Submission on the draft Agricultural and Veterinary Chemicals Amendment Bill – Dr Sandra Baxendell

This draft Bill has been open for public consultation since November 2011. The draft Bill along with a package of information explaining the reforms on the DAFF website at http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals and that the draft Bill will be available for comment until the end of February 2012 with comments to be sent to the Agvet Reform Team, Department of Agriculture, Fisheries and Forestry by email agvetreform@daff.gov.au

I have comments below on the Bill in general and also from the viewpoint of the Australian goat industry.

GENERAL

- Many of the changes in the draft Bill were not raised as points in the previous discussion paper. This could give the impression of a system not responsive to industry needs and it is hoped that submissions on this draft Bill are taken very seriously.
- The stated objectives are to reduce red tape and improve costs effectiveness of the APVMA as well as reducing the backlog of chemicals requiring review. However it is unclear how this will be achieved as workloads will increase due to re-registrations (continuations).
- This process has been run separately from the COAG directed reform of the whole regulatory system and has been managed solely by DAFF. There are even separate DAFF website – i.e. http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals as opposed to the PSIC website of http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/domestic-policy/psic which deals with the COAG directed review of the whole system. Both processes should be combined.
- The later sections of the draft bill on ensuring a better compliance tool kit and electronic submissions are strongly supported. Re Schedule 3: Improving the quality and efficiency of assessment, the onus on the applicant to notify of any new adverse information is strongly supported. Overseas data should be used where-ever applicable but not when the pathogens, environmental and production systems are very different. Re Schedules 4&5: Enforcement and Data Protection, these changes are supported and long overdue. Schedules 6&7: Arrangements for levy collection and miscellaneous appear to be sensible changes and give flexibility to the Federal government to improve administrative efficiency.

REMOVAL OF TRADE AND EFFICACY AS MANDATORY CONISDERATIONS

TRADE

- The major change is that trade and efficacy would no longer be mandatory considerations in the Registration process as is currently the case. This would be discretionary and this discretion would be applied by the APVMA on the basis of a yet to be published risk framework. From the fact sheet the following is stated “In

certain circumstances, the APVMA may use discretion in determining whether consideration of a particular aspect is necessary, such as efficacy and potential impact on international trade. For example, the APVMA would not need to consider prejudice to international trade when considering registrations for companion animal products or approvals for active constituents. However, if a chemical product would be used on export exposed animals or plants, the APVMA would retain the discretion to consider this matter." But a fact sheet has no legislative basis.

- Consideration of trade must be mandatory for major animals and plant who's produce are exported and discretionary for minor crops and animals such as goats and alpaccas. These should be listed in a schedule to the regulations so that there is Ministerial oversight of any changes. This would allow the objective of a risk based approach as desired by COAG but would protect the sheep and cattle industry

EFFICACY

- As a veterinarian, I don't want rubbish registered as veterinary medicines in Australia. Veterinary medicines are essential tools for veterinary surgeons who do not want to be in a situation where treatments would not have any guarantee to whether they would work or not. This would have animal welfare implications if treatments did not work.
- The buyer beware principle should apply to veterinary medicines as pet and livestock owners, including goat owners may not have the skills to research and monitor whether a vet medicine works or not.
- It is critical that the APVMA still consider efficacy assessment to manage zoonoses, biosecurity and animal health risks. These include the efficacy of vaccines to manage biosecurity risk, efficacy of anthelmintics to manage parasite resistance and the need for products to work effectively as described on the label to avoid adverse animal welfare outcomes for the treated animal.
- I attended the recent lecture tour by Professor Kaplan, USA talking about worm control and resistance development (with support from MLA) . He was very critical of the USA situation where many worm drenches are being marketed that actually now have no effect due to resistance being so widespread yet the registrants can still claim on their labels the original efficacy results when first registered. This causes major problems in goats and horses but also in sheep
- Resistance may develop more rapidly if efficacy is not considered during registration as surviving worms, fungi, insects would breed up quickly and spread the resistance genes. If efficacy was kept as a consideration then registrants would have a strong interest in ongoing education of users to ensure use patterns would support the maintenance of efficacy e.g. GMO cotton management plans with trap crops etc. GMO cotton seed is registered by the APVMA once outside the research arena (which is controlled by the Office of the Gene Technology Regulator).
- Similarly, if agricultural chemicals do not work efficaciously, then farmers will be tempted to apply at higher rates in order to kill insects or disease organisms.
- There are benefits to not including efficacy in reduced costs for registrants during both registration and continuation assessments. However sometime the consequences of a non efficacious product could be severe and not able to be judged by the normal primary producer. Vaccines would need to always have their efficacy considered. In goats a good example is enterotoxaemia vaccine- in sheep these are needed only annually at the most after the initial 2 doses, but in dairy goats on high grain diets deaths can still occur unless the vaccination interval is less than 5-6 months.

- Many goat producers use sheep anthelmintics. However without efficacy data the correct dose rates for goats would not be given on the labels. This leads to underdosing and faster development of resistance for both sheep and goats. A system that allows for easier registration of sheep anthelmintics for goats is needed such as reduced fees or less rigorous data requirements. This would benefit both sheep and goat industries. Assuming that a label restriction that "this product must not be used on goats" actually prevents its use is over-optimistic. It is better to for the veterinary medicine manufacturers and distributors to work with the goat industry to educate them on all methods of worm control and correct husbandry to protect both industries from resistance. It should not be expected that goat producers watch their animals die from worms without going to their local produce merchant to buy something that could help even if only registered for sheep.

Continuations (re-registrations)

- Re-registration (continuation of registration) is a concern if it results in loss ofagvet chemicals and will need careful monitoring. Some manufacturers may not provide data to support re-registration if they have subsequently brought out a newer, more expensive alternative.
- In the goat industry, resistance has meant that some older veterinary medicines are needed to be brought back as existing anthelmintics etc no longer work due to resistance.

Missing from the draft Bill and should be added

- Animal welfare considerations on pest control products are not included in this draft Bill, despite calls to do so. Pest animals do need to be killed but should be done in as humane a method as possible. However consideration of animal welfare should not remove all available products for controlling particular pest animal predators. Instead the most humane of the options available should be chosen. Pest predators are of grave concern to large scale goat farmers. Kids are hidden rather than following their mothers (as occurs with ewes and lambs) and hence are more susceptible to predation efforts of feral cats. foxes, wild dogs etc. 1080 baits are essential to control pest predators and must remain until other methods have been developed. Current controls are working well to protect accidental deaths in non target species.
- Minor use agvet chemicals have not been addressed. Minor species such as goats need access to a full range of veterinary medicines and incentives are needed to encourage their addition to label statements. Data protection may help but will not solve this problem. Reducing the data requirements for minor species such as goats, once registered for a major species such as sheep, may help. The requirement for residues studies to be done under GLP (Good Laboratory Practice) could be removed for minor crops and species. This would make registration easier for minor uses. If laboratories have NATA accreditation and professional oversight, then this should be enough to ensure the minor use data is valid. The number of GLP labs in Australia is severely limited and often booked out months or even years in advance.

Submitted by :
Dr Sandra Baxendell, PSM, BVSc (Hons), PhD MACVSc, GCertAppSC(RurExt), GCertPSectMgt, PGDAppSc, MRurSysMan
Director, Goat Veterinary Consultancies - goatvetoz
goatvetoz@gmail.com Mobile 0477 813278
Contact details are on OnePage card at http://myonepage.com/goatvetoz #onepage