

**23 March 2017**  
**[08–17]**

Approval report – Application A1133

## Maximum Residue Limits for Avilamycin in specific Pig Commodities

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Elanco Animal Health to harmonise MRLs for avilamycin in specific pig commodities in the *Australia New Zealand Food Standards Code* with the Codex Alimentarius.

On 7 November 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received one submission and one late comment.

FSANZ approved the draft variation on 9 March 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 22 March 2017.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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### Supporting documents

The [following document](#)<sup>1</sup> which informed the assessment of this Application is available on the FSANZ website.

SD1           Risk assessment on approved maximum residue limits for avilamycin in specific pig commodities (at Approval)

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<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1133MRLs-for-Avilamycin.aspx>

## Executive summary

Elanco Animal Health lodged an Application seeking to harmonise maximum residue limits (MRLs) in the *Australia New Zealand Food Standards Code* (the Code) for avilamycin in specific pig commodities, with MRLs established by the Codex Alimentarius Commission (Codex).

Avilamycin is an orthosomycin antibiotic. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has permitted its use in broiler chickens in Australia and there are existing MRLs for poultry in the Code with the residue definition 'inhibitory substance, identified as avilamycin'. However, there are currently no MRLs in the Code for pig commodities and its use is not currently permitted in domestic pig production by the APVMA.

Dietary exposure assessments undertaken for the Australian population indicate that the MRLs of 0.2 mg/kg on selected pig products and 0.3 mg/kg for pig liver using the residue marker, 'dichloroisoeverninic acid (DIA)' for avilamycin residues did not substantially increase estimates of potential dietary exposure. In addition, the supplementary microbiological assessment concluded that, based on the available data, harmonising with the requested MRLs for avilamycin, the risk to consumers for the development of resistance to antimicrobials commonly used in human medicine was negligible.

FSANZ has approved a variation to the table to section S20—3 in Schedule 20 (an Australia only Standard) to harmonise MRLs for specific pig commodities in the Code with Codex MRLs using the residue definition DIA for avilamycin. This will permit the sale of specific pig food products containing legitimate residues at levels that are consistent with the effective control of pests and diseases and which do not present public health and safety concerns.

# 1 Introduction

## 1.1 The Applicant

Elanco Animal Health is a division of Eli Lilly and Company, a global pharmaceutical corporation and is a supplier of products and services within the animal health sector.

## 1.2 The Application

The Application sought to harmonise MRLs in the table to section S20—3 for avilamycin in specific pig commodities and thus facilitate trade in pig commodities between the United States of America (USA) and Australia. The MRLs requested for the specific pig commodities would align MRLs in the Code with Codex and allow the importation/sale of food with legitimate residues.

Table 1 outlines current MRLs for pig commodities established by Codex for the chemical avilamycin and which were requested by the Applicant.

**Table 1: Commodities and MRLs requested by the Applicant to align the Code with Codex for the chemical avilamycin**

Chemical	Commodity	Requested MRL (mg/kg)
Avilamycin <i>Residue definition: dichloroisovevorninic acid (DIA)</i>	Pig fat/skin	0.2
	Pig kidney	0.2
	Pig liver	0.3
	Pig meat	0.2

## 1.3 The current Standard

Schedule 20 – Maximum residue limits is an Australia only Standard. The table to section S20—3 lists the MRLs for agricultural and veterinary (agvet) chemical residues which may occur in foods. Limits prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class, whether produced domestically or imported. Food products with residues exceeding the relevant limit listed in the Code cannot legally be sold in Australia. This ensures that residues of agvet chemicals in food are kept as low as possible, are consistent with the approved uses of chemical products to control pests and diseases of plants and animals, and are at levels that have been assessed as being safe for human consumption.

Avilamycin currently has permissions for both domestically produced and imported food in the table to section S20—3 for poultry commodities only<sup>2</sup>. No MRLs are listed for pig commodities.

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<sup>2</sup> The permitted residue definition for poultry MRLs in the table to S20—3 is “*Inhibitory substance, identified as avilamycin*”.

