7 November 2016
[28–16]

Call for submissions – Application A1133

Maximum Residue Limits for Avilamycin in specific Pig Commodities

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FSANZ has assessed an Application submitted by Elanco Animal Health to establish MRLs for avilamycin in specific pig commodities in the *Australia New Zealand Food Standards Code* and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 5 December 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
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PO Box 10559
The Terrace WELLINGTON 6143
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Supporting document

The following supporting document[1] which informed the assessment of this Application is available on the FSANZ website

SD1 Risk assessment on proposed maximum residue limits for avilamycin in specific pig commodities

[1] 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* for avilamycin in specific pig commodities with MRLs established by the Codex Alimentarius Commission.

Avilamycin is an orthosomycin antibiotic and the Australian Pesticides and Veterinary Medicines Authority (APVMA) has permitted its use to improve feed efficiency in broiler chickens in Australia and there are existing MRLs for poultry in the Code. There are currently no MRLs in the Code for pig commodities.

Dietary exposure assessments undertaken for the Australian population indicate that the proposed limits for avilamycin residues in specific pig commodities did not substantially increase dietary exposure. In addition, the supplementary microbiological assessment concluded that, based on the available data, including an avilamycin MRL of 0.2 mg/kg on selected pig products and 0.3 mg/kg for pig liver does not present a risk to consumers for the development of resistance to antimicrobials commonly used in human medicine.

Including MRLs in the Code as proposed 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. FSANZ has therefore prepared a draft variation to the table to section S20—3 in Schedule 20 (an Australia only standard). The table lists the MRLs for agricultural and veterinary chemical residues which may occur in foods in Australia, whether produced domestically or imported.

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 was lodged on 24 May 2016. It sought to vary MRLs in Schedule 20—3 to include MRLs for avilamycin in specific pig commodities to harmonise MRLs and thus facilitate trade in pig commodities between the United States of America (USA) and Australia. The MRLs requested for specific pig commodities would align MRLs in the Code with Codex and allow the sale of food with legitimate residues.

1.3 The current Standard

Schedule 20 – Maximum residue limits is an Australian only standard. The table to 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.

1.3.1 National and International standards

The veterinary chemical avilamycin requested for consideration in this Application is currently permitted for use[2] in Australia by the APVMA to increase weight gain and improve feed efficiency in broiler chickens[3]. This chemical currently has permissions for both domestically produced and imported food in the table to S20—3 for poultry commodities only. No MRLs are listed for pig commodities.

MRLs for avilamycin for pig and poultry commodities were adopted by Codex in 2009 based on data assessed in the Joint Expert Committee on Food Additives (JECFA) evaluation[4].

In May 2015, the US Food and Drug Administration approved for use in swine[5], a veterinary medicine Kavault® (NADA 141-438)[6] containing the active ingredient avilamycin. Elanco Animal Health has requested MRLs for pig commodities due to the possibility that there will be an increased use of the newly approved product on pigs and the potential for trade in pig meat between the USA and Australia to increase in the future.

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[2] Public Release Summary for Elanco AF0375 Surmax 100 Avilamycin premix http://apvma.gov.au/node/14116 (accessed 13/7/2016)

[3] 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 13/7/2016)

[4] 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 (accessed 17/8/2016)

[5] Macquarie dictionary definition of 'Swine' is a 'domestic pig'

[6] US FDA approval of Kavault® (NADA 141-438) containing the pharmaceutical active avilamycin http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm363948.htm (accessed 13/7/2016)

Table 1 outlines current MRLs for pig commodities established by Codex for the chemical avilamycin and which were considered in the assessment of this Application.

Table 1: Commodities and MRLs requested by the applicant to align the Code with Codex for the chemical Avilamycin

Commodity	Requested MRL (mg/kg)
Pig fat/skin	0.2
Pig kidney	0.2
Pig liver	0.3
Pig meat	0.2

1.4 Reasons for accepting Application

The Application was accepted for assessment because.

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

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 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, dichloroisoeverninic acid (DIA).

The requested MRLs were adopted by Codex in 2009 using an analytical method to report on the chemical residue marker DIA for avilamycin. JECFA's 2009 evaluation reviewed specific data when recommending MRLs for avilamycin which included the selection of DIA as the most appropriate residue marker. DIA is a moiety present in avilamycin, flambic acid and other possible metabolites, which can be released by chemical hydrolysis and advantage is taken of this hydrolysis in the analytical procedure to measure residues derived from avilamycin. The report demonstrated a validated routine analytical method for the determination of the marker in edible tissues of pigs was available and allows the appropriate monitoring and detection of the avilamycin residue in Australia. The report also stated avilamycin is poorly absorbed, rapidly excreted and extensively metabolised.

