these risks. Rather the key point is that there is a wide range of risks in assessment applications, and that a considerable proportion of applications may have the potential for reduced assessment.

**3.57** In addition to registering agvet chemical products, the NRA is responsible for registering a range of non-agvet chemical products, such as fly and insect sprays and swimming pool and spa chemicals. While some of these are potentially high risk, manufacturers claim that as a class of chemicals they generally represent a lower risk as the chemical properties of these products are well known and the products are generally in wide use. The NRA agrees that many non-agvet chemical products present a lower risk profile. In the ANAO's view these points emphasise the need for a more structured approach to risk management.

**3.58** For its part the NRA has emphasised the need to consider all the complexities and inherent risks in a product. It acknowledges and supports the scope for enhanced risk management approaches to assessment.

**3.59** The precise scope for improved efficiency and effectiveness from enhanced risk management of the assessment process is difficult to establish, but the ANAO considers that it is significant. Some of the recent initiatives such as pre-screening, tiered assessment and exemption, reflect elements of a more risk based approach, and as such seek to address some of the potential for improvement identified by the ANAO for reduced assessment.

### *Conclusion*

**3.60** The ANAO suggests that an appropriate risk management approach to this situation is to establish the risk profiles to determine how the registration process should proceed. The major advantage of such an approach would be to shift the management focus from the registration process and place it squarely on the registration outcomes, that is, when and where the product is to be used and what the implications of its use are. This in turn can be seen to be more directly linked to the NRA's corporate objectives.

**3.61** Having assessed the level of risk for the particular product, a lower risk case could be handled by a range of assessment procedures appropriate to the level of risk; for example, for very low risk chemical products, exemption from assessment may be possible. Where constituents are already in wide use (and where the risk profile is well known), options may include registration by administrative action.

**3.62** Whilst the NRA has introduced elements of a risk based management approach, the ANAO considers that the full benefits will not be achieved until there is a comprehensive, structured, explicit use of risk based principles, fully integrating planned approaches to such aspects as registration, compliance and good manufacturing practice.

## Recommendation No. 5

**3.63** The ANAO *recommends* that the NRA adopts a comprehensive risk management approach to the overall assessment arrangements applying to applications for registration, including categorising applications based on an assessment and analysis of risk and determining treatment regimes that are consistent with any risk assessments and analyses.

### *Agency response*

**3.64** Agreed, with comments as provided in response to recommendation 4 applying. These two recommendations overlap considerably.

# 4. External Service Provision

*This chapter considers the way in which the NRA manages its relationships with those government organisations that provide technical advice and assistance for the evaluation of more complex applications for registration. Enhancements to existing agreements are recommended which should result in better value for money and improved accountability.*

## Introduction

**4.1** The NRA, in carrying out its responsibilities for the registration of agvet chemical products, seeks advice from a number of Commonwealth and State government agencies. Effective management of external service provision is an important element of ensuring the NRA's assessment processes are efficient and effective.

## Contractual arrangements with Commonwealth service providers

**4.2** There are three Commonwealth agencies which, as service providers, assist the NRA in assessing the more complex applications for the registration of agvet chemical products. These are Therapeutic Goods Administration (TGA); Environment Australia (EA); and Worksafe Australia (Worksafe).

**4.3** Between August and December 1996, the NRA formalised its relationship with its Commonwealth service providers with the signing of a series of Memoranda of Understanding (MOU) and Service Agreements.

**4.4** It is critical that the Service Agreements clearly state the services to be provided, the performance and quality standards to be met, the timing of delivery and the payments involved. The absence or insufficient detailing of any of these factors increases the risks of the NRA not receiving value for money and not meeting its statutory obligations.

## The MOUs and agreements with Environment Australia (EA) and Worksafe

**4.5** The NRA has formalised the purchaser/provider nature of its relationship with both EA and Worksafe through essentially identical MOUs and Agreements. The purpose of the MOUs is to:

- record the mutual understanding of the parties' respective roles and responsibilities;
- establish principles for cooperation; and
- agree on principles to apply to the provision of professional assistance by EA and Worksafe.

**4.6** The MOUs provide for separate Service Level Agreements to be developed which formalise the operational arrangements between the NRA and the two agencies. The Agreements require EA and Worksafe to provide a range of professional services including the scientific evaluation of certain chemical products, the reporting of those evaluations, attendance at meetings as required, and any other scientific service, advice or information required on an *ad hoc* basis. The agencies are also required to provide their services in a timely manner that enables NRA to meet its statutory obligations. Details of the services to be provided are set out in Schedules to the Agreements.

**4.7** For their professional services, the NRA has agreed to pay the agencies a fixed sum (in 1996-97, $742 300 to the EA and $823 540 to Worksafe) to fund certain levels of staff resources. The parties agree to renegotiate the amount each year and the NRA agrees to involve the agencies in its annual budgeting process.

### *Comment*

**4.8** The MOUs and Service Level Agreements also provide a broad framework for cooperation between the NRA, and EA and Worksafe. The MOUs have established the respective roles and responsibilities of each party, while the Agreements set out the types of professional assistance to be provided and the payments involved. However, the MOUs and Agreements do not include sufficient detail of how the professional assistance is to be provided, the performance and quality standards required and the actual timing of delivery of assistance. Specifically:

- the parties have not developed or documented procedural/working arrangements for the provision of professional assistance as required under the MOUs and Agreements;

- there is limited indication of how the work is to be done or the quality at which it is to be done;
- performance measures are inadequate. The only performance measure is that the agencies are to provide professional assistance within a timeframe that enables the NRA to meet its statutory obligations. Without clear indications of how the agencies are to carry out their contractual obligations, it is difficult to establish performance specifications and measure success against those standards; and
- funding under the Agreements is based on a specified level of staff resources being allocated to providing the NRA with professional assistance. It is difficult to see how value for money for each service can be assured with such an arrangement. The ANAO considers that a cost-based study should be undertaken by the NRA in conjunction with the agencies, against appropriate procedures and performance standards, in order to establish levels of fees for services provided, enabling greater assurance about value for money and providing benchmarks to facilitate contestability.

**4.9** The ANAO concludes that there is limited formal assurance that the NRA receives value for money in terms of the services provided.

## Interim Service Level Agreement (ISLA) with the TGA

**4.10** Given that the TGA was being restructured at the time, the ISLA with the TGA was a truncated version of the EA/Worksafe MOU and Agreement. Under the Agreement, the TGA agreed to provide defined types of professional advice or assistance to the NRA and keep records of professional advice or assistance, acquit the funds expended, and provide a reasonable level of reports to the NRA on request. In turn, the NRA agreed to seek advice from the TGA on all applications received in defined categories and pay the TGA a fixed sum of approximately $2m for providing the above services.

**4.11** The TGA also agreed to a cost-based activity analysis of work undertaken, in consultation with NRA. The results of the analysis were used as a basis for 1997-98 budget discussions**.**

**4.12** The ISLA was for one year (1 July 1996 to 30 June 1997), although the ANAO notes that at the time of this report they are yet to re-negotiate.