### 1.3.1 National and International Standards

In 1999, avilamycin was [permitted for use](#)<sup>3</sup> in Australia by the APVMA to increase weight gain and improve feed efficiency in broiler chickens<sup>4</sup> only. There are currently no permissions in the APVMA MRL Standard for the use of avilamycin in pig production. However, an APVMA assessment for a research permit application in 2003 recommended the establishment of avilamycin MRLs (as per the current poultry residue definition) for pig meat and offal. This permit was only issued until February 2005. Since 2005, no further uses of avilamycin have been considered and as there was no approved use of avilamycin in pigs in Australia after 2005, the MRLs in the APVMA MRL Standard and the Code were consequently removed.

More recently, the [European Medicines Agency, Committee for Medicinal Products for Veterinary Use](#)<sup>5</sup> recommended the inclusion of MRLs for avilamycin in pig commodities in Annex I of Council Regulation (EEC) No. 2377/90 in 2007. MRLs for avilamycin for pig and poultry commodities were also adopted by Codex in 2009 based on data assessed in the [Joint Expert Committee on Food Additives \(JECFA\) evaluation](#)<sup>6</sup>.

In May 2015, the US Food and Drug Administration approved for use in swine<sup>7</sup>, a veterinary medicine Kavault® (NADA 141-438)<sup>8</sup> containing the active ingredient avilamycin. Following the USFDA approval of Kavault®, Elanco Animal Health submitted an application requesting FSANZ consider varying Schedule 20 to harmonise avilamycin MRLs for pig commodities with Codex. FSANZ acknowledged the request to harmonise with Codex MRLs for the same parent compound (avilamycin), however noted Codex MRLs for pig commodities were permitted using a different residue marker<sup>9</sup> to existing poultry MRLs for the same chemical currently listed in the table to section S20—3.

## 1.4 Reasons for accepting Application

The Application was accepted for assessment because it:

- complied with the procedural requirements under subsection 22(2)
- warranted the variation of a food regulatory measure.

FSANZ and the APVMA have shared responsibilities in relation to MRL-setting. FSANZ considers requests to harmonise MRLs for import purposes based on those established by Codex or by a regulatory authority in a recognised jurisdiction where the commodity is produced. This is undertaken in consultation with the APVMA.

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<sup>3</sup> [Public Release Summary for Elanco AF0375 Surmax 100 Avilamycin premix](#) <http://apvma.gov.au/node/14116> (accessed 16/1/2017).

<sup>4</sup> The Agricultural and Veterinary Chemicals Code Instrument 4 (MRL Standard) lists MRLs for agvet chemicals in agricultural produce particularly produce entering the food chain. Access via the Register of Legislation website at <https://www.legislation.gov.au/Series/F2012L02501> (accessed 16/1/2017).

<sup>5</sup> European Medicines Agency, Committee for Medicinal Products for Veterinary Use, Avilamycin summary report, 2007:

[http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500010750](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500010750)

<sup>6</sup> Seventieth report of the Joint FAO/WHO Expert Committee on Food Additives- evaluation of Avilamycin:

[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_954\\_eng.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_954_eng.pdf) (accessed 16/1/2017).

<sup>7</sup> Macquarie dictionary definition of 'Swine' is a 'domestic pig'.

<sup>8</sup> US FDA approval of Kavault® (NADA 141-438) containing the pharmaceutical active avilamycin

<http://www.fda.gov/downloads/animalveterinary/products/approvedanimaldrugproducts/foiadrugsummaries/ucm449239.pdf> (accessed 17/2/2017).

<sup>9</sup> Codex MRLs for pig commodities were established on the residue marker "dichloroisoevernic acid (DIA)".

## 1.5 Procedure for assessment

The Application was assessed under the General Procedure.

## 1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

Consultation is a key part of FSANZ's Standards development process and FSANZ sought public comment to help finalise the assessment of the proposed MRLs. Comments were invited on any impacts on importing food and any public health and safety considerations associated with the proposed MRL variations.

