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

Supporting document 1

Risk and technical assessment report (Approval)

Application A1054

Dibromo-dimethylhydantoin (DBDMH) as a Processing Aid

Executive Summary

FSANZ received an Application from Elanco Animal Health seeking an amendment to Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code). The Application seeks to amend the Table to clause 12: Permitted bleaching agents, washing and peeling agents, to include dibromo- dimethylhydantoin (DBDMH) as an antimicrobial agent for use during the processing of 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 food technology assessment considered 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. It concluded DBDMH performs the technological function consistent with the stated purpose given by the Applicant. In aqueous solution, DBDMH hydrolyses to form hypobromous acid which is the active compound that possesses antimicrobial activity, and dimethylhydantoin (DMH). Hypobromous acid subsequently degrades to inorganic bromide which, along with DMH, can remain a residue in the treated food. The Application requested maximum permitted levels (MPLs) of 2.0 mg/kg for inorganic bromide and 2.0 mg/kg for DMH in the final food.

An Acceptable Daily Intake (ADI) for inorganic bromide of 0-1 mg/kg bodyweight (bw) was established by the Joint FAO/WHO Meeting on Pesticide Residues in 1967 and reaffirmed in 1988. No subsequent data have been identified which would indicate a need to amend this ADI. For DMH, an ADI of 0-0.025 mg/kg bw was established by the Australian New Zealand Food Authority (ANZFA) in 2000. Derivation of this ADI included the application of a large uncertainty factor to account for the limited toxicological database available at the time. In 2004, the US Environmental Protection Agency evaluated an adequate toxicological database on DMH to arrive at ADIs of 0-3 mg/kg bw for the general population and 0-1 mg/kg bw for females of reproductive age. These ADIs are considered appropriate for use in the current risk assessment of DMH.

Estimates of dietary exposure to inorganic bromide and DMH from all potential sources 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 dibromo-dimethylhydantoin as a processing aid for all food which results in residues of inorganic bromide and DMH that are at, or below, the proposed MPLs.

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1. Introduction

1.1 Background

On 9 August 2010, Food Standards Australia New Zealand (FSANZ) received an Application from Elanco Animal Health seeking an amendment to Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code). The Application seeks to amend the Table to clause 12: Permitted bleaching agents, washing and peeling agents, to include dibromo-dimethylhydantoin (DBDMH) as an antimicrobial agent for use during the processing of all food, although its primary use would be for the treatment of meat and poultry.

The Table to clause 12 currently includes a related compound, bromo-chloro-dimethylhydantoin (BCDMH), for use in the course of manufacture of all foods. During its use as an aqueous solution, BCDMH chemically degrades forming chlorine, inorganic bromide and dimethylhydantoin (DMH) which can remain as residues in the final food. The Table to clause 12 specifies maximum permitted levels (MPLs) for these residues of 1.0, 1.0 and 2.0 mg/kg, respectively. The Application states that DBDMH also degrades when used as an aqueous solution, potentially leaving residues of inorganic bromide and DMH. The Application has requested MPLs of 2.0 mg/kg for inorganic bromide and 2.0 mg/kg for DMH.

1.2 Risk Assessment Questions & Scope

The following questions are addressed in this Risk and Technical Assessment Report:

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

This Risk and Technical Assessment Report is structured to address the above questions and comprises the following components:

(1) Food Technology Assessment, which describes the chemical properties of DBDMH and considers whether its use is technologically justified.

(2) Hazard Assessment, which determines the intrinsic toxicity of inorganic bromide and DMH.

(3) Dietary Exposure Assessment (DEA), which estimates the levels of dietary exposure to inorganic bromide and DMH residues arising from the proposed uses of DBDMH and other source chemicals as bleaching, washing and peeling agents in Australia and New Zealand.

(4) Risk Characterisation, which compares the estimated levels of dietary exposure to inorganic bromide and DMH residues with the corresponding reference health standards (e.g. Acceptable Daily Intake).

2. Food Technology Assessment

2.1 Dibromo-dimethylhydantoin Characteristics

2.1.1 Identity

Simple name: Dibromo-dimethylhydantoin (DBDMH)

CAS name: 1,3-dibromo-5,5-dimethylhydantoin

IUPAC name: 1,3-dibromo-5,5-dimethylimidazolidine-2,4-dione

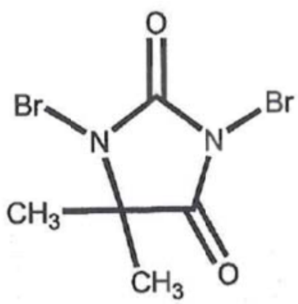
CAS number: 77-48-5

Molecular formula: $C_5H_6Br_2N_2O_2$

Molecular Weight: 285.9 g/mol

2.1.2 Chemical structure

DBDMH is a halohydantoin, in this case a dimethylhydantoin ring structure to which bromine atoms are attached to the two nitrogen atoms (at position 1 and 3) in the hydantoin ring (as indicated in the structure below).



2.1.3 Physical properties

Appearance: stable white to off-white crystalline solid

Melting point: 197-203° C

Boiling point: 368-376° C

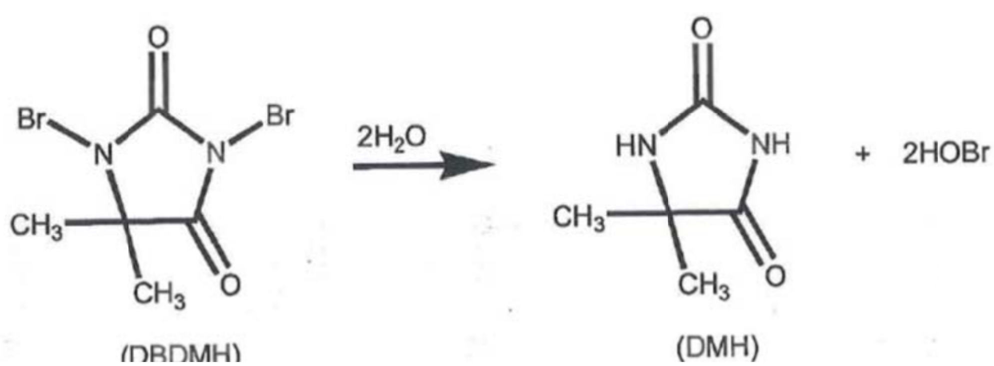
Flash point: 155° C

Solubility: 0.1% w/w in water at 20° C

pH (1% slurry in water): 6.6

2.1.4 Chemical reactivity, hydrolysis

When DBDMH is added to water it rapidly hydrolyses to form two molecules of hypobromous acid (HOBr) which is the actual active antimicrobial agent, and another reaction by-product, DMH.



