

26 March 2012

[7-12]

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

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Elanco Animal Health on 9 August 2010. The Application sought to amend Standard 1.3.3 – Processing Aids, of the *Australia New Zealand Food Standards Code* (the Code), to permit the use of dibromo-dimethylhydantoin (DBDMH) as a processing aid. The Applicant proposed 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 effective against *Escherichia coli* 0157:H7 and *Salmonella*.

The Code contains permission for a similar antimicrobial washing agent, the halohydantoin bromo-chloro-dimethylhydantoin (BCDMH) to treat all foods, in the Table to clause 12 of Standard 1.3.3. The Applicant 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 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 halohydantoins.

Risk assessment

A risk and technical assessment was performed for this Application with the findings detailed in the Risk and Technical Assessment Report (Supporting Document 1, **SD1**). As part of this assessment, a Food Technology Assessment was undertaken to determine whether the use of DBDMH, as an antimicrobial washing 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 are safe for consumption.

FSANZ concluded that the use of DBDMH as a processing aid is technologically justified and raises no public health and safety issues.

Risk management

FSANZ proposed including DBDMH as a separate entry in the Table to clause 12: Permitted bleaching agents, washing and peeling agents, to clearly distinguish the different 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 of the currently approved processing aid, BCDMH.

While there is a specification for BCDMH in the Schedule to Standard 1.3.4 – Identity and Purity it does not include purity information. Currently, there is no specification for DBDMH. FSANZ has insufficient information about the purity of BCDMH to recommend a joint purity specification that would characterise both halohydantoins. FSANZ prepared a specification for DBDMH to be added to the Schedule for Standard 1.3.4 and does not propose to make a variation to the existing specification for BCDMH.

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 was assessed under the General Procedure which included one round of public comment.

During assessment and subsequent development of a food regulatory measure, FSANZ 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 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 arise from the development or variation of the food regulatory measure.
- There are no other measures that are more cost-effective than a variation to Standards 1.3.3 and 1.3.4 that would achieve the same end.
- Any relevant New Zealand standards
- Any other relevant matters

Decision

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

Reasons for decision

An amendment to the Code approving the use of DBDMH as a processing aid in Australia and New Zealand was approved on the basis of the best available evidence and because:

- A detailed safety assessment concluded 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 variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

Consultation

Public submissions were invited on the Assessment Report between 15 November and 22 December 2011. Comments were requested on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of DBDMH as a processing aid.

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

In total, four submissions were received. Issues raised in submissions have been addressed by FSANZ and the report amended to reflect any changes. The summary of the submissions is in Table 3 of Section 11.1 of the Report.

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SUPPORTING DOCUMENT

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

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

SD1 Risk Assessment Report (Approval)

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.

The Application sought to amend Standard 1.3.3 – Processing Aids, of the *Australia New Zealand Food Standards Code* (the Code), to permit the use of dibromo-dimethylhydantoin (DBDMH) as a washing agent processing aid to treat all foods. Its primary use is likely to be as a treatment for meat and poultry carcasses, parts, trim, organs, hides and heads. The Applicant 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 are made up of several halogenated compounds.

The Applicant asked that 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 characterising both halohydantoins.

The Applicant stated 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 claimed 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 can be used to process food sold in Australia and New Zealand. Washing agents are considered to be processing aids and are regulated accordingly 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 can be granted.

2. Background

2.1 Current Standard

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 in Standard 1.3.3. 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.

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

2.2 International regulations

The US Food and Drug Administration (USFDA) publishes an inventory of food contact substances demonstrated to be safe for their intended use. The inventory includes the following Food Contact Substance Notifications (FCNs), 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.
- FCN 1102 – for use as an antimicrobial agent in water applied to pig, goat, and sheep carcasses and their parts and organs.

The US Food Safety and Inspection Service (FSIS) Directive 7120.1 (Rev 10) 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 six FCNs for DBDMH are included in the Directive.

