

24th July 2017

To whom it may concern.

RE:FSANZ Proposal M1014: Maximum Residue Limits (2016)

'Submission'

Phibro Animal Health Ltd. (Phibro), has reviewed Proposal M1014 to amend selected existing MRLs relating to its proprietary compounds, nicarbazin and virginiamycin.

The company wishes to comment on these proposals, and respectfully proposes alternative values as detailed below.

In summary Phibro proposes

- The new MRL for nicarbazin in eggs be established at 5 µg DNC/ g. This proposal should achieve the avoidance of vexatious residue violations of no consequence to human food safety. Phibro believes the original proposal for a 0.3 µg DNC/ g will not achieve the desired goal.
- The existing MRLs for virginiamycin in pig tissues not be withdrawn. Phibro believes the availability of numerical MRLs provides a considerably better commercial framework in trade than the absence of a MRLs. Phibro believes the removal of swine tissue MRLs will be perceived as an anti-free trade action by swine producers in countries in which virginiamycin is approved for use in swine. These countries include China, USA, Canada, Brazil and others. Phibro recognizes the poor systemic bioavailability of virginiamycin means food tissue residues are not practically observed, none the less the company has had decades of experience in managing these trad concerns and as recently as 2015 submitted for, and obtained MRLs for virginiamycin in poultry tissues in the EU for the sole purpose of resolving trade concerns. Australia and New Zealand are leading proponents of the free trade of agricultural commodities and related supporting safety based SPS supporting standards. Phibro strongly requests the existing swine tissue MRLs be retained despite the absence of domestic approval or use of virginiamycin in pigs in Australia and New Zealand.

Nicarbazin

Nicarbazin (NCB) is a veterinary medicine, approved by the APVMA for administration to chickens to prevent coccidial disease. Is not deliberately administered to egg laying birds, however, NCB residues may occur through the unintended low-level cross-contamination of NCB in mills producing feed for both meat and egg producing chickens. At higher levels NCB adversely affects the appearance of table eggs making them commercially unsalable. At very low administration levels the table egg quality, and food safety are not adversely affected by NCB, however, with no established MRL there would be a technical breach of the food standard.

HEALTHY ANIMALS. HEALTHY FOOD. HEALTHY WORLD.®

Unit 1 /7-10 Denoci Close, Wetherill Park, NSW 2164 • Phone,02 9616 3700
Email, orders.phibroaustralia@pahc.com



Phibro understands and appreciates, the proposal by FSANZ to introduce a NCB MRL for edible eggs is intended to avoid a trivial, but nonetheless, breach of the food standards while ensuring the wholesomeness and safety of affected eggs for human consumption.

M1014 proposes to introduce a new 0.3 mg/kg MRL for edible chicken eggs.

Phibro is concerned that the proposed MRL is too conservative to achieve the desired objective. Data elucidating the relationship between dietary NCB and egg concentrations are very limited, and likely to be quite complicated due to the likely limited metabolism and lack of excretion of residues from the egg. Additionally, the mass of the egg and its individual components (shell, albumen, yolk) change quite dramatically in the days and hours prior to oviposition. Accordingly, an adverse dietary exposure from NCB containing feed in the few days immediately preceding oviposition will likely generate much greater egg residues than will be observed in an egg from the same bird a few days later as the residue will be diluted as the egg mass increases in the absence of circulating DNC.

Phibro has one unpublished internal study¹ in which Pekin Ducks were used a model. Pekin ducks were used rather than chickens as the purpose of the study was to examine the effect of inadvertent exposure of wild ducks to the related pest bird contraceptive product, Ovocontrol™. Ovocontrol is not available in Australia. While these data are very limited, with extrapolation they provide a good basis, when combined with other information regarding adverse egg effects and established MRLs for other edible tissue, for proposing an MRL that meets the objective of avoiding vexatious standards violations of no consequence to food safety standards.

Feed exposure levels in excess of 10 g/tonne NCB typically result in undesirable cosmetic changes to internal appearance and unacceptable decolorization of colored shells, therefore, exposures above this level need not be considered in this process as the resultant eggs should not enter the food chain for other commercial reasons.

The pekin duck 30 g NCB/tonne feed exposure data demonstrates egg yolk concentrations of up to 10 µg DNC/ g yolk can be reached after 7 days exposure. Extrapolating these data we can derive that 10 g/t feed exposure could reach 3 µg DNC/ g yolk. This value is tenfold higher than the proposed 0.3 mg/kg (µg/g) MRL for eggs.

Of course commercial pragmatism must only be a secondary consideration after human food safety consideration have been satisfied.

The current Australian MRLs for NCB (measured as mg DNC/kg (=ppm)) are: kidney 20; liver 35; muscle 5; skin/fat 10. These values were established based on a 1982 NOAEL of 240mg/kg bwt/d and an ADI incorporating of 2mg/kg bwt/d implying an approximate 100 fold safety factor over the NOAEL.