Hypobromous acid is an excellent oxidising agent that can be used as a disinfectant to treat water used to treat food, especially to reduce the food pathogens *Escherichia coli* and *Salmonella* on meat surfaces (e.g. beef and poultry carcasses). The Applicant notes that hypobromous acid is more effective than hypochlorous acid, particularly with high organic load and/or where the pH is above 7.5. It is further claimed that hypobromous acid can be used to replace or complement different pH and heat-based treatments to control pathogens during food processing. Importantly, it is claimed that treatment with DBDMH on meat and carcasses does not produce any meat discolouration or damage that can be associated with high-temperature washes.

DBDMH is a solid which releases the active ingredient hypobromous acid as a reaction product after dissolution in water. There are advantages to using DBDMH rather than bromine or hypobromous acid itself as it is easier and safer to store, handle and use. DBDMH, being solid, is quite stable with a long shelf life, provided it is kept dry. The amount of hypobromous acid formed and used for treatment can be carefully adjusted by altering the flow of water over the solid DMDMH. The active ingredient, hypobromous acid, is also produced just prior to spraying the food, so it is quite active as there is little chance for it to degrade.

The Applicant notes that DBDMH is preferred to be used to treat meat and poultry carcasses in preference to BCDMH which is preferred for treating fresh fruit and vegetables.

2.1.5 Production of DBDMH

Solid DMH is dissolved in water with added sodium hydroxide. Excess bromine is then added to ensure the reaction is completed, that is both nitrogen atoms are brominated. The DBDMH product precipitates out of solution, is filtered and dried to a powder, which can be tableted or granulated.

2.1.6 Analytical method for DMH and inorganic bromide by-products

As noted earlier DBDMH hydrolyses once it is prepared by dissolving in water to produce the active anti-microbial agent which is hypobromous acid and the other by-product which is DMH. Food treated with the preparation will not contain residues of the original compound, DBDMH, but may contain residues of DMH and also inorganic bromide.

Maximum permitted levels will be required for both inorganic bromide and DMH for food treated with DBDMH. There are already maximum permitted levels for food treated with BCDMH in the Code for the by-products of reaction, being inorganic bromide and DMH.

Therefore no new analytical methods need be developed due to this Application. However FSANZ provides these extra comments below related to their analysis.

There are a variety of analytical methods for determining inorganic bromide levels which experienced analysts could use because a maximum residue limit (MRL) for inorganic bromide in various food commodities (mainly fruit and vegetables) has been listed in Schedule 1 for Standard 1.4.2 – Maximum Residue Limits (Australia only) for many years. Therefore, an analytical method would be required for these products. There are also MRLs for inorganic bromide for food sold in New Zealand so the same point applies.

There is an early reference (Lau et al, 1973) that provides an analytical method for the determination of DMH, using gas chromatography with electron capture detection.

2.1.7 Specification

There is no specification for DBDMH in any of the primary or secondary references within clause 2 and 3 respectively in Standard 1.3.4 – Identity and Purity, or in the Schedule to the Standard. However there is a specification for the comparable product BCDMH in the Schedule.

The Applicant provided a suggested specification for DBDMH to be added into the Schedule to Standard 1.3.4. The Application suggested that the current BCDMH specification could be amended to also include the new chemical DBDMH, so that a new combined specification would be written. The Applicant's suggested new combined specification is provided in Figure 1.

Specifications for the halohydantoins
Bromochloro dimethylhydantoin and Dibromo dimethylhydantoin

Bromo-chloro dimethylhydantoin (CAS Number: 126-06-7)
Formula: $C_5H_6BrClN_2O_2$

Dibromo-dimethylhydantoin (CAS Number: 77-48-5)
Formula: $C_5H_6Br_2N_2O_2$

Structurally, the halohydantoins consist of a central organic hydantoin ring moiety, dimethylhydantoin to which halogen atoms (bromine and/or chlorine) can be attached at both the 1 and 3 positions on the hydantoin ring.

Both bromochloro-dimethylhydantoin and dibromo-dimethylhydantoin are >90% pure

Form: Solid or free-flowing, off white granules, tablets

In the dry state halohydantoins are stable. Upon usage, which involves addition to water, the halohydantoins rapidly hydrolyse and form hypochlorous acid and/or hypobromous acid, which are the actual antimicrobial agents. The solution also contains the halogen carrier hydantoin ring, dimethylhydantoin (DMH).

Figure 1: Applicant's suggested joint specification for BCDMH and DBDMH

The current specification for BCDMH in the Schedule for Standard 1.3.4 is provided in Figure 2.

Specification for bromo-chloro-dimethylhydantoin

Bromo-chloro-dimethylhydantoin (CAS Number: 126-06-7)

Formula:	$C_5H_6BrClN_2O_2$
Formula weight:	241.5

<u>Chemical Properties</u>

Appearance:	Solid or free flowing granules
Colour:	White
Odour:	Faint halogenous odour
Melting Point:	163-164ºC
Specific gravity:	1.8-2
Solubility in water:	0.2 g/100 g at 25ºC
Stability:	Stable when dry and uncontaminated

<u>Chemical Tests</u>	
Manufacturing process:	Solid dimethylhydantoin (DMH) is dissolved in water with bromine and chlorine. The reaction is 0.5 mole bromine and 1.5 mole chlorine for one mole DMH. During the reaction the pH is kept basic by the addition of caustic soda. The wet product is transferred to a drier where it is dried to a powder at low temperature. The powder may then be tableted or granulated.
<u>Assay</u>	
Procedure:	Various analytical methods exist for analysis, namely, GLC, HPLC, UV and NMR. HPLC offers the best sensitivity.

Figure 2: Current specification for BCDMH in the Schedule for Standard 1.3.4

FSANZ has received insufficient information about the purity of BCDMH and therefore is unable to recommend a specification addressing both BCDMH (current approved processing aid) and the new chemical DBMDH. 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, possibly as part of a Proposal.

FSANZ's therefore proposes the specification for DBDMH provided in Figure 3 be added into the Schedule for Standard 1.3.4.

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% w/w
	Sodium bromide not greater than 2% w/w
	Water not greater than 1% w/w

*Figure 3**:** Proposed specification for DBDMH to be added to the Schedule for Standard 1.3.4.*

2.2 Assessment of Technological Function

The proposed use of DBDMH is as an antimicrobial treatment in poultry and meat processing to reduce pathogen levels on 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.

Hypobromous acid (the active ingredient once DBDMH has been dissolved in aqueous solution) reacts with unsaturated fatty acids within cell membranes causing disruption to the cell membrane which contributes to cell lysis (Carr et al 1998).