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

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

2.3 Nature of the processing aid

DBDMH takes 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 proposed using DBDMH as an antimicrobial washing agent to treat all foods, although its primary use 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 *E. coli 0157:H7* and *Salmonella*.

The technological function of DBDMH is described in more detail in the Supporting Document 1 (**SD1**, Risk and Technical Assessment Report).

3. Objectives

The objective of this Assessment was to determine whether it is appropriate to amend Standard 1.3.3 of the Code 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 COAG Legislative and Governance Forum on Food Regulation (the Forum)¹ 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.

¹ Formerly called the Australia and New Zealand Food Regulation Ministerial Council

4. Variations from application

FSANZ 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 has proposed 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 reflects an effective level of use for DBDMH that would achieve the required technological function.

Additionally, the level of DBDMH is approximately equivalent to the level of BCDMH used to achieve the technological function, since DBDMH has two bromine atoms and BCDMH has one.

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 was proposed. FSANZ received insufficient information about the purity of BCDMH and was therefore unable to recommend a specification addressing both BCDMH and DBDMH. FSANZ noted that 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

In assessing this Application, FSANZ considered the following key questions:

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

The answers to these questions are provided in the Risk Assessment Summary, taken from the more detailed assessment in **SD1**.

Risk Assessment

An assessment of the safety and technical function of the processing aid was undertaken for the Application

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

Acceptable Daily Intakes (ADIs) have been established for both inorganic bromide and DMH. Estimates of dietary exposure to inorganic bromide and DMH from all potential sources for treating all foods, including bromine in food from other sources for treating all foods were assessed. These indicate no exceedances of the respective ADIs for all population groups assessed, including children. Thus there are no public health and safety concerns for the use of DBDMH as a processing aid that results in residues of inorganic bromide and DMH that are at or below the proposed maximum permitted levels.

6.3 Technological justification

FSANZ concluded from the assessment of 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, that it performs the technological function as described by the Applicant and meets its stated purpose. That is, that DBDMH is an effective antimicrobial treatment against *E. coli 0157:H7* and *Salmonella*.

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 does not raise any public health and safety risks. Therefore, there were no specific safety risks to manage.

7.2 Limitations on food type treated

The Applicant 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 BCDMH.

The Hazard Assessment and Dietary Exposure Assessment (**SD1**) concluded that DBDMH is safe as an antimicrobial washing agent to treat all foods. The Food Technology Assessment (**SD1**) 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 noted that while its use is likely to be limited to treating meat and poultry carcasses, parts, trim, organs, hides and heads, there were no safety reasons preventing extending the permission for DBDMH to treat all foods.

In their submission to the Assessment Report, the New South Wales Food Authority stated that while they did support the use of DBDMH in meat and poultry processing, they believed there was insufficient information to adequately demonstrate the technological function of DBDMH in foods other than meat and poultry.

The Applicant requested permission for the use of DBDMH in all foods, and noted that BCDMH is used for treating fresh fruit and vegetables, while DBDMH is to be used to treat meat and poultry carcasses.

However, no information was provided by the Applicant or subsequently found by FSANZ to indicate that the DBDMH is used to treat foods other than meat and poultry products.

DBDMH performs the same technological function as the currently approved processing aid, BCDMH. FSANZ considers there is no specificity for a particular food group for either processing aid to achieve their technological function of reducing the microbial load. In addition, the microbes targeted for control (*E coli 0157:H7* and *Salmonella*) are ubiquitous in food and in the environment, rather than specific to certain types of foods.

FSANZ also notes that there are other regulatory control limits relating to microbial limits in food. Food safety controls are applied by industry to ensure that food products are safe for consumption. The food industry is likely to conduct their own technological evaluations to determine whether DBDMH is more effective than existing treatments in reducing the microbial load on foods other than meat and poultry.

Furthermore, BCDMH is already approved for use as a washing agent in all foods, and there are no public health or safety concerns with this approach. Similarly, the dietary exposure assessment for the new processing aid indicated there were no safety concerns if DBDMH was permitted to treat all foods (see **SD1**).