**4.13** Unlike the Agreements with the other two agencies, the ISLA specifies the levels of advice and assistance to be provided and states that any services are subject to prior negotiation. However, the agreement does not define the

particular functions to be performed, performance or quality standards or timeframes against which those services are to be delivered. Furthermore, the ISLA does not set out the specific roles and responsibilities of each party.

### *National Drugs and Poisons Schedule Committee*

**4.14** The National Drugs and Poisons Schedule Committee (NDPSC) is a technical body, made up of Commonwealth and State Government officials responsible for determining the retail distribution of drugs and poisons by 'scheduling' their availability by controlling who can dispense and/or have access to certain drugs and poisons. Certain agvet chemical products registrable by the NRA fall under the NDPSC's jurisdiction. The TGA provides the secretariat support to the NDPSC.

**4.15** The ANAO understands that the administrative arrangements for the NDPSC are now under review by the Government. The ANAO considers that the NRA should consider the opportunity in any revised administrative arrangements to improve the coordination of its activities with those of the Committee. One opportunity might be to incorporate the liaison arrangements with the NDPSC into the finalised Service Agreement with TGA, should the Committee be positioned with the TGA.

## Recommendation No. 6

**4.16** The ANAO *recommends* that the NRA ensures that service agreements are established with all significant service providers which include:

- clear documentation of professional assistance to be provided, including appropriate performance standards, technical and quality standards and specific timeframes for the delivery of such assistance; and
- establishing appropriate fees for service based on providing value for money.

### *Agency response*

**4.17** Agreed. The NRA already has in place service level agreements or memoranda of understanding with external service providers which define requirements for services and associated fees. It is, however, appropriate as part of the next round of renewal of these agreements that they are closely reviewed to ensure that clear performance standards, including technical requirements, timeframes, and fees for service, are included. As part of this process, activity based costing exercises have already been undertaken with

some external agencies and this information has been used as a basis for existing agreements.

## Contestability

**4.18** The public sector now operates in a far more contestable environment, in which, in the interests of improving performance and providing greater value for money, the Government is considering alternative methods for the delivery of services, including the use of the private sector.

**4.19** Accordingly, the ANAO considers that the NRA should examine the possible use of alternative sources of professional assistance. An integral aspect of this is establishing the appropriate service fee data and benchmarks, as discussed above, for existing service providers. The use of such alternative sources has the potential to assist the NRA to improve its own performance as well as introducing a level of competition among potential service providers.

**4.20** The ANAO is therefore of the view that, in order to achieve more cost effective outcomes, the NRA should consider the possible use of alternative sources of professional advice before finalising any service agreement with the TGA as well as when the EA and Worksafe agreements are up for renewal.

## Recommendation No. 7

**4.21** The ANAO *recommends* that the NRA assesses the possibility of using alternative sources of advice, in place of either any one or all of the existing agencies, in order to provide a more informed and contestable framework for the delivery of services to the NRA.

### *Agency response*

**4.22** Agreed. The NRA notes that this recommendation is consistent with overall Government policy regarding contestability of services. Consideration will need to be given to the extent of availability of alternative service providers capable of meeting the NRA's technical and regulatory needs on an enduring basis.

## State and Territory efficacy reviews

### *Efficacy review process*

**4.23** The State and Territory Governments assist with the assessment of the more complex applications by conducting efficacy reviews to ascertain the effectiveness of agvet chemical products against their intended use. This involvement of the State and Territory Governments is in line with their partnership role under the National Registration Scheme as well as their responsibility for control-of-use activities including licensing of pest control operations and aerial spraying within their boundaries. The States and Territories also provide expert advice to the NRA based on detailed knowledge of local soil, climatic, and other relevant conditions and agricultural practices.

**4.24** Each State and Territory has the opportunity to participate in every review, with the position of leading or coordinating State/Territory reviewer normally being rotated through each State/Territory. If a particular agvet chemical product has specific application in only certain part(s) of Australia, the position of lead reviewer would go to the most relevant State or Territory.

**4.25** The actual reviews are carried out by personnel from the leading State or Territory's department of primary industries or equivalent. If there is no suitably qualified personnel within the local public sector, then academic or research institutions are approached. While the lead State/Territory is primarily responsible for the review process, the work is supplemented and/or checked by experts in the other States and Territories.

### *ANAO comment*

**4.26** The need for efficacy reviews of the effectiveness of agvet chemicals against their intended use recognises the less than benign nature of chemical products, and the potential danger to the environment and public health of having excess quantities of unused chemical products that have proved to be ineffective in the community. The ANAO found that there was a general acceptance amongst agvet chemical manufacturers of both the need for these reviews and the role of State and Territory Governments in the process.

**4.27** The ANAO found that although there are guidelines for reviews they have not been updated since 1993 and are not clear on a number of aspects of the process. For example, there is no clear guidance on priority of this work even though the reviews are generally carried out by State or Territory officials or institutional experts in addition to their normal duties. This has led to expressions of concern by some manufacturers concerning the priority and

sufficiency of time to perform the reviews. The ANAO considers that improved guidance for efficacy reviews should include clear parameters as to the priority of and the time(s) required for them.

## Recommendation No. 8

**4.28** The ANAO *recommends* that the NRA, in conjunction with the States and Territories, updates guidelines to establish clearly the purpose, parameters and priority of the efficacy reviews undertaken by States and Territories of the effectiveness of agvet chemical products against their intended use. The new guidelines should cover the duties and responsibilities of reviewers.

### *Agency response*

**4.29** Agreed. The process of updating guidelines for efficacy reviews has already commenced.

# 5. Other NRA Programs

*This chapter describes the NRA's programs in addition to the assessment of applications for registration of agvet chemicals. The chapter comments on the performance of these programs and concludes that all NRA programs should be incorporated into a structured risk management plan.*

## Introduction

**5.1** A structured approach to risk management needs to take into account all the NRA's regulatory programs, not just applications for the registration of agvet chemical products. A fully integrated approach would seek to provide the most cost effective mixture of treatments to respond to assessed risks.

**5.2** This chapter therefore examines issues relating to the following NRA programs:

- Existing and Special Chemical Review Programs (ECRP and SPRC);
- Compliance;
- Technical Grade Active Constituents (TGAC);
- Manufacturers' Licensing Scheme; and
- Adverse Experience Reporting Program.

## Chemical review

### *The role of the chemical review programs*

**5.3** In 1993, it was estimated that there were more than 600 agvet active ingredients available in Australia, in 7 000 - 8 000 products owned by some 400-500 registrants. One of the responsibilities of the NRA is to undertake an Existing Chemical Review Program to examine systematically agricultural and veterinary chemicals registered prior to the National Registration Scheme in order to determine whether they meet current registration standards. It is intended to ensure both that existing registered chemicals are safe when used properly, and that good agricultural practices are clearly set out. The Special

Review Program reviews specific aspects of active constituents, chemical products or labels, following notification of particular areas of concern.

