

# Submission on the Harmonised Agvet Chemical Control of Use Task Group (HACCUT) updated proposal:

The national harmonisation of minimum veterinary prescribing and compounding regulatory requirements for veterinary practitioners – Treatment of Livestock.

#### **Section A: General information** Purpose of this form For individuals and organisations to provide submissions on the HACCUT updated proposal: the national harmonisation of minimum veterinary prescribing and compounding regulatory requirements for veterinary practitioners - Treatment of Livestock. Use this form to provide a submission or to write a long-form response. You can also attach a separate response. Before responding See HACCUT updated proposal: national harmonisation of minimum veterinary prescribing and compounding regulatory requirements for veterinary practitioners - Treatment of Livestock. **Closing date** 2pm, Friday 14 December 2018 To complete this form Save the document to your computer. Your submission must a completed and signed submission form include where relevant, supporting information from organisations, written on their official letterhead. Post or email **Agvet Chemicals Branch** (preferred) your Agvet Chemicals, Fisheries and Forestry Division submission Department of Agriculture and Water Resources GPO Box 858 Canberra ACT 2601 Email agvetpolicy@agriculture.gov.au

### **Section B: Applicant**

#### 1 Organisation name (if applicable) Goat Veterinary Consultancies – goatvetoz

2 Contact person				
Given name(s) Sandra		Family name Baxendell		
Work phone 0733556404 Mo		Mobile phone 0477 813 278		
Email goatvetoz@gmail.com				
3 Contact address				
Postal address 22 Lesina St., Keperra				
Suburb/town/city Brisbane		State/territory QLD Postcode 4054		
Section C: Confidentiality				
4 Is all of your submission confidential?				
No :	x_			
Yes Clearly mark the submission 'In confidence'				
5 Is part of your submission confidential?				
No >	C			
Yes [	Yes Clearly mark the relevant section(s) 'In confidence'			
Section D: Publication of submissions on the department website				
Unless you request otherwise, the department will publish your name, organisation and the title of your submission on its website. Your contact information will not be made available.				
6 Do you agree to your submission being made publicly available?				
No [	Go to question 8			
Yes >	C Go to question 7			
7 Do you agree to your name and state/territory being listed?				
No [				
Yes X [				
8 Do you agree to the department contacting you about your submission if required?				
No [				
Yes >	K 🗌			

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Section E: Submission type	
9 What type of submission are you making? (Sele	ect one box only)
Response to key topics in the proposal	$\rightarrow$ Go to section F
Long-form response to the whole proposal	→ Go to section G
Separate response in an attached document	→ Go to section H
Section F: Response to key topics in the co	onsultation paper
Please refer to the Discussion section in the proposupport your answers with references.	osal for additional information about the questions.
Use under Exceptional Circumstances	
<b>10.</b> Do you support veterinary chemical product species being treated in the same way as unregist	ered veterinary chemical products?
No – should be separate as lower risk than unreging	stered chemicals.
products?	in the same way as unregistered veterinary chemical
	e vets can use their knowledge to provide the best
treatment for animals under their care. However	_
	so vet medicine manufacturers do not need to do
the milk with-holding periods trials for goats. How	
periods for goats for some of these anthelmintics resistant worms is a huge problem in goats and ve	-
anthelmintics to prevent animal suffering and to p	<del>-</del>
-	ne of the new drenches (Startech or Zolvix, neither
•	thes from multiple drench families. Levamisole is a
	drenches (none of which are registered for goats).
	nas a 4 day with-holding period in the USA for goat
meat and 3 days for goat milk (see	
https://docs.wixstatic.com/ugd/aded98 c7a6cc3k	o624043aeaefe8693f9f13c71.pdf ). In
Australia there is no levamisole product registered	d for goats.
We already know that goat farmers are widely usi	ng unregistered drenchis but currently
veterinarians cannot legally do prescribe a sheep	
used for human consumption except for Panacur	(and its generics) and Caprimec. Goat farmers can
buy sheep drenches from any produce merchant,	rural supplier or on-line and used without any
veterinary input A past survey showed this pract	tice was wide-spread <sup>ii</sup> and unfortunately many are

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using the sheep dose rate on the label rather than the needed higher dose rate required for goats.

**12.** Please indicate which of the two alternative approaches to exceptional circumstance conditions, if either, you support?

Where a DrenchCheck or a Drench Resistant Test has shown that registered worm drenches for goats are no longer working, veterinarians must be able to prescribe drenches that do work and at the higher dose rates than on the label for sheep, even if there is a "Do Not Use" statement on the label. This is needed to stop goat dying from worms.

