

15 November 2011

[22-11]

APPLICATION A1054 DIBROMO-DIMETHYLHYDANTOIN (DBDMH) AS A PROCESSING AID ASSESSMENT REPORT

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Elanco Animal Health on 9 August 2010. This Application seeks to amend Standard 1.3.3 – Processing Aids in the *Australia New Zealand Food Standards Code* (the Code), to permit the use of dibromo-dimethylhydantoin (DBDMH) to treat all foods. It is proposed that DBDMH will be used as an antimicrobial washing agent for treating all foods. It will be used in particular for meat and poultry products, as well as to treat water used in ice-making systems for general use in the poultry processing industry.

The Applicant proposes that DBDMH will be used as an antimicrobial washing agent to treat all foods, although its primary use is likely to be to treat meat and poultry carcasses, parts, trim, organs, hides and heads, and to treat water in ice-making systems. When added to water, DBDMH hydrolyses to form hypobromous acid, which is the active compound that possesses antimicrobial activity. Hypobromous acid kills bacteria present on the surface of food. It is claimed to be effective against *Escherichia coli* 0157:H7 and *Salmonella*.

The Code contains permission for a similar antimicrobial washing agent, the halo-hydantoin bromo-chloro-dimethylhydantoin (BCDMH) to treat all foods, in the Table to clause 12 of Standard 1.3.3. The Applicant has requested the entry for BCDMH be replaced with a joint entry for DBDMH and BCDMH in the Table to clause 12: Permitted bleaching agents, washing and peeling agents. The Applicant has also suggested replacing the existing specification for BCDMH in the Schedule to Standard 1.3.4 – Identity and Purity with a joint specification that would characterise both halo-hydantoins.

Risk and Technical Assessment

A food technology assessment was undertaken to determine whether the use of DBDMH, as an antimicrobial agent for treating meat and poultry products and to treat water used in ice-making systems for general use in the poultry processing industry, is technologically justified. In addition, a hazard assessment and dietary exposure assessment evaluated whether foods produced through the use of DBDMH were safe for consumption.

The food technology assessment concluded that DBDMH performs the technological function as described by the Applicant and meets its stated purpose. The hazard assessment and dietary exposure Assessment raised no public health and safety concerns.

Risk Management

FSANZ is proposing to include DBDMH as a separate entry in the Table to clause 12: Permitted bleaching agents, washing and peeling agents, to clearly express the residues from each chemical and their levels.

The permission for DBDMH would include maximum permitted levels (MPLs) of 2.0 mg/kg for dimethylhydantoin (DMH) and 2.0 mg/kg for inorganic bromide in the treated food. The MPL for inorganic bromide from the new chemical differs to the maximum amount of 1.0 mg/kg of inorganic bromide residue permitted, arising from the use from the currently approved processing aid, BCDMH.

While there is a specification for BCDMH in the Schedule to Standard 1.3.4 – Identity and Purity, there is no specification for DBDMH. FSANZ has prepared a draft specification for DBDMH to be added to the Schedule for Standard 1.3.4. FSANZ has insufficient information to recommend a purity specification for BCDMH and is not proposing to make a variation.

There are no labelling requirements for DBDMH, as substances used as processing aids in accordance with Standard 1.3.3 – Processing Aids are exempt from labelling under clause 3 of Standard 1.2.4 – Labelling of Ingredients. Dibromo-dimethylhydantoin does not contain any substance that requires mandatory declaration under clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

Assessing the Application

The Application is being assessed under the General Procedure which includes one round of public comment.

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.
- There are no other measures that would be more cost-effective than a variation to Standards 1.3.3 and 1.3.4 that could achieve the same end.
- Any relevant New Zealand standards
- Any other relevant matters

Preferred Approach

To prepare a draft variation to the Table to clause 12 of Standard 1.3.3 – Processing Aids, to permit the use of dibromo-dimethylhydantoin as a washing agent processing aid to treat all food.

To prepare a draft variation to Standard 1.3.4 – Identity and Purity to include a specification in the Schedule for dibromo-dimethylhydantoin.

