

5 March 2002

Citrus Industry Inquiry
Productivity Commission
Locked Bag 2
Collins Street East
MELBOURNE VIC 8003

Dear Sir/Madam

Please find enclosed a brief submission from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) relating to aspects of chemicals availability and use within the citrus industry as outlined in the recent Position Paper.

The NRA would be pleased to further elaborate on these or other chemical-related issues if necessary.

Yours sincerely

ALISON TURNER
Chief Executive Officer

NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS

SUBMISSION IN RESPONSE TO THE POSITION PAPER IN REGARD TO THE PRODUCTIVITY COMMISSION'S INQUIRY INTO THE CITRUS GROWING AND PROCESSING INDUSTRY

BACKGROUND TO NRA

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is the Australian agency responsible for the assessment and registration of agricultural and veterinary chemical products prior to sale and their regulation up to and including the point of retail sale. The regulation of the products once in use rests with the States and Territories.

The NRA administers the National Registration Scheme for agricultural and veterinary chemicals in partnership with the State and Territory Governments and the active involvement of other Commonwealth agencies. Through the National Registration Scheme, the NRA delivers product registration, quality assurance and compliance. In particular, the NRA:-

- Assesses the safety and performance of products;
- Determines whether their use is likely to jeopardise trade;
- Regulates the supply of agvet chemicals to the Australian market by approving product labels and specifying conditions of use.

The work of the NRA safeguards the health of people, animals and the environment, and international trade.

CUSTOMERS AND STAKEHOLDERS

The NRA's main customers are people and companies who must:-

- Register products;
- Obtain approval of active constituents;
- Obtain permits to use chemicals in emergency, research and off-label situations, or obtain manufacturing licences.

The NRA has a large number of stakeholders. They include the agricultural and veterinary chemicals industry, farmers, rural sector organisations, environmental, consumer and community groups, other Commonwealth and State/Territory government agencies that help administer the National Registration Scheme, and overseas regulatory authorities with similar functions and responsibilities.

Availability of Agricultural Chemicals Within the Citrus Industry

The Position Paper makes a number of comments about the availability, cost and timeliness of the introduction of new chemicals which have application in the citrus industry.

It must be made clear, that the NRA is not responsible for bringing new products to the market. That is the responsibility of chemical manufacturers. While it is often stated that the reason for not introducing new products is because of regulatory costs, a more accurate position, having regard to the overall cost of new product development, would most likely be commercial considerations associated with the size of the industry and therefore the limited return on investment.

In addition, prospective registrants will also consider the rigor of the regulatory process and whether products are supported by adequate data to substantiate standards of product safety and performance that are required in Australia. While new products may appear more quickly in some overseas markets, the reason behind such decisions must therefore be viewed more broadly than solely in terms of registration fees.

Costs

In regard to costs the fees and charges established by the Government to support product registration are modest by world standards having regard to the extensive scientific evaluation that accompanies the registration of pesticide products.

A comparison of some charges between countries with rigorous evaluation standards are as follows:-

Fee Category	Australia¹	UK²	Canada¹	USA³
Screening Fee	620	13,055	10% of fee	Nil
New Chemical	20,620	250,000	216,000	129,250
Extension of Use	10,310	4,450-250,000	146,400	29,500
Minor Use Permit	Nil	19,960	Nil	Nil
Annual Renewal Fee	200-1000	N/A	3,228(max)	Nil

Note: for comparison purposes, fees have been converted to \$Australian (approx).

1. Australia and Canada also place a levy on annual sales.
2. The UK is considering the introduction of a levy on sales of all new active ingredients.
3. US fees are linked to the establishment of tolerances (MRLs). The fees listed are minimum and increase with the number of food crop uses.

Use of Overseas Test Results

It is claimed that the additional registration costs incurred in Australia relate to the lack of recognition of overseas test results in evaluating the use of chemicals in Australia. This is not so. The NRA will use the data and assessment of reputable overseas registration authorities when that data is relevant to Australian use-patterns and agricultural practices. It is not appropriate, we believe, nor in the best interests of sound chemicals management, consumer and user safety or environmental protection and

trade, to utilise overseas data as a basis for the necessary risk assessment and regulatory decision making if those data do not reflect Australian use practices.

