FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

3-07
23 May 2007

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A590

MAXIMUM RESIDUE LIMITS
AVOPARCIN AND OXOLINIC ACID (ANTIBIOTICS)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 July 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Application A590 seeks to amend Maximum Residue Limits (MRLs) for veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code) by deleting all entries for avoparcin and oxolinic acid. It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the status of two antibiotic veterinary chemicals currently not registered or permitted for use in Australia.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits. As the variation under consideration is deleting all entries for the antibiotics avoparcin and oxolinic acid from Standard 1.4.2, conducting dietary exposure assessments is not required. FSANZ considers that the application raises no safety concerns from a dietary exposure or microbiological perspective.

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

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only. Submissions are now invited on this Report to assist FSANZ make a Final Assessment.

Purpose

The purpose of this Application is to update the Code by deleting MRLs for two veterinary chemicals not currently registered or permitted for use in Australia. As there are no approved uses for avoparcin or oxolinic acid, it is proposed the MRLs for these antibiotics be deleted this will remove discrepancies between agricultural and food standards.

Preferred Approach

FSANZ recommends accepting Application A590 and the proposed draft variation to Standard 1.4.2 – Maximum Residue Limits.

Reasons for Preferred Approach

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and the proposed draft variation to Standard 1.4.2 for the following reasons:

- FSANZ does not consider it appropriate to retain MRLs in the Code for specific food/chemical combinations where these residues are unlikely to occur in food. This approach ensures that the dietary exposure assessment is as accurate as possible for the chemical concerned. This approach also ensures openness and transparency in relation to the residues that could reasonably occur in food.

- To protect public health and safety, FSANZ assesses the implications of antimicrobial residues in food on human health. The proposed deletion of all MRLs for avoparcin and oxolinic acid poses no adverse consequences to human health.

- The proposed draft variation would remove discrepancies between agricultural and food standards and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.

- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variation is necessary and cost-effective.

- The proposed changes are consistent with the FSANZ Act section 10 objectives.

Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act, not to invite public submissions in relation to Application A590 prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Act 1975*, application may be made to the Administrative Appeals Tribunal for review of a decision made by FSANZ under section 36 of the FSANZ Act.

FSANZ is seeking public comment on this Initial / Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- any impacts (costs/benefits) of the proposed deletions;

- any public health and safety considerations associated with the proposed deletions;

- likely costs and benefits impacting food imports; and

- any other affected parties to this Application.

Further details on making submissions are provided in the Invitation for Public Submissions section of this report.

CONTENTS

INVITATION FOR PUBLIC SUBMISSIONS 2

INTRODUCTION 3

1. BACKGROUND 4
   - *1.1 Current Standard 4*
   - *1.2 Use of Agricultural and Veterinary Chemicals 4*
   - *1.3 Maximum Residue Limit Applications 4*
   - *1.4 Proposed Variation to Standard 1.4.2 - Maximum Residue Limits 5*
   - *1.5 Antimicrobial Resistance 6*
   - *1.6 Australia and New Zealand Joint Food Standards 7*
2. THE ISSUE / PROBLEM 7
3. OBJECTIVES 7
4. KEY ASSESSMENT QUESTIONS 8

RISK ASSESSMENT 8

5. SAFETY ASSESSMENT 8

RISK MANAGEMENT 8

6. OPTIONS 8
   - *6.1 Option 1 – no change to existing avoparcin and oxolinic acid MRLs in the Code 8*
   - *6.2 Option 2 – vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to omit avoparcin and oxolinic acid MRLs and all associated entries as proposed 9*
7. IMPACT ANALYSIS 9
   - *7.1 Affected Parties 9*
   - *7.2 Benefit Cost Analysis 9*
   - *7.3 Comparison of Options 11*

COMMUNICATION 11

8. COMMUNICATION 11
9. CONSULTATION STRATEGY 11
   - *9.1 World Trade Organization 12*

CONCLUSION 13

10. CONCLUSION AND PREFERRED OPTION 13
    - *10.1 Reasons for Preferred Approach 13*
11. IMPLEMENTATION AND REVIEW 14

ATTACHMENT 1 - DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE* 15

ATTACHMENT 2 - A GUIDE TO THE TABLE OUTLINING THE REQUESTED VARIATION TO STANDARD 1.4.2 – MAXIMUM RESIDUE LIMITS OF THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE* AND TERMS USED IN DIETARY EXPOSURE ASSESSMENTS 16

ATTACHMENT 3 - BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS 19

INVITATION FOR PUBLIC SUBMISSIONS

Food Standards Australia New Zealand (FSANZ) invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variations to the *Australia New Zealand Food Standards Code* (the Code) for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 4 July 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

This Application was received from the APVMA on 6 October 2006 seeking to vary the Code. The proposed variation to Standard 1.4.2 – Maximum Residue Limits would remove all MRLs for the antibiotics avoparcin and oxolinic acid from the Code. These MRLs have been deleted from the APVMA MRL Standard.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits.

