2 May 2008

Australian Government
Productivity Commission

Re: **Submission to the Productivity Commission in the Chemicals and Plastics Regulation Issues Paper**

HAL appreciates the importance of the issues being addressed in the Draft Report and is supportive of many of its recommendations. However, HAL also has some serious reservations about some elements of the Draft Report and the resulting recommendations. The following is our response detailing these concerns, and in some cases requesting clarification. The issues covered are: MRL setting, use of international data, recognition of overseas schemes, control-of-use and minor use.

Firstly, HAL welcomes

- Draft recommendation 5.9 that maximum residue levels set by the APVMA should be automatically incorporated into the food standards code;
- and Draft recommendation 6.3 that APVMA approved labels should be recognised as being sufficient for workplace requirements.

HAL however, has significant reservations over Draft recommendation 4.6, that the National Registration Scheme should be extended to cover control-of-use. HAL agrees that the states and territories having their own differing control-of-use regimes is not desirable; but believes that having different state based schemes per se is not problematic provided they achieve the same outcome. At present HAL does not believe this is the case and welcomes the Report highlighting this point.

The concerns are largely over the potential implications of control-of-use becoming a federal responsibility while being administered at the state level. Such an arrangement would require federal funding of any state based activities in this area. As the APVMA operates under a cost-recovery structure, costs associated with such a shift would be borne by registrants and ultimately the users, i.e., the farmers. How would such a proposed shift be managed in practice? HAL is concerned that the cost of implementation and management to the farming community, and ultimately the consumer, could be considerable.

HAL would appreciate clarification of what is meant by more extensive “utilisation of international data” HAL acknowledges that there are elements of duplication in risk assessments undertaken by the APVMA, but understands that initiatives aimed at

reducing duplication exist at the international level, ie, OECD work share projects, seeking to develop guidelines to increase opportunities for greater harmonisation.

Notwithstanding such initiatives HAL would be concerned if the APVMA were to consider moving away from its current science based approach in which agricultural chemicals are assessed within an Australian context, e.g., residue and efficacy data that relates to Australian use patterns.

In terms of "greater recognition of appropriate overseas schemes and more extensive utilisation of international data and modelling tools" HAL queries what would be viewed as 'appropriate' and by whom. The current risk assessment tools and models used within the European Community have been developed within a policy framework driven by the Precautionary Principle, where safety factors used are often not wholly science based.

An example of this is the current debate over suitable variability factors when estimating acute dietary intake of pesticides. In Australia, the US and at JMPR[1], a variability factor of 3 is used. However, the European Community currently refuses to accept this value and insists on a variability factor of 5, 7 or higher, ostensibly to provide greater safety margins. This is despite a recent EFSA discussion paper [2]indicating that utilising a factor of 3 had a marginal impact on the number of compounds qualifying for MRLs. As a consequence HAL would be very concerned if future regulatory decisions made in Australia were to be based primarily upon assessments undertaken overseas.

HAL also queries the statement regarding timeliness, since the statutory timeframe for gaining a new agricultural chemical registration in Australia is shorter than for either the USA or the European Community. The Report indicates problems in achieving these timeframes were highlighted by manufacturers. However, as indicated by the ANAO audit[3], statutory timeframes were met for 95-87% of pesticide applications from 2001-02 to 2005-06. This suggests that where timeframes were not met, issues other than recognition of overseas data or duplication of risk assessments played a role.

In regard to minor use, HAL believes there may have been some misunderstanding in the Report over the costs of achieving an approval, compared to the cost of gaining a registration per se. The major impediment to pesticides access in minor crops is the cost associated with data generation, not the application fees.

In granting approval for the use of a pesticide in minor crops, the APVMA must be satisfied that the product is: safe to the crop; efficacious; and poses no concerns in terms of consumer exposure or trade. In many cases aspects related to use in minor crops can be extrapolated from uses in major or related crops.

However, extrapolation is not possible in some instances, so local data has to be generated. The cost of such data generation can be prohibitive, particularly for small

---

[1] Report of the 2006 Joint FAO/WHO Meeting on Pesticide Residues.

2 Opinion of the Scientific Panel on Plant protection products and their Residues on acute dietary intake assessment of pesticide residues in fruit and vegetables. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178629328713.htm

[3] ANAO (Australian National Audit Office) 2006, Regulation of Pesticides and Veterinary Medicines, Australian Pesticides and Veterinary Medicines Authority, Audit report no. 14, Canberra.

or emerging industries. Furthermore, to help growers of minor crops fully understand how a product can be used effectively, and be confident in its performance, suitable trial data may also be required

The Report indicates that benefits from public funding of pesticide research need to be clearly articulated, and where possible quantified. A recent study (Crowe *et al*. 2006[4]) reported that the benefits of public investment in grains herbicide research were gained primarily by farmers with a benefit: cost ratio of 1.5 and an internal rate of return of 28%. It was concluded that since Australia exports most of its grain, the grain farmers rather than consumers or manufacturers gained the lion's share of benefit.

Applying this rationale in the context of Australian horticulture, it is fair to conclude that the community would be the main beneficiaries of horticultural pesticide research as the majority of locally produced commodities are consumed domestically.

Thank you again for the opportunity to provide input into this issue.

Sincerely,

(unsigned for electronic transmission)

Brad Wells
Plant Health Manager
Horticulture Australia Limited

[4] Bronwyn Crowe, Bob Lindner, & Rick Llewellyn. 2006. The benefits and beneficiaries of "public" investment in herbicide use research and development. 50th AARES Conference, Sydney.