REGISTRATION BY REFERENCE

This paper describes some possible options for giving effect to a registration by reference policy in the revised agvet chemical regulation scheme (revised scheme).

Policy Outcome

The policy outcome is to provide that the APVMA must register a product based on a decision to register a product made under a comparable international regulatory system (by a comparable overseas regulator), except where there are specific circumstances to Australia that need to be considered (which the Panel envisages that the APVMA would be required to consider).

Issues to Consider

- the supply and use of a product in Australia must have a sponsor or advocate that would convince the regulator to authorise the supply and use (is this the primary problem with the current system?)
- the Panel has proposed that for an overseas registered product, the regulator will be taken to be satisfied about the appropriateness of a chemical product, must register the product and the only grounds to decline or defer registration would be where there are specific circumstances unique to Australia that need to be considered
    - while registration is one means by which an overseas registered product may be authorised, it is not the only means and there are other options for authorising the supply and use of an overseas registered product. How focussed is the Panel on 'registration'?
    - could we licence persons to deal with overseas registered products, as an alternative to registration?
    - could we exempt (or permit) persons who deal with overseas registered products as an alternative to registration?
- there must be a means for considering the specific circumstances unique to Australia - when should this consideration occur, how should this consideration be undertaken, what should the consideration include and who should do it?
    - poisons scheduling/regulation (states and territories)
    - maximum residue limits for residues in human food in the Food Standards Code as without these residue limits the treated produce could not be legally sold under food legislation
    - maximum residue limits for residues in animal food in the APVMA MRL Standard as without these residue limits the treated produce could not be legally sold under state and territory animal food legislation
    - what else?
- the Panel has contemplated that the regulator is also likely to still need to approve labels for containers of products, consider any appropriate signal words required by the Poisons Standard and instructions related to the 'prevention of undue prejudice to Australian trade'. It is an 'approved label' or 'adequate instructions for use' that perhaps should be the focus? And should this exclusively be the regulator's responsibility?
- the key reason for authorising the supply and use of overseas registered products is to provide more flexibility in relation to the use of these products. Will this need to be balanced with more effort from suppliers and users to ensure that the risks are adequately managed through risk management plans?

- what community and industry perceptions may apply to a 'registered product', 'licensed supply of an overseas registered product' and an 'exempt overseas registered product' or 'a permit'?
- the general product obligations could apply for all supply and use, and these could provide a general basis for managing the risks associated with overseas registered products.

Options

Option 1 - Overseas Registered Product Permit Scheme

Similar to the existing permit scheme in the Agvet Code (which is really an exemption scheme by another name) would provide for the supply and use of an overseas registered product through a permit, with appropriate permit conditions, determined following APVMA assessment.

Option 2 - Overseas Registered Product Registration Scheme

Under this option, agvet legislation would be amended to provide that an overseas registered product must be registered by the APVMA unless the APVMA has determined that there are specific circumstances unique to Australia that need to be assessed before the product is registered. How will the APVMA know there are specific circumstances that need to be assessed unless it does an assessment? How will the APVMA determine appropriate conditions?

Option 3 - Overseas Registered Product Licensing Scheme

Under this option, agvet legislation would provide for an overseas registered product to be supplied and used in Australia under a licensing arrangement (and exempt from registration), with the regulations to set out the licensing arrangement that the APVMA would implement. Licence conditions would require the licence holder to have a 'risk management plan' that identifies and includes control measures for managing the risks associated with the supply, use and disposal of these products, as well as providing monitoring data and relevant reporting data to the regulator. This option devolves the assessment to the licence holder.

Option 4 - Overseas Registered Product Authorisation Scheme

Under this option, agvet legislation would provide for an overseas registered product to be exempt from registration if certain conditions in the exemption are complied with. These conditions would set out a requirement that a person dealing with the exempt product would need to have a 'risk management plan' that identifies and includes control measures for managing the risks associated with the supply, use and disposal of these products, as well as providing monitoring data and relevant reporting data to the regulator. This devolves the assessment to the person supplying or using the exempt product.