Halohydantoins are effective antimicrobial treatments used as water disinfectants and as alternatives to chlorine based disinfectants in poultry, meat and fruit and vegetable processing (USEPA 2007; ANZFA 2000; FAO/WHO 2008). In a study by Kalchayanand et al (2009), DBDMH effectively reduced levels of *E. coli* and *Salmonella* on inoculated cutaneous trunci muscle sections and beef hearts by between 1.5 - 2.1 log and greater than 1 log respectively.

2.3 Food Technology Conclusion

FSANZ concludes from the assessment of using 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 that it performs the technological function as described by the Applicant to meet its stated purpose.

3. Hazard Assessment

3.1 Background

3.1.1 Chemistry

Details of the physicochemical properties of DBDMH, including product specifications, are included in the Food Technology Assessment (Section 2). As discussed, when used as an antimicrobial processing aid DBDMH degrades to produce two chemical residues which may be present in the final food: (i) DMH and (ii) inorganic bromide (Br^-).

3.1.2 Previous FSANZ/ANZFA Assessment

Toxicity data on DMH were considered as part of the assessment of Application A393 - Bromo-chloro-dimethylhydantoin (BCDMH) as a Processing Aid (ANZFA 2000). An Acceptable Daily Intake (ADI) of 0-0.025 mg/kg bodyweight (bw) was derived from the No Observed Effect Level (NOEL) of 50 mg/kg bw/day observed in a 13 week rat study and application of a large uncertainty factor of 2000 to account for the limited toxicological database available at the time.

For inorganic bromide an ADI of 0-1 mg/kg bw was cited by ANZFA (2000). This ADI was established in 1966 by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and reaffirmed in 1988 as indicated below (FAO/WHO 1967; FAO/WHO 1989).

3.1.3 Assessments by Other Agencies

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

At its 1966 meeting, JMPR established an ADI for inorganic bromide of 0-1 mg/kg bw based on a minimum pharmacologically effective dosage in humans of approximately 900 mg of potassium bromide, equivalent to 600 mg of bromide ion (FAO/WHO 1967). In 1988, JMPR evaluated data from animal toxicity studies and human studies and reaffirmed the ADI of 0-1 mg/kg bw (FAO/WHO 1989). DMH has not been assessed by JMPR.

European Food Safety Authority (EFSA)

EFSA has not assessed DMH or inorganic bromide. For inorganic bromide, the ADI of 0-1 mg/kg bw established by JMPR is included in the EFSA list of pesticide toxicological reference values (EFSA 2008).

US Environment Protection Agency (USEPA)

USEPA evaluated halohydantoins for re-registration eligibility in 2004 and determined that the toxicological database was sufficient for reregistration. Evaluation of unpublished animal studies on DMH led to the establishment of a chronic reference dose[1] (RfD) for the general population of 3 mg/kg bw/day (USEPA 2004). This chronic RfD was derived from the No Observed Adverse Effect Level (NOAEL) of 300 mg/kg bw/day in a 2-year rat carcinogenicity study and application of an uncertainty factor of 100.

[1] Definition is equivalent to that for Acceptable Daily Intake.

For females of reproductive age (13-50 years), a chronic RfD of 1 mg/kg bw/day was derived from the NOAEL of 100 mg/kg bw/day in a rabbit developmental toxicity study and application of an uncertainty factor of 100. FSANZ has considered the USEPA evaluation and concludes that these chronic reference doses are appropriate for use as ADIs for the risk assessment of DMH. USEPA did not consider inorganic bromide as part of their re-registration eligibility assessment.

3.2 Current Application

No published or unpublished studies relevant to the hazard assessment of DMH or inorganic bromide were submitted by the Applicant. A search of PubMed conducted in July 2011 did not result in the identification of any publications that would indicate a need to revise the ADI for inorganic bromide established by JMPR or the chronic RfDs (=ADIs) for DMH established by USEPA.

3.3 Hazard Assessment Conclusion

The ADI for inorganic bromide of 0-1 mg/kg bw is unchanged from that used in the risk assessment of bromo-chloro-dimethylhydantoin conducted by ANZFA in 2000.

For DMH, USEPA has evaluated unpublished toxicity studies that support ADIs of 0-3 mg/kg bw for the general population and 0-1 mg/kg bw for females of reproductive age.

4. Dietary Exposure Assessment

4.1 Introduction

FSANZ conducted a dietary exposure assessment (DEA) to estimate the potential exposure of Australian and New Zealand consumers to inorganic bromide and DMH arising from the proposed uses of DBDMH and other source chemicals as bleaching, washing and peeling agents.

Dietary exposure was calculated by combining chemical concentration data with food consumption data from the most recent Australian and New Zealand National Nutrition Surveys (NNS).

A summary of the FSANZ approach to conducting DEAs is included in Appendix 1**.** A more detailed description of the DEA process can be found on the FSANZ website: *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009a).

4.1.1 Derivation of DMH and inorganic bromide concentration data used in the DEA

An overview of the information taken into account in deriving inorganic bromide concentration data for use in the DEA assessment is discussed in detail below and in Figure 1. Two sets of concentration data were derived:

1. One based on existing and proposed MPL permissions in the Code for DMH and inorganic bromide for all foods.

2. One based on existing Maximum Residue Limits (MRL) permissions for inorganic bromide in fruit, vegetables, cereal grains, herbs and spices in Australia and for all foods in New Zealand with an import adjustment factor applied to take account of different use practices in other countries. There are no MRL permissions for DMH.

Where two different concentration levels for the same commodity were derived using methods 1 and 2 above the highest value was taken for use in the DEA.

4.1.2 Australia New Zealand Food Standards Code, Standard 1.3.3 -Processing Aids

The Applicant seeks to amend the Table under Clause 12: Permitted bleaching agents, washing and peeling agents, in Standard 1.3.3 to permit the use of DBDMH and to increase the associated MPL for inorganic bromide from 1 to 2 mg/kg for all foods.

4.1.3 Derivation of inorganic bromide concentrations from Australian and New Zealand MRLs

Another potential source of inorganic bromide in the diet arises from Australian and New Zealand MRL permissions for the use of methyl bromide, a fast acting fumigant which is used to eradicate pests. As the MRL permissions in New Zealand are much wider than those in Australia (Tables 1, 2), inorganic bromide concentration data for use in the DEAs for the two countries were derived in slightly different ways. The planned phase out of use of methyl bromide was also taken into account.