Veterinarians must also need to be pro-active and use the recommended quarantine drench protocols in the absence of evidence of drench failure e.g. the current sheep quarantine recommendation is to use combination drenches plus one of the newer drenches i.e Zolvix or Startect (see http://www.wormboss.com.au/tests-tools/management-tools/drench-resistance/quarantine-drenches.php ) and goat producers and their goats deserve the same protection.

If goats are not treated for worms as they need to be i.e. with vet oversight, then they will develop resistance and then these resistant worms will spread to sheep, putting Australia's sheep industry at greater risk.

Having special interest group (SIG) of the AVA doing minor use permit applications is totally unrealistic – these are voluntary, not-for-profit organisations run by busy vets. The SIG executives don't have the skills to use the APVMA online application software, the time, the access to R&D data nor the money to apply for minor use permits. Also it is noted that Horticulture Australia Ltd refused to hold minor use permits due to concerns about potential liability. I am a member of the Sheep Camelid and Goat SIG and couldn't apply for all the needed goat minor use permits.

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**13.** Do you think the proposed parameters for managing unregistered use, off-label use of veterinary chemical products registered for animals other than for food or trade species, and use contrary to a restraint statement are appropriate?

If you think they are inappropriate, can you:

- a. please explain why?
- b. suggest alternative parameters or an alternative approach?

I do not support the use of the cascade system as it limits the options for treating animals by vets. For example there is 1 product that is both registered for treating lice in goats that is still available but it is Pestene Powder which is only available in small pack sizes and suitable for pet goats where the animals can be handled and dusted all over with the powder and this repeated in 2-3 weeks. It is totally unsuitable for use in a large commercial herd of goats, where a backliner or product applied via a commercial spray unit is the only practical option. Clout S is still registered but no longer sold and also had resistance problems. Sheep lice treatments are needed for commercial goat herds. See case study on lice at the end of this document.

The cascade system doesn't take into account when products are registered but not commercially available from normal vet wholesalers due to temporary shortages or manufacturers keeping registration options open but no longer manufacturing it.

It is unrealistic to expect veterinarians to have data about impurities in unregistered products and supporting data re risk of residues and WHP for minor livestock species. This information is not available either in Australia or overseas. Veterinarians can make reasonable assumptions and a margin for error for using sheep products in goats based on with-holding periods in other similar species.

For best animal welfare vets must be able to prescribe and use the veterinary medicines (other than antimicrobials) they think best for that farm and that disease situation. I understand that antimicrobials have to have additional safeguards to protect their use in humans but restrictions on vets should be minimal especially as the main MAR risk is from imported food and tourism. Antimicrobial resistance is a global issue and Australia needs to put more diplomatic pressure on the countries of the word where their misuse is common and more inspections of food products from these countries. Vets need to be able to treat animals with antibiotics for welfare reasons even if the choices are restricted.

**14** If you support the reporting of this type of use, at what frequency should reporting occur i.e. monthly, quarterly etc?

Off label use should be done via a vet's prescription with copies held by both the vet and the owner
for 2 years. Medicated feed records should be kept by all 3 parties as indicated on the form.
No other reporting should be needed.
The APVMA has data on sales of veterinary medicines

#### Under the Care of the Veterinary Practitioner

**15.** Do you believe that a period of 3 months is too short a maximum period for revisiting a property to reassess animals being treated, in relation to ongoing treatment?

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#### If you do, please:

- a. give clear examples of where you believe this period would be inappropriate.
- a. advise what period and conditions you believe would be appropriate and why?

Three months is too short for farms where access to vets is too difficult due to distance or in the case of goats, where local vets will not treat goats. Visits every 3 months is also unnecessary and expensive for owners.

While photos and video are useful alternative for visits every 3 months, there needs to be provision for test results as an alternative for a farm visit. I do annual written worm control plans for some of my clients and give prescriptions for sheep drenches as part of this. I then monitor by having the farmer send faecal samples for worm egg counts and cultures to a commercial laboratory and adjust the plan as needed. In this case 12 months farm visits are all that is needed.

Similarly, I monitor dairy goat farms and provide prescriptions for mastitis treatments after the owner has taken sterile milk samples to a veterinary laboratory for a culture and sensitivity test. I have trained my dairy goat clients on how to do take a sterile milk sample and send via email a sample submission form. My clients are often closer the vet lab than I am and deliver samples personally. Getting a culture and sensitivity test is more important than a farm visit for prescriptions for mastitis treatments.

#### I suggest rewording to the following:

Change 3 months to 6 months and then add the following. "Where an annual disease control plan has been provided, a vet visit is only needed every 12 months with reviews and adjustments made by phone and email communication.