### *ECRP activities*

**5.4** Eligibility criteria, instructions for nomination and nomination forms were established for the ECRP in 1995 following a consultative exercise which commenced in 1993. The selection criteria aim to present a qualitative scoring system based on examining the extent to which existing chemicals have an impact on key agricultural, environmental, public health and occupational health and safety areas. The NRA has indicated that the selection criteria are not exclusive, and other factors would be considered in determining the priority for a chemical's review. These included whether the chemical had been reviewed recently in another NRA program or overseas, the chemical's importance, and its level of use.

**5.5** The first round of reviews of five existing chemicals did not commence until between March and May 1996. A key reason affecting the start of the first cycle was the need to obtain data from industry, with this activity being slowed by debate over issues such as data protection.

**5.6** The NRA is now completing the first round of reviews, and a second round has begun on seven chemicals.

**5.7** The NRA has recently sought to improve project management and accountability of the chemical review programs by devolving responsibility for particular chemicals and for meeting established milestones. There is regular reporting to the Board on progress of the review programs.

### *ANAO comment*

**5.8** The ECRP was instituted to review comprehensively existing chemicals on a priority basis. As currently managed, ECRP will not be able to review a significant proportion of active ingredients registered prior to the establishment of the National Registration Scheme for a number of years.

## Compliance

### *The role of the compliance program*

**5.9** The National Compliance Program monitors the supply of agricultural and veterinary chemical products to ensure that only registered products are

sold and that they bear approved labels. The program operates on a partnership arrangement, funded and managed by the NRA and staffed by inspectors located in State and Territory jurisdictions.

**5.10** The Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) was involved in setting up the State and Territory legislation before the NRA was in existence. This legislation later formed the basis of the establishment of the agreement between the States and Territories and the NRA, with complementary Federal, State and Territory legislation substantially underpinning the program.

**5.11** The Compliance Section of the NRA was formed in early 1994. A Compliance Agreement with the States and Territories has been finalised and includes an annual work plan which defines the program funding and priorities and which lists the products to be tested in a particular year.

### *A risk-based approach - review of the national compliance program*

**5.12** The NRA has recognised that there is considerable scope to improve the efficiency and efficacy of the compliance program and conducted a review of the program which was completed in January 1997. The review found that the program '….. is extravagant, especially in the area of routine visits by inspectors'. It found also that dealing with violations was inefficient, with many offenders not prosecuted for practical reasons. The review emphasised the desirability of adopting a risk management approach to the compliance program while keeping in mind the NRA Board's objectives that the program be effective as well as fair, nationally consistent and predictable.

**5.13** The review considered that the NRA should adopt an approach that encouraged compliance and remedied non-compliance rather than punishing or penalising offenders. It recommended focussing on industry self-regulation with the NRA taking an 'auditing' role, enforcing legislative provisions on offenders who knowingly breach the industry's quality assurance procedures. Stakeholders, including State and Territory authorities, industry and consumers have been asked to comment on the review.

**5.14** The recommended approach would mean a significant change to the compliance strategy. It would need to have regard to the type of product, concentrate on manufacturers, importers and major distributors rather than on retailers, and limit surveillance of low risk products such as fly sprays and swimming pool chemicals. Legislative change might be necessary to establish other options to encourage and enforce compliance and to allow the NRA to take effective action to reduce risks when a breach has occurred.

**5.15** The changes under consideration represent a more risk-based approach to compliance, which the ANAO considers is necessary on grounds of both efficiency and effectiveness. The ANAO considers that such enhancements cannot be viewed in isolation - for example, the efficacy of changes in the compliance program will be influenced by the impact of the Manufacturers' Licensing Scheme. A risk-based approach to the compliance program therefore needs to be undertaken within a broader application of risk management principles if it is to be fully successful.

## Technical Grade Active Constituents program (TGAC)

**5.16** The NRA is charged with ensuring that technical grade active constituents intended for use in formulated products pass NRA evaluation for quality and standard of manufacture. The TGAC program has been established to carry out this responsibility.

**5.17** Because there were no transitional provisions in place when the Agvet Code came into effect in March 1995, all approvals under previous arrangements had to be reconsidered and legally recognised under the NRS. The NRA received about 550 requests for renewal by the end of June 1996 and nearly 100 new applications.

**5.18** The NRA developed criteria for the exemption of some TGACs and published a list of those exempted in April 1996.

**5.19** In early 1996 the NRA conducted a review of the TGAC program and concluded that the processes applied were 'inadequate to ensure the fitness for use of actives in agvet chemical products'. This prompted plans for the development and implementation of a new, more comprehensive program, featuring risk-based measures and a national register of analytical methods. The more comprehensive program was identified by the NRA as a priority for 1996-97; however, no specific timeframe was given. While some progress has been made, with several hundred TGACs being gazetted and a register of analytical methods now being developed, the comprehensive program is yet to be implemented.

**5.20** The ANAO notes that the NRA has questioned its ability to pursue legislative breaches under the TGAC program. Unlike agvet chemical products, there are currently no powers to recall a TGAC if it is unapproved or fails to meet specifications. There are also no legislative provisions that allow the NRA to require a person to sample and test TGACs. This would appear to

limit the efficacy of the program, and improvements in the legislative framework through recall and testing provisions would appear warranted.

## Manufacturers' Licensing Scheme and Good Manufacturing Practices (GMP)

### *Background*

**5.21** The purpose of the licensing scheme is to ensure that quality is built into products at the time of manufacture. At the moment only the manufacturers of veterinary chemical products must be licensed because, in part, of the criticality of biologically based products for expensive animals and the possible impacts on trade and public health.

**5.22** According to legislation, only those who eventually satisfy the manufacturing principles determined by the NRA are to be licensed, and the principles may include codes of good manufacturing practice (GMP) or other appropriate standards. The NRA has adopted GMP as the standard against which veterinary chemical manufacturers will be licensed. Applicants for a licence will be audited against GMP standards.

**5.23** The NRA has established a priority for audits of manufacturers according to the 'criticality' of the products concerned. Details of the categories are at Appendix F.

### *The NRA's risk approach to licensing*

**5.24** The NRA received around 220 applications from manufacturers required to be licensed by 30 June 1996. The first round of audits began in August 1996 and examined 'Category 1' (i.e., the most critical); approximately 20 manufacturers were audited. There are 86 'Category 2 and 3' manufacturers to be audited in 1998 and 72 'Category 4 to 6' manufacturers to be audited after November 1998.