FSANZ therefore considers it expedient to extend the permission for DBDMH to all foods, to align with the permission for the currently approved processing aid, BCDMH.

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 DMH 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 decided it is simpler and more transparent to have individual entries for both chemicals.

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 **SD1**.

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 suggested replacing the existing specification for BCDMH with a specification that would characterise both halohydrantoin. 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 **SD1** for suggested specification).

FSANZ amended the Applicant's suggested specification. The specification to be added to the Schedule for Standard 1.3.4 is for DBDMH only.

FSANZ decided on a simplified specification, noting that extraneous information such as appearance and physical properties are not required for regulatory purposes. The rationale for the approach is described more fully in the Food Technology Assessment in **SD1**.

Purity for the two chemicals was proposed by the Applicant to be greater than 90%, with the remaining 10% not characterised. Additionally, the Applicant stated 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 in 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 – Processing Aids 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.

8. Options

As processing aids require a pre-market approval under Standard 1.3.3, it was not appropriate to consider non-regulatory options. Two regulatory options were considered for this Application:

Option 1: Reject the draft variations to the Code on which submissions were sought

Option 2: Approve the draft variations to Standard 1.3.3 and Standard 1.3.4.

9. Impact Analysis (RIS ID: 12065)

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all community sectors, 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 was commensurate to the nature of the Application and significance of the impacts.

In accordance with the Best Practice Regulation Guidelines, a preliminary assessment for this Application indicated it would have a low or negligible impact. The Office of Best Practice Regulation provides a standing exemption from the need to assess whether a Regulation Impact Statement (RIS) is required for processing aid applications because they are minor or machinery nature and the permission would be voluntary. A RIS was therefore not needed.

9.1 Affected parties

The affected parties to this Application may include:

- 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 Cost benefit analysis

9.2.1 Option 1: Reject the draft variations to the Code on which submissions were sought

Rejecting the draft variations 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 affected by the decision to reject the draft variations.

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: Approve the draft variations to Standard 1.3.3 and Standard 1.3.4.

This option allows the food industry choice in 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. No additional costs to consumers are expected.

The use of processing aids by manufacturers is a commercial decision and is therefore voluntary. It is expected that industry may incur minor costs as a result of changing from one treatment method to another. However, there is likely to be financial gains from the reduced energy expense when using DBDMH.

Jurisdictions would continue to incur costs related to monitoring and compliance activities. The replacement by industry of existing treatments with DBDMH means these costs are likely to be minor.

9.3 Comparison of options

Given 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, the decision was made to approve the variations to the Code.

Communication and Consultation Strategy

10 Communication

FSANZ applied a basic communication strategy for this Application. The strategy involved notifying subscribers and any interested parties about the availability of reports for public comment and placing the report on the FSANZ website. A media release was also prepared to announce a call for submissions.

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

The Applicant, individuals, and organisations making submissions on this Application, are notified at each stage of the Application. The Applicant, stakeholders and submitters, including the public, are notified of the gazetted changes to the Code in the national press in Australia and New Zealand and on the FSANZ website.

11 Consultation

11.1 Issues raised in submissions

Public comments were sought on scientific aspects of the Application, which included any safety aspects and technological function of using DBDMH as a processing aid to treat food. Comments were also sought on the proposed draft variations (**Attachment 1**) to Standards 1.3.3 and 1.3.4.

Four submissions were received. The summary of the issues raised, the submitter and FSANZ's response is provided in Table 1.