FSANZ will not agree to adopt MRLs into the Code where dietary exposure to residues of a chemical presents a risk to public health and safety. In assessing this risk, FSANZ reviews dietary exposure assessments in accordance with internationally accepted practices and procedures. As the variation under consideration is deleting all entries for the antibiotics avoparcin and oxolinic acid from Standard 1.4.2, conducting dietary exposure assessments is not required. FSANZ considers that the Application raises no safety concerns from a dietary exposure perspective.

MRLs in the Code apply in relation to the sale of food under State and Territory food legislation and the inspection of imported foods by the Australian Quarantine and Inspection Service.

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could possibly result from the registered conditions of use. The concentration is expressed in milligrams of the chemical per kilogram (mg/kg) of the food.

MRLs are used as standards for international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.

MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product.

The MRLs proposed for deletion in this Application are at the limit of quantification (LOQ); this is indicated by an * in front of the MRL. MRLs at the LOQ mean that no detectable residues of the relevant chemical should occur. The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

1. Background

1.1 Current Standard

The APVMA has advised that there are no registered or permitted uses for veterinary chemical products containing the antibiotics avoparcin or oxolinic acid in food producing species in Australia and has made amendments to its MRL Standard accordingly. Consequently there are discrepancies between the APVMA MRL Standard and Standard 1.4.2 of the Code.

Currently there are MRLs at the LOQ for avoparcin in edible offal (mammalian); meat (mammalian); milks; poultry, edible offal of and poultry meat and for oxolinic acid in Pacific salmon in Standard 1.4.2.

1.2 Use of Agricultural and Veterinary Chemicals

In Australia, APVMA is responsible for assessing and registering agricultural and veterinary chemical products, and regulating them up to the point of sale. Following sale of such products, use of the chemicals is regulated by State and Territory 'control of use' legislation.

Before registering a product, APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected.

When a chemical product is registered for use or a permit for use granted, APVMA includes MRLs in the APVMA MRL Standard. These MRLs are then adopted into control of use legislation in some jurisdictions and assist States and Territories in regulating the use of agricultural and veterinary chemicals.

APVMA has advised that currently there are no registered or permitted uses for avoparcin or oxolinic acid in food producing animal species in Australia and accordingly MRLs are not required. Avoparcin has been used in livestock feeds to improve animal feed conversion efficiency in broiler chickens, growing pigs, calves and beef cattle; and in the prevention of necrotic enteritis *(Clostridium perfringens)* in broiler chickens. Oxolinic acid is not registered as an approved active; there are no veterinary products containing it registered for use in Australia and no permits have ever been issued for its use in any food producing species, including fish. APVMA advised that Australia produces no Pacific salmon and imports very little of the commodity.

1.3 Maximum Residue Limit Applications

After registering agricultural or veterinary chemical products, or varying use patterns based on scientific evaluations, APVMA makes applications to FSANZ to adopt or vary MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by APVMA and validates whether dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs in Standard 1.4.2. As the variation under consideration in this Application is deleting all entries for the antibiotics avoparcin and oxolinic acid from Standard 1.4.2, conducting dietary exposure assessments is not required.

FSANZ notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variations to Standard 1.4.2, the MRLs are automatically adopted by reference into the food laws of the Australian States and Territories.

1.4 Proposed Variation to Standard 1.4.2 - Maximum Residue Limits

The amendment under consideration in Application A590 is deleting the antibiotics avoparcin and oxolinic acid and all associated entries from Standard 1.4.2. The requested changes are outlined in the table below.

A guide to the table with notes on terms used and a list of acronyms appearing in MRL application reports are provided in Attachment 2.