Also add in that "a diagnostic test submitted by the owner, in consultation with a veterinarian, with results provided to all parties should be able to take the place of a 6 monthly visit".

Also the current wording "It is proposed that the use of electronic photos and videos may assist in managing more remote clients " This is too vague and also the current AVA guidelines which the Qld Vet Surgeons Board uses for registering vets doesn't support so this would also need to change. Is "remote" the Australian Bureau of Statistics definition i.e.

http://www.abs.gov.au/websitedbs/D3310114.nsf/home/remoteness+structure? There are many non-remote locations where no existing vets will treat some minor species.

We need a clear statement that the use of videos and photos be a clear alternative for a vet visit prior to prescribing but this is at the vet's discretion as to whether a diagnosis can be reached or not.

#### **Increased Auditing**

**16.** What forms of cost recovery would be acceptable, to enable increased and nationally consistent government auditing?

There is no need for additional cost recovery- instead make it mandatory for milk factories and supermarkets to share any residue findings above the MRL.

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<u>Similarly LPA audits with corrective actions should be shared with state regulators so existing funds</u> for residue testing and checking can be better targeted.

<u>Instead of fines</u>, <u>enforceable undertakings should be used and these should fund additional audits</u> and testing of samples plus also extension efforts to promote responsible use of vet medicines.

The APVMA currently does not have the resources to investigate all notifications even when obvious breaches advertised on the www and social media are sent to them. It should not waste resources on routine monitoring of vets.

#### → Go to section H

#### Section G: Long-form response to the consultation paper

#### 23 Please support your response with references, and attach additional sheets if necessary.

The prescription form/advice note is not suitable as often the veterinarian does not sell the product to the animal owner and the expiry date and batch number should be either optional or able to be added later by the owner and not needed on the vet's copy e.g. in the case of worm drenches and lice treatments for goats the vet will prescribe but not sell the product as it is cheaper for the owner to purchase themselves online. The expiry date is currently needed on Qld vet prescriptions and I have to send many emails or make phone call to get owners to tell me the expiry date when they have purchased sheep drench containers that they purchase on-line or from rural stores and that I have prescribed. Instead allow the vet's prescription copy to have the expiry date and batch number blank when the vet does not actually sell the client the product and have this information only added to the client's copy.

The advice note should not need an acknowledgement if a copy is also emailed to the client and a copy of this email is saved electronically by the vet. This is needed for remote clients and where photos and videos or lab tests are used by a vet to make a diagnosis as well.

The definition of major food and trade species need clarity – currently it is defined on page 4 as "at least cattle, sheep, pigs and chickens". The goat industry needs to know if they are in or out of this definition.

## Case Studies to demonstrate how unworkable these proposed changes are for vets working with minor species

#### Case study 1 Disbudding goat kids

Currently I disbud dairy and miniature goat kids using alfaxan anaesthesia with prior administration of Buccalgesic gel at between 3-7 days of age. Neither drug is registered for use in goats nor do I have no data on WHPs. Alfaxan anaesthesia is recommended for disbudding by the British Goat Veterinary Society. I use the UK default WHP used in the UK i.e. 45 days for meat, although it is extremely unlikely these kids would be used for meat as kids after paying a vet for disbudding. However cull old dairy goats may eventually end up being sold for meat, which for large commercial goat dairies is the only practical option for culled does.

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There is goat data to show that Meloxicam injections work for goats for disbudding with half-life details but no residue data. Buccalgsic gel has no data that I am aware of for goat residues.

Xylazine which is registered for goats is not recommended for neonates due to the high risk of overdosing. Xylazine also needs the use nerve blocks and which in goats means 4 nerve blocks (not the 2 as with cattle) and hence the risk of overdosing for kids as the toxic dose is only 2 mls for a 4kg kid. Most lignocaine local anaesthetic products are not registered for goats and hence could not be used without residue and WHP data. Only 1 local anaesthetic product is registered but found to be available from veterinary wholesalers when a search was done on their on-line catalogues (see photo at the end of case study 4).

Under the current proposed changes, vet could not prescribe alfaxan and Buccalgesic for goats unless

- The Sheep Camelid and Goat SIG of the AVA applies for a permit to use alfaxan and Buccalgesic - assuming they have the data (which may not be available), the time, the volunteers with expertise and the funds to do so.
   OR
- An individual vet has data as required under Exceptional Circumstances Option 1 i.e. (ix) there are supporting data indicating that there will be minimal risk to trade ..................... Or a permanent WHP applies i.e. animals treated with alfaxan or Buccalgesic could never be slaughtered for meat consumption for humans. Vets have no such access to this data for alfaxan or Buccalgesic. They could however make a reasonable estimate based on sheep WHPs for Buccalgesic but the proposals do not allow for any extrapolation nor any default WHP.