Reasons for Preferred Approach

An amendment to the Code approving the use of DBDMH as a processing aid in Australia and New Zealand is proposed on the basis of the best available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of DBDMH as an antimicrobial washing agent to treat all foods does not raise any public health and safety concerns.
- The use of DBDMH as a processing aid to treat meat and poultry products and to treat water used in ice-making systems for general use in the poultry processing industry is technologically justified as an alternative to currently approved washing agents.
- Permitting the use of this processing aid would not impose significant costs for government agencies, consumers or manufacturers.
- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of DBDMH to be used as a processing aid.

In addition, comments are also sought on the specification proposed for DBDMH.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Assessment Report will be used to develop the Approval Report for this Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation/s to the Code based on regulation impact principles 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 further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the 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, separate it from your submission and provide justification for treating it as confidential commercial material.

Section 114 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. 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 [Changing the Code](#) tab and then through [Documents for Public Comment](#). Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 22 December 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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**

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CONTENTS

INTRODUCTION	2
1. THE ISSUE / PROBLEM.....	2
2. CURRENT STANDARD.....	2
2.1 <i>Background</i>	2
2.2 <i>International Regulations</i>	3
2.3 <i>Nature of the processing aid</i>	3
2.4 <i>Technological Function</i>	3
3. OBJECTIVES	4
4. VARIATION FROM APPLICATION.....	5
5. QUESTIONS TO BE ANSWERED	5
RISK ASSESSMENT.....	5
6. RISK ASSESSMENT SUMMARY	5
6.1 <i>Hazard assessment</i>	5
6.2 <i>Dietary Exposure</i>	6
6.3 <i>Technological justification</i>	6
RISK MANAGEMENT	6
7. RISK MANAGEMENT ISSUES.....	6
7.1 <i>Risk to public health and safety</i>	6
7.2 <i>Limitations on food type treated</i>	6
7.3 <i>Residue limits for treated food</i>	6
7.4 <i>Methods of analysis</i>	7
7.5 <i>Specification</i>	7
7.6 <i>Labelling</i>	8
7.7 <i>Ministerial Policy guidance</i>	8
8. OPTIONS	8
9. IMPACT ANALYSIS (RIS ID: 12065).....	8
9.2 <i>Benefit Cost Analysis</i>	9
COMMUNICATION AND CONSULTATION STRATEGY.....	10
10. COMMUNICATION	10
11. CONSULTATION.....	10
11.1 <i>World Trade Organization (WTO)</i>	10
PRIMARY LEGISLATIVE OBJECTIVES.....	11
12. ADDRESSING THE PRIMARY OBJECTIVES OF SECTION 18 OF THE FSANZ ACT	11
12.1 <i>Risk to public health and safety</i>	11
12.2 <i>Providing adequate information to enable informed consumer choice</i>	11
12.3 <i>Prevention of misleading and deceptive conduct</i>	11
CONCLUSION.....	11
13. CONCLUSION AND PREFERRED OPTION	11
13.1 <i>Reasons for Preferred Approach</i>	12
14. IMPLEMENTATION AND REVIEW	12
ATTACHMENT 1 - DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	13
ATTACHMENT 2 - DRAFT EXPLANATORY STATEMENT.....	15

SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1054dibr4947.cfm>

SD1 Risk Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Elanco Animal Health on 9 August 2010. Elanco Animal Health is a division of Eli Lilly Australia Pty Ltd.

This Application seeks to amend Standard 1.3.3 – Processing Aids, in the *Australia New Zealand Food Standards Code* (the Code), to permit the use of dibromo-dimethylhydantoin (DBDMH) to treat all foods, although its primary usage is likely to be as a treatment for meat and poultry carcasses, parts, trim, organs, hides and heads. The Applicant has also stated that DBDMH would be used in ice-making systems for general use in the poultry processing industry. DBDMH is one of a group of chemicals known as halohydantoins, which comprise of several halogenated compounds.

