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Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604

Via email: standards.management@foodstandards.gov.au

Dear Sir/Madam

Submission Re: Proposal M1014 – Maximum Residue Limits (2016)

Thank you for the opportunity to provide comment on proposed variations to certain maximum residue limits (MRLs) in the *Australia New Zealand Food Standards Code* (the Code) – Proposal M1014. Animal Medicines Australia is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. As such, we have a strong interest in ensuring that these products can continue to be used safely, responsibly and sustainably.

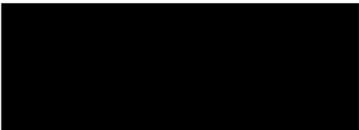
Two proposed MRL variations are relevant to AMA members. These are for:

- Nicarbazin; and
- Virginiamycin.

AMA's comments on these MRL variations are included in this submission. Our priority is to ensure that our member's products can continue to be used safely, responsibly and sustainably. Safe and responsible use of our members products is critical to:

- Support the health and welfare of production animals,
- Promote safe, sustainable and responsible farming enterprises, and
- Protect access to Australian domestic and export markets.

Veterinary medicines and animal health products are subject to rigorous pre-market assessments that ensure that when they are used in accordance with label instructions, risks to human health, safety and the environment can be minimised. Should you have any questions in relation to this submission, please contact me.


Ben Stapley

Executive Director

Virginiamycin

AMA notes that FSANZ proposes to omit the existing MRL:

Permitted residue: Inhibitory substance, identified as virginiamycin (mg/kg)

Eggs	*0.1
Pig, edible offal of	0.2
Pig fat	0.2
Pig meat	*0.1

Virginiamycin is currently approved by the APVMA for use in horses, cattle, sheep and chicken meat production. These approved uses are to:

- Treat acidosis in sheep and cattle,
- Treat necrotic enteritis in chickens, and
- Protect against laminitis in horses.

Currently, there are no approved products for use by either pork producers or by chicken egg producers.

The product is applied to animal feed, either on-farm, or at a commercial feed mill. The virginiamycin pre-mix product is combined with animal feed in a rotating container and thoroughly mixed to ensure even distribution and consistent dosing.

As a result of this process, residues of virginiamycin may remain present on and within equipment used to mix animal feed with virginiamycin product. While appropriate, thorough cleaning processes should remove almost all residues from feed preparation equipment, minute residues may remain with the potential to be transferred to animal feed subsequently prepared using the same equipment.

Chicken and pigs fed with feed containing minute residues of virginiamycin may subsequently retain detectable residues of virginiamycin, even though no inappropriate or off-label use of the product has occurred and after significant efforts to clean product residues from feed mixing equipment have been made.

To avoid a technical breach of the food standards code, AMA therefore recommends that FSANZ retain the egg and pig virginiamycin MRLs. FSANZ should consider the risks and costs that will accrue to feed and food production industries if these MRLs are omitted:

- To reduce the risk of contamination, feed manufacturers may need to consider whether additional mixing/treatment equipment is required specifically for virginiamycin products. Additional investment is likely to increase costs for manufacturers and farmers with no net improvement in either food safety, trade risk or farm productivity.
- Alternatively, feed manufacturers may decide to not supply feed treated with virginiamycin, resulting in poorer animal health outcomes for cattle, sheep, chickens and horses that would benefit from treatment with this product.

Should these MRLs be omitted, current food regulatory requirements specify that there must be no detectable residue within the food commodity. This ‘zero tolerance’ approach has caused concern

for regulatory agencies as well as agricultural producers. This concern was recognised by FSANZ through Proposal P1027, which was conducted to address the inadvertent presence of low level agvet chemical residues in food commodities. P1027 expressly excluded veterinary medicines from this project because their use is species specific. FSANZ noted that as the APVMA sets MRLs in animal food commodities to control the use of veterinary drugs (i.e. not as a safety measure), residues should only occur where there are specific approved uses.

While this reasoning holds true for most veterinary medicines, this is not the case for products that are added to animal feed, as explained above. Under these circumstances, retention of the current MRL would be appropriate.

Nicarbazin

AMA notes that FSANZ proposes to add a new MRL for nicarbazin:

Permitted residue: 4,4'-dinitrocarbanilide (DNC) mg/kg

Eggs	0.3
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AMA supports an appropriate MRL for nicarbazin, and notes that an appropriately set MRL will ensure that egg producers are able to continue to safely produce chicken eggs.

Nicarbazin is currently approved for use in broiler chickens to both manage coccidia exposure levels and control disease. Currently, there are no nicarbazin products approved for use for egg-producing chickens.

Application/dosage of nicarbazin products occurs via thorough mixing with chicken feed to ensure even distribution. Preparation of chicken feed may occur at either a feed manufacturing facility or on-farm. Even with thorough cleaning of feed preparation equipment, some nicarbazin residue from feed manufacturing equipment may be transferred to the feed for layer hens.

An appropriately set MRL will ensure that technical breaches of the food standards code will not occur due to the inadvertent presence of nicarbazin residues originating from feed preparation equipment.