**5.25** The NRA advised that the GMP codes were developed with extensive consultation with manufacturers, and are being introduced in a tiered fashion. Nevertheless, criticisms have been raised about the need to licence all manufacturers, particularly for low risk and/or low volume products. Small manufacturers claim that the cost of complying with GMPs and the licensing program in general is prohibitive and renders certain products unprofitable. In response, the NRA has indicated that it is taking a pragmatic approach and is seeking to educate manufacturers to understand their legal responsibilities

better; it will not be expecting smaller manufacturers to have the same amount of documentation as larger manufacturers.

**5.26** There has been a high level of non-compliance by the Category 1 manufacturers when assessed against the GMP code - of the order of 60% according to the NRA. The NRA has indicated that a high failure rate is to be expected in the initial stages of the scheme, and that similar patterns occurred overseas. The NRA has identified lack of industry awareness and knowledge of the GMP as key factors in the high failure rate. It has run GMP awareness seminars in capital cities. The ANAO considers that it is important for the NRA to extend its analysis of the reasons for the failures to include the adequacy of industry practices, the relevance and appropriateness of the GMP codes and the auditing process. This should lead to the development of appropriate strategies to achieve a higher level of compliance. The ANAO understands that the current Australian GMP standard falls short of the standards operating in major comparable overseas schemes.

## Recommendation No. 9

**5.27** The ANAO *recommends* that the NRA reviews the outcomes of the administration of the Manufacturers' Licensing Scheme in order to develop appropriate strategies to achieve a higher level of compliance. This should include examining the codes and guidelines, auditing standards and manufacturer liaison and education practices.

### *Agency response*

**5.28** Agreed. This will be done as an integral part of the ongoing implementation of the Manufacturers' Licensing Scheme. As the scheme currently operates, a key part is to analyse the reasons for failure of manufacturers to comply with audit requirements, with manufacturers being advised on what corrective actions are necessary for them to achieve compliance. Overall reasons for failure to date have included a lack of industry awareness and knowledge of GMP. To help industry achieve the necessary standards, GMP awareness seminars have now been held in mainland capital cities.

## Adverse Experience Reporting Program (AERP)

**5.29** The Adverse Experience Reporting Program was introduced by the NRA in January 1995. The program requires manufacturers to report adverse

effects of veterinary chemical products to the NRA. In addition, it enables product users (and members of the public generally) to notify the NRA voluntarily of any unexpected adverse effect involving animals, human beings or the environment, that appears to be associated with a veterinary chemical product when it has been used in accordance with the label directions. The NRA considers a lack of efficacy to be an adverse effect.

**5.30** The NRA has commissioned its Community Consultative Committee to undertake a project which will develop a proposal for a program for agricultural chemical products. The fully costed proposal will be considered by the Board in the second half of 1998.

**5.31** Adverse reports are referred by the NRA to the manufacturer for investigation and comment. The NRA assesses the manufacturer's response, considering, among other things, information published by other monitoring agencies, and takes appropriate action. This may include keeping the product under review (if the evidence about whether the experience is product related is inconclusive), requiring the manufacturer to change the product label or its formulation or, in extreme cases, enforcing product recall or revoking registration.

**5.32** The NRA undertakes to respond to those who lodge reports, advising them of action proposed. It also proposes to publish reports summarising all reported adverse experiences.

## Conclusion

**5.33** The NRA has acknowledged that improvements in many of its programs are possible through the introduction of an integrated risk management strategy. For example, the ANAO recognises that by ranking chemicals against a set of selection criteria, as it is doing in the ECRP, the NRA has taken an initial step towards a risk management approach to the review of existing chemicals. However, given the potential number of reviews to be conducted and the delays experienced to date in beginning the program reviews, it might be possible to improve this approach by considering the risk profile of individual chemicals in the light of compensating mechanisms and controls that the NRA can employ. These include licensing, compliance and adverse experience reporting. Such programs are not without their own problems, however, and it is important to examine ways to improve their efficacy and efficiency.

**5.34** In so doing, the NRA must have regard to its statutory obligations. Risk management provides a means of analysing the relative priorities in the objectives included in the preamble to the Act.

**5.35** The ANAO considers a comprehensive risk-based approach to be critical to the success of the National Registration Scheme and concludes that there would be benefits in the NRA adopting a risk management approach that would involve the NRA addressing issues related to all its program activities in an integrated manner, including its approach to chemical product registration. The ANAO urges the NRA to give a high priority to the development of such an approach, including the allocation of sufficient resources to progress implementation.

## Recommendation No. 10

**5.36** The ANAO *recommends* that all NRA programs be incorporated into a structured risk management plan to assist in fulfilling the NRA's objectives. The risk treatment regime identified in the plan would guide the development and priorities of, and balance between, each of the programs.

### *Agency response*

**5.37** Agreed. The NRA has recently conducted an evaluation of organisational risk, in conjunction with other stakeholders, which could form a sound basis for development of a structured NRA risk management plan. The NRA considers that the risk management plan will provide an important element in its corporate planning process.

# 6. Resource Allocation and Fee Implications

*This chapter comments on the NRA's approach to resource management and proposes a review of the cost recovery model.*

## Resource allocation

**6.1** Under the *Agricultural and Veterinary Chemicals (Administration) Act 1992,* the NRA has the power to determine the terms and conditions of employment of its employees and consultants. Accordingly the NRA has developed a salary structure based on six salary bands that correspond broadly to the Australian Public Service Administrative Service Officer and Senior Officer Grades.

**6.2** Since commencing operations in June 1993, NRA staff numbers have steadily increased from 48 to 102 at end June 1997 (Appendix A). This increase coincided with an increase in the registration workload as well as the progressive taking on of additional responsibilities; including the Existing Chemical Review Program, the licensing of chemical manufacturers, the residues function, a compliance program, a manufacturers' licensing program and the NCRIS database.

### *Matching resources and workload*

**6.3** The NRA indicates that the allocation of staff resources reflected an evaluation of the minimum resources necessary to conduct the initial and ongoing registration functions and provide corporate support functions. It also reflects the resources identified as being necessary to commence and develop the new functions the NRA was required to develop, including a stronger compliance program and greater throughput of the review programs.

**6.4** One of the challenges for the NRA has been to match resources to the application workload to improve registration performance, as discussed in Chapter 3. However, the ANAO is concerned that the NRA did not undertake a comprehensive quantitative analysis to determine the actual overall number of NRA staff required or where and how staff could be best utilised in meeting the organisation's responsibilities. In this context the ANAO notes that a staff survey conducted in December 1996 indicated that registration staff

consistently had a lower level of staff satisfaction than other areas of the NRA. The ANAO also notes high levels of staff turnover (43% in 1995-96 and 32% in 1996-97).

**6.5** The ANAO considers that risk management and quantitative analysis would provide a framework to guide resource allocation, while taking into account the different areas of risk that the NRA needs to consider. This would provide senior management and the Board with greater assurance that the staffing allocation was appropriate.

### *The opportunities for a more analytical approach*

**6.6** The NRA's own efforts have demonstrated the benefits of using appropriate tools to help decision-making about resources. A benchmarking study of the Corporate Services area in 1996 resulted in a saving of five full-time equivalent staff positions. The ANAO suggests that other areas of the NRA would also benefit from a more structured approach in determining appropriate staffing levels.