The Applicant has requested the entry for the currently permitted halohydantoin, bromo-chloro-dimethylhydantoin (BCDMH), be replaced with a joint entry for BCDMH and DBDMH in the Table to clause 12: Permitted bleaching agents, washing and peeling agents. The Applicant also suggested the existing specification in the Schedule to Standard 1.3.4 – Identity and Purity for BCDMH be replaced with a joint specification that would characterise both halohydantoins.

The Applicant states that DBDMH will be used as an alternative to chlorine, lactic acid, steam or hot water treatments to decontaminate the surface of meat hides and heads, and the carcasses, parts, trim and organs of meat and poultry. The Applicant claims that, unlike steam or hot water treatments, DBDMH does not cause meat discolouration or damage carcasses. DBDMH is purported to be safe for workers, plant equipment and the environment. It is also considered a cost effective treatment as there is no requirement to heat the DBDMH solution.

1. The Issue / Problem

A pre-market assessment and approval is required before any new processing aid is permitted to be used to process food sold in Australia and New Zealand. Washing agents are considered and regulated as processing aids in the Code.

A safety assessment of the processing aid, as well as an assessment of the technological function for its proposed use, must be undertaken before any permission may be granted.

2. Current Standard

2.1 Background

Processing aids used in food manufacture are regulated under Standard 1.3.3.

A processing aid is described in clause 1 of Standard 1.3.3.

processing aid means a substance listed in clauses 3 to 19, where –

- (a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and
- (b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.

Permitted washing agents are regulated under clause 12: Permitted bleaching agents, washing and peeling agents. The Table to clause 12 contains a list of approved washing agents, the food that can be treated using washing agents, and the maximum permitted level (MPL) of any residues remaining in the final treated food.

There is currently one halohydrantoin (BCDMH) that is permitted as an antimicrobial washing agent for all foods.

Currently there is no permission to use DBDMH as an antimicrobial washing agent to treat food.

2.2 International Regulations

The US Food and Drug Administration (USFDA) publishes an inventory of food contact substances that have been demonstrated to be safe for their intended use. The inventory includes Food Contact Substance Notifications (FCNs), including for DBDMH:

- FCN 334 – for use as an antimicrobial in chiller water used during poultry processing.
- FCN 357 – for use as an antimicrobial in water applied to poultry via an Inside-Outside Bird Washer (IOBW) and in water used for Off-Line Reprocessing (OLR) of poultry.
- FCN 453 – for general use as an antimicrobial agent in water used in poultry processing for disinfecting poultry carcasses and their parts and organs.
- FCN 775 – for use as an antimicrobial in water supplied to ice machines to make ice intended for general use in the poultry processing industry.
- FCN 792 – for use as an antimicrobial in water applied to beef hides, carcasses, heads, trim, parts, and organs.

The US Food Safety and Inspection Service (FSIS) Directive 7120.1 identifies the food grade substances that have been approved for use in 21 Code of Federal Regulations (CFR) as an antimicrobial agent in meat, poultry and egg products. All five FCNs for DBDMH are included in the Directive.

The Applicant states that an application for permission to use DBDMH has been made in Canada.

Chemical treatments used in meat processing are not permitted in meat that is exported to Europe.

2.3 Nature of the processing aid

DBDMH is in the form of white to off-white granules or tablets, which rapidly hydrolyse in water to form hypobromous acid and dimethylhydantoin (DMH). Hypobromous acid subsequently degrades to inorganic bromide which, along with DMH, can remain as residues in the treated food.

2.4 Technological Function

The Applicant proposes that DBDMH be used as an antimicrobial washing agent to treat all foods, although its primary usage is likely to be as a treatment for meat and poultry carcasses, parts, trim, organs, hides and heads.

It is also proposed to be added to water used in ice-making systems for general use in the poultry processing industry. When added to water, DBDMH hydrolyses to form hypobromous acid, which is the active compound that possesses antimicrobial activity. Hypobromous acid kills bacteria present on the surface of food. It is claimed to be effective against *Escherichia coli 0157:H7* and *Salmonella*.

The technological function of DBDMH is described in more detail in the Supporting Document SD1 (Risk and Technical Assessment Report).