The fact that the NRA will utilise the work of other agencies is also reflected in the fact that:-

- We routinely exchange assessment reports with overseas countries
- Fees and charges are based on a modular system that allows charges to only apply when work is done by the Authority.

It should also be stated that the NRA will accept submissions for new pesticide products in the international format determined by the OECD. This allows registrants to submit the same registration dossier in all OECD countries including the USA, EU, Canada, and Japan. This is a further measure to improve efficiency for both government and industry, reduce industry costs and encourage the earliest introduction of new chemical products.

It is a fact, that efficacy and residue data often do need to be generated for local conditions, though we would stress that if those pest, disease and growing conditions reflect those of other citrus producing countries, then that data could be used either wholly or in part. It would be our view however, that it may be short sighted by the citrus industry to press for reduced data or data totally from other countries. Local and overseas consumers expect the assessment of residue implications to receive careful attention by health and regulatory agencies on the basis of appropriate and rigorous scientific evaluation. Furthermore, should the citrus industry wish to seek Codex Maximum Residue Limits (MRL) to minimise potential international trade barriers, then Australia would be expected to supply high quality residue data reflective of Australian agricultural practice. To utilise overseas data may not allow the industry's needs to be recognised within Codex. Specific overseas markets would most likely expect similar justification for the MRLs set in Australia.

There is also a growing international concern in regard to the overuse of pesticides as some registrants seek to minimise claims of liability associated with possible failures in pest control. To a significant extent, local efficacy and residue data help to demonstrate the rigor of the Australian regulatory system in ensuring that only the minimum amounts of chemical are applied. This clearly has industry benefits in terms of cost associated with chemical use, the demonstration of responsible chemical use and consumer confidence that residues have been kept to a minimum.

Timeliness

Claims about delays in the registration process cannot be substantiated. What needs to be recognised by chemical registrants and growers is that because of the extensive scientific data to be reviewed, the process is, by necessity, lengthy.

However, NRA timeframes for assessment are much shorter than those of comparable registration systems overseas. New products can be assessed in 15 months given quality submissions while the extension of existing products into new uses can take less than 3 months. The NRA has now demonstrated over successive years that it meets all legislative timeframes in excess of 95% of submissions. It is our understanding that this is not the case overseas (where timeframes in the USA and EU can range from 2-4

years), with the possible exception of countries where the quality of chemicals assessment and management may not be in keeping with Australian Standards.

Minor Uses

Chemical uses that are of little or no commercial value to chemical manufacturers and for which registration will not be sought are deemed minor uses. The NRA has an extensive program of evaluating permit applications for minor uses when no registered alternative chemical is available. The minor use permit scheme does however still require data to support approval and particularly to establish MRLs. However, in some cases, a much reduced data package might be acceptable. The minor use needs of producer industries should be discussed with the NRA at the earliest opportunity.

Some industries eg the vegetable industry have taken the initiative to identify priorities, and generate and fund data to support their minor use needs. This also assists the NRA by ensuring that industry's highest priorities are being addressed. The NRA has applauded the efforts of the vegetable industry in this regard and sees it as a model for others to follow.

Finally, the NRA would note that:-

- 1) Industries can facilitate the registration of useful chemicals which would otherwise not be economic for chemical manufacturers
- 2) In an increasingly globalised market the chemical industry may in future be less supportive of industries where the volume of chemical used is not commercially attractive compared to that which may be used in other industries or in larger overseas markets.
- 3) The Government's consideration of a regime of data protection for pesticide registration data would, if introduced, be a significant measure in encouraging new product development and early introduction into the market. Data protection would also make the generation of data by producer industries themselves more attractive as the commercial value of protected data is significantly enhanced.

Further information about the NRA including information on the registration process, fees and levies, timeframes for assessment and the minor use program can be obtained from the NRA's website at www.nra.gov.au