2.1.1 Dietary exposure assessment (DEA)

To assess the public health and safety implications of chemical residues in food, FSANZ estimates the dietary exposure to chemical residues from potentially treated foods in the diet and compares the dietary exposure with the relevant Health-Based Guidance Value, for example the acceptable daily intake (ADI) or the acute reference dose (ARfD).

The ADI and ARfD for individual agvet chemicals are established by the Australian Office of Chemical Safety (OCS) following an assessment of the toxicology of each chemical. In the case that an Australian ADI or ARfD has not been established, a Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues (JMPR)/ JECFA ADI or ARfD may be used for risk assessment purposes. The OCS has established an ADI for avilamycin. An ARfD has not been established by the OCS, JMPR or JECFA.

The chronic dietary exposure to avilamycin was estimated 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 is concluded that the chronic dietary exposure to avilamycin (with the proposed residue definition: measured as dichloroisoeverninic acid) is acceptable.

A summary of the dietary exposure estimate for avilamycin, including requested pig commodities for this Application are provided in section 1 of SD1.

FSANZ conducts and reviews DEAs using internationally recognised risk assessment methodology. Variations to MRLs in the Code will not be supported where the estimated dietary exposure to residues of a chemical indicate a potential public health and safety risk for the Australian population or population sub-group.

Further information on how FSANZ conducts DEAs is available on the FSANZ website[7].

2.1.2 Microbiological assessment

To assess any microbiological implications of avilamycin residues in specific pig commodities, FSANZ 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.

The available data indicates that it is highly unlikely for avilamycin residues in edible pork products to have a disruptive effect on the colonisation barrier of consumers or select for antimicrobial resistance. Neither avilamycin nor evernimicin[8] are used in human medicine and no cross-resistance or co-resistance to other antibiotics used in veterinary or human medicine have been identified. FSANZ concludes that an avilamycin MRL of 0.2 mg/kg on selected pork products and 0.3 mg/kg for pig liver does not present a 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 in SD1.

2.1.3 Conclusion

FSANZ concludes that the harmonisation of MRLs in the Code with those requested by the Applicant and established by Codex for avilamycin at 0.2 mg/kg for pig fat/skin, pig kidney and pig meat and 0.3 mg/kg for pig liver using the appropriate residue definition DIA, do not pose any public health and safety concerns.

[7] http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandin4438.aspx

[8] Avilamycin is structurally closely related to evernimicin and has a similar and has a similar binding site in the 50S ribosomal subunit (Adrian et al 2000a; Adrian et al 2000b; Aarestrup and Jensen 2000; McNicholas et al 2000; Mann et al., 2001; Treede et al 2003)

2.2 Risk management

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 important. FSANZ will only approve variations to limits in the Code where the risk assessment concludes that the estimated dietary exposure to the agvet chemical is within HBGVs. FSANZ may consider including MRLs in the Code that do not present safety concerns and which are harmonised with those established by Codex or another trading partner in certain circumstances.

Two options were considered:

1. prepare a draft variation to Schedule 20 to include MRLs at the requested Codex MRLs of 0.2 mg/kg for pig fat/skin, pig kidney and pig meat and 0.3 mg/kg for pig liver with the proposed residue definition DIA for the veterinary chemical avilamycin in the specified pig commodities; or

2. reject the Application

FSANZ has decided to prepare a draft variation to Schedule 20 as the risk assessment has shown no public health or safety concerns resulting from consumption of the relevant foods that may potentially contain residues of avilamycin at the requested Codex MRL levels. The Applicant has also provided evidence of the importation of pig commodities from the USA to Australia and demonstrated this trade is expected to increase. However, due to the separate residue definition required to harmonise with the established Codex MRLs, appropriate testing methodology may need to be implemented by Australian laboratories at a cost to importers.

2.3 Risk communication

2.3.1 Consultation

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

Throughout the risk assessment process, FSANZ has consulted with the APVMA and the relevant laboratory at the National Measurement Institute (NMI) regarding appropriate residue testing methodologies.

FSANZ has adopted a basic communication strategy for this Application, with a focus on alerting the community that changes to the Code are being considered. FSANZ publishes details about proposed changes, submissions and subsequent reports on its website. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the call for public comment.

All comments are welcome on the proposed variation to the Code, however FSANZ is particularly interested in comments on any impacts (costs/benefits) of the proposed variations. In particular, FSANZ is interested in the likely impacts on importing food and any public health and safety considerations associated with the proposed changes.

Individuals and organisations making submissions on the proposed amendments will be notified at each stage of the assessment.

