

Queensland commentary on the Agricultural and Veterinary Chemicals Legislation (Streamlining Regulation) Bill 2018

Proposal 1 – Provisional registration or variation with conditions for efficacy (provisional registration of chemical products)

Precedent

In the preceding years prior to the introduction of *Agricultural and Veterinary Chemicals Code Act 1994*, clearance certificates were given by various national technical committees. The certificates were then used by the state registration agencies as a basis for approving the registration in each state.

As part of that system, provisional clearance certificates were issued whilst the various technical committees obtained more data from the registrant. This is analogous to the current proposal whereby registration of a product can occur whilst further efficacy data are generated by the registrant.

In 1994, chlorfluazuron residues were detected in Australian beef and forced considerable loss of market access for Australian Beef producers. The chlorfluazuron product 'Helix Insecticide' registration was based on a provisional clearance certificate.

McMullin & Anor v ICI Australia Operations Pty Ltd and Ors ("the Helix decision") is an important case study in how provisional registration type programs can lead to inadequate consideration of risks. Whilst the proposed scheme is solely about efficacy, the case study shows how information in one kind of risk assessment can provide important information about other types of risks.

The issue in question in the Helix case was what was known about the product's bioaccumulation in animal tissues. The environmental technical committee was concerned about bioaccumulation and the effect of the product on aquatic organisms. However, the overarching clearance certificate committee was did not translate those concerns to potential issues for residues in livestock.

The conclusion drawn is that provisional registration systems have the potential for adverse consequences due to a lack of a coherent overarching picture of risks from conducting all the registration criteria.

ALARA Principle

Chemical products are not used to minimise risk, they are used to control pest and disease etc. Therefore, efficacy is the fundamental basis for the registration of a chemical product because it supports the product's purpose. The other forms of risk assessment are conducted to manage the risks to acceptable levels whilst the product achieves its primary purpose. Accordingly, the As Low As Reasonably Achievable (ALARA) principle requires that a registrant demonstrate that the use pattern has been optimised to minimise risks.

The consequence of not following the ALARA principle is that product rates can be higher than necessary which results in higher residues for each use. For products with high chronic toxicity and many uses on the labels this can mean that the Acceptable Daily intake is exceeded preventing further uses from being approved.

Applicability of overseas data

The proposal assumes that the use pattern will be supported by International data at the time of registration. This is only true when the pests or disease is the same in Australia as overseas and there are no other geographic or cultural differences that influence the pest or disease management. From an examination of Joint Meeting on Pesticide Residue (JMPR) data on use patterns, it can be seen that Australian use patterns are generally different to those overseas. Therefore the usefulness of this proposal appears questionable.

Interconnectivity of trial data

Typically, trials are conducted in a manner to optimise the data collection to fulfil as many data requirements as possible. This means that when a chemical product is applied to an animal or crop in a trial situation, data are often collected for not just efficacy but for crop or animal safety and residues as well. The proposal is going to be of questionable value if the registrant's are required to collect these other types of data prior to registration.

Proposal 3 – Prescribed approvals and registrations (approval and registration for active constituents, chemical products or labels)

This new process would only apply for those active constituents, chemical products and labels where minimal or no assessment of technical information is required. It is unclear how active constituents could be approved without a technical assessment as the route of manufacture and starting materials dictate the relevant impurities. Assessors need to predict the relevant impurities and ensure that the batch testing provides adequate information to determine if active constituent meets the specification.

Proposal 4 – Data protection incentives for certain uses of chemical products (limits on use of information)

In general, the Queensland Department of Agriculture and Fisheries supports this initiative but notes it is unlikely to apply to the vast majority of products because data protection periods are only current for a limited number of products.

It is questioned whether the proposal could be manipulated by a registrant to apply for one crop (such as apples) and then at the end of the protection period apply for pome fruit by submission of pear data thereby getting 4 years of data protection even though they may have had the data all along. Does the system adequately encourage registrants to apply for crop groups at the original application?

Proposal 9 – Standards for registered chemical product constituents (definition of registered chemical product)

It is unclear if the proposal includes that active constituents can have their concentration varied. It is recommended that the proposal solely relate to non active constituents as there a range of consequences including residue changes from alteration of active constituents.

There is nothing inherently unreasonable about changes in formulants. Concentration ranges should take into account both formulation manufacturing and analytical uncertainties. It would seem reasonable to set concentration ranges as defaults based on their concentration (as occurs with active constituents). However, the intentional manipulation of a formulation beyond the uncertainties mentioned should dictate the consideration of the physical characteristics and potentially the stability of active constituent. It is recommended that if there is any intentional

change in a formulation that the physical properties and relevant impurities of the formulation should be re-measured by the registrant.