**6.7** The NRA also has the basis for a more structured approach to workload matching through its work on ISO accreditation, which involved extensive assessment and documentation of the processes of registration. This could provide the basis for resource/workload models, and for benchmarking of processes and their costs. Organisations in diverse sectors have found substantial efficiency gains from such approaches.

**6.8** Using a more quantitative approach, building on the process mapping and benchmarking work already undertaken, should provide the basis for enhanced approaches to, and greater efficiency of, resource allocation. In addressing this, it is important that resource allocation decisions are made consistent with outcomes of the risk management process discussed throughout this report.

## Recommendation No. 11

**6.9** The ANAO *recommends* that, as part of its resource management, the NRA:

- undertakes as far as possible an appropriate quantitative analysis of its operations to provide a structured approach to determining staffing levels; and

- reflects the outcomes of risk assessment and analysis activities in the allocation of resources to individual programs.

### *Agency response*

**6.10** Agreed. This analysis should occur as part of overall organisational risk evaluation and management planning. The degree to which it can be implemented will be influenced by availability of resources.

## Cost recovery

**6.11** The NRA operates on a cost recovery basis, i.e., the revenue raised by the charges on the agvet chemical industry is used to fund a range of NRA activities in addition to the assessment and registration of agvet chemical products.

**6.12** In developing the cost recovery model there were extensive consultations by the NRA with Commonwealth and State Governments and the industry associations representing the various sectors of the agvet chemical industry. There was general agreement that a multi-part tariff represented the most equitable means of recovering costs.

**6.13** A major consideration in the development of the NRA's fees and charges was the diverse nature of the agvet chemical industry. Some products have multi-million dollar sales while many have sales less than $10 000 per annum (see Appendix G). Also many products are used on a regular basis while others are used on a more seasonal basis, and industry-wide sales can change substantially from year to year depending on climatic factors, economic conditions, etc.

**6.14** A three-part tariff structure therefore forms the basis of the NRA's cost recovery regime comprising:

- fees for the registration of new agvet chemical products or for changes to already registered products, graduated according to the level of assessment required and indexed annually in line with the CPI. As at March 1997 the fees ranged from $620 for minor administrative/technical changes to $20 620 for the registration of new products involving a full toxicology/environmental/ residues/efficacy assessment;
- annual re-registration fees, ranging from $200 to $1 000 per product based on the annual sales of each product, with possible annual CPI indexation; and

- an annual levy of 0.75% of sales on products with annual sales in excess of $100 000, with an upper limit on the levy of $25 000 per product. The levy is reviewed annually and was increased from 0.70% in October 1996.

**6.15** At Appendix H is a table showing the fees applied in Australia and its overseas counterparts.

### *Revenue collected*

**6.16** Of total revenue in 1996-97 of $15.1 million, the NRA received $14.1 million in application and renewal fees and levies, with $2.3 million from application fees, $3.6 million from re-registration charges and $8.2 million from levies. In 1997-98 the NRA estimates that its revenue from applications, renewals and levies will increase to $15.0 million, ($2.3 million from application fees, $3.7 million from re-registration charges and $9.0 million from levies). Thus the levy on sales of individual products in excess of $100 000 constitutes the major source of the NRA's revenue.

**6.17** Notwithstanding the general support among the agvet chemical industry for the three-part tariff, in discussions with the ANAO a number of individual agvet chemical manufacturers expressed concerns about the level of fees and charges. These could be summarised as:

- some smaller agvet chemical manufacturers who believed the initial application fees were too high and therefore discouraged the development of new products with potentially low sales volume; and

- some larger agvet chemical manufacturers who queried why they should, through the levy, provide the bulk of the funding for the NRA's operations. These manufacturers believed, under user-pays principles, that they should only fund the NRA's assessment and registration activities.

**6.18** Particular consideration has been given to cases involving the development of speciality chemical products, for use on minor crops, with potential sales so low that the prospective profits would exceed the regulatory costs associated with getting the product on to the market. Related to this difficulty, the Commonwealth Government in 1996-97 provided a Budget appropriation of $77 000 for the Minor Use Program. The NRA indicates that in 1997-98 it will undertake further analysis of the issues that are involved as part of its annual work program.

### *Effectiveness of current fee structure*

**6.19** Cross-subsidisation is an integral element of the NRA's agreed fee structure. While it is accepted that some manufacturers may have concerns about this aspect, it formed a conscious part of the Government's decision when establishing the NRA and its funding sources. The model applied is an industry cost recovery approach rather than a strict fee-for-service approach, and also recognises the legislative requirements for follow-up activities on quality of products and on continued compliance with standards.

**6.20** The Prices Surveillance Authority (PSA) in its report, *The Prices of Farm Chemicals*,[3] pointed to the inherent lack of constraint on costs associated with the NRA's cost recovery model and the consequential cross-subsidisation of the organisation's operations by the larger chemical manufacturers.

**6.21** The PSA recommended that, once the NRA had been in operation for about two years, there be a review of the registration fees structure, including the appropriateness of applying a price-cap on any future fee or levy increases. This it said would impose financial discipline on the NRA, and lead to greater operational efficiency and effectiveness. This review has not yet taken place.

### *Comment*

**6.22** The ANAO also has concerns that the NRA's cost recovery model does not in itself impose any demands for improvements in efficiency and effectiveness by maintaining any downward pressure on the NRA's costs. Even in circumstances of low inflation, economic growth can provide steady increases in revenue from a levy on sales. Consistent with better practice associated with cost management, the NRA should consider mechanisms to ensure continuous improvement in administration efficiency. Currently the only control is that under legislation the levy is set at no higher than 0.75% of product sales.

**6.23** Accordingly, the ANAO considers that there should be a review of the NRA's cost recovery model. Any such review should also take account of the concerns of manufacturers of low volume products discussed earlier in this Chapter.

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[3] PSA Report No 49, 23 August 1993.

## Recommendation No. 12

**6.24** The ANAO *recommends* that there be a review of the NRA's cost recovery model. The review should be undertaken following the implementation of formal risk management processes and should address appropriate means of ensuring pricing or review mechanisms to provide downward pressure on NRA costs.

### *Agency response*

**6.25** Agreed with qualifications. Such a review is likely to involve substantial resource and any changes to the cost recovery model which may eventuate may involve legislative change. Such a review may well address growing concerns that the NRA has limited ability to conduct public good functions because it is essentially fully funded by industry. This situation is in marked contrast to similar overseas bodies and many other Australian industry regulatory bodies. The issue is, however, essentially a matter for government.

**6.26** With regard to the issue of fees within the cost recovery model, the NRA has previously reviewed its fee structure on two occasions when industry was fully consulted. The current fee structure reflects industry's preference, although they consider that government funding should be available to support public good functions. However, it may be timely to review the NRA fee structure in the light of changes in product mix, evaluation requirements, new technologies and the impacts of the chemical review programs. It is interesting to note that the overall NRA fees compare favourably with those in place in other countries (Appendix H).

