Comment on the Draft Productivity Commission Report on Cost Recovery

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1. Introduction

Avcare welcomes this opportunity to comment on the report and participate in further hearings before the Commission.

Avcare supports the recommendations of the Commission. In particular we strongly advocate that the government adopt the recommendation to develop a clear policy on cost recovery and implement the recommendations of the Commission.

Avcare's interests are primarily focused on the health and safety regulatory agencies such as the National Registration Authority, ANZFA, OGTR, AQIS, and NICNAS. It also has an interest in IP Australia.

We make our comments in this submission in relation to exclusive capturable commercial benefit in the ANZFA model for cost recovery, cross subsidisation in the NRA model and some of the questions raised by the Commission in the report.

2. ANZFA Exclusive Capturable Commercial Benefit (ECCB).

We note that the commission has referenced the ANZFA ECCB cost recovery model. This model is of particular concern to Avcare in the way it is being implemented. ANZFA is applying ECCB for applications that include the first entry of a Maximum Reside Limit (MRL) for a new agricultural and veterinary (agvet) chemical into the Food Standard A14, but not any additional MRLs for existing chemical or variations to existing MRLs. This is likely to impact about 10% of the MRL applications to ANZFA.

MRLs are used to monitor correct and safe use of an agvet chemical on crops and animals used for food and feed. As such they are ***assessed*** and approved by the NRA taking into account product use practice and ***public health risk***.

NRA approval of MRLs is part of the product registration process, and once registration is granted the registrant may legally sell the agvet chemical product. However, State health laws dictate that ANZFA must also ***assess*** the MRL for **public health risk** as a prerequisite for adoption into State legislation. This is a duplication of regulatory process and now in 10% of situations adds another layer of regulatory cost. While on the surface this may not seem a significant issue, Avcare believes ECCB is being applied incorrectly. The definition of ECCB is given in (Section 69 (9)(a) and (b) of the Australia and New Zealand Food Authority Act 1991).

> *…an exclusive capturable commercial benefit applies where*
>
> *a) the applicant can be identified as a person or body that may derive a financial gain from the adoption of the draft standard or draft variation of the standard that would be prepared in relation to the application: and*
>
> *b) any other unrelated persons or bodies, including unrelated commercial entities would require the agreement of the applicant in order to benefit financially from the approval of the application.*

It is our view that registrants are not the beneficiaries from the adoption of the draft standard. Registrants have a legal right to sell the product once they hold a registration from the NRA and have no requirement under the *Australia New Zealand Food Authority Act 1991* to apply to have an MRL adopted as a food standard.

It is our view that the users of an agvet product which contains the active constituent for which there is an MRL required are the **beneficiaries** as they require to have that MRL (food standard) adopted in order to legally sell food and feed commodities in compliance with State food legislation. Users do not require the registrant's agreement in order to **benefit financially** from the approval of the application. The registrant does not sell to users, rather it sells to either a distributor or retailer.

Avcare believes that the ECCB model as defined in the *Australia New Zealand Food Authority Act 1991* is not a workable model because it is open to ambiguity over who the beneficiary is.

3. Cross subsidies - NRA model.

Avcare believes that while the NRA model provides the very important stable and predictable revenue stream it also leads to considerable cross subsidisation. For instance the majority (56%) of the NRA income is derived from the sales levy. Cost recovery for application assessment services (17% of income) covers on average 30% of the actual cost of an assessment. It should be noted that the high sales products are used as farming inputs and that these subsidise the low sales products which are not only used on farms but are also commonly products used in swimming pools, on companion animals, in homes and for public and environmental health.

Avcare agrees that cross subsidies may be justified where an industry levy is used to fund activities that benefit the industry as a whole, for example aspects of compliance that maintain the integrity of the regulatory scheme.

The NRA model was developed almost 8 years ago. Since that time Avcare members who members contribute about 80% of the NRA income from about 20% of the registered products and only represent about 5% of registrants have gained considerable experience with the model.

Avcare would argue that the approach of spreading pre-market costs over the life of the product can lead to higher than necessary regulatory costs being imposed on some products. For instance the actual assessment cost for a new product based on a new active constituent is about $100,000, (the NRA fee is about $20,000). This cost is independent of the future sales of the product.

The NRA model greatly benefits registrants who have products with low sales volumes, and excluding the 26% of products with no sales 44 % of products have sales, of less than $100,000 per year and 67% less than 1 million per year.

Currently there is no levy on sales below $100,000, although they do attract a $1000 annual registration fee. **Actual activity based assessment fees range from around $1000 up to about $100,000, and are independent of future sales of the product**. Under this scenario the full cost of assessment is unlikely to ever be fully paid for many assessments.

On the other hand a product with $1,000,000 in sales attracts a $1000 annual registration fee plus a levy of $6,500 per year, even though it may never have undergone a significant assessment by the NRA since 1995 when it commenced full cost recovery. The issue is heightened for those products with even higher sales where the levy component could be up to $25,000 per year over the life of the product which can be 50+ years. Furthermore, the NRA has recommended in its recent fee review to lift the cap to $100,000, and it is believed that the signatories to the National Registration Scheme (States) who make the ultimate decision will remove the cap altogether. . It is worth noting that for the 1999 financial year 60% of products had sales of $100,000 or less, 31% between $100,000 and $1,000,000, 6% between 1,000,000 and 3,000,000 and 3% over $3,000,000, indicating that only a few products are carrying most of the annual costs of operating the NRA and obtaining no additional benefits over the others.

Avcare believes that the use of levies to subsidise application costs imposes greater regulatory costs than warranted on those firms that have products with significant sales.