FSANZ received a submission from Queensland Health which included comments from Safe Food Production Queensland. FSANZ also received late comments from the Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport and Resources. A summary of the issues raised and FSANZ's response are provided in Table 2. The issues raised by Victoria have been included in Table 2 for ease of reference.

**Table 2: Summary of issues**

Issue	Raised by	FSANZ response
The APVMA has not approved avilamycin for use in the treatment of pigs in Australia.	Queensland Health and Safe Food Production Queensland (Qld)  Victorian Department of Health and Human Services, the Victorian Department of Economic Development, Jobs, Transport and Resources (Vic)	There are currently no registered uses in Australia for avilamycin in the treatment of pigs. See section 1.3.1 of the Approval report in regards to APVMA's previous assessment of avilamycin use in pigs in Australia.  Australian producers are able to make an application to the APVMA to extend the registered uses of avilamycin at any time.  FSANZ's responsibility is to undertake dietary exposure assessments of residues in the diet as part of the MRL setting process and can also consider requests to harmonise MRLs for import purposes established by Codex or by a regulatory authority in a recognised jurisdiction where the commodity is produced. During the risk assessment process, FSANZ has regard for the safety, legitimacy and justification for the presence of the residues in food.  As with any veterinary chemical request, FSANZ consulted closely with the APVMA in regards to the requested harmonisation of the proposed MRLs and the residue marker. The APVMA did not raise any issues with the proposed MRLs or the residue marker.

Issue	Raised by	FSANZ response
		<p>The Code currently includes several chemicals that have no registered uses in Australia, that is, they are not listed in the APVMA MRL Standard. Similarly, there are commodities listed under many chemicals that have a higher MRL than those in the APVMA MRL Standard. The inclusion of MRLs for avilamycin is consistent with the inclusion of these other MRLs in the Code as part of FSANZ's harmonisation proposals.</p>
<p>Possible negative impacts on local growers/producers and the pork industry due to the competitive advantage gained by overseas markets where avilamycin is permitted for use</p>	<p>Qld</p>	<p>The Applicant provided supporting data to demonstrate that the current trade relationship between the US and Australia in pig commodities is expected to continue. There is an avenue for domestic food producers to make an application to the APVMA to extend the registered uses of any agvet chemical, including avilamycin if required.</p> <p>The Application requested harmonisation with the Codex MRLs for avilamycin. FSANZ's MRL harmonisation program ensures that the absence or magnitude of an Australian MRL does not pose a barrier to trade as is required to meet Australia's WTO obligations under the Sanitary and Phytosanitary Agreements.</p> <p>FSANZ recognises that agricultural and veterinary (agvet) chemicals are used differently in different countries around the world as pests, diseases and environmental factors vary and because of this, product use patterns may also differ. Therefore, the harmonisation process is undertaken in accordance with the <a href="#">Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food</a> (Guideline)<sup>10</sup>.</p>
<p>How compliance of imported product with the proposed MRLs will be monitored at the border</p>	<p>Qld</p>	<p>While the Code is developed and administered by FSANZ, it is enforced at the border through the Imported Food Inspection Scheme by Australian Department of Agriculture and Water Resources (DAWR). All food imported into Australia must comply with the requirements of the Code. FSANZ is satisfied appropriate testing methodology exists and is available to test for the marker residue DIA.</p>