Canberra ACT
18 December 1997

P. J. Barrett
Auditor-General

# Appendices

# Appendix A

## NRA staff numbers

| Activity | NRA staff numbers[1] | | | | |
|---|---|---|---|---|---|
| | 30/06/93[2] | 30/06/94 | 30/06/95 | 30/06/96 | 30/06/97 |
| Registration | | | | | |
| Agricultural[3] | | 17 | 13 | 16 | 21 |
| Veterinary | | 14 | 13 | 15 | 15 |
| Residues[3] | | 5 | 10 | 12 | 14 |
| National Chemical Information System | | 6 | 1 | 3 | 5 |
| Improvement Projects | | - | - | 1 | 2 |
| **Total** | **27** | **42** | **37** | **47** | **57** |
| Policy | | | | | |
| Chemical Review | | 6 | 4 | 6 | 8 |
| Compliance | | 2 | 5 | 6 | 9 |
| International & Development Projects | | 3 | 1 | 4 | 5 |
| Communication | | - | 1 | 2 | 3 |
| **Total** | **2** | **11** | **11** | **18** | **25** |
| Corporate | | | | | |
| Finance & H.R. | 8 | 12 | 11 | 8 | 5 |
| Legal & Secretariat | 4 | 5 | 3 | 3 | 6 |
| Information Services & Information Technology | 3 | .4 | 4 | 5 | 4 |
| **Total** | **15** | **21** | **18** | **16** | **15** |
| Executive | 4 | 5 | 4 | 6 | 5 |
| **TOTAL** | **48** | **79** | **70** | **87** | **102** |

1. NRA provided data.
2. Estimates based on Ernst & Young report into NRA, '1993 Review Of Resources', insufficient information to provide any disaggregation.
3. Before 1995 'Agricultural' included chemistry evaluation and since 30 June 1995 this function has been included with 'Residues'.

# Appendix B

## The risk management process

**1.** Risk management is defined as the systematic application of management policies, procedures and practices to the tasks of identifying, analysing, assessing, treating and monitoring risk.[4] Source material on risk management used in the audit was MAB/MIAC Report No 22, *Guidelines for Managing Risk in the Australian Public Service* and the Australian/New Zealand Standard AS/NZS 4360: 1995, *Risk Management.*

**2.** Risk management is a logical and systematic process that can be used when making decisions to improve the efficiency and effectiveness of performance. It is a management tool to identify and prepare for contingencies. Managing risk involves taking action to avoid or reduce unwanted exposure to the costs or other effects of these events, or to maximise the potential of any opportunities identified.[5]

**3.** The benefits of prudent risk management are:

- a more rigorous basis for strategic planning as a result of a structured consideration of the key elements of risk;
- no costly surprises - because undesirable risks are identified and managed;
- better outcomes in terms of program effectiveness and efficiency, eg improved client service and/or better use of resources;
- greater openness and transparency in decision-making and ongoing management processes; and
- a better preparedness for, and facilitation of, positive outcomes from subsequent internal/external review and audit processes.[6]

### *Characteristic features of effective risk management*

**4.** The ANAO considers that an efficient and effective risk management process should demonstrate the following characteristics:

- *consistent strategic approach* - implemented in a consistent and strategic way across the organisation's various components;

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1. Australian/New Zealand Standard 4360: 1995, *Risk Management,* p. 5.
2. MAB/MIAC Report No 22, p. 11.
3. Ibid. p. 12.

- *transparency and visibility* - the essence of accountability, promotes more effective and equitable allocation of resources, justification for the decisions and explanation of the outcomes;
- *flexibility* - allows areas within the organisation to use tools and techniques specific to their needs, while maintaining consistent risk management criteria across the whole organisation;
- *documentation* - to maintain a record of key steps and activities in risk management process; and
- *evidence of an integrated and managed process* - should be integrated with other organisational planning and management techniques - a well managed process promotes coordination, effectiveness and efficiency, timeliness, concentration on the organisation's core processes and issues, and integration with decision-making and resource allocation processes.

### *Six step process*

**5.** Both the AS/NZS 4360 and the MAB/MIAC guidelines describe a six step methodology that will assist an organisation to introduce risk management successfully. These six steps help establish the system that is an essential ingredient of genuine risk management. The six steps are:

i. *Establishing the context* - this involves determining the relationship between the organisation's external and internal operating environments - its strengths, weaknesses, opportunities and threats; and its goals, objectives and policies. The consequences of the organisation not meeting its goals and objectives should be considered along with the criteria for identifying those risks. Finally, the organisation needs to develop the risk management process itself, including its own goals, objectives and strategies, and resource requirements.

ii. *Risk identification* - The aim of this step is identify the risks to be managed. Comprehensive identification using a well structured systematic process is critical. An unidentified risk cannot be treated and may pose a major threat to the organisation. Identification should include all risks whether or not they appear to be under the control of the organisation and should be from the perspective of both the organisation and stakeholders.

iii. *Risk analysis* - the purpose of the risk analysis step is to estimate likelihood and effects (consequences) of risk events and to combine these to develop risk levels as a precursor to setting risk priorities. The analysis should include a description of each risk and how it might arise, possible initiating factors, the main assumptions and a list of the principal sources of

information. It is important that existing controls be considered as they influence the estimates of likelihood and effects.

iv. *Assessing and setting priorities of risk* - the risk assessment step involves decisions about whether risks are acceptable or unacceptable. The output from the risk assessment step should be a list of acceptable risks, showing the reasons they are considered acceptable, together with a list of unacceptable risks, in priority order, both currently being actioned and requiring further action. The process usually involves a comparison of likelihoods, consequences and initial risk levels. Often the review process generates a priority triage:

- major risks are generally likely to arise and have severe effects;
- moderate risks may be less likely to arise, and/or have less severe effects; and
- minor risks are those that can be managed using standard or routine procedures.

i. *Risk treatmen*t - risk treatment involves identifying the range of options for treating risks, evaluating those options, preparing risk treatment plans and implementing them. Typically, there are four classes of responses from which treatment options plans can be chosen:

- risk prevention - responses directed at eliminating a source of risk, or reducing the likelihood of its occurrence;
- effect mitigation - responses directed at reducing or coping with the consequences of a risk event;
- risk transfer - responses directed at transferring the risk to another party, or sharing it; and
- risk retention - retaining or accepting the risk.

ii. *Monitoring and review* - as risks and organisational priorities change through time and a changing environment, risks and risk treatments should be monitored as part of the management cycle. Ongoing review is essential to ensure that management plans remain relevant. It is also beneficial to monitor the effectiveness of risk treatment plans and strategies as well as the management system set up to control implementation of treatments.