Requested MRLs			Dietary Exposure Estimates
Avoparcin Avoparcin is a glycopeptide antibiotic with a gram positive spectrum of activity produced by fermentation of a strain of *Streptomyces candidus*. Glycopeptides are used in human medicine, most notably vancomycin and teicoplanin. Avoparcin has been used in livestock feeds to improve animal feed conversion efficiency in broiler chickens, growing pigs, calves and beef cattle; and in the prevention of necrotic enteritis *(Clostridium perfringens)* in broiler chickens. APVMA confirms that there are no currently registered or permitted uses for avoparcin in food-producing animal species in Australia and accordingly MRLs are not required. The whole entry for this chemical is to be omitted.			Complete chemical deletion – dietary exposure assessment not required.
Edible offal (mammalian)	Omit	*0.1	
Meat (mammalian)	Omit	*0.1	
Milks	Omit	*0.01	
Poultry, edible offal of	Omit	*0.1	
Poultry meat	Omit	*0.1	
Oxolinic acid Oxolinic acid belongs to the quinolone class of antibiotics. It effects antibacterial activity by inhibiting DNA gyrase or topoisomerase IV enzyme. Oxolinic acid is not used in human therapeutics in Australia. APVMA confirms that oxolinic acid is not registered as an approved active; there are no veterinary products containing it currently registered for use in Australia; no permits have ever been issued for its use in any food producing species, including fish; and Australia produces no Pacific salmon and imports very little of the commodity. Accordingly, MRLs are not required. The whole entry for this chemical is to be omitted.			Complete chemical deletion – dietary exposure assessment not required.
Salmon, Pacific	Omit	*0.01	

Formatted: French (France)

In considering the issues associated with MRLs it should be noted that MRLs and variations to MRLs in the Code do not permit or prohibit the use of agricultural or veterinary chemicals. Other Australian Government, State and Territory legislation regulates use and control of agricultural and veterinary chemicals.

1.5 Antimicrobial Resistance

Avoparcin is a glycopeptide antibiotic with a gram positive spectrum of activity produced by fermentation of a strain of *Streptomyces candidus*. Avoparcin was in continual use in Australian livestock feeds from 1978 until 2000 to improve animal feed conversion efficiency in broiler chickens, growing pigs, calves and beef cattle. It was also used in the prevention of necrotic enteritis *(Clostridium perfringens)* in broiler chickens. It is not used in human medicine. Other glycopeptides are used in human medicine, most notably vancomycin and teicoplanin.

The National Health and Medical Research Council established the Expert Advisory Group on Antimicrobial Resistance (EAGAR) to provide advice to government and regulatory agencies on antimicrobial resistance and measures to reduce the risks of antimicrobial resistance. Vancomycin and teicoplanin are classified as antibiotics of high importance in the EAGAR *Importance Ratings and Summary of Antibiotic Uses in Humans in Australia*. This indicates that if resistance develops there will be limited or no alternatives available to treat serious bacterial infections. Glycopeptides are used to treat serious infections including those caused by multiresistant *Staphylococcus aureus*, enterococci and antibiotic resistant pneumococci. Antibiotics of high importance have also been called 'last line' or 'last resort' antibiotics.

The APVMA (then the National Registration Authority for Agricultural and Veterinary Chemicals (NRA)) began a review of avoparcin in 1998. This followed concerns that the continued use of avoparcin in food producing animals may lead to development of acquired bacterial resistance in the gut of the animals and pose a possible threat to human health through contributing in the emergence of Vancomycin Resistant Enterococci (VRE). The review report notes that although several studies concluded that avoparcin residues were highly unlikely to enter the human food chain and factor in the emergence of VRE in humans, the primary registrant informed the NRA that it was withdrawing avoparcin from the market for commercial reasons. The other registrant also allowed the registration of its product to lapse. The NRA did not continue with the review as it was unlikely to have been completed before the anticipated withdrawal.

Oxolinic acid belongs to the quinolone class of antibiotics; it is active against gram-negative organisms. It effects antibacterial activity by inhibiting DNA gyrase or topoisomerase IV enzyme. It is used as both a prophylactic and a therapeutic agent in aquaculture internationally. Although many more recently developed quinolone analogues are more effective, it remains a cost effective option in aquaculture. Oxolinic acid, a first generation quinolone, is not used in human therapeutics in Australia. Quinolones are classified as antibiotics of medium importance in the EAGAR Importance Ratings and Summary of Antibiotic Uses in Humans in Australia. This indicates that there are alternatives available, but fewer than for those classified as low.

As avoparcin and oxolinic acid are not currently registered as approved actives and there are no permitted uses for these chemicals in Australia, there are no anticipated public health and safety concerns arising from this Application.

