ISSUES PAPER ON CHEMICALS AND PLASTICS REGULATION

Horticulture Australia Limited (HAL) welcomes this opportunity to contribute to the Productivity Commission study into the regulation of chemicals and plastics in Australia.

HAL is the industry body for the Horticulture sector, the fastest growing agricultural industry in Australia with production in excess of $6.0 billion annually. HAL works towards meeting both the current and strategic needs of individual horticulture industries. As access to and use of farm chemicals is integral to sustainable production for many horticultural commodities HAL believes that having an efficient regulatory system is fundamental to the sectors long-term viability.

HAL believes that a primary outcome of this study should be a move towards achieving greater regulatory clarity and efficiency while not increasing the regulatory burden on farmers. Specific areas in need of consideration include the lack of consistency in the regulation of pesticides by both State and Federal agencies, concerns over the possible introduction of the GHS, an overhaul of the flawed processes involved in achieving listed registration and reservation from registration and the development of new approaches to handle the advent of novel pest management technologies. These issues are elaborated on in greater detail below with regard to the specific questions posed by the issues paper.

Where are the greatest inconsistencies in regulation: between the Australian Government and the states and territories, between the states and territories, or within jurisdictions, that warrant reform?

What elements of chemicals and plastics regulation can most appropriately be dealt with through uniform national approaches (for example, should the Agvet code be extended to include control of use)?

Lack of consistency – Control of Use

At present the role of the Commonwealth in pesticide regulation stops at the level of the chemical retailer, with the responsibility for oversight of pesticide use resting with individual State authorities. Unfortunately, the States differ in terms of how pesticide

use is regulated and who has responsibility for administering those regulations. HAL believes that a more nationally consistent approach is needed as the current differences are in all likelihood anti-competitive and have the potential to impact adversely on international trade.

HAL, however, does not believe that extending the Agvet Code to include control of use is necessarily the answer. To regulate control of use via the Agvet Code, presumably through the APVMA would require a substantial increase in the organisation capacity of the regulator and potentially lead to a significant duplication of regulatory activity, e.g., State environmental controls cover a range of human activities not just pesticide use, whereas an Agvet Code based approach would focus solely on pesticides. Such a separation could conceivably result in confusion where the cause of an environmental incident is uncertain, i.e., who has jurisdictional authority.

Lack of consistency - MRLs

Currently, Australia has, in effect, two separate systems for the establishment of MRLs:

- the APVMA system, through the MRL Standard, which regulates use of a pesticide on crops;
- and the FSANZ system, through the Food Standards Code, which regulates the resultant pesticide residues occurring in food.

This dual approach has in the past caused unnecessarily protracted timeframes for the promulgation of MRLs into the Food Standards Code, resulted in a number of anomalies, which has translated into widespread problems and confusion for growers.

It has been recognised for some time that this 'dual' system is inefficient, slow, duplicates effort and is generally unsatisfactory. The Blair Review (The Commonwealth Food Regulation Review) examined existing food regulation in Australia in 1998[1] and found that the overlap between the functions of the APVMA and FSANZ (which included the Code and the supporting arrangements) led to

1 "Food a Growth Industry, Report of the Food Regulation Review" August 1998, Chaired by Dr Bill Blair OAM, ISBN 0 642 34518 X

inefficiencies in the development of MRLs. The review recommended that legislative and administrative processes be amended to streamline MRL setting.

More recently the Ministerial Council agreed to a harmonization process for MRL setting procedures between the APVMA and FSANZ, the aim being to establish a single set of published MRLs. The agreed approach is to be based on the harmonisation of administrative processes, monitoring and review of the new harmonised assessment process and, subject to these being satisfactory, the issuing of a single MRL.[2] At this point in time it appears that substantive changes, recommended by the Blair Review, have yet to be implemented.

We are hopeful that the current review will result in the current flawed process being address. We believe that the most significant problems arise from:

- the onerous consultative requirements;
- the lack of differentiation between MRLs and other food standards, and within MRLs;
- and the overly bureaucratic process involved in gaining approval of MRLs.

HAL strongly recommends amendments in these areas to significantly streamline the process and remove the unwanted inefficiencies. Please find specific comments relating to MRL setting below.

Consultation

Under the current regulatory regime the establishment of an MRL can potentially undergo up to three rounds of public consultation, by FSANZ and the APVMA. Reducing this overlap and duplication must be a priority. The establishment of a mechanism whereby a joint consultation could occur would seem reasonable. HAL understands that a pilot scheme is planned however, is uncertain of details and as a result uncertain what benefits would be gained.

[2] FSANZ Annual Report 2003/04

MRL types

Under the current approach FSANZ does not differentiate between different categories of MRLs. HAL accepts the need to review MRLs fully for new active constituents but questions the need to implement repeated full risk assessments for each and every proposal to amend or add MRLs to the Food Standards Code for existing compounds, i.e., those that have previously been fully assessed. Given that the APVMA already assess such proposals in terms of potential environmental, OH&S and trade impacts, HAL believes that the FSANZ component of this process, the completion of dietary intake assessments, should be streamlined so as to be relatively uncomplicated and prompt.

In addition, the current FSANZ system appears to have difficulty with the setting of temporary MRLs by the APVMA, which often relate to the issuing of minor use permits. These can be established for the use of pesticides in minor crops where few pest management tools exist. By their nature these crops are small and constitute only a minor part of the diet and constitute minimal risk. HAL believes that the development of a simple mechanism, whereby such time-limited MRLs can be included in the Food Standards Code, would be advantageous.