# Appendix C

## Organisations and associations interviewed during the audit

### Agvet chemical manufacturers

- Ausvac Pty Ltd
- Bayer Australia Limited
- Ciba-Geigy Australia Limited
- Controlled Medications Pty Ltd
- Crop Care Australasia Pty Ltd
- CSL Limited
- Elanco Annual Health
- Hoechst Australia Limited
- Hoechst Schering AgrEvo Pty Ltd
- Inca (Flight) Company Pty Ltd
- Jurox Pty Ltd
- Mallinckrodt Veterinary Ltd
- Mastra Corporation Pty Ltd
- Merck Sharp and Dohme (Australia) Pty Limited
- Monsanto Australia Limited
- Nufarm Limited
- Pfizer Pty Ltd
- Rhone-Poulenc Rural Australia Pty Ltd
- Rohm and Haas Australia Pty Ltd
- Sandoz Australia Pty Ltd
- Uniroyal Chemical Pty Ltd
- VIRBAC (Australia) Pty Limited
- Young's Animal Health Pty Limited

**Industry associations**

- Australian Chemical Specialties Manufacturers' Association
- Australian Paint Manufacturers' Federation
- Avcare Limited - National Association for Crop Protection and Animal Health
- Veterinary Manufacturers' and Distributors' Association

**Primary producer groups**

- Cattle Council of Australia
- New South Wales Farmers' Federation
- Victorian Farmers' Federation

**Consumer and environmental groups**

- Australasian College of Nutritional and Environmental Medicine
- Australian Conservation Foundation
- Individual members of the NRA's Community Consultative Committee
- National Toxics Network

**Commonwealth Government agencies**

- Australian New Zealand Food Authority
- Department of Industry, Science and Tourism
- Department of Primary Industries and Energy
- Environment Australia
- Therapeutic Goods Administration
- Worksafe Australia

**State Government agencies**

- New South Wales Department of Agriculture
- New South Wales Environment Protection Authority
- Queensland Department of Primary Industries
- Victorian Department of Natural Resources and Environment

# Appendix D

## NRA initiatives to improve registration processes

### *Submit Once Review Once Initiative*

**1.** In July 1995, soon after the NRA assumed its full responsibilities, steps were taken to improve the quality of applications with the Submit Once Review Once (SORO) initiative. The aim was to reduce the delays in processing applications by minimising the number of applications returned to applicants due to incomplete information.

**2.** This was a problem recognised by both the NRA and agvet chemical manufacturers, given the highly technical nature of the information required for registration as well as the fact that over 50% of applicants had only one or two registered products and therefore were not familiar with requirements.

### *Registration guidelines*

**3.** In November 1996, as part of the SORO initiative, the NRA began to issue a series of registration manuals aimed at giving applicants a much better indication of registration requirements. The new manuals give a much clearer indication of the general registration process and the range of technical data required for registration.+

**4.** Until the release of the new guidelines, applicants had to work from a range of 'interim requirement' documents, dating back as far as July 1993, when preparing applications.

### *Application pre-screening*

**5.** Application pre-screening is another initiative by the NRA to improve both the quality of, and the turn around times for, the less complex applications.

**6.** Trialed in late 1996 and now in full operation, pre-screening aims at identifying deficient applications within days of arrival, and singles out the less complex applications for immediate attention. Each application goes through three levels of pre-screening before being assigned to an evaluator, starting with the administrative pre-screening. The table below details the role of each level of pre-screening.

**7.** The results of pre-screening has shown that between November 1996 and February 1997, more than 50% of applications were deficient in some way. In many cases the deficiencies were minor, resolved with a telephone call.

However, there were cases where major manufacturers, with many products already registered with NRA, still failed to provide key information.

### *NRA pre-screening processes*

| Type of pre-screening | Frequency | Process | Benefits |
|---|---|---|---|
| Administrative pre-screening | Daily | Checks that application form is completed and signed, and appropriate fee is enclosed. | Applicants are advised quickly of omission. |
| Technical pre-screening | Weekly | Identifies and processes non-technical applications, as well as any obvious deficiencies with applications e.g., insufficient data. | Administrative and non-technical changes are completed within days not months; applicants informed earlier of any deficiencies. |
| Agency pre-screening | Bi-monthly | NRA, TGA, Worksafe and Environment Aust. evaluators meet to check major applications for missing or poor quality data. | Applicants know within two weeks if applications are deficient in any way. They receive one letter, not three from each of the specialist agencies. |

### *Registration seminars*

**8.** In another initiative to improve the quality of applications, in May 1997 the NRA held the first in a proposed series of registration seminars. The aim of the seminars is to assist registrants and registration consultants, used by many chemical manufacturers in preparing applications, as well as NRA's own staff, to have a better understanding of the registration process.

## More efficient and effective processes

**9.** In addition to the steps towards improving the quality of applications, the NRA has taken action to streamline assessment procedures.

### *Approval of draft labels*

**10.** The first of these initiatives was in March 1996, involving approval of labels at the draft stage rather than at the final printed stage.

**11.** Prior to this initiative, several copies of the proposed label, in final form, had to be provided to the NRA for approval prior to registration. The actual approval process involves both the NRA and, from a control of end use perspective, various State Government agencies. This was quite expensive for applicants, as short or special colour print runs of the final label were required for registration, as well as the cost of any required label redesign or wording change.

**12.** Under the revised arrangements, labels are now approved at the draft stage, provided they satisfy the NRA labelling code. This allows for quicker finalisation of applications as there is no need to wait for the printing of labels. This gives applicants greater flexibility to determine such issues as font size and size, colours and graphics, provided there are no wording changes and proposed labels meet labelling guidelines.

### *Notification of minor changes*

**13.** Another streamlining initiative involves the handling of minor administrative changes to records and labels by notification as opposed to formal application. The aim of the initiative is to reduce paperwork and provide a quicker response.

**14.** Under the previous arrangements, formal applications were required to make changes to labels and records concerning such issues as:

- company name and address;
- company logo; and
- label amendments in line with new NRA labelling codes.

**15.** The new arrangements aim for a response target of 10 workings days from the receipt of the notification, as opposed to the three month period under the NRA's statutory timeframes.

**16.** If the new arrangements prove effective, the NRA may extend the handling of minor changes by notification. In 1995/96, some 40 percent of applications received by the NRA were for label changes. Therefore, any initiative that streamlines the processing of such changes has major implications for easing the NRA's assessment workload.

### *Registration Process Section*

**17.** In April 1997, the NRA undertook a major initiative to improve the management of the assessment process, particularly for the major type of

applications which can take up to 18 months to complete. This involved the setting up of a new section, the Registration Process Section, to manage the registration process, freeing individual product evaluators to concentrate on the technical aspects of the process.

**18.** The duties of the new section will involve:

- receiving and recording applications;
- handling the simpler applications, including labels and notifications;
- conduct and/or coordinate pre-screening activities;
- monitor and report on timeframe performance of major applications; and
- being the initial customer contact point for queries on progress and referring of technical matters.