1.6 Australia and New Zealand Joint Food Standards

The Treaty excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand commenced on 1 May 1998. The following provisions apply under the TTMRA.

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.

- Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, 2007 can be legally sold in Australia.

2. The Issue / Problem

Currently there are MRLs in the Code for avoparcin and oxolinic acid and there are no registered or permitted uses for these chemicals in Australia. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. Deleting MRLs from the Code has the effect of prohibiting the sale of treated produce. It is illegal to sell foods containing chemical residues where there is no MRL.

3. Objectives

In assessing this Application FSANZ aims to ensure that accepting the proposed draft variation does not present public health and safety concerns. APVMA has already deleted the avoparcin and oxolinic acid MRLs under its legislation, and now seeks to have them omitted from the Code through this Application to vary Standard 1.4.2.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives set out in section 10 of the FSANZ Act:

- the protection of public health and safety;

- the provision of adequate information relating to food to enable consumers to make informed choices; and

- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;

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

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

- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

The proposed draft variation to Standard 1.4.2 is consistent with the FSANZ Act section 10 objectives of food regulatory measures.

4. Key Assessment Questions

The primary role of FSANZ in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not present public health and safety concerns.

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code Act 1994* (Ag Vet Code Act) requires APVMA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity.

As noted in the table in section 1.4, since Application A590 seeks to delete the antibiotics avoparcin and oxolinic acid and all associated entries in Standard 1.4.2, dietary exposure assessment is not required in this case.

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the Code where the dietary exposure to the residues of a chemical could represent a risk to public health and safety. In assessing this risk, FSANZ reviews dietary exposure assessments in accordance with internationally accepted practices and procedures. The approach FSANZ takes in assessing the public health and safety implications of proposed new or varied chemical residues is outlined in Attachment 3.

RISK ASSESSMENT

5. Safety Assessment

The variation under consideration in Application A590 is deleting all entries for the antibiotics avoparcin and oxolinic acid from Standard 1.4.2. FSANZ considers that the Application raises no safety concerns from a dietary exposure or microbiological perspective.

RISK MANAGEMENT

6. Options

6.1 Option 1 – no change to existing avoparcin and oxolinic acid MRLs in the Code

Under this option, the *status quo* would be maintained and there would be no changes to existing MRLs in the Code.

6.2 Option 2 – vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to omit avoparcin and oxolinic acid MRLs and all associated entries as proposed

Under this option, the avoparcin and oxolinic acid MRLs would be approved for deletion.

7. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory provisions. Information from public submissions is needed to make a final assessment of the proposed change.

7.1 Affected Parties

The parties affected by proposed MRL amendments include:

- domestic and international consumers;
- growers and producers of domestic and export food commodities;
- importers of agricultural produce and foods; and
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

7.2 Benefit Cost Analysis

7.2.1 Option 1 – no change to existing avoparcin and oxolinic acid MRLs in the Code

7.2.1.1 Benefits

- for consumers there are no discernable benefits;
- for growers and producers of domestic and export food commodities, this option would not result in any discernable benefits;
- for importers, this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, this option would not result in any discernable benefits.

7.2.1.2 Costs

- for consumers there are unlikely to be any discernable costs;

- for producers of domestic and export food commodities a discrepancy between agricultural and food standards may create uncertainty, inefficiency and confusion;

- for importers, this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, adopting this option would allow discrepancies between agricultural and food standards thereby potentially creating uncertainty, inefficiency and confusion in the enforcement of regulations.

7.2.2 Option 2 – vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to omit avoparcin and oxolinic acid MRLs and all associated entries as proposed

7.2.2.1 Benefits

- maintaining consumer confidence in the food supply in relation to residues of agricultural and veterinary chemicals;

- consistency between agricultural and food standards potentially minimises compliance costs for producers of domestic and export food products;

- for importers, removing the discrepancy between agricultural and food standards would promote certainty; and

- for Australian Government, State and Territory agencies, this option would foster community confidence that regulatory authorities are maintaining standards to minimise residues in the food supply and removing the discrepancy between agricultural and food standards would create certainty and allow efficient enforcement of regulations.

7.2.2.2 Costs

- for consumers there are no discernable costs;

- for growers and producers of domestic and export food commodities, there are no discernable costs, as there are no registered or permitted uses for avoparcin or oxolinic acid;

- for importers there are no discernable costs as the MRLs proposed for deletion are at the LOQ this means that no detectable residues of the chemicals should occur currently; and

- for Australian Government, State and Territory agencies, this option would not result in any discernable costs.