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend Standard 1.3.3 to permit the use of DBDMH as a processing aid in the antimicrobial treatment of food.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- 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 Ministerial Council Policy Guideline, *Addition to Food of Substances other than Vitamins and Minerals*, includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be permitted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i. e. the 'stated purpose'); and
- the addition of the substance to food is safe for human consumption; and
- the amounts added are consistent with achieving the technological function; and
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
- no nutrition, health or related claims are to be made in regard to the substance.

4. Variation from Application

FSANZ has considered the Applicant's suggestion for:

- a joint entry for BCDMH and DBDMH in the Table to clause 12 of Standard 1.3.3.
- a joint specification for BCDMH and DBDMH in the Schedule to Standard 1.3.4.

FSANZ is proposing a separate entry for DBDMH in the Table to clause 12 of Standard 1.3.3, as this would clearly express the differences in the residues and their permitted levels from each halohydrantoin. An MPL of 2.0 mg/kg inorganic bromide from DBDMH is appropriate because the molecule contains two bromine atoms.

FSANZ is not proposing to vary the existing permission for BCDMH in the Table to clause 12 of Standard 1.3.3. As BCDMH contains one bromine atom, the existing MPL of 1.0 mg/kg for BCDMH should remain. It would also be incorrect to refer to an MPL of chlorine for both halohydrantoin, when DBDMH does not yield chlorine residues.

No variation to the current specification for BCDMH is proposed. FSANZ received insufficient information about the purity of BCDMH and is therefore unable to recommend a specification addressing both BCDMH and DBDMH. It may be appropriate to amend the current specification for BCDMH to include a purity limit, but that would need to be addressed by another mechanism for varying the Code.

5. Questions to be answered

For the assessment of this Application, FSANZ has considered the following key questions:

- Are foods produced through the use of DBDMH safe for consumption?
- Is the use of DBDMH as processing aid technologically justified?

The answers to these questions are provided in the Risk Assessment Summary, taken from the more detailed assessment in Supporting Document 1 (The Risk and Technical Assessment Report).

RISK ASSESSMENT

An assessment of the safety and technical function of the processing aid was undertaken (Refer to Supporting Document 1).

In addition to information supplied by the Applicant, other available resource material, including published scientific literature and general technical information, was used by FSANZ in this assessment.

6. Risk Assessment Summary

6.1 Hazard assessment

The use of DBDMH as an antimicrobial washing agent for the treatment of food raises no public health and safety issues.

6.2 Dietary Exposure

Estimates of dietary exposure to inorganic bromide and DMH from all potential sources for treating all foods, including bromine in food from other sources, indicate no potential exceedances of the respective reference health standards, Acceptable Dietary Intakes (ADIs), for all population groups assessed, including children. The use of DBDMH as a processing aid results in residues of inorganic bromide and DMH that are at or below the proposed MPLs. Thus there are no public health and safety concerns.

6.3 Technological justification

FSANZ has concluded that DBDMH, when used as an antimicrobial agent for treating meat and poultry products and when used to treat water used in ice-making systems for general use in the poultry processing industry, performs the technological function as described by the Applicant and meets its stated purpose.

Risk Management

7. Risk Management Issues

7.1 Risk to public health and safety

The Risk and Technical Assessment Report concluded that the use of DBDMH as a processing aid in food production did not raise any public health and safety risks. The Report also concluded that its use was technologically justified as an antimicrobial washing agent for meat and poultry products and in water used in ice-making systems for general use in the poultry processing industry. There are therefore no specific safety risks to manage.

7.2 Limitations on food type treated

The Applicant has requested the current entry in the Table to clause 12 of Standard 1.3.3 be amended to become an entry for the halohydrantoin, BCDMH and DBDMH. Under this proposal, the permission for DBDMH would extend to all foods, which would align with the existing permission for the BCDMH.

The hazard assessment and dietary exposure assessment (Supporting Document 1) concluded that DBDMH was safe as an antimicrobial washing agent to treat all foods. The food technology assessment (Supporting Document 1) assessed DBDMH as an appropriate antimicrobial washing agent to treat meat and poultry products and to treat water used in ice-making systems for general use in the poultry processing industry.