The likely outcome is that goat kids will be disbudded by owners without anaesthesia or any pain relief – which is allowed under the goat welfare code.

#### Case study 2 Example 1

Q drench is widely used on Australian goats by goat owners and is an excellent drench for *Haemonchus* areas. However for goats the dose rate should be 1.5 times the sheep dose rate and hence a vet's prescription is needed. For goat herds with deaths due to *Haemonchus*, Q drench is the treatment of choice as it is a combination drench and one with a long acting active for *Haemonchus*. Unfortunately many goat owners just buy Q drench from produce merchants and use at the label sheep dose rate, leading to resistance.

Under the current proposed changes, vet could not prescribe for goats unless

- The Sheep Camelid and Goat SIG of the AVA applies for a permit- assuming they have the data (which may not be available), the time, the volunteers with expertise and the funds to do so.
- An individual vet has data as required under Exceptional Circumstances Option 1 i.e. (ix) there are supporting data indicating that there will be minimal risk to trade ............. Or a permanent WHP applies i.e. animals treated with Q drench could never be slaughtered for meat consumption for humans. Vets have no such access to this data for Q drench. They could however make a reasonable estimate based on sheep WHPs but the proposals do not allow for any extrapolation nor any default WHP.

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#### Case study 3

A commercial goat dairy farm has a problem with mastitis and their veterinarian wants to put into place both best practice treatment options and prevention for further cases. However for treatments there are:

- 1 No intra-mammary antibiotic treatments registered for goats (see photo below of the PubCRIS database search)
- 2 The two pain relief injections (flunixin and meloxicam) registered for use in dairy cows with mastitis are not registered for goats

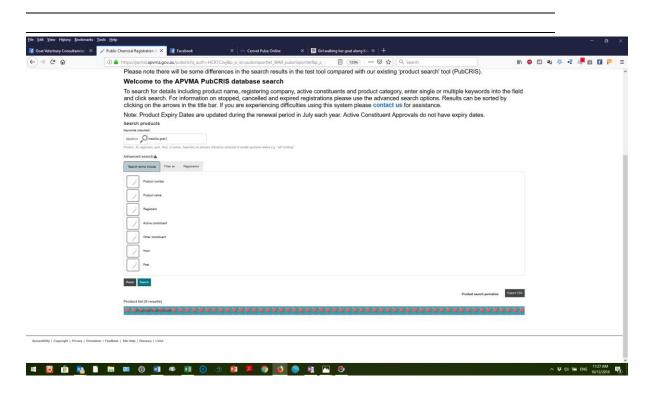
Also for prevention there are

- 3 No teat sanitisers registered for goats to prevent mastitis (only for dairy cattle)
- 4 No intra-mammary treatments for goats to use during their dry period (which is the best time to treat) and to prevent acute cases at the next kidding

As their vet cannot provide WHP data as required under 41 (xi) these dairy goats can never be sold after their productive life for human meat consumption.

The dairy goat farmer has therefore only 2 options

- A) never sell any dairy goats for meat at significant economic loss and practical problems of dealing with large numbers of goats at the end of their productive life.
- B) Not to use the preventative measures that work in dairy cows and only use antibiotics injected into the muscles (which is less effective) and no pain relief for clinical case of mastitis

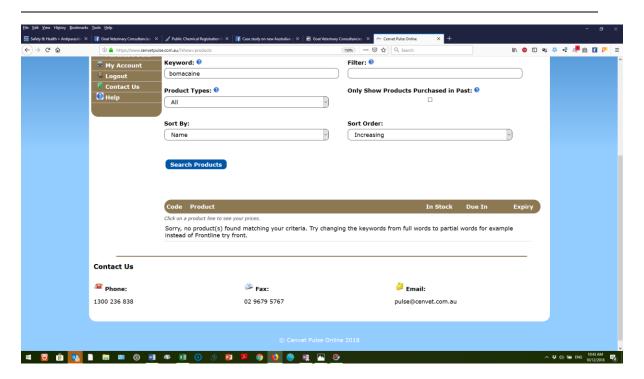


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#### Case study 4 Caesarean or cervical prolapse in a goat

A vet is presented with a Boer goat in need of a caesarean or treatment for a cervical prolapse. The vet has been unable to source the only local anaesthetic registered for goat, Bomacaine, as it is not stocked by the vet's wholesaler- see below. The vet cannot therefore use a registered local anaesthetic for an epidural in this goat. As the vet has no data on lignocaine with-holding periods, the owner is informed that the doe will therefore need to have a permanent with-holding period and can never be sold for meat for human consumption. (see page 8 of the proposed vet prescribing rights - exceptional circumstances option 1 (ix)) The owner then decides to take the goat home and shoot it instead.