7.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia. For Application A590, there are no options other than a variation to Standard 1.4.2.

FSANZ preferred approach is to adopt option 2 – to vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to omit avoparcin and oxolinic acid MRLs and all associated entries as proposed for the following reasons:

- There are no public health and safety concerns associated with the proposed MRL amendment (this benefit also applies to option 1).

- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.

- The change would update the Code by removing discrepancies between agricultural and food standards assisting enforcement.

Option 1 is an undesirable option.

- Consequent discrepancies between agricultural and food standards could have negative impacts on compliance costs for primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

COMMUNICATION

8. Communication

Applications by the APVMA to amend maximum residue limits in the Code do not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

FSANZ publishes the details of the Application and subsequent assessment reports on its website, notifies the community of the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone advice service, responds to industry enquiries.

Should the media show an interest in any of the chemicals being assessed, FSANZ or the APVMA can provide background information and other advice, as required.

9. Consultation Strategy

FSANZ decided, pursuant to section 36 of the FSANZ Act, to omit to invite public submissions in relation to Application A590 prior to making a Draft Assessment. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received.

FSANZ made its decision under section 36 because it was satisfied that Application A590 raised issues of minor significance or complexity only.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of the decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

FSANZ is seeking public comment on this Initial / Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- any impacts (costs/benefits) of the proposed deletions of specific MRLs;
- any public health and safety considerations;
- likely costs and benefits in relation to the importation of food if the proposed deletions to specific MRLs are advanced; and
- any other affected parties to this Application.

9.1 World Trade Organization

As a member of the WTO Australia is obligated to notify WTO member nations 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.

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 exceeding the relevant MRL set out in the Code cannot legally be supplied in Australia.

Application A590 requests deleting all MRLs for avoparcin and oxolinic acid from the Code. Codex Alimentarius Commission (Codex) standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. There are no avoparcin or oxolinic acid MRLs in the international Codex standard. Avoparcin and oxolinic acid residues may have an effect on trade in food products between WTO members. The existing MRLs in the Code for avoparcin and oxolinic acid are at the LOQ. This means that residues should not occur. Deleting the MRLs would prohibit the sale of treated produce. It is illegal to sell foods containing chemical residues where there is no MRL. It is considered unlikely that the proposed variation will have an effect on trade as the proposed variation to delete the avoparcin and oxolinic acid entries would not change the current Standard in that residues of these veterinary chemicals are not permitted currently. For these reasons it was determined that there is no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

Internationally, countries set MRLs under their own regulations and according to Good Agricultural Practice (GAP) or Good Veterinary Practice (GVP). Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because permissions for products differ.

This means that residues in imported foods may be different from those in domestically produced foods. Residues of oxolinic acid have not been detected in domestic or imported farmed fish in the Australian market.

Avoparcin has not been used in New Zealand since 2000. There are no avoparcin MRLs listed in the New Zealand MRL Standards. New Zealand has not established MRLs above the generally accepted default level of 0.1 mg/kg for oxolinic acid. Avoparcin is not authorised for use in veterinary medicine in the European Union. The European Agency for the Evaluation of Medicinal Products currently permits oxolinic acid residues in tissues of food producing species in the European Union. Avoparcin is not approved for use in the United States and off label use of glycopeptides is prohibited. Quinolones are not approved for use in food fish in the United States. The United States Environmental Protection Agency has not established tolerances for residues of avoparcin or oxolinic acid.

FSANZ requests comment on any possible ramifications of the deletion of MRLs in this Application for imports.

CONCLUSION

10. Conclusion and Preferred Option

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and the proposed draft variation to Standard 1.4.2. – Maximum Residue Limits.

The preferred approach is to adopt option 2 to vary Schedule 1 of Standard 1.4.2 – Maximum Residue Limits to omit avoparcin and oxolinic acid MRLs and all associated entries as proposed.

Preferred Approach

FSANZ recommends accepting Application A590 and the proposed draft variation to Standard 1.4.2 – Maximum Residue Limits.

10.1 Reasons for Preferred Approach

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and the proposed draft variation to Standard 1.4.2 for the following reasons:

- FSANZ does not consider it appropriate to retain MRLs in the Code for specific food/chemical combinations where these residues are unlikely to occur in food. This approach ensures that the dietary exposure assessment is as accurate as possible for the chemical concerned. This approach also ensures openness and transparency in relation to the residues that could reasonably occur in food.