Avcare fully supports the Commission's recommendation that where it is desirable to support a specific group or industry for social, cultural, equity or other reasons direct mechanisms rather than discounts or cross subsidies in cost recovery arrangements should be used.

4. Commission request for further evidence of the effect of cost recovery on firms, particularly in relation to:

- ***The introduction of new and innovative products***
- ***Adoption of new technology; and***
- ***Innovation and research.***

(Chapter 6 page 143)

In pre-market regulatory schemes such as the NRA, OGTR, ANZFA and some AQIS activities the major cost impost on firms is the generation the data required by the regulator. The fees are a relatively minor cost, for example adding a new crop use to an ag-chemical product label typically costs about $250,000 to generate the data and about $10,000 for the NRA assessment fee. The major obstacle to the innovation and research leading to the introduction of new and innovative agvet products is the lack of data protection which allows free-riding. The patents (which have an effective life for only 10-12 years) for most (about 90%) Agvet products on the market have expired, however the potential for innovative developments such as new uses and better formulations which are not patentable continues throughout the commercial life of the product which is often 50+ years. The current NRA, ANZFA and OGTR approval processes for new and innovative products allows free-riding to occur on data generation costs can not be overcome through manipulation of only the regulatory assessment cost recovery.

Avcare believes that cost recovery fees should not be used to deal with intellectual property issues.

The Report on page 135 suggests that fees associated with pre-market assessment and initial product registration are more likely to discourage innovation than post-market annual registration fees or industry levies which are often based on sales levies (and thus unlikely to discourage products which are not yet for sale). Several regulatory agencies including the NRA are said to have recognised this and in the case of the NRA implemented a:

> "lowered initial assessment fee and increased ongoing sales levy so as to minimise discouragement of new registrations with the idea that firms will pay the approximate costs of regulations over the lifetime of the product rather than prior to entering the market. This system includes a 'minor use permit which issued free of charge to companies wishing to use chemicals for research purposes to help develop new products or activities."

In fact fees are charged to firms for minor use permits and for permits to conduct large scale trials, they are only free of charge to primary producers (users) and government departments.

The report indicates on page 138 that there are small business effects whereby small firms are disadvantaged because they may not be able to spread the additional cost of the charges across large product ranges or sales in the same way as larger firms. It may take them longer to recoup pre-market regulatory costs, or they may not be able to recover the annual registration fees as readily. Avcare believes that this argument is flawed for agvet products, it implies that large companies have large product ranges and small companies do not. Also large companies are expected to cross subsidise regulatory costs from one product to another whereas small companies are not. New products enter the market with no sales and have to build sales volume, each firm regardless of size has the same opportunity to build sales. If financial assistance is a small firm this can give them a market advantage, hence it should be a matter for the Government's National Competition Policy to determine appropriate direct assistance not for the regulator to use a fee structure to implement subsidies.

The above approach is in our view using an ability to pay approach, well exemplified in the NICNAS scheme and which is unacceptable to Avcare members.

5. Commission request for comment on the usefulness of the guidelines for deciding whether or not cost recovery should be introduced and for identifying the best approach to recovering costs. (Chapter 9 page 196)

Avcare fully supports the guidelines and advocates that the government adopt them, including the recommendation that they be applied to:

- all new cost recovery proposals
- significant amendments to existing cost recovery arrangements; and
- existing cost recovery arrangements with a 5 year completion time for these reviews.

Table 9.1 on page 201 would benefit from including agvet chemicals as an example of a policy objective to assess or approve product quality to the benefit of consumers. A major cost impost on Australian registrants is the NRA requirement for assessment of product efficacy and target species safety. Hence Agvet chemicals fall into three of the objectives listed:

- Provide information to consumers on product safety
- Assess or approve product quality to the benefit of consumers
- Reduce the risks of harmful spillovers (including enforcing safety and quality standards that would affect the broader community.

It is also worth noting that Genetically Modified Organisms licensed under the Gene Technology Act have the same three objectives. Avcare believes that the guidelines will provide a sound basis for determining an appropriate cost recovery scheme for the Office of Gene Technology Regulator.

6. Commission request for information about:

- ***The use of minimum and maximum levies and the application of formulae to decide on individual charges within that band***
- ***Establishing cost recovery arrangements for new organisations where the startup costs are high and the regulated industry is small***
- ***The timing of cost recovery payments particularly in the case of new product approvals where the product is still to be marketed.***

(Chapter 9 Page 226)

<u>Minimum and maximum levies</u>

Avcare supports the use of levies providing that they do not introduce inequity into cost recovery and has commented on this aspect of levies above.

<u>Cost recovery where startup costs are high</u>

Cost recovery should not be imposed on pre-market regulatory assessments related to research and development. These costs should be seen as supporting Australian business and appropriated from government. It is appropriate to recover the cost for the pre-market assessment required to approve a product for sale and then spread the cost over time.

<u>Timing of cost-recovery</u>

It would be beneficial to spread the pre-market assessment costs related to an approval for sale over a reasonable period after the approval, providing over recovery does not occur. The NRA model with some refinements to deal with cross subsidisation issues and over recovery is an appropriate one. As assessment costs are independent of the level of sales achieved by a product, refinements could include placing a levy on lower selling products to better recover actual assessment costs; and a cap on higher selling products to prevent over recovery. These refinements to be coupled with the reduced assessment fee approach.

7. Commission request for views on the key issues that are likely to emerge during implementation of the guidelines: (Chapter 10 page 238)

1. In depth consultation between the government agency responsible for the guidelines, the policy makers for the regulatory agencies, the regulatory agencies, and regulated entities

will be required along with an education program to explain the benefits of the guidelines to regulated entities.

2. Some regulated firms will pay more than they currently do, so some phase in of the extra charges would be required.