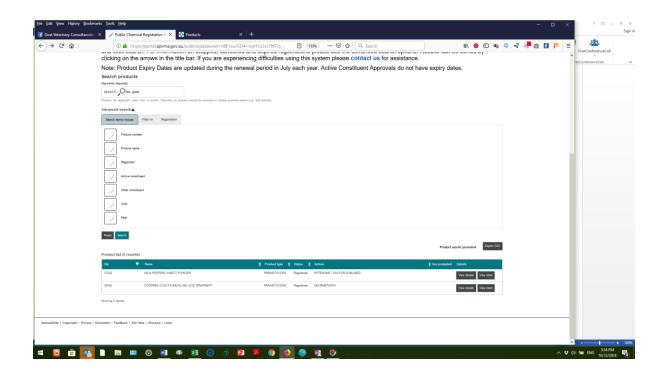


#### Case Study 5 Lice in Goats

A commercial goat herd of 1000 goats has a lice infestation. Currently there is only 2 available product registered for lice in goats – Pestene Powder and Clout S as shown below. However Clout S is no longer commercially available (see <a href="http://www.coopersanimalhealth.com.au/products">http://www.coopersanimalhealth.com.au/products</a>). Under the "cascade" system proposed (page 8 section 38 (a)) then a veterinarian must prescribe Pestene powder as it is the only product registered for goats. Pestene powder is only available in 500 gram containers and individually dust all 1000 goats, rub into their skins and repeat weekly. Clearly this is not practical. Currently a vet can prescribe one of the many sheep lice products after making an educated extrapolation from the sheep product WHP. Under the proposed changes vets will only be allowed to prescribe sheep lice treatment if they have data to back up a WHP or if the goats are permanent kept out of the human food chain. What will most likely happen is that either goats won't get treated or the goat owner will just buy the sheep lice products on-line or at a local farm supply store and treat the goats without any veterinary input into the likely needed WHPs.

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#### **Section H: Applicant declaration**

To be completed by the person listed in section B of this application.

I understand that:

the Australian Government reserves the right to refuse to publish submissions, or parts of submissions, that contain offensive language, potentially defamatory material or copyright infringing material

a request may be made under the Freedom of Information Act 1982 for a submission marked confidential to be made available. Such requests will be determined in accordance with provisions under that Act

if I provide personal information about an individual other than myself, I must make that person aware of the privacy notice in <u>section I</u> of this form and draw their attention to the department's privacy policy.

Signature (type or sign your name) S A Baxendell

Date (dd/mm/yyyy) 11/12/18

Full name Dr Sandra Ann Baxendell PSM, BVSc (Hons), PhD MANZCVS, GCertAppSC(RurExt), GCertPSectMgt, PGDAppSc, MRurSysMan

Director, Goat Veterinary Consultancies -goatvetoz

#### **Section I: Privacy notice**

'Personal information' means information or an opinion about an identified individual, or an individual who is reasonably identifiable.

The collection of personal information by the Department of Agriculture and Water Resources in relation to this submission is for the purposes of gathering information for the Harmonised Agvet Chemical Control of Use Task Group updated proposal for the harmonisation of minimum veterinary prescribing and compounding regulatory requirements for veterinary practitioners – Treatment of Livestock. If you do not provide this information, the department will be unable to contact you to discuss your submission.

Under the Freedom of Information Act 1982, submissions marked confidential may be made available. Such requests will be determined in accordance with provisions under that Act.

Personal information may be published on the department's website, disclosed to other Australian agencies, persons or organisations where necessary for these purposes, provided the disclosure is consistent with relevant laws, in particular the Privacy Act 1988. Your personal information will be used and stored in accordance with the Privacy Principles.

See the department's <u>Privacy Policy</u> to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933.

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Lyndal-Murphy, M., P. James, P. Bowles, R. Watts and S. Baxendell (2007). Options for the control of parasites in the Australian Goat Industry A situational analysis of parasites and parasite control NORTH SYDNEY, Meat & Livestock Australia Limited

1- 107.

1- 107.

ii Ibid.

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<sup>&</sup>lt;sup>1</sup> Lyndal-Murphy, M., P. James, P. Bowles, R. Watts and S. Baxendell (2007). Options for the control of parasites in the Australian Goat Industry A situational analysis of parasites and parasite control NORTH SYDNEY, Meat & Livestock Australia Limited