- To protect public health and safety, FSANZ assesses the implications of antimicrobial residues in food on human health. The proposed deletion of all MRLs for avoparcin and oxolinic acid poses no adverse consequences to human health.

- The proposed draft variation would remove discrepancies between agricultural and food standards and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.

- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variation is necessary and cost-effective.

- The proposed changes are consistent with the FSANZ Act section 10 objectives.

11. Implementation and Review

The use of chemical products and MRLs are under constant review as part of the APVMA Existing Chemical Review Program. In addition, regulatory agencies continue to monitor health, agricultural and environmental issues associated with chemical product use. Residues in food are also monitored through:

- State and Territory residue monitoring programs;

- Australian Government programs such as the National Residue Survey; and

- dietary exposure studies such as the Australian Total Diet Study.

These monitoring programs and the continual review of the use of agricultural and veterinary chemicals mean that there is considerable scope to review chemical residues in foods.

It is proposed that the amendment in this Application should take effect on gazettal and that the relevant food commodities be subject to existing monitoring arrangements.

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. A Guide to the Table Outlining the Requested Variation to Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* and Terms Used in Dietary Exposure Assessments
3. Background to Dietary Exposure Assessments

Attachment 1

Draft Variation to the *Australia New Zealand Food Standards Code*

To commence: on gazettal

[1] ***Standard 1.4.2*** *of the Australia New Zealand Food Standards Code is varied by omitting from* Schedule 1 *all entries for the following chemicals –*

Avoparcin
Oxolinic acid

Attachment 2

A Guide to the Table Outlining the Requested Variation to Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* and Terms Used in Dietary Exposure Assessments

ADI – Acceptable Daily Intake - The ADI is the daily intake of an agricultural or veterinary chemical, which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is based on all the known facts at the time of the evaluation of the chemical. The ADI is expressed in milligrams of the chemical per kilogram of body weight.

ARfD – Acute Reference Dose - The ARfD is the estimate of the amount of a substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation.

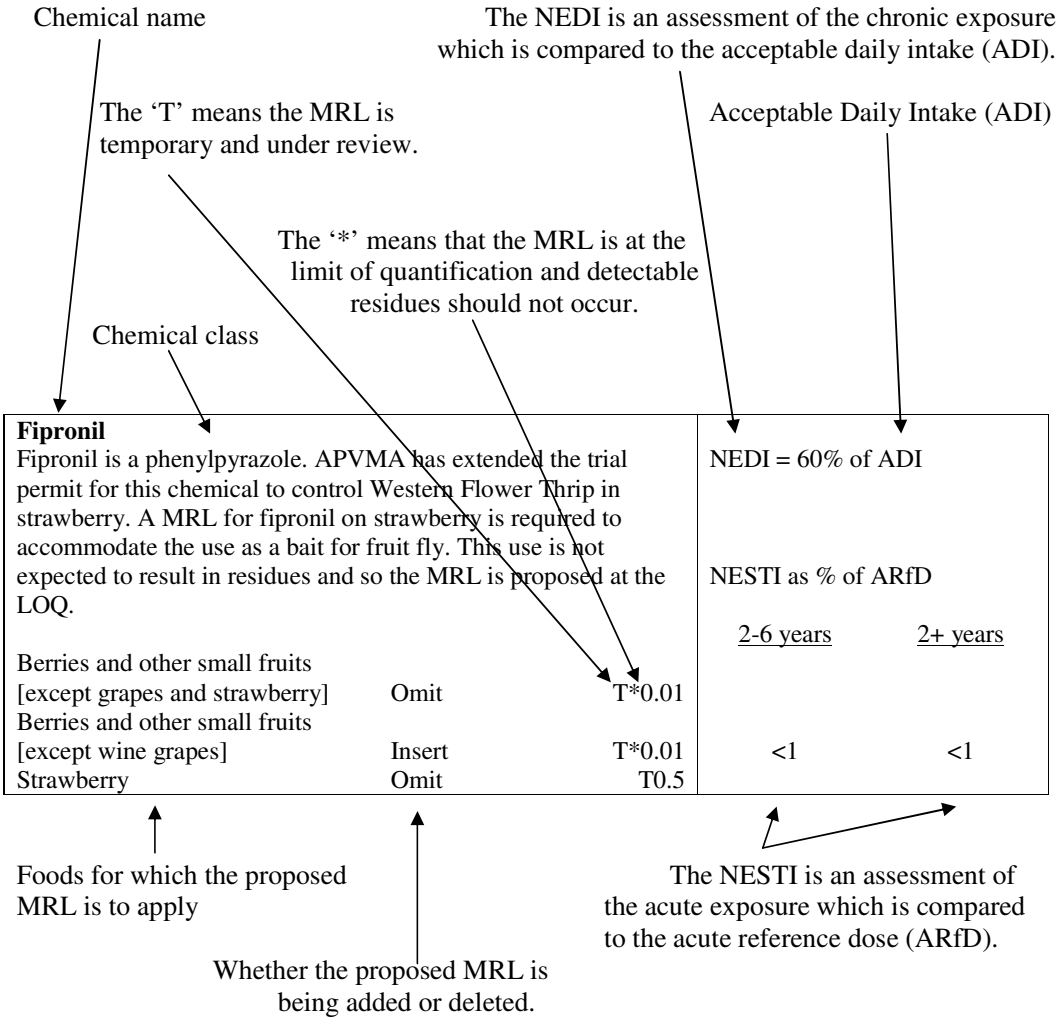
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate more specific food consumption data including that for particular sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because more specific residue data are often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 NNS and the MRL when the supervised trials median residue (STMR) is not available to calculate the NESTIs.