<sup>10</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Issue	Raised by	FSANZ response
Dietary exposure for the proposed MRLs does not take into account if avilamycin was permitted for use by Australian pig farmers	Qld	<p>FSANZ conducts and reviews dietary exposure assessments (DEAs) for MRLs using the best available scientific data and internationally recognised risk assessment methodologies. Variations to MRLs in the Code are supported where estimated dietary exposures to the residues of a chemical indicate no potential public health and safety risk for the Australian population or population sub group.</p> <p>The DEA for A1133 assumed that all pork consumed in Australia would have avilamycin residues at the proposed MRL and did not differentiate between imported and domestically produced pork.</p> <p>The estimated dietary exposure for avilamycin used food consumption data from the 1995 National Nutrition Survey as well as consumption data from the most recent 2011-12 National Nutrition and Physical Activity component of the Australian Health Survey. This information is provided in the Supporting Document 1 - Risk assessment – Application A1133. This provides a worse-case estimate of dietary exposure to avilamycin. If the APVMA were to receive an application for the approval of avilamycin for additional uses in Australia, the APVMA would undertake an assessment with FSANZ checking and providing comment on the DEA prior to gazettal in the APVMA MRL Standard and variations in the table to section S20—3.</p>
The purpose for which avilamycin has been approved for use in pigs/ pig production in the USA is not clear	Qld, Vic	<p>The US FDA approval summary for Kavault as a new animal drug application states the avilamycin product was specifically approved in the USA for “the reduction in incidence and overall severity of diarrhoea in the presence of pathogenic <i>Escherichia coli</i> in groups of weaned pigs.” Limitations on the administration of Kavault include the requirement for a valid veterinary feed directive to dispense the drug and dosing restrictions of 80ppm medicated feed as the sole ration for 21 consecutive days on swine/weaned pigs up to 14 weeks of age.</p> <p>The <a href="#">JECFA monograph</a><sup>11</sup> (Codex) describes the intended use to control bacterial enteric infections. The monograph also states avilamycin exhibits good antimicrobial activity against Gram-positive pathogens (e.g. <i>Clostridium</i>)</p>

<sup>11</sup> JECFA monograph for avilamycin (2009): <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=5871> (accessed 16/1/2017)



Issue	Raised by	FSANZ response
Lack of reference to the Australian Government National Antimicrobial Resistance Strategy 2015-2019 and its report.	Qld	<p>FSANZ's risk assessment considered the potential for the development of antimicrobial resistance (AMR) at the proposed MRL of avilamycin residues in specific pig commodities.</p> <p>Avilamycin is poorly absorbed and is extensively metabolised in the gastrointestinal (GI) tract of pigs and poultry and remaining residues in tissues are not microbiologically active (JECFA 2009). Avilamycin and related antibiotics are not used in human medicine. The proposed MRL for avilamycin ensures that consumers will not be exposed to residues that could select for AMR bacteria.</p>

## 2.2 Risk assessment

To assess potential public health and safety implications of avilamycin residues in food, FSANZ considered the best available toxicological and microbiological information and undertook a dietary exposure assessment when considering whether to harmonise with MRLs of 0.2 mg/kg and 0.3 mg/kg established by Codex for avilamycin in selected pig commodities using the residue marker, DIA.

FSANZ estimated the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure against the ADI, the relevant Health-Based Guidance Value (HBGV). No acute assessment was undertaken as no relevant acute HBGVs have been established by the Australian Government Department of Health's Office of Chemical Safety or JECFA.

The chronic dietary exposure to avilamycin was assessed by the national estimated dietary intake (NEDI) calculation encompassing all current permissions for avilamycin in the table to section S20—3, the proposed commodity MRLs in the Application, and the mean daily dietary consumption data derived from the relevant national nutrition surveys. The NEDI for avilamycin is <1% of the ADI. It was concluded that the chronic dietary exposure to avilamycin (with the proposed residue definition: measured as DIA) did not substantially increase dietary exposure.

A summary of the dietary exposure estimate for avilamycin, including the requested pig commodities for this Application are provided in section 1 of SD1. Following the Call for Submissions, a minor clarification was made to SD1 to ensure accuracy in relation to the DEA process. Further information on how FSANZ conducts DEAs is available on the [FSANZ website](#)<sup>12</sup>.

FSANZ also undertook a microbiological risk assessment. This assessed the antibiotic's mode of action, reviewed the microbiological activity of residues in edible pork (pig) and considered any antimicrobial resistance effects. FSANZ concluded that the proposed MRLs present a negligible risk to consumers for the development of resistance to antimicrobials commonly used in human medicine. The complete microbiological risk assessment for this Application is provided in section 2 of SD1. The microbiological risk assessment was provided to the Australian Strategic and Technical Advisory Group on Antimicrobial Resistance (ASTAG) for expert review.