### *Milestone management*

**19.** Another recent step taken towards improving the assessment process involves trialing the management of the major applications on the basis of elapsed time, using milestones to measure performance against set timeframes.

**20.** This is a departure from the NRA's normal 'clock time' approach to the management of the assessment process. The new approach will involve the setting of milestones for each major application and regular reporting to applicants on progress. This demonstrates the NRA's recognition of the importance of adopting a more performance and customer oriented stance.

## Appendix E

## Timeframe breaches by application types

| Period | Product type | Application type[1] | No. finalised | Within statutory timeframes[2] | Outside of statutory timeframes |
|---|---|---|---|---|---|
| 1/10/95-31/12/95 | Agricultural | E | 12 | 6 | 6 |
| | | I | 164 | 92 | 72 |
| | | Total | 176 | 98 | 78 |
| | Veterinary | E | 20 | 15 | 5 |
| | | I | 108 | 93 | 15 |
| | | Total | 128 | 108 | 20 |
| 1/1/96-31/3/96 | Agricultural | E | 21 | 8 | 13 |
| | | I | 160 | 98 | 62 |
| | | Total | 181 | 106 | 75 |
| | Veterinary | E | 11 | 4 | 7 |
| | | I | 74 | 51 | 23 |
| | | Total | 85 | 55 | 30 |
| 1/4/96-30/6/96 | Agricultural | E | 19 | 7 | 12 |
| | | I | 194 | 122 | 72 |
| | | Total | 213 | 129 | 84 |
| | Veterinary | E | 26 | 20 | 6 |
| | | I | 197 | 167 | 30 |
| | | Total | 223 | 187 | 36 |
| 1/7/96-30/9/96 | Agricultural | E | 20 | 8 | 12 |
| | | I | 289 | 161 | 128 |
| | | Total | 309 | 169 | 140 |
| | Veterinary | E | 31 | 20 | 11 |
| | | I | 178 | 145 | 33 |
| | | Total | 209 | 165 | 44 |

[1] 'E' refers to external agency involvement in assessment, 'I' refers to NRA only assessment.

[2] Statutory timeframes refer to 'clock time'

## Timeframe breaches by application types (c'td)

| Period | Product type | Application type | No. finalised | Within statutory timeframes | Outside of statutory timeframes |
|---|---|---|---|---|---|
| 1/10/96-31/12/96 | Agricultural | E | 20 | 13 | 7 |
| | | I | 295 | 134 | 161 |
| | | Total | 315 | 147 | 168 |
| | Veterinary | E | 36 | 21 | 15 |
| | | I | 205 | 191 | 14 |
| | | Total | 241 | 212 | 29 |
| 1/1/97-31/3/97 | Agricultural | E | 16 | 9 | 7 |
| | | I | 289 | 138 | 151 |
| | | Total | 305 | 147 | 158 |
| | Veterinary | E | 26 | 13 | 13 |
| | | I | 183 | 169 | 14 |
| | | Total | 209 | 182 | 27 |
| 1/4/97-30/6/97 | Agricultural | E | 16 | 7 | 9 |
| | | I | 174 | 66 | 108 |
| | | Total | 190 | 73 | 117 |
| | Veterinary | E | 12 | 9 | 3 |
| | | I | 119 | 108 | 11 |
| | | Total | 131 | 117 | 14 |

# Appendix F

## Criticality for good manufacturing practice purposes

| Category | Type of manufacturer | Product type |
|---|---|---|
| Category 1 | Sterile and or immunobiological products | Immunobiological and sterile products, pre-filled sterilisation or post-filled sterilisation products |
| Category 2 | Non-sterile veterinary preparations except Categories 3,4 and 5 | Tablets, capsules, cream, ointment, pastes and liquids (some contain antibiotics and other therapeutics that are potentially harmful if not manufactured properly) |
| Category 3 | Ectoparasiticides | Liquids, pastes and powders (contain insecticide that are potentially harmful if not manufactured properly) |
| Category 4 | Premix/supplements | Premix/supplements (which require registration) (some contain antibiotics and other therapeutics that are potentially harmful if not manufactured properly) |
| Category 5 | Exempt | |
| Category 6 | Single step (involved in packaging, labelling, analysis and testing) | |

## Appendix G

### Number of products in various sales brackets for 1994, 1995 and 1996

| Sales $ | No. of products | | |
|---|---|---|---|
| | **1994** | **1995** | **1996** |
| 0-10 000 | 2 349 | 2 587 | 2 567 |
| 10 000-50 000 | 1 280 | 1 342 | 1 272 |
| 50 000-100 000 | 562 | 642 | 661 |
| 100 000-500 000 | 984 | 982 | 1 080 |
| 500 000-1 million | 241 | 281 | 316 |
| over 1 million | 275 | 321 | 346 |
| **Total** | **5 691** | **6 155** | **6 242** |

## Appendix H

### International comparisons

| | Australia | New Zealand | Canada | | UK | | USA | EC |
|---|---|---|---|---|---|---|---|---|
| | Ag/Vet | Ag/Vet | Ag | Vet | Ag | Vet | Ag | Vet |
| New registration | $20 620 | $2 763 | modular (eg $166 055 for new active constituent) | modular (eg $50 193 for new active constituent) | $122 449 | $29 082 | no set fee; $79 839 per tolerance application | $110 844 |
| Reregistration | nil | nil | modular | modular | $131 428 | | $185 780 | $31 670 |
| Annual Renewal Fee | $200-$1 000 based on disposals | $493.42 (Ag) and $296.05 (Vet) | $137.60-$2 467 per quarter based on disposals | $46-$229 | | | $805 for first registration then $1 610 for each additional registration up to max $50 459. Then $87 156 for 50 or more registrations | |
| Minor Amendment | nil | $49.34 | modular (eg minor label change $141) | $92-$229 | $582 | $295 | | $7 917 |

## International comparisons[8] (c'td)

| | Australia | New Zealand | Canada | | UK | | USA | EC |
|---|---|---|---|---|---|---|---|---|
| | Ag/Vet | Ag/Vet | Ag | Vet | Ag | Vet | Ag | Vet |
| Major Amendment | $10 310 | $740.13 | modular (eg major new use $78 899) | $27 982 (eg another food species) | $65 714 | $16 857 | higher tolerance, same as for new registrations, else $17 123 | $47 505 |
| Annual Levy % | 0.75% for sales above $100 000 (to $25 000 maximum) | nil | no levy proposed | 0.7% for sales above $93 431 | 1.46% | 0.6% up to $2.8mil, 0.4% above that | nil | |
| Cost Recovery (%) | Yes (100%) | No | Yes (70%) | Yes (40%) | Yes (100%) | Yes (100%) | Yes (partial) | Yes |

Source NRA *News*, Vol 4, No 1, April-May 1997; based on overseas data covering years 1996 and 1997.