The NESTI calculation incorporates the large portion (97.5^{th} percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; the STMR, representing typical residue in an edible portion resulting from the maximum permitted pesticide use pattern; processing factors which affect changes from the raw commodity to the consumed food and the variability factor.

The following are examples of entries and the proposed MRLs listed are not part of this Application.



There is more information on the NEDI, NESTI ADI and ARfD above and in Attachment 3. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the ADI. And that the acute dietary exposure to the residues of a chemical is acceptable where the best estimate of acute dietary exposure does not exceed the ARfD.

Information about the use of the chemical is provided so consumers can see the reason why the residues may occur in food.

Data from the 19th and 20th Australian Total Diet Surveys (ATDS) are provided when available because they provide an indication of the typical exposure to chemicals in table ready foods. The ATDS results are more realistic because analysed concentrations of the chemical in foods are used; the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure.

Chlorpyrifos Chlorpyrifos is an acaricide, nematicide and insecticide APVMA has approved an extension of use for the control of pests in coffee crops.			NEDI = 83% of ADI 20th ATDS = <1% of ADI for all population groups assessed 19th ATDS = 3% of ADI for toddlers 2 years, 1% of ADI for boys 12 years and <1% of ADI for other population groups assessed NESTI as % of ARfD 2-6 years: 8 2+ years: <1
Coffee beans	Insert	T0.5	

Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual studies.

Acronyms:

1.	**ADI**	Acceptable Daily Intake
2.	**APVMA**	Australian Pesticides and Veterinary Medicines Authority
3.	**ARfD**	Acute Reference Dose
4.	**ATDS**	Australian Total Diet Survey
5.	**the Code**	*Australia New Zealand Food Standards Code*
6.	**DIAMOND**	Dietary Modelling of Nutritional Data
7.	**FSANZ**	Food Standards Australia New Zealand
8.	**JMPR**	Joint FAO/WHO Meeting on Pesticide Residues
9.	**LOQ**	Limit of Analytical Quantification
10.	**MRL**	Maximum Residue Limit
11.	**NEDI**	National Estimated Daily Intake
12.	**NESTI**	National Estimated Short Term Intake
13.	**NNS**	National Nutrition Survey of Australia 1995
14.	**OCS**	Office of Chemical Safety
15.	**T or TMRL**	Temporary MRL
16.	**TGA**	Therapeutic Goods Administration
17.	**WHP**	Withholding Period

Attachment 3

Background to Dietary Exposure Assessments

Determination of the Residues of a Chemical in a Treated Food

APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable APVMA to determine what the likely residues of a chemical will be on a treated food. These data also enable APVMA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, APVMA determines a MRL.

The MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into standards means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent a risk to public health and safety.

Determining the Acceptable Reference Health Standard for a Chemical in Food

Office of Chemical Safety (OCS) assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical. In the case that an Australian ADI or ARfD has not been established, a JMPR ADI or ARfD may be used for risk assessment purposes if appropriate.

Both APVMA and FSANZ use these reference health standards in dietary exposure assessments.