Table 1: Australian MRLs for inorganic bromide

Commodity	MRL (mg/kg)
Avocado	75
Cereal grains	50
Citrus fruits	30
Dates, dried	100
Dried fruits [except as otherwise listed under this chemical]	30
Dried grapes	100
Dried herbs	400
Dried peach	50
Figs, dried	250
Fruit [except as otherwise listed under this chemical]	20
Peppers, sweet	50
Prunes	20
Spices	400
Strawberry	30
Vegetables [except as otherwise listed under this chemical]	20

Source: Australia New Zealand Food Standards Code, Standard 1.4.2 Maximum Residue Limits (Australia only).

Table 2: New Zealand MRLs for inorganic bromide

Commodity	MRL (mg/kg)
Nuts	200
Spices	400
Any other food	50

Source: New Zealand Food Safety Authority Maximum Residue Limits of Agricultural Compounds (NZ).

4.1.4 Phase out of methyl bromide in Australia and New Zealand

Methyl bromide has been identified as an ozone depleting substance and has been largely phased out in Australia and New Zealand. Australia and New Zealand are parties to the Montreal Protocol on Substances that Deplete the Ozone Layer 1989 (the Montreal Protocol). All uses other than certified quarantine and pre-shipment (QPS), approved feedstock applications or approved critical use exemptions have been prohibited (Department of Sustainability, Environment, Water, Population and Communities, 2011).

The Montreal Protocol targets are for total phase out of methyl bromide in developed countries by 2005 and in developing countries by 2015 (20% reduction by 2005 and phase out by 2015), excluding critical use exemptions.

Methyl bromide for non-QPS purposes is only permitted in Australia for:

- Soil fumigation in the production of strawberry runners; and
- Treatment of rice packaged in Australia for domestic use.

There are currently no non-QPS permissions in NZ (Biosecurity NZ, 2011).

4.1.5 MRL import factors for methyl bromide

In reality, MRL permissions for inorganic bromide therefore apply to imported foods only (with the exception of strawberries and rice in Australia) and hence these foods are the only potential source of inorganic bromide arising from methyl bromide use. To account for this, FSANZ applied 'import multiplication factors' to the MRL concentrations for inorganic bromide for food groups included in the DEA to represent the proportion of foods which may potentially be exposed to methyl bromide (Figure 1).

Australia

FSANZ used Australia's latest food statistics derived from the Department of Agriculture, Fisheries and Forestry (DAFF) 2011 report: Australian Food Statistics 2009-10 to calculate Australian import multiplication factors. The percentage imports figure was calculated as shown in ***Equation 1***. This is a conservative estimate as not all imported foods are fumigated with methyl bromide. The import multiplication factor was derived using ***Equation 2***. The import multiplication factors used for Australia are outlined in Table 3.

$$\text{Percentage imports} = \frac{\text{Amount of imports}}{\text{Amount of food available for consumption}} \times 100\%$$

Equation 1: *Calculation of percentage imports*

$$\text{Import multiplication factor} = \frac{\text{Percentage imports (rounded } \mathbf{up} \text{ to nearest 5\%)}}{100}$$

Equation 2: *Calculation of import multiplication factors*

Table 3**: **Australian import multiplication factors used in the DEA

Commodity	Imports (kt)	Food available for consumption (kt)	% imports	Import multiplication factor
Cereal	340	1,757	19	0.20
Vegetables	380	2,028	19	0.20
Fruit	748	2,179	34	0.35
Pulses	12	33	36	0.40
Starchy roots	197	1,141	17	0.20

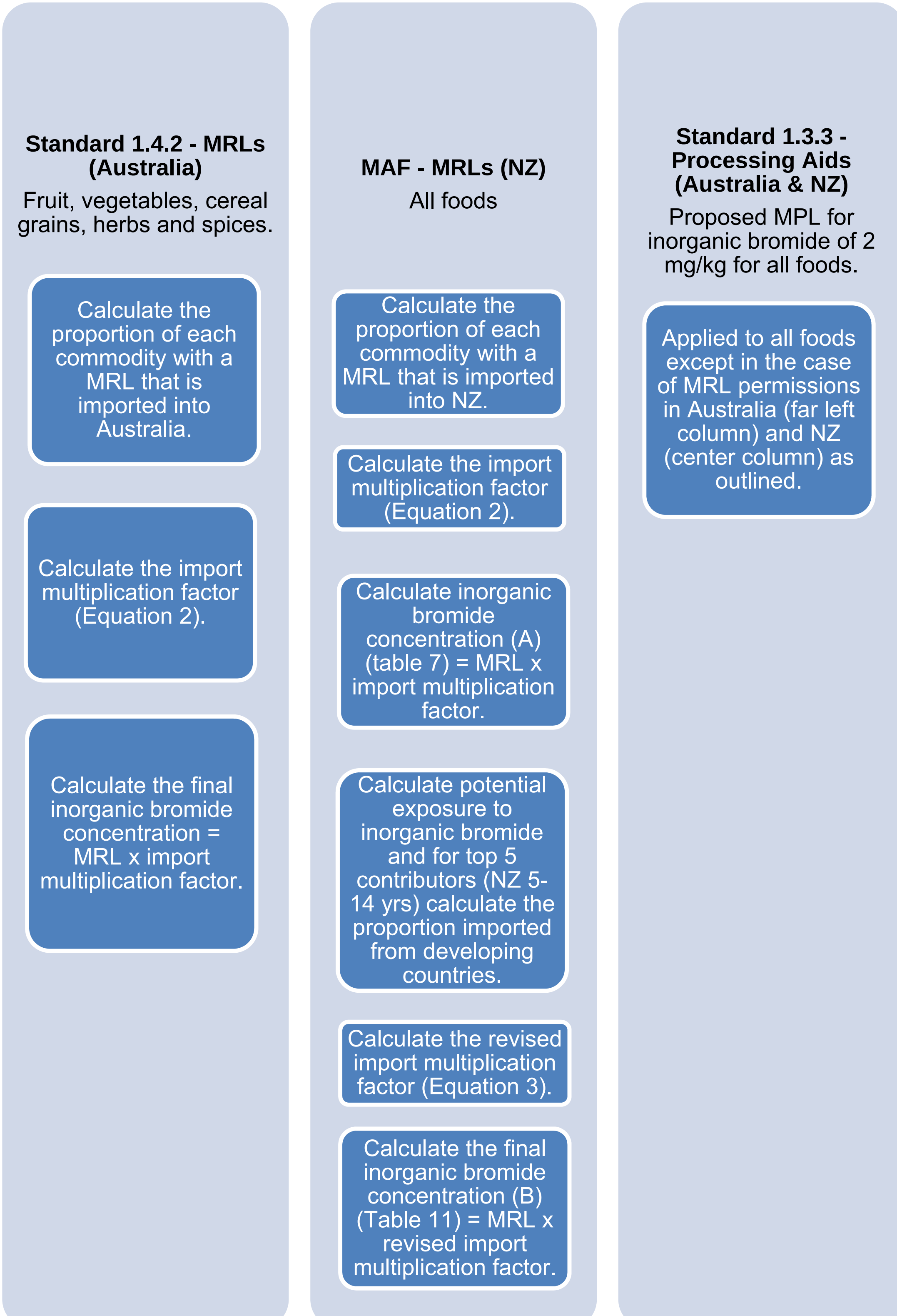
Source: Australian Food Statistics 2009-10 (DAFF 2011).
kt – Kilo tonnes.