2.3.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

For this Application, there are existing relevant international standards. Amending the Code to include MRLs for avilamycin residues in specific pig commodities may have a significant effect on international trade as 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 has been made to enable other WTO members to comment on the proposed amendments. As Schedule 20 applies to Australia only, a New Zealand notification will not be made.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 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 (RIS) was required for applications relating to MRLs as they were machinery in nature and their use was voluntary (ID 12065).

A limited impact analysis on different stakeholders is provided below. It indicates that 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 proposed 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 proposed additional 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 where proposed additional MRLs are not progressed as this may unnecessarily limit sources of pig meat. 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 appropriate analytical test based on the residue definition.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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[9] 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.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 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 do not present any public health and safety concerns. FSANZ also concluded the proposed MRLs do not present a microbiological risk to consumers.

2.4.2.2 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.

[9] Information about New Zealand MRL Standard available on New Zealand Ministry for Primary Industries website at http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/ (accessed 3/08/2016)

2.4.2.3 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. Testing and surveillance of chemical residues 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.

2.4.3 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 draft variation is based on a 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 2.4.2.1, 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 determined inclusion of a different residue definition (DIA) to poultry MRLs currently established in the Code, is the most appropriate approach.

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

The proposed MRL variations would further align the Code with Codex and other international trading partner standards. The proposed variation 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 proposed MRL variation provides clarity and transparency on MRLs for the avilamycin and pig commodities. It facilitates trade through the addition of 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**

Section 2.4.1.1 and 2.4.3 lists 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 draft variation has been developed having regard to the Forum's *Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food*[10]. The proposed 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.

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4 References

Full references for Section 2.1 Risk Assessment are provided in SD1.

Aarestrup FM and Jensen LB (2000) Presence of variations in ribosomal protein L16 corresponding to susceptibility of enterococci to oligosaccharides (Avilamycin and evernimicin). Antimicrob Agents Chemother 44(12):3425-7.

Adrian PV, Mendrick C, Loebenberg D, McNicholas P, Shaw KJ, Klugman KP, Hare RS, Black TA (2000a) Evernimicin (SCH27899) inhibits a novel ribosome target site: analysis of 23S ribosomal DNA mutants. Antimicrob Agents Chemother 44(11):3101-6.

Adrian PV, Zhao W, Black TA, Shaw KJ, Hare RS, Klugman KP (2000b) Mutations in ribosomal protein L16 conferring reduced susceptibility to evernimicin (SCH27899): implications for mechanism of action. Antimicrob Agents Chemother 44(3):732-8.

Mann PA, Xiong L, Mankin AS, Chau AS, Mendrick CA, Najarian DJ, Cramer CA, Loebenberg D, Coates E, Murgolo NJ, Aarestrup FM, Goering RV, Black TA, Hare RS, McNicholas PM (2001) EmtA, a rRNA methyltransferase conferring high-level evernimicin resistance. Mol Microbiol 41(6):1349-56.

McNicholas PM, Najarian DJ, Mann PA, Hesk D, Hare RS, Shaw KJ, Black TA (2000) Evernimicin binds exclusively to the 50S ribosomal subunit and inhibits translation in cell-free systems derived from both gram-positive and gram-negative bacteria. Antimicrob Agents Chemother 44(5):1121-6.

Treede I, Jakobsen L, Kirpekar F, Vester B, Weitnauer G, Bechthold A, Douthwaite S (2003) The avilamycin resistance determinants AviRa and AviRb methylate 23S rRNA at the guanosine 2535 base and the uridine 2479 ribose. Mol Microbiol 49(2):309-18.

Attachments

A. Draft variation to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statement

[10] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx (accessed 28/10/2016)

Attachment A – 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

Agvet chemical: Avilamycin	
Permitted residue: Dichloroisoeverninic acid (DIA)	
Pig fat/skin	0.2
Pig kidney	0.2
Pig liver	0.3
Pig meat	0.2

Attachment B – Draft 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.

FSANZ accepted Application A1133 which seeks to establish MRLs for avilamycin in specific pig commodities for import harmonisation purposes. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose

The purpose of the proposed variation to the table to section S20—3 is to include maximum residue limits for avilamycin for specific pig commodities.

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 particular 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.

Maximum residue limit variations may be required to permit the sale of foods containing legitimate residues. These are technical amendments following changes in use patterns of agricultural and veterinary chemicals available to chemical product users.

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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.4.2 are likely to have a minor impact on business and individuals and an exemption has been granted by the Office of Best Practice and Regulation.

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 draft 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 dichloroisoeverninic acid in four specific pig commodities.