The ADI is the daily intake of an agricultural or veterinary chemical, which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the chemical per kilogram of body weight.

The ARfD of a chemical is the estimate of the amount of a substance in food, expressed on a body weight basis that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation.

Calculating Dietary Exposure

APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either OCS or Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) has established an ARfD.

APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest National Nutrition Survey (NNS).

The Australian Bureau of Statistics with the then Australian Government Department of Health and Aged Care undertook the latest NNS over a 13-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents an estimate of chronic dietary exposure. Chemical residue data, as opposed to the MRL, are the preferred concentration data to use if they are available, as they provide a more realistic estimate of dietary exposure. The NEDI calculation may incorporate more specific data including food consumption data for particular sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. Monitoring and surveillance data or data from total diet studies may also be used, such as the 19th and 20th Australian Total Diet Surveys (ATDS).

FSANZ is currently planning the next ATDS (now the Australian Total Diet Study). The study will analyse the levels of various agricultural and veterinary chemicals in food and estimate the potential dietary exposure of population groups in Australia to those chemicals.

In conducting chronic dietary exposure assessments, APVMA and FSANZ consider the residues that could result from the permitted uses of a chemical product on foods. Where data are not available on the specific residues in a treated food, a cautious approach is taken and the MRL is used. The use of the MRL in dietary exposure estimates may result in considerable overestimates of exposure because it assumes that the entire national crop is treated with a pesticide and that the entire national crop contains residues equivalent to the MRL. In reality, only a portion of a specific crop is treated with a pesticide; most treated crops contain residues well below the MRL at harvest; and residues are usually reduced during storage, preparation, commercial processing and cooking. It is also unlikely that every food for which a MRL is proposed will have been treated with the same pesticide over the lifetime of consumers.

The residues that are likely to occur in all foods are multiplied by the mean daily consumption of these foods derived from individual dietary records from the latest NNS. These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. The estimated exposure for each food is added together to provide the total dietary exposure to a chemical from all foods with MRLs.

The estimated dietary exposure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight. This is compared to the ADI. It is therefore the overall dietary exposure to a chemical that is compared to the ADI - not the MRL. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of exposure does not exceed the ADI.

Further, where these calculations use the MRL they are considered to be overestimates of dietary exposure because they assume that:

- the chemical will be used on all crops for which there is a registered use;
- treatment occurs at the maximum application rate;
- the maximum number of permitted treatments have been applied;
- the minimum withholding period has been applied; and
- this will result in residues at the maximum residue limit.

In agricultural and animal husbandry this is not the case, but for the purposes of undertaking a risk assessment, it is important to be conservative in the absence of reliable data to refine the dietary exposure estimates further.

Acute Dietary Exposure Assessment

The National Estimated Short Term Intake (NESTI) is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

The NESTI is calculated in a similar way to the chronic dietary exposure. The residues of a chemical in a specific food are multiplied by the 97.5^{th} percentile food consumption of that food, a variability factor is applied, the exposure divided by a mean body weight for the population group being assessed and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by OCS and JMPR, the consumption data from the 1995 NNS and the MRL when the data on the actual residues in foods are not available. FSANZ considers that the acute dietary exposure to the residues of a chemical is acceptable where the best estimate of acute dietary exposure does not exceed the ARfD.

Risk Assessment Summary

APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable APVMA to determine what the likely residues of a chemical will be on a treated food. These data also enable APVMA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, APVMA determines a MRL.

APVMA assesses appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in MRL Applications.

OCS undertakes an appropriate toxicological assessment of the chemical products and establishes relevant ADIs and where applicable, an ARfD.

FSANZ reviews the dietary exposure assessments submitted by APVMA as part of its Applications to assess whether the residues associated with the MRLs present any public health and safety concerns. This is determined by comparing estimates of dietary exposure to the chemical (calculated using food consumption data and MRLs or residue data), with the ADI and in some cases with the ARfD. In addition, the MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation and standards means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent an unacceptable risk to public health and safety.

In reality, only a portion of a specific commodity is treated with a pesticide; most treated commodities contain residues well below the MRL before they appear on the market; and residues are usually reduced during storage, washing, preparation, commercial processing and cooking. It is also unlikely that every food for which a MRL is proposed will have been treated with the same pesticide during production and eaten over the lifetime of consumers.

The additional safety factors inherent in calculation of the ADI and ARfD mean that there is negligible risk to public health and safety when estimated exposures are below these reference health standards.