New Zealand

FSANZ used food statistics for New Zealand derived from the DAFF 2011 report: Australian Food Statistics 2009-10 to calculate the percentage of imported foods for several commodities (see Table 4 below).

While inorganic bromide is permitted on meat products at 50 mg/kg under MRL permissions they were excluded from the DEA after receiving advice from the New Zealand Ministry of Agriculture and Forestry that very little, if any, imported animal products would be treated with methyl bromide (A Pearson, pers. com).[2] Meat products have been assigned an inorganic bromide concentration of 2 mg/kg in line with the proposed changes to Standard 1.3.3 – Processing Aids.

[2] Andrew Pearson, Senior Adviser (Toxicology), Ministry of Agriculture and Forestry (NZ), 26.8.11.



Final inorganic bromide concentration = Proposed MPL of 2 mg/kg for all foods from Standard 1.3.3 except in the case of higher MRL permissions in Australia (left) and New Zealand (centre).

Figure 4: Methodology for calculating inorganic bromide concentrations in foods

Table 4: New Zealand import multiplication factors

Commodity	Imports (kt)	Food available for consumption (kt)	Percentage imports	Import multiplication factor	Revised import multiplication factor
Cereal	530	380	100	1.00	1.00
Wheat				1.00	0.10‡
Starchy roots	86	280	31	0.35	0.35
Potato				0.35	0.04‡
Carrot				0.35	0.04‡
Pulses	9	20	45	0.45	0.45
Vegetables	82	555	15	0.15	0.15
Fruit	327	464	70	0.75	0.75
Apples				0.75	0.08‡
Oranges				0.75	0.08‡
Mandarin				0.75	0.08‡
Pear				0.75	0.08‡
Vegetable oil	116	41	100	1.00	1.00
Sugar cane				1.00	0.10‡

Source: Australian Food Statistics 2009-10 (DAFF, 2011) & Statistics NZ, 2011
kt – Kilo tonnes.
‡ This figure represents 10% of total imports to account for methyl bromide usage in developing countries and other critical use exemptions.

4.1.6 Food and concentration data used in the DEA

DMH

The DMH concentrations used in the Australian and New Zealand DEAs were based on the MPLs outlined in Standard 1.3.3 – Processing Aids of 2 mg/kg for all foods.

Inorganic bromide

The inorganic bromide concentrations used in the DEAs are as outlined in Table 5 for Australia and in Table 6 for New Zealand. The inorganic bromide concentrations incorporate import factors that consider the percentage of commodities that are imported and, for New Zealand, those that are imported from developing countries. This represents the potential concentrations of inorganic bromide in foods for the populations of Australia and New Zealand over a period of time.

***Table 5**: Inorganic bromide concentrations for Australian foods*

Commodity	Inorganic bromide concentration from MRL or Standard 1.3.3 (mg/kg)	Import multiplication factor	Final inorganic bromide concentration (mg/kg)#
Avocado	75	0.20	15
All foods (except those listed elsewhere)*	2	NA	2
Cereal grains (except rice)	50	0.20	10
Citrus fruits	30	0.35	10.5
Dates, dried	100	0.35	35
Dried fruits [except those listed elsewhere]	30	0.35	10.5
Dried grapes	100	0.35	35
Dried herbs	400	1.00	400
Dried peach	50	0.35	17.5
Figs, dried	250	0.35	87.5
Fruit [except those listed elsewhere]	20	0.35	7
Peppers, sweet	50	0.20	10
Prunes	20	0.35	7
Pulses	20	0.40	8
Rice†	50	1.00	50

Commodity	Inorganic bromide concentration from MRL or Standard 1.3.3 (mg/kg)	Import multiplication factor	Final inorganic bromide concentration (mg/kg)#
Spices	400	1.00	400
Strawberry†	30	1.00	30
Vegetables [except those listed elsewhere]	20	0.20	4

***** Arises from potential domestic use of BCDMH and DBDMH. No import factor applied. † Arises from potential domestic use (non-QPS critical use exemption). No import factor applied.
[#] Bromide ion concentration for the food= (MRL or Standard 1.3.3 bromide ion concentration) x import multiplication factor

***Table 6**: Inorganic bromide concentrations (A) for NZ foods*

Commodity	Inorganic bromide concentration from MRL or Standard 1.3.3 (mg/kg)	Import multiplication factor	Inorganic bromide concentration (A) (mg/kg)#
All foods (except those listed elsewhere)*	2	NA	2
Cereals (except those listed elsewhere)	50	1.00	50
Fruits (except those listed elsewhere)	50	0.75	37.5
Herbs	50	1.00	50
Plant products (except those listed elsewhere)	50	1.00	50
Potato	50	0.04	2
Pulses	50	0.45	22.5
Root and tuber vegetables	50	0.35	17.5
Spices	400	1.00	400
Tea	50	1.00	50
Tree nuts	200	1.00	200
Vegetable (oil)	50	1.00	50
Vegetables (except those listed elsewhere)	50	0.15	7.5

***** Arises from potential domestic use of BCDMH and DBDMH. No import factor applied.
[#] Bromide ion concentration for the food= (MRL or Standard 1.3.3 bromide ion concentration) x import multiplication factor

4.1.7 Consumption data used

Food consumption data from the latest national nutrition surveys in Australia and New Zealand were used for the DEA:

- 1995 Australian National Nutrition Survey (1995 NNS): Surveyed 13,858 people aged 2 years and above. The survey used one 24 hour recall for all respondents.

- 1997 New Zealand National Nutrition Survey (1997 NZNNS): Surveyed 4,636 people aged 15 years and above. The survey used one 24 hour recall for all respondents.

- 2002 New Zealand National Children's Survey (2002 NZNNS): Surveyed 3,275 people aged 5-14 years. The survey used one 24 hour recall for all respondents.

- 2007 Australian National Children's Survey (2007 NCNPAS): Surveyed 4,487 people aged 2-16 years. The survey used two non-consecutive 24 hour recalls for all respondents. Consumption data was calculated as the 2-day average for all respondents.

The design of these surveys varies somewhat and key attributes of each, including survey limitations, are set out in Appendix 1.