FSANZ notes that while its usage is likely to be limited to the treatment of meat and poultry carcasses, parts, trim, organs, hides and heads, there are no safety reasons preventing extending the permission for DBDMH to treat all foods.

7.3 Residue limits for treated food

The Applicant requested maximum permitted (residue) levels of 2.0 mg/kg for inorganic bromide and 2.0 mg/kg for DBDMH in treated food, in a joint entry for BCDMH and DBDMH in the Table to clause 12: Permitted bleaching agents, washing and peeling agents.

FSANZ has decided it is simpler and more transparent to have individual entries for both chemicals (See Attachment 1). The proposed entry to be added to Standard 1.3.3 is provided below in Table 1.

Table 1: Proposed entry for dibromo-dimethylhydantoin

Substance	Food	Maximum permitted level (mg/kg)
Dibromo-dimethylhydantoin	All foods	2.0 (inorganic bromide) 2.0 (dimethylhydantoin)

7.4 Methods of analysis

Residues from DBDMH (inorganic bromide and DMH) are also by-products of BCDMH. New analytical methods are therefore not required as a result of this Application. However, FSANZ located an analytical method to analyse for the by-product DMH, using gas chromatography, which is noted in section 2.1.6 in Supporting Document 1.

7.5 Specification

The purpose of Standard 1.3.4 is to regulate the identity and purity of substances. There is no specific specification for DBDMH in Standard 1.3.4 – Identity and Purity. The Schedule to this Standard does, however, include a specification for the similar processing aid, BCDMH.

The Applicant has suggested replacing the existing specification for BCDMH with a specification that would characterise both halohydantoin. The specification proposed in the Application includes information about their molecular structures and physical properties, and a purity level of greater than 90% for both chemicals (refer to Supporting Document 1 for suggested specification).

FSANZ has amended the Applicant's suggested specification (See Attachment 1). The proposed specification to be added to the Schedule for Standard 1.3.4 (provided below in Table 2) is for DBDMH only.

Table 2: Proposed specification for DBDMH

Specification for Dibromo-dimethylhydantoin	
Chemical name:	Dibromo-dimethylhydantoin (DBDMH) (CAS Number: 77-48-5)
Formula:	$C_5H_6Br_2N_2O_2$
Purity:	DBDMH greater than 97%
	Sodium bromide not greater than 2%
	Water not greater than 1%

FSANZ is proposing a simplified specification, noting that extraneous information such as appearance and physical properties are not required for regulatory purposes. The rationale for the proposed approach is described more fully in the Food Technology Assessment in Supporting Document 1.

Where purity for the two chemicals was proposed by the Applicant to be greater than 90%, the remaining 10% was not characterised. Additionally, the Applicant states the purity for DBDMH to be greater than 98%.

FSANZ sought clarification from the Applicant and determined that the purity for DBDMH is greater than 97%, and that remaining components comprised sodium bromide and water.

7.6 Labelling

Labelling provisions are included within the Code to protect public health and safety and to provide adequate information to enable consumers to make informed choices.

Substances used as processing aids in accordance with Standard 1.3.3 are not subject to ingredient labelling in the final food, under clause 3 of Standard 1.2.4 – Labelling of Ingredients. DBDMH does not contain any substance that requires mandatory declaration under clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

7.7 Ministerial Policy guidance

As noted in Section 3, FSANZ is also required to have regard to the relevant Ministerial Council Policy Guidelines when developing or varying food standards. For this Application FSANZ had regard to the Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals*, which for processing aids are the Special Order Policy Principles – Technological Function, listed in Section 3 of the report.

The Applicant has clearly articulated the technological function (the stated purpose), as being an antimicrobial washing agent to treat meat hides and heads, and the carcasses, parts, trim and organs of meat and poultry. FSANZ's safety assessment confirmed the use of DBDMH to treat all food is safe. The food technology assessment concluded that, at the amounts and in a form proposed by the Applicant, DBDMH is able to achieve the technological function. Furthermore, FSANZ considers DBDMH would be effective for all foods where it is feasible to a washing treatment. The Applicant makes no nutrition, health or related claims due to the use of DBDMH.