<sup>12</sup> <http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandin4438.aspx> (accessed 16/1/2017)

ASTAG, together with the Department of Health and the Department of Agriculture and Water Resources, agreed with FSANZ's conclusion.

From the results of the microbiological and dietary exposure risk assessments undertaken, FSANZ concluded that the proposed MRLs for avilamycin residues in selected pig products do not present public health and safety concerns.

## **2.3 Risk management**

This Application requested harmonisation with the established Codex MRLs for the legitimate use of avilamycin in pigs and the most appropriate Codex residue marker was used. FSANZ is committed to maintaining limits in the Code that reflect agvet residues that may legitimately occur in food; this ensures that such food may be sold. The safety of the residues in the context of the Australian diet is also important. FSANZ only approves variations to limits in the Code where the risk assessment concludes that the estimated dietary exposure to the agvet chemical is within HBGVs.

The FSANZ Board has approved a variation to Schedule 20 to include MRLs to align the Code with Codex MRLs of 0.2 mg/kg for pig fat/skin, pig kidney and pig meat and 0.3 mg/kg for pig liver. The approved MRLs will be listed in the table to section S20—3 with the Codex residue definition of DIA for the veterinary chemical avilamycin in the specified pig commodities.

FSANZ considered including the MRLs in the Code as the risk assessment showed no public health or safety concerns resulting from consumption of the relevant foods that may potentially contain residues of avilamycin at the Codex MRL levels. The Applicant also provided evidence of the importation of pig commodities from the USA to Australia and demonstrated this trade is expected to increase.

The implementation, monitoring and enforcement of the MRL requirements in the Code are undertaken within Australia by state and territory food regulatory agencies and at the national borders by the Department of Agriculture and Water Resources. During the risk assessment and approval process, FSANZ also thoroughly considered the need for a separate residue definition to harmonise with the established Codex MRLs and acknowledged appropriate testing methodology is available for the residue marker DIA.

## **2.4 Risk communication**

### **2.4.1 Communication Strategy**

FSANZ has adopted a basic communication strategy for this Application and has developed a communication plan for stakeholders. The key messages highlight the low levels of avilamycin residues in the specified pig commodities and the negligible risk they pose to the development of antimicrobial resistance because the residues are not biologically active and the avilamycin is not used in human medicine.

### **2.4.2 Consultation**

Consultation is a key part of FSANZ's standards development process.

FSANZ called for public comment on proposed changes to the Code to help finalise the assessment. Submissions were called for on 7 November 2016 for a four-week consultation period and was notified via the FSANZ Notification Circular, media release, and Food Standards News. One submission was received and one late comment from domestic stakeholders.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. All comments were welcomed on the proposed variation to the Code and both submissions received on the application were considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

### **2.4.3 World Trade Organization (WTO)**

As a member of the World Trade Organization (WTO), Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and where the proposed measure may have a significant effect on trade.

In terms of this Application, FSANZ was satisfied that the proposed measures were not inconsistent with existing international Standards. FSANZ was also satisfied that the proposed measure would be unlikely to have a significant effect on trade.

However, FSANZ still issued a WTO notification in relation to this Application in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. FSANZ did so as there are existing relevant international Standards. Amending the Code to include MRLs for avilamycin residues in specific pig commodities would also be a trade-liberalising measure which harmonised with Codex international Standards. MRLs prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products which exceed limits prescribed in the Code cannot legally be sold in Australia. Therefore, a notification to the WTO under Australia's obligations under the WTO Application of Sanitary and Phytosanitary Measures Agreement was made to enable other WTO members to comment on the proposed amendments. As Schedule 20 applies to Australia only, a notification by the New Zealand Government was not required.

No WTO member nation provided comment on this Application.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

#### **2.5.1.1 Consideration of costs and benefits**

In 2010, the Office of Best Practice Regulation provided a standing exemption from the need to assess if a Regulation Impact Statement was required for applications relating to MRLs as they are machinery in nature and their use is voluntary (ID 12065).