4.1.8 Population sub-groups for DEA

DMH

The toxicological assessment of DMH identified two reference health standards to be used in the DEA. These are Acceptable Daily Intakes (ADIs) of 1 mg/kg bw/day for females 13-50 years of age and 3 mg/kg bw/day for the rest of the population.

The population groups selected for the DEA were matched with the most recent food consumption data available. These do not match exactly with the ADI population group for females 13-50 years of age due to confidentiality restrictions on age reporting. The population sub groups included in the assessment are:

- 2007 NCNPAS – Australian populations aged 2-6 years and 7-16 years.
- 1995 NNS – Australian populations aged 17 years and above, and females aged from 13-49 years.
- 2002 NZNNS – New Zealand population aged 5-14 years
- 1997 NZNNS – New Zealand populations aged 15 years and above, and females aged from 15-50 years.

Inorganic bromide

The toxicological assessment of inorganic bromide identified an Acceptable Daily Intake (ADI) of 1 mg/kg bw/day for the whole population.

The population sub-groups included in the assessment are:

- Australians aged 2-6 years, 7-16 years, and 17 years and above.
- New Zealanders aged 5-14 years, and 15 years and above.

4.1.9 Assumptions and limitations of the DEA

Assumptions made in the DEA include:

- In line with the proposed amendments to Standard 1.3.3 – Processing Aids, it is assumed that DBDMH could be used on all foods.
- Where an inorganic bromide or DMH concentration is allocated to a food or a group of foods in Table 5-6 all foods in the group were considered to contain the chemical at the level specified.
- Where a food has a specified inorganic bromide and/or DMH concentration, this concentration was carried over to mixed foods where the food has been used as an ingredient (e.g. beef in a stir-fry; oranges in mixed fruit juice etc.).
- There were no reductions in chemical concentrations from food preparation or due to cooking.
- The 'import multiplication factors' and 'revised import multiplication factors' were applied to the inorganic bromide exposure calculation to represent the potential exposure arising from MRL permissions for food imports.

These assumptions are likely to lead to a considerable over-estimate for both inorganic bromide and DMH dietary exposure.

In addition to the specific assumptions made in relation to this DEA, there are a number of limitations associated with the dietary survey data upon which the DEA is based. A discussion of these limitations is included in Section 6 of the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009a).

4.2 Estimation of dietary exposure

Potential dietary exposures to inorganic bromide and DMH were first calculated for each respondent in each of the four NNSs. Chemical exposure statistics (mean and 90th percentile) were derived for inorganic bromide and DMH for each population group for consumers only. Consumers are those people in each NNS who reported consuming any food potentially containing each chemical. The 90th percentile exposure for each chemical was calculated after ranking all consumers' exposures on a mg/kg bw/day basis. The population exposure estimates were then reported as a proportion of the ADI for inorganic bromide and proportion of the chronic reference doses for DMH for each population group.

4.2.1 Dietary exposure estimates for each population group assessed

DMH

The dietary modelling scenario assumed that DMH was included in all foods and hence 100% of respondents could potentially be consumers. Estimated mean and 90th percentile exposure to DMH was below the ADI for all population groups assessed (see Table 7 and Table 8). Estimated dietary exposure at the 90th percentile was less than 10% of the ADI for all population groups assessed in Australia and New Zealand.

Table 7: Mean and 90th percentile estimated dietary exposure to DMH (mg/kg bw/day) for all population groups assessed

Country	Age (years)	DMH dietary exposure (mg/kg bw/day)	
		Mean	**P90**
Australia	2-6	0.18	0.25
	7-16	0.10	0.15
	Females 13-49	0.05	0.09
	17 and above	0.05	0.09
NZ	5-14	0.10	0.16
	Females 15-50	0.05	0.08
	15 and above	0.05	0.08

Table 8: Mean and 90th percentile estimated dietary exposure to DMH (percentage of the ADI) for all population groups assessed

Country	Age (years)	DMH dietary exposure as a % ADI^	
		Mean	**P90**
Australia	2-6	6	8
	7-16	3	5
	Females 13-49	5	9
	17 and above	2	3
NZ	5-14	3	5
	Females 15-50	5	8
	15 and above	2	3

^ADI is set at 1 mg/kg bw/day for females aged 13-49 years (AUS) and 15-50 years (NZ), and 3 mg/kg bw/day for the rest of the population

Inorganic bromide

The initial modelling scenario used inorganic bromide concentrations (A) derived from Table 6. It was assumed that inorganic bromide was included in all foods and hence 100% of respondents could potentially be consumers. Estimated mean and 90th percentile exposures to inorganic bromide are included in Table 9 and Table 10 below. All potential exposures were below the ADI, except for New Zealand children aged 5-14 years.

New Zealand children aged 5-14 years had the highest exposure (145% of the ADI at the 90th percentile). Further refinements were made to the New Zealand inorganic bromide dietary exposure estimates incorporating revised import multiplication factors (see Table 4 and Table 7). The results can be found in Section 4.2.2.

Australian children aged from 2-6 years had an estimated 90th percentile exposure of 65% of the ADI, higher than that for adults. This result is expected due to children's higher food consumption on a per body weight basis.

Table 9: Mean and 90th percentile estimated dietary exposure to inorganic bromide (mg/kg bw/day) for all population groups assessed

Country	Age (years)	Inorganic bromide dietary exposure (mg/kg bw/day)	
		Mean	**P90**
Australia	2-6	0.44	0.66
	7-16	0.24	0.39
	17 and above	0.13	0.23
NZ	5-14	0.88	1.46
	15 and above	0.43	0.74

Table 10: Mean and 90th percentile estimated dietary exposure to inorganic bromide (% ADI) for all population groups assessed

Country	Age (years)	Inorganic bromide dietary exposure as a % ADI	
		Mean	**P90**
Australia	2-6	45	65
	7-16	25	40
	17 and above	15	25
NZ	5-14	90	145
	15 and above	45	75

Note that the ADI for inorganic bromide is 1 mg/kg bw/day.

4.2.2 Refinement of DEA calculations for inorganic bromide (New Zealand only)

Refinement of the DEA calculations was undertaken for potential exposure of inorganic bromide for New Zealanders. All countries which exported foods to Australian and NZ during 2010 are either a member of the Montreal Protocol or, for developing countries, have met the required targets for phase out of methyl bromide (UNEP, 2011). This means that apart from possible critical use exemptions from all other developed nations, only foods imported from developing countries may have been exposed to methyl bromide. Hence the dietary exposure estimate can be further refined by adjusting for the proportion of imported foods from developing countries. This refinement was not considered necessary for Australia, as estimated dietary exposure to inorganic bromide was less than the ADI for all population groups at the mean and 90th percentile of exposure, when using the conservative assumption that all imported foods were exposed to methyl bromide.