Table 1: Summary of issues raised in submissions and FSANZ's response

Issue	Submitter(s)	FSANZ's response
<p>Little evidence to indicate why DBDMH is preferred to be used to treat meat and poultry in preference to BCDMH which is preferred for treating fruit and vegetables.</p> <p>Considers there is insufficient information to demonstrate technological function in foods other than meat and poultry. Does not support the use of DBDMH as a processing aid in all foods.</p>	New South Wales Food Authority	<p>FSANZ notes that the meat and poultry processing industry will make a commercial decision to use DBDMH, and that it will be used when it is the most effective washing treatment.</p> <p>DBDMH performs the same technological function as the currently approved processing aid BCDMH, which is permitted to be used to treat all foods. The technological function would therefore be the same across all food groups. There are no safety concerns if DBDMH is permitted for use in all foods.</p>

Issue	Submitter(s)	FSANZ's response
Supports the Application and the variation to the Code	Queensland Health New Zealand Ministry of Agriculture and Forestry Food Technology Association of Australia	No issues raised

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

12.1 Protection of 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 Provision of adequate information to enable informed consumer choice

For this Application, this objective was 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.

12.4 Subsection 18(2) considerations

FSANZ must also have regard to the matters set out in subsection 18(2) of the FSANZ Act (as copied in Section 3 of this Report). FSANZ considered these matters as follows:

- The Applicant submitted a comprehensive dossier of scientific studies and reports to FSANZ. In addition to the information supplied by the Applicant, other available resource material, including published scientific literature and general technical information, was used in the safety assessment.
- There is no international (Codex) standard for processing aids. However, DBDMH is permitted as a washing agent in the US to treat meat and poultry products.
- Permitting the use of DBDMH as an antimicrobial washing agent assists the Australian and New Zealand meat and poultry processing industries as it provides an alternative antimicrobial treatment that has advantages over currently approved treatments.

- There are no fair trading issues.

12.4.1 Consistency with Policy Guidelines established by the Forum

FSANZ is required to have regard to the Policy Guidelines relevant to the Application. For this Application, the Policy Guideline: Addition to Food of Substances other than Vitamins and Minerals was considered. Since the purpose for use of DBDMH is as a washing agent processing aid, consideration falls under 'Technological Function'. FSANZ therefore considered the Application under the five specific policy principles noted in Section 3.

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 has confirmed the use of DBDMH to treat all food is safe. The Food Technology Assessment has 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 use a washing treatment. The Applicant makes no nutrition, health or related claims in relation to the use of DBDMH.

Conclusion

13. Conclusion and Decision

This Application was assessed against the requirements of section 29 of the FSANZ Act and the applicable Policy Guideline.

FSANZ concluded that the use of DBDMH as a processing aid does not pose any public health and safety risk and is technologically justified.

Therefore, based on the available scientific information, the decision has been made to approve the variation to Standard 1.3.3 allowing DBDMH as a washing agent processing aid to treat all food sold in Australia and New Zealand. A specification for DBDMH to be added to the Schedule of Standard 1.3.4 has also been approved.

Decision

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

Reasons for Decision

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

- A detailed safety assessment 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 variation to the Code is consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

14. Implementation

The variation will come into effect on gazettal.

Attachment

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

Variations 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 these variations 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 Variations 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 $C_5H_6Br_2N_2O_2$

Purity

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

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).²

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 sought approval to use 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 approved a draft Standard.

Following consideration by COAG Legislative and Governance Forum on Food Regulation² (the Forum), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose and operation

The Authority has approved a variation to Standard 1.3.3 to permit the use of dibromo-dimethylhydantoin as a washing agent processing aid. 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 approved 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.

The Authority has also approved a variation to the Schedule of Standard 1.3.4 to include a specification for dibromo-dimethylhydantoin. Currently, there is currently no specification for dibromo-dimethylhydantoin in the Code.

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 included one round of public consultation following an assessment and the preparation of draft variation. An Assessment Report (which included the draft Standard) was released on 15 November 2011 for a five-week consultation period.

² Previously known as the Australia and New Zealand Food Regulation Ministerial Council

A Regulation Impact Statement 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. Statement of compatibility with human rights

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

6. Variations

Item [1] 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.

Item [2] inserts a specification for dibromo-dimethylhydantoin in the Schedule of Standard 1.3.4.