However, FSANZ undertook a limited cost benefit analysis that indicated the direct and indirect benefits to the community, government or industry that would arise from varying the regulatory measure as a result of the application outweigh the costs.

The MRL variation benefits Australian Government, state and territory agencies and producers, in that it serves to minimise trade disruption, further harmonise agricultural and food Standards, and thereby facilitate efficient enforcement. Achieving further consistency between agriculture and food legislation will also minimise compliance costs to primary producers and permit the sale of foods containing legitimate residues.

The approval of the MRLs in the Code may benefit importers and subsequently consumers in that this may extend the options to source safe foods. Conversely, importers and consequently consumers may be disadvantaged if the MRLs are not approved as this may unnecessarily limit sources of pig meat.

The draft variation may generate a perceived negative impact on domestic producers as the chemical is not currently approved for use in Australia on the specified commodities. However, there is an avenue available for domestic producers to apply to use this product if required.

By including a separate Avilamycin residue definition in the Code to enable the harmonisation with Codex MRLs for pig commodities, there may be a cost to importers for the implementation of existing analytical tests for DIA.

#### **2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of the Application. As explained above, the current absence of an MRL for Avilamycin in pig commodities means in effect that the importation and sale of those products is banned in Australia by Australian food law. The only measure available to end that ban is to provide an appropriate MRL.

#### **2.5.1.3 Any relevant New Zealand Standards**

Schedule 20 is an Australian only Standard.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty) excludes MRLs for agvet chemicals in food from the system setting joint food Standards. Australia and New Zealand independently and separately develop MRLs for agvet chemicals in food.

All domestically produced food sold in New Zealand must comply with the [New Zealand \(Maximum Residue Limits of Agricultural Compounds\) Food Standards 2012](#)<sup>13</sup> and any amendments (the New Zealand MRL Standards).

There is an exception for food imported into New Zealand from Australia. This food is subject to the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA provides that this food can be sold in New Zealand if it complies with Australian requirements. The result is that food imported into New Zealand from Australia must comply with any one of the following: the New Zealand MRL Standards; the Codex MRLs; or the Code and its MRLs. The TTMRA also provides that food exported from New Zealand to Australia can be sold in Australia if it complies with New Zealand requirements.

Under the New Zealand MRL Standards, agricultural chemical residues in food must comply with the specific MRLs listed in the Standards. The New Zealand MRL Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical-commodity combinations not specifically listed.

Limits in the Code and in the New Zealand MRL Standards may differ for a number of legitimate reasons including differing use patterns for chemical products as a result of varying pest and disease pressures and varying climatic conditions.

#### **2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

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<sup>13</sup> Information about New Zealand MRL Standard available on New Zealand Ministry for Primary Industries website at <http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm> (accessed 16/1/2017)

## **2.5.2. Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### **2.5.2.1 Protection of public health and safety**

FSANZ conducted a risk assessment to assess the safety of MRLs requested by Elanco Animal Health. The DEA, undertaken using the best available scientific data and internationally recognised risk assessment methodology, concluded that MRLs at 0.2 mg/kg and 0.3 mg/kg with the proposed residue definition measured as DIA does not present any public health and safety concerns. FSANZ also concluded the approved MRLs present a negligible microbiological risk to consumers.

### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

This objective is not relevant to matters under consideration in this Application.

### **2.5.2.3 The prevention of misleading or deceptive conduct**

In Australia, compliance with the Code for all foods is monitored by food authorities in the states and territories and Department of Agriculture and Water Resources for food at the border. Appropriate testing methodologies and surveillance of chemical residues is available and is undertaken to ensure imported foods are compliant with MRLs established in the Code. No other issues were identified for this Application relevant to this objective.

## **2.5.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for Standards to be based on risk analysis using the best available scientific evidence**

The variation to the Code is based on a thorough risk assessment that used the best available scientific evidence.