To gain a more realistic estimate of exposure to inorganic bromide from use of methyl bromide for New Zealand, FSANZ sourced figures from the Statistics New Zealand website on the percentage of individual cereals, fruit and vegetables with high consumption levels that are imported into New Zealand from developing countries that belonged to the top 5 contributors to inorganic bromide dietary exposures for 5 to 14 year olds.

These were cereal (29%), pome fruits (13%), sugar cane molasses (12%), citrus fruits (11%) and root and tuber vegetables (8%), see Table 17.

Developing countries were classified as low to middle income economies based on the World Bank List of Economies web link accessed on 18 July 2011. The percentage (by weight) of the selected imported commodities from developing countries was well under 10%:

- apples 6%
- pear 6%
- oranges <1%
- sugar cane molasses <1%
- wheat <1%
- carrots 0%
- mandarin 0%
- potato 0%

FSANZ revised the import multiplication factor for these selected foods to account for the low proportion of foods likely to contain methyl bromide due to the low proportion of imports from developing countries to New Zealand and possible critical use exemptions from all other developed nations, by assuming a maximum of 10% of imported foods could have been exposed to methyl bromide (multiplication factor of 0.1, see Table 11).

$$\text{Revised import multiplication factor} = \frac{\text{Percentage imports (rounded } \textbf{up} \text{ to nearest 5\%)}}{100} \times 0.1$$

***Equation 3**: Calculation of revised import multiplication factors for inorganic bromide*

The final inorganic concentrations (B) used in the assessment can be found in Table 11.

Table 11: Final inorganic bromide concentrations (B) for NZ foods

Commodity	Inorganic bromide concentration from MRL or Standard 1.3.3 (mg/kg)	Revised import multiplication factor	Final inorganic bromide concentration (B) (mg/kg)#
Apple	50	0.08	4
All foods (except those listed elsewhere)*	2	NA	2
Carrot	50	0.04	2
Cereals (except those listed elsewhere)	50	1.00	50
Fruits (except those listed elsewhere)	50	0.75	37.5
Herbs	50	1.00	50
Mandarins	50	0.08	4
Oranges	50	0.08	4
Pear	50	0.08	4
Plant products (except those listed elsewhere)	50	1.00	50
Potato	50	0.04	2
Pulses	50	0.45	22.5
Root and tuber vegetables	50	0.35	17.5
Spices	400	1.00	400
Sugar cane molasses	50	0.10	5
Tea	50	1.00	50
Tree nuts	200	1.00	200

Commodity	Inorganic bromide concentration from MRL or Standard 1.3.3 (mg/kg)	Revised import multiplication factor	Final inorganic bromide concentration (B) (mg/kg)#
Vegetable (oil)	50	1.00	50
Vegetables (except those listed elsewhere)	50	0.15	7.5
Wheat	50	0.10	5

***** Arises from potential domestic use of BCDMH and DBDMH. No import factor applied.
[#] Bromide ion concentration for the food= (MRL or Standard 1.3.3 bromide ion concentration) x revised import multiplication factor

The final dietary exposure estimates for the New Zealand population groups are given in Tables 12 and 13.

Table 12: Mean and 90th percentile estimated dietary exposure to inorganic bromide (mg/kg bw/day) for all New Zealand population groups assessed (refined estimate)

Age (years)	Inorganic bromide dietary exposure (mg/kg bw/day)	
	Mean	**P90**
5-14	0.36	0.64
15 and above	0.23	0.42

Table 13: Mean and 90th percentile estimated dietary exposure to inorganic bromide (% ADI) for all New Zealand population groups assessed (refined estimate)

Age (years)	Inorganic bromide dietary exposure as a % ADI	
	Mean	**P90**
5-14	35	65
15 and above	25	40

Note that the ADI for inorganic bromide is 1 mg/kg bw/day.

The DEA could be further refined by repeating this process for all imported foods, except meat (already excluded), rather than just for the major contributors to inorganic bromide exposure. However, the resources required were not justified as results in Table 13 indicate dietary exposure estimates for inorganic bromide are well below the ADI at the mean and 90th percentile of exposure.

4.2.3 Major food contributors

Major foods contributing to DMH and inorganic bromide dietary exposures have not been included in the assessment. This is because all foods were included in the modelling which is highly unlikely to reflect any potential DBDMH usage.

4.3 Dietary Exposure Assessment Conclusion

The DEA indicates that uses of DBDMH at the levels proposed in the application and estimated exposures to breakdown products DMH and inorganic bromide from all potential sources would not result in any exceedances of the respective reference health standards.

Predicted 90th percentile exposure to DMH was less than 10% of the ADI for all population groups assessed

Predicted 90th percentile dietary exposure to inorganic bromide was at 65% or less of the ADI for children and 40% or less of the ADI for adults in Australia and New Zealand. Mean dietary exposure was at 45% or less of the ADI across all population groups in Australia and New Zealand.

5. Risk Characterisation

Comparisons of the dietary exposure to inorganic bromide with the ADI of 0-1 mg/kg bodyweight indicated that for all groups of Australian and New Zealand consumers assessed (including children), estimated dietary exposures were below this safe level of exposure. The estimated mean dietary exposures for consumers who may be exposed to inorganic bromide correspond to 35% of the ADI for Australian children aged 2-6 years, 20% of the ADI for Australian children aged 7-16 years, 10% of the ADI for Australians aged 17 and above, 30% of the ADI for New Zealand children aged 5 to 14 years, and 20% of the ADI for New Zealanders aged 15 and above. The estimated 90th percentile dietary exposures for consumers who may be exposed to inorganic bromide correspond to 55% of the ADI for Australian children aged 2-6 years, 30% of the ADI for Australian children aged 7-16 years, 20% of the ADI for Australians aged 17 and above, 60% of the ADI for New Zealand children aged 5 to 14 years, and 40% of the ADI for New Zealanders aged 15 and above.

Comparisons of the dietary exposure to DMH with the ADIs of 0-3 mg/kg bw for the general population and 0-1 mg/kg bw for females of reproductive age indicated that estimated dietary exposures correspond to less than 10% of the ADIs for all Australian and New Zealand population groups assessed, including children.

The above comparisons raise no public health and safety concerns for the use of dibromo-dimethylhydantoin as a processing aid which results in residues of inorganic bromide and dimethylhydantoin that are at or below the proposed maximum permitted levels of 2.0 mg/kg in the final food.

6. Conclusions

DBDMH functions as an antimicrobial agent suitable for the treatment of poultry and meat products. In aqueous solution DBDMH hydrolyses to form hypobromous acid which possesses antimicrobial activity, and DMH. Hypobromous acid subsequently degrades to inorganic bromide which, along with DMH, can remain as residues in the treated food.