8. Options

As processing aids require a pre-market approval under Standard 1.3.3, it is not appropriate to consider non-regulatory options. Consequently, two regulatory options were identified for this Application:

Option 1: Reject the Application

Option 2: Prepare a draft variation to permit the use of DBDMH as a processing aid to treat food.

9. Impact Analysis (RIS ID: 12065)

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code have been analysed using regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this Application indicated a low or negligible impact. The Office of Best Practice Regulation has advised that as the Application appears to be of a minor or machinery nature and any approval would be voluntary a Regulatory Impact Statement is not required.

9.1 Affected Parties

The affected parties to this Application include:

- those sectors of the food manufacturing industry who wish to use DBDMH as an antimicrobial washing agent to treat food
- consumers of food produced using DBDMH as an antimicrobial washing agent
- Government agencies with responsibility for ensuring compliance with the Code.

9.2 Benefit Cost Analysis

9.2.1 Option 1: Reject the Application

This option is the status quo, where no changes are made to the Code.

However, rejecting the Application would disadvantage meat and poultry processors as they would be unable to capture potential energy savings and improved food quality and safety of their products. In addition, beef exporters to the US, which mandates strict food safety requirements, would be denied using an approved antimicrobial treatment. Although the Applicant has stated that poultry exports are currently minor, future exports of poultry products could also be impacted by the decision to reject the Application.

Where chlorine interventions continue to be used in poultry processing, other measures would be needed to ensure a comparable level of safety. Likewise, plant, equipment and water system conditions would continue to be adversely affected by lactic acid and chlorine treatments.

9.2.2 Option 2: Prepare a draft variation

This option allows the food industry choice in relation to the antimicrobial treatment used for food, particularly for meat and poultry carcasses, parts, trim, organs, hides and heads. For the proposed foods, the Applicant claims that DBDMH would provide the following product and processing benefits:

- it does not cause meat discolouration and carcass damage
- it provides a reduced energy expense as it does not require heating
- it is less corrosive to plant equipment, floors and water systems than lactic acid and chlorine treatments
- it is safer for workers and the environment than chlorine treatments.

Some consumers may oppose the use of any chemical antimicrobial treatment in favour of traditional hot water and steam interventions. In contrast, other consumers may view the use of an alternative treatment to chlorine in poultry processing as a benefit.

The use of processing aids by manufacturers is voluntary and not subject to limits in the Code. Therefore, there is not predicted to be any significant cost impost on jurisdictions to determine compliance with the proposed amendment compared with current monitoring and compliance activities. Similarly, no added costs to consumers are expected.

9.3 Comparison of Options

Given that the changes proposed by this Application impose no financial burden on any sector of the community, and given that the use of DBDMH as an antimicrobial washing agent to treat all foods raises no public health and safety issues, Option 2 was the preferred option.

Communication and Consultation Strategy

10. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the assessment report for public comment and placing the report on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the Application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ approval reports.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify its decision to the Ministerial Council. If no review of the Board's decision is requested by the Ministerial Council, the Applicant, stakeholders and submitters will be notified of the gazetted changes to the Code in the national press and on the FSANZ website.

11. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to the scientific aspects of the Application, including any safety aspects and technological function of using DBDMH as a processing aid to treat food. Comments are also sought on the proposed draft variation (**Attachment 1**) to the Code.

11.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are 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.

There are no relevant international standards for processing aids used to process food. Amending the Code to allow DBDMH as a permitted processing aid is unlikely to have a significant effect on international trade. Therefore, notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

Primary Legislative Objectives

12. Addressing the primary objectives of section 18 of the FSANZ Act

FSANZ is required by its legislation to meet the section 18 objectives of the FSANZ Act when it is developing or varying a food standard as noted in Section 3 of this report.

The primary objective relevant to consideration of this Application is the protection of public health and safety. The other two objectives have less direct relevance to FSANZ's assessment.

12.1 Risk to public health and safety

FSANZ's risk assessment concluded that the use of DBDMH as an antimicrobial washing agent to treat all foods does not pose any public health and safety concerns.