FSANZ's primary role in developing food regulatory measures for residues of agvet chemicals in food is to ensure that estimated dietary exposures to potential residues are within HBGVs. As described in Section 2.5.2.1, FSANZ conducts DEAs using Australian food consumption data and internationally recognised risk assessment methodologies.

FSANZ has also had regard to the best available scientific evidence when recommending the inclusion of a separate residue definition for pig commodity MRLs for avilamycin. Risk assessment advice and international assessments supported including a different residue definition (DIA) than that included for poultry MRLs currently established in the Code.

- **the promotion of consistency between domestic and international food Standards**

The approved MRL variations will further align the Code with Codex and other international trading partner Standards. Varying the Code also provides a consistent approach to addressing where agvet chemicals are used differently in other countries due to variations in pests, diseases and environmental factors. This means that residues in imported foods may legitimately differ from those in domestically produced foods.

- **the desirability of an efficient and internationally competitive food industry**

The approved MRL variation provides clarity and transparency on MRLs for avilamycin use in pig commodities. It facilitates trade by adding MRLs in Schedule 20 for certain pig commodities, where otherwise a zero tolerance approach to residues (i.e. no detectable residue) would apply.

- **the promotion of fair trading in food**

Sections 2.5.1.1 and 2.5.3 list a number of considerations that address fair trading with respect to variations to MRLS for this Application.

FSANZ's assessment did not identify any further issues relevant to this criterion,

- **any written policy guidelines formulated by the Forum on Food Regulation**

The variation to the Code was developed with regard to the [Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food](#)<sup>14</sup>. The approach addresses:

- the need to promote a consistent approach to MRLs for both domestic and imported foods, where appropriate
- the need to be consistent with Australia's obligations under the WTO Sanitary and Phytosanitary Agreement (SPS Agreement)
- not reduce the capacity of governments to prohibit the presence of any residue of a particular chemical in food where it would present an unacceptable public health risk.

## **Attachments**

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

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<sup>14</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

## **Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code***



### **Food Standards (Application A1133 – Maximum Residue Limits for Avilamycin in specific Pig Commodities) Variation**

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Application A1133 – Maximum Residue Limits for Avilamycin in specific Pig Commodities) Variation*.

**2 Variation to a Standard in the Australia New Zealand Food Standards Code**

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**[1]** The table to section S20—3 in **Schedule 20** is varied by inserting in alphabetical order

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**Agvet chemical: Avilamycin**

*Permitted residue: dichlorisoeverninic acid (DIA)*

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Pig fat/skin	0.2
Pig kidney	0.2
Pig liver	0.3
Pig meat	0.2

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## **Attachment B – Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of Standards and variations of Standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including Standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1133 which sought to harmonise Codex MRLs for avilamycin in specific pig commodities with the Australia New Zealand Food Standards Code. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a variation to Schedule 20.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the Standard or draft variation of a Standard.

Section 94 of the FSANZ Act specifies that a Standard, or a variation of a Standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### **2. Purpose**

The Authority has approved a variation to the table to section S20—3 to include maximum residue limits for avilamycin for specific pig commodities to harmonise with Codex MRLs.

Section S20—3 lists the limits for agricultural and veterinary chemical residues which may occur in foods. If a limit is not listed for a particularly agricultural or veterinary chemical/food combination, there must be no detectable residues of that chemical in that food. This general prohibition means that, in the absence of the relevant limit in the Code, food may not be sold where there are detectable residues.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1133 included one round of public consultation following an assessment and the preparation of a draft variation to Schedule 20 and associated report. Submissions were called for on 7 November 2016 for a four-week consultation period.

A Regulation Impact Statement was not required because the Office of Best Practice Regulation provided an exemption relating to MRLs in 2010 (ID 12065).

## **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## **6. Variation**

The variation amends the table to section S20—3 by inserting into that table an entry for the chemical avilamycin. The new entry will provide maximum residue limits for avilamycin using the permitted residue marker, dichloroisoeverninic acid for four specific pig commodities.