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, 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 which results in residues of inorganic bromide and DMH that are at or below the proposed maximum permitted levels.

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Appendix 1: Dietary Exposure Assessments at FSANZ

A DEA is the process of estimating how much of a food chemical a population, or population sub group, consumes. Dietary exposure to food chemicals (or intake of nutrients) is estimated by combining food consumption data with food chemical concentration data. The process of doing this is called 'dietary modelling'.

Dietary exposure = food chemical concentration x food consumption

FSANZ's approach to dietary modelling is based on internationally accepted procedures for estimating dietary exposure to food chemicals. Different dietary modelling approaches may be used depending on the assessment, the type of food chemical, the data available and the risk assessment questions to be answered. In the majority of assessments FSANZ uses the food consumption data from each person in the national nutrition surveys to estimate their individual dietary exposure. Population summary statistics such as the mean exposure or a high percentile exposure are derived from each individual person's exposure.

An overview of how DEAs are conducted and their place in the FSANZ Risk Analysis Process is provided on the FSANZ website at:
http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/dietaryexposureandin4438.cfm

FSANZ has developed a custom built computer program 'DIAMOND' to calculate dietary exposures. More information on DIAMOND is available on the FSANZ website at:
http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/fsanzdietaryexposure4439.cfm

Further detailed information on the principles and practices of conducting DEAs at FSANZ is provided in Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ, 2009), available at:
http://www.foodstandards.gov.au/_srcfiles/Principles%20&%20practices%20exposure%20assessment%202009.pdf

Food consumption data used

The most recent food consumption data available were used to estimate exposures to DMH and inorganic bromide for the Australian and New Zealand populations. The national nutrition survey (NNS) data used for these assessments were:

- The 2007 Australian National Children's Nutrition and Physical Activity Survey (also known as 'Kids Eat Kids Play') (2007 NCNPAS)
- The 1995 Australian National Nutrition Survey (1995 NNS).
- The 2002 New Zealand National Children's Survey (2002 NZNNS).
- The 1997 New Zealand National Nutrition Survey (1997 NZNNS)

The estimated dietary exposure results for Australian children aged 2-16 years were reported using the 2007 NCNPAS. For the population aged 17 years and above and females aged 13-49 years, the 1995 NNS was used. The design of each of these surveys varies somewhat and key attributes of each are set out below. Similarly, dietary exposures were estimated for New Zealand children aged 5-14 years using the 2002 NZNNS. For the population aged 15 years and above and females aged 15-50 years, the 1997 NZNNS was used.

2007 Australian Children's Nutrition & Physical Activity Survey (2007 NCNPAS)

The 2007 NCNPAS collected data on nutrition (including foods consumed and dietary supplements) and physical activity for 4,487 children aged 2-16 years across Australia. The survey was conducted over a seven month time period, from February to August 2007.

In contrast to other national nutrition surveys used to date by FSANZ (the 1995 Australian and 1997, 2002 New Zealand surveys), in the 2007 NCNPAS each respondent completed two 24 hour recalls on non-consecutive days. The availability of two days of food consumption data provides a more realistic estimate of long term consumption of infrequently consumed foods, because it takes account of those who may eat a food on one day of the survey but not on the other. Using one 24-hour recall may capture an unusual eating occasion for an individual that does not describe how they normally eat.

In this assessment, exposures to DMH and inorganic bromide were estimated from each consumer's average exposures from foods potentially containing the chemicals across Day 1 and Day 2. The results of the 2007 NCNPAS were weighted to represent the overall population of Australian children because stratified sampling with non-proportional samples was used in the survey.

1995 Australian National Nutrition Survey (1995 NNS)

The 1995 NNS provides comprehensive information on dietary patterns of a sample of 13,858 Australians aged from 2 years and above (McLennan & Podger 1998). It is the most recent NNS for Australians aged 17 years and above. The survey used a 24-hour recall method for all respondents, with 10% of respondents also completing a second 24-hour recall on a second, non-consecutive day. Food frequency data are available for a subset of the national sample (respondents aged 12 years and above) as are responses to a series of short dietary questions about food habits. These data are used unweighted in DIAMOND.

2002 New Zealand National Nutrition Survey (2002 NZNNS)

The 2002 New Zealand Children's National Nutrition Survey provides comprehensive information on the dietary patterns of a nationally representative sample of 3,275 New Zealand children aged 5-14 years, including sufficient numbers of children in the Māori and Pacific groups to enable ethnic-specific analyses. The survey was conducted using a 24-hour recall methodology and collected data on dietary supplements as well as foods and beverages. A repeat 24-hour diet recall was obtained from a subsample of 15% of respondents, which enabled the statistical adjustment of the data to present the 'usual' intake distribution for nutrients by subgroup. The results of the 2002 NZNNS were weighted to represent the overall population of New Zealand children because stratified sampling with non-proportional samples was used in the survey.

1997 New Zealand National Nutrition Survey (1997 NZNNS)

The 1997 NZNNS provides comprehensive information on the dietary patterns of a sample of 4,636 respondents aged from 15 years and above. The survey was conducted on a stratified sample over a 12 month period. The survey used a 24-hour recall methodology with 15% of respondents also completing a second 24-hour recall with an additional food frequency questionnaire and questions on food consumption patterns. These data are used unweighted in DIAMOND.

Further information on the National Nutrition Surveys used to conduct DEAs is available on the FSANZ website at:

http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/foodconsumptiondatau4440.cfm

Change in approach for ‘high consumers’

Because of the exaggeration of extremes of consumption that arise where estimates of dietary exposure are based on food consumption data from one or two days of single 24-hour recall from NNSs, FSANZ has adopted a policy that a high consumer’s chronic dietary exposure is best represented by the 90th percentile of exposure. This replaces the previous standard use of the 95th percentile and is in line with international best practice. For further information on the use of the 90th percentile for DEAs, refer to the FSANZ information paper: Protecting ‘high consumers’ (FSANZ 2009b).

For more information on FSANZ DEA principles, methodology, assumptions and limitations and uncertainties of the concentration and food consumption data, see the FSANZ document, Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009a).

Limitations of dietary exposure assessments

DEAs based on 2007 NCNPAS, 1995 NNS, 2002 NZNNS and 1997 NZNNS food consumption data provide the best estimates of actual consumption of a food and the resulting estimated dietary exposure for Australian children aged 2-16 years, Australian adults aged 17 years and above, New Zealand children aged 5-14 years and the New Zealand population aged 15 years and above, respectively. However, it should be noted that NNS data do have limitations. Further details of the limitations relating to DEAs undertaken by FSANZ are set out in the FSANZ document, Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009a).