12.2 Providing adequate information to enable informed consumer choice

For this Application this objective is taken to relate to labelling of processed foods.

As noted in Section 7.6, processing aids are not subject to ingredient labelling so there are no labelling requirements for using DBDMH as an antimicrobial washing agent. This is the same situation as for other approved washing agents.

12.3 Prevention of misleading and deceptive conduct

FSANZ has considered this objective and concluded that there are no misleading or deceptive conduct aspects to this Application.

Conclusion

13. Conclusion and Preferred Option

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variations to Standards 1.3.3 and 1.3.4. FSANZ has concluded that the use of DBDMH as a processing aid does not pose any public health and safety risk and is technologically justified.

An draft variation to the Code giving permission to use DBDMH as a processing aid in Australia and New Zealand has been prepared on the basis of the available scientific information.

The proposed draft variation is provided in **Attachment 1**.

Preferred Approach

To prepare a draft variation to the Table to clause 12 of Standard 1.3.3 – Processing Aids, to permit the use of dibromo-dimethylhydantoin as a washing agent processing aid to treat all food.

To prepare a draft variation to Standard 1.3.4 – Identity and Purity to include a specification in the Schedule for dibromo-dimethylhydantoin.

13.1 Reasons for Preferred Approach

An amendment to the Code approving the use of DBDMH as a processing aid in Australia and New Zealand is proposed on the basis of the best available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of DBDMH as an antimicrobial washing agent to treat all foods does not raise any public health and safety concerns.
- The use of DBDMH as a processing aid to treat meat and poultry products and to treat water used in ice-making systems for general use in the poultry processing industry is technologically justified as an alternative to currently approved washing agents.
- Permitting the use of this processing aid would not impose significant costs for government agencies, consumers or manufacturers.
- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

14. Implementation and Review

The draft variation to the Code will come into effect on gazettal.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Statement

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



Food Standards (Application A1054 – Dibromo-dimethylhydantoin (DBDMH) as a Processing Aid) Variation

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 Standard commences on the date specified in clause 3 of this variation.

Dated TO BE COMPLETED

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

1 Name

This instrument is the *Food Standards (Application A1054 – Dibromo-dimethylhydantoin (DBDMH) as a Processing Aid) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

[1] **Standard 1.3.3** is varied by inserting in alphabetical order in the Table to clause 12 –

Dibromo-dimethylhydantoin	All foods	2.0 (inorganic bromide) 2.0 (dimethylhydantoin)
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[2] **Standard 1.3.4** is varied by inserting in the Schedule –

Specification for dibromo-dimethylhydantoin

Dibromo-dimethylhydantoin (CAS Number 77-48-5)

Formula C₅H₈Br₂N₂O₂

Purity

Dibromo-dimethylhydantoin	No less than 97%
Sodium bromide	No more than 2%
Water	No more than 1%

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 A1054 which seeks to approve the use of dibromo-dimethylhydantoin as a washing agent processing aid for all foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose and operation

Currently there is no permission for using dibromo-dimethylhydantoin as a washing agent processing aid to treat any food. The draft variation is proposed to address this. Dibromo-dimethylhydantoin is proposed as a washing agent to treat all foods with maximum permitted levels of 2 mg/kg of inorganic bromide and 2 mg/kg of dimethylhydantoin in the final treated food.

There is currently no specification for dibromo-dimethylhydantoin in the Code. Therefore, FSANZ is proposing to include a specification for dibromo-dimethylhydantoin to be incorporated into the Schedule of Standard 1.3.4.

3. Documents incorporated by reference

The variation does 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 A1054 will include one round of public consultation following an assessment and the preparation of draft variation. A Report (which includes the draft Standard) will be released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations to Standards 1.3.3 and 1.3.4 are likely to have a minor impact on business and individuals.

5. Variations

5.1 Item [1]

This item inserts a permission in the Table to clause 12 of Standard 1.3.3 to permit the use of dibromo-dimethylhydantoin to treat all foods as a washing agent processing aid.

5.2 Item [2]

This item inserts a specification for dibromo-dimethylhydantoin in the Schedule of Standard 1.3.4.