The food safety impact of consuming NCB residues is managed through the ADI which is an aggregate value driven by the sum of the permissible tissue residues and the assumed quantity consumed of those tissues. The process assumes relentless daily consumption at these values through the entire life of the consumer. Current JECFA supported daily food tissue intake values (food basket) are kidney 50g; liver 100g; muscle 300g; fat 50g; eggs 100g.

HEALTHY ANIMALS. HEALTHY FOOD. HEALTHY WORLD.®

Unit 1 /7-10 Denoci Close, Wetherill Park, NSW 2164 • Phone, 02 9616 3700
Email, orders.phibroaustralia@pahc.com



As previously described it is possible that egg tissue may contain 3 ppm DNC. Using the accepted food basket value of 100g egg per day it would not be unreasonable from a safe food perspective to apply the same MRL for liver or 2x the kidney MRL to eggs. This would imply an MRL value of 35 to 40 ppm DNC. The argument presented indicate this value would be safe to consumers, but would be unnecessarily high. A more practical approach would be to apply the muscle tissue value of 5 ppm which would provide an abundance of safety, while providing a pragmatic solution to the current vexatious regulatory situation resulting from having no established MRL. The proposed 0.3 ppm would be a change in the right direction, but based on the calculations presented would be excessively restrictive in that it would not completely solve the underlying problem.

Summary: Phibro Animal Health Ltd requests the proposed 0.3 µg/ g MRL for edible eggs be amended to 5 µg/g.

Virginiamycin

Virginiamycin (VM) is streptogramin antimicrobial approved for use in Australia in chickens, sheep and cattle, and chickens in New Zealand. The use of virginiamycin in Australia and New Zealand requires mandatory veterinary authorization. Phibro is the pioneer registrant and sole global producer of commercial VM. Internationally, in addition to approvals for use in chickens, sheep and cattle VM is approved for use in swine, turkeys, and other species.

Phibro recognizes that for all practical purposes, due to very poor systemic absorption and rapid metabolism following oral administration, the use of VM in food species does not result in detectable VM residues in edible tissues.

Phibro also understands the administrative rationale underlying the proposal to withdraw the existing pig tissue MRLs for VM as there are no currently approved uses of VM in Australia or New Zealand.

Phibro has had decades of experience in managing fear based irrational trade concerns and as recently as 2015 submitted for, and obtained MRLs for VM in poultry tissues in the EU for the sole purpose of resolving trade concerns relating to export to that region.

Phibro respectfully requests FSANZ retain numerical MRLs for VM in pig tissues to avoid the misinterpretation that are likely to occur in trade. This is not necessarily trade involving Australia or New Zealand. Both countries are international leaders in the promotion of science based free trade and the SPS standards that support this trade.

Phibro understands it is not the responsibility of Australia and New Zealand to resolve or prevent agricultural trade confusion, particularly when it may not even impact Australia or New Zealand directly, however, it is very refreshing when countries do step up to provide scientific leadership that is often lacking from larger economies.

Phibro believes the availability of numerical MRLs provides a considerably better framework for clarity in trade than the absence of MRLs. Consequently, Phibro believes the removal of the existing pig tissue MRLs in Australia and New Zealand will create potential uncertainty in some less sophisticated

HEALTHY ANIMALS. HEALTHY FOOD. HEALTHY WORLD.®

Unit 1 /7-10 Denoci Close, Wetherill Park, NSW 2164 • Phone, 02 9616 3700
Email, orders.phibroaustralia@pahc.com



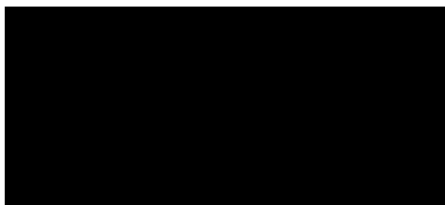
countries, and could be perceived as an anti-free trade action by swine producers in countries in which VM is approved for use in swine. The countries in which VM is approved in swine include China, USA, Canada, Brazil, Russia and others. Australia and New Zealand are leading proponents of free trade of agricultural commodities and related supporting mechanisms, Phibro strongly requests the existing swine tissue MRLs be retained despite the absence of domestic approval for the use of VM in pigs.

Phibro believes there is no food safety issue associated with the company's proposal as residues are not practically detectable following oral administration of virginiamycin to pigs or other species.

This PAH proposal was prepared by Phibro's SVP scientific and regulatory affairs, Dr Richard Coulter, who is based in the USA but remains a registered veterinarian in Australia, and prior to moving to the USA was a practising poultry veterinarian in Australia and also a senior executive with Ridley Agriproducts, so has direct experience with these products and their use in Australia.

PAH will provide additional support documentation if required.

Yours Sincerely



Thomas Wakeford
Managing Director Southern Oceans Region



¹ Pekin duck model for action of nicarbazin on fertility. G.F. Barbato & A. MacDonald, Pennsylvania State University, University Park, PA 16902, USA (Unpublished).