MRL Approval (Sign-off)

HAL believes that the current requirement for Ministerial Council sign-off on all MRLs is administratively burdensome and unnecessarily time consuming and in effect constitutes a potential fourth round of consultation. HAL recommends that the establishment of MRLs should be science-based and the responsibility for approval should rest within the relevant agency. In summary, HAL would support the development of a coherent joint approach that recognized the roles of the two regulators while removing the inefficiencies and streamlining the process.

Is the regulatory system sufficiently flexible to incorporate and respond to changing knowledge and understanding of issues over time?

To what extent are existing processes for assessing and registering chemicals in Australia impairing the entry of new chemicals, and what effect is this having on the achievement of public health, worker safety and environmental outcomes, and on competition and economic efficiency?

Listed and reserved

As alluded to in the issues paper the current approach to low regulatory concern chemicals (LRCC), i.e., pesticides reserved from and listed registrations, is not achieving the desired effect. Only recently, i.e., October 30 2007, has it been indicated that a Standard or Condition is likely to be placed into regulation[3]. The major difficulty with the current approach is that it is disproportionate, in requiring the establishment of a regulation, to finalise approval for what are essentially minimal risk uses. The current approach, as a result has been found to be inefficient and impractical.

HAL believes that a process by which approval for a Standard or a Condition is achieved should be at the level of the APVMA, i.e., follow a similar path to that of current chemical approvals. It seems incongruous, for example, that the application of a pesticide by aircraft can be authorised by the APVMA but the establishment of a Standard for a general disinfectant requires enacting a regulation.

In addition to simplifying the processes involved in setting Standards or Conditions, HAL believes a review of the criteria associated with the development of conditions of reservation should occur so as to allow easier access to low risk products.

Low risk products

Increasingly horticultural industries are wishing to gain access to low or reduced risk products or alternative pest management technologies such as biorational pesticides, e.g., plant oils, plant extracts or antagonist micro-organisms. Specific areas of potential use include organic farming; integrated pest management (IPM) and high value minor crops where the cost of development and registration coupled with low

[3] http://www.apvma.gov.au/new/hottopics.shtml#legal

potential returns discourage the development of conventional pesticides. However, the ability of industries to access such products has been limited.

A significant barrier to their increased availability, unfortunately, is the Australian regulatory system with its current data requirements and associated high costs of achieving regulatory approval. This is primarily a result of biorational products being dealt with in the same manner as conventional synthetic pesticides, i.e., regulators requiring data packages essentially identical to those for conventional pesticides.

The need to foster the development and use of biorational pesticides has been recognised internationally. In the US, it has been accepted that biorational pesticides differ markedly from traditional synthetic chemical pesticides with initiatives taken to facilitate their registration[4]. In the US system the data required to support a typical biopesticide can be significantly less than for conventional pesticides as it recognised that biopesticides tend to pose fewer risks than conventional pesticides. For example, in assessing risks to human health the EPA takes into account the origins of the biorational pesticide, e.g., if they are found in common foods or approved as food flavourings. Notwithstanding the revised requirements the EPA still undertakes thorough risk assessments to ensure that a biorational pesticide will not have adverse effects on human health or the environment.

The European Commission, in its policy paper *Sustainable use of plant protection products* stressed the importance of IPM and the replacement of older pesticides with safer and more selective products such as biorational pesticides. The OECD has also recognised that the adoption of IPM and pesticide risk reduction strategies will be slow due to the lack of viable alternative control methods and the fact that in general regulatory procedures are not flexible enough to deal with biological or reduced risk products.

Biorational pesticides will only have a future in Australia if regulatory requirements are scaled down for certain groups of plant protection products with reduced risk profiles, the process is simplified and becomes less expensive. Unless there is

[4] In 1994, the Biopesticides and Pollution Prevention Division was established in the US EPA's Office of Pesticide Programs.

significant change, access to such products in Australian will continue to lag or be non-existent. As a consequence, growers will be at a competitive disadvantage and the wider community will miss the benefits of them not having access to safer, environmentally friendly alternatives to conventional pesticides.

HAL therefore suggests that consideration be given to the development of a separate approach for the regulation of biorational pesticides, i.e., a more pragmatic approach. One that provides a process that facilitates the development of such products through reduced data requirements and registration costs. This is particularly important given the current high cost of product development, testing and registration and uncertainty over commercialisation.

Should the GHS be implemented across all sectors of the chemicals and plastics industry, including agricultural and veterinary chemicals and scheduled drugs and poisons?

HAL does not believe that the GHS should be implemented across Australian agriculture. As indicated in the issues paper the GHS seeks to harmonize criteria for classifying chemicals according to their health, physical and environmental hazards. Essentially ignoring potential risk mitigation factors that might be associated with a chemicals use pattern or formulation.

Further HAL understand that a primary aim of the GHS, through harmonising classification and labelling of chemical hazards, is the development of greater consistency among countries while promoting safer transportation and handling of chemicals in international trade. Given this focus HAL is uncertain as to the relevance of the GHS format and content to chemical management at the farm user level. In particular HAL is concerned that adoption of the GHS will introduce added complexity with little benefit. For example the GHS Safety Data Sheets (SDSs) consist of a core set of 16 headings containing a level of detail tailored to industrial scale chemical handling and manufacture rather than the scope of the average farmer or farm worker[5].

[5] http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/English/08e_annex4.pdf

HAL believes that pesticide labels are an important element of pesticide management being the prime medium for risk communication. Their correct interpretation is seen as an important factor in ensuring unwanted consumer, user or environmental pesticide exposures do not occur. Farmers want to use pesticides correctly and need to have labels that contain relevant information that is presented in a clear and understandable manner. HAL does not consider that the wholesale introduction of GHS would address these needs.