Agvet Reform

From: Mike Tichon <mike.tichon@competitive-advantage.com.au>
Sent: Wednesday, 19 July 2017 2:08 PM
To: Agvet Reform
Subject: Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 [SEC=UNCLASSIFIED]

I refer to the Consultation Document on the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 and submit the following comments:

- Proposal 1 - Clarifying confidential commercial information provisions.
  - I note the purpose of this proposal is to reduce uncertainty for APVMA staff and to allow more efficient processing of applications.
  - APVMA is concerned that citing formulation and other details for a currently registered product and confirming those are similar or closely similar could result in the disclosure of CCI.
  - The need to clarify CCI provisions would be removed if the reforms allowed a more flexible definition of similar and closely similar so that the applicant for registration of a product claimed to be similar or closely similar could provide risk based information. Provisions similar to the interchangeable ingredients provision of the *Agricultural and Veterinary Chemicals Code Regulations 1995* would reduce if not eliminate the need for indirect disclosure of formulation details:
    - Regulation 19AEB allows APVMA to determine ingredients as being interchangeable.
    - Regulation 19AEB(5) states the criteria APVMA must be satisfied about before allowing interchangeable ingredients.
    - I suggest that similar criteria could be applied to define when formulations are similar and closely similar so that precise details do not need to be 'disclosed' by APVMA when APVMA determines a formulation is similar or closely similar to that of a registered product. The decision on the similarity would be based on matters such as whether the signal words as required by the Poisons Standard were different or not, whether the formulation type was the same or not and whether the applicant had adequately addressed the safety, efficacy and trade implications of the proposed product so that APVMA could conclude those criteria are not different to those of the reference product or not.
  - Using such criteria would allow APVMA to confirm the criteria are satisfied without the need for the formulation details to be the same. This would overcome the need for APVMA to potentially disclose details of the reference product formulation by accepting the proposed product is similar or closely similar.

- Proposal 2 - Simplifying reporting requirements for annual returns.
  - The proposal is acceptable.

- Proposal 3 - Increase the APVMA's flexibility to manage minor errors in applications at preliminary assessment.
  - The proposal is acceptable.
  - However, the short timeframe is a concern if a critical person in a company is away during the period when a response is required. This is a particular problem in smaller companies.
  - The short timeframes would be acceptable if APVMA's electronic systems were more flexible.

        - The systems need to allow easy transfer or delegation of projects to others within an organisation including delegation of specific tasks by one person within an organisation to another person in the same organisation.
        - Such flexibility does not currently exist.

- Proposal 4 - APVMA amendment of the relevant particulars or conditions in a variation application.
    - The proposal is acceptable.

- Proposal 5 - Timeframe for notifying Food Standards Australia New Zealand (FSANZ) about variations to the Maximum Residue Limit Standard.
    - The proposal is acceptable.

- Proposal 7 - Amend the definition of 'expiry date' .
    - I make not comment in relation to this proposal.

- Proposal 8 - Add antimicrobial resistance as a specific safety consideration.
    - I note the purpose is to add the potential for human exposure to antimicrobial resistant microorganisms as a safety consideration. No limitations are discussed in the proposal on whether all products or types of products would need to address potential resistance of microorganisms of concern to human health or if only specific types of products would need to address the potential for antimicrobial resistance..
    - The underlying purpose is worthwhile but the implementation of the proposal needs to be carefully considered.
    - The requirement should apply only to those products that are known to have potential to be of concern.
    - The requirement should not be imposed such that applicants are required to assess potential for human exposure to antimicrobial resistant microorganisms for substances that are not of concern. As an example applicants for registration of insecticides should not be required to confirm the products have no potential to induce antimicrobial resistance unless there is a reason to suspect this might be relevant to a specific product or group of products.
    - Applicants should not be prevented from registering products that might have potential for antimicrobial resistance if those same or similar products are available for other uses not regulated by APVMA, e.g. registration of a dairy sanitiser should not be prevented because it might select for tolerant microorganisms of concern to humans if that same or a similar products are widely used in food processing plants and/or in medical facilities. A risk based approach should be accepted.

- Proposal 9 - Including civil penalty provisions for false or misleading information.
    - The proposal is acceptable.

- Proposal 10 - Minor technical amendments to the Administration Act and Agvet Code.
    - I make not comment in relation to this proposal.

Michael Tichon

Competitive Advantage
Telephone: +61 2 8861 5000
Facsimile: +61 2 9633 9489
E-mail: mike.tichon@competitive-advantage.com.au

Physical Address:
Suite 1, Level 2, 38-40 George Street, Parramatta, NSW 2150 Australia

Postal Address:
P.O. Box 403, Parramatta, NSW 2124 Australia