20 September 2000
05/01

FULL ASSESSMENT REPORT AND REGULATORY IMPACT STATEMENT

APPLICATION A393

BROMO-CHLORO-DIMETHYLHYDANTOIN (BCDMH) AS A PROCESSING AID

EXECUTIVE SUMMARY

- ANZFA received an application on 29 June 1999 from Wobelea Pty Ltd to amend the *Food Standards Code* so as to permit the use of bromo-chloro-dimethylhydantoin (BCDMH) as a processing aid in Standard A16.

- Five submissions were received in response to the preliminary assessment (section 14) notice. Three of these supported the application while the other two reserved their position pending a full toxicological and technical assessment by ANZFA.

- The scientific evaluations indicated that there are no public health and safety concerns with the use of BCDMH as a washing agent and its use is technologically justified. The New Food Standards Code proposes changes to Standard A16 are consistent with ANZFA's section 10 objectives. The requested changes should be implemented and commence on gazettal.

- The Regulatory Impact Statement supports the requested amendments and concludes that the preferred option is Option 2, to permit BCDMH as a processing aid in Standard A16.

OBJECTIVES AND BACKGROUND OF THE APPLICATION

This application seeks approval of bromo-chloro-dimethylhydantoin (BCDMH) as a processing aid in Standard A16 of the Australian *Food Standards Code*. Standard A16 regulates water-disinfecting agents (such as chlorine, ozone and chlorine dioxide), in Table II, Group II - Bleaching Agents, Washing and Peeling Agents and in Table VI-Processing Aids Used in Packaged Water and in Water Used as an Ingredient in Other Foods.

The proposed use of BCDMH is for sanitising water used to wash fruit and vegetables, both post harvest and in the production of minimally processed fruit and vegetable products. Currently, chlorine is the agent most commonly used for this purpose mainly through the use of hypochlorites. The use of chlorine, however, has some disadvantages such as difficulty in controlling effective levels with varying pH, corrosion of water systems, and product tainting and spotting. Other compounds, which have also been widely used for water sanitation, are ozone and chlorine dioxide but they also present disadvantages such as worker safety and cost. This application seeks to include BCDMH in Standard A16 as an alternative washing agent to these compounds.

RELEVANT PROVISIONS

Australian Food Standards Code:

- **Standard A16** – Processing Aids.

There are no provisions in the New Zealand Food Regulations for processing aids.

Codex does not regulate the use of processing aids but does maintain an Inventory of Processing Aids. BCDMH is not included in this inventory, though nor are other water treatment agents such as chlorine, ozone and chlorine dioxide.

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) evaluated BCDMH and registered its use in post-harvest wash systems as an agricultural chemical. It is currently listed in Table 5 of the NRA's *MRL Standard* – Uses of substances where maximum residue limits are not necessary.

PUBLIC CONSULTATION

A notice requesting public comment was posted on 15 September 1999 and submissions closed on 27 October 1999.

Submissions were received from the New Zealand Ministry of Health, Food Technology Association of Victoria, InforMed Systems, National Council of Women of New Zealand and the Western Australian Food Advisory Committee (WAFAC). The main issues raised are summarised below.

Western Australia Food Advisory Committee

WAFAC had previously requested information as to whether there is a withholding period (WHP) for BCDMH, as the information provided at preliminary assessment suggested that BCDMH is registered for use in situations where the residues are identical or indistinguishable from natural food components. The Committee suggested that claims of low residue levels detailed in the preliminary assessment report should be considered in regard to the effect of a WHP.

The Committee was concerned that only a comparative assessment against hypochlorite and not against other bactericidal compounds such as quaternary ammonium compounds or chlorine dioxide solution had been made. However, WAFAC also noted the claim that BCDMH has a very low phytotoxicity and remains active over a wide pH range when compared to calcium hypochlorite and **supported the application** on this basis.

InforMed Systems Ltd

InforMed Systems were of the view that this was not a simple application and that the safety of BCDMH should be established before any recommendation is made.

New Zealand Ministry of Health

The NZ Ministry of Health's submission raised concern as to whether the correct classification of BCDMH is as a processing aid and not a food additive. Further comment on this application was not provided as the Ministry of Health wishes to consider ANZFA's assessment of the technical and toxicological data before making a more informed response.

National Council of Women of New Zealand

The National Council of Women of New Zealand noted the benefits BCDMH may provide over products such as calcium hypochlorite, and would not oppose the application provided the toxicological report determined no safety concerns.

Food Technology Association of Victoria Inc.

The Food Technology Association of Victoria supported the application, providing the toxicology report was acceptable.

OPTIONS

1. Maintain the *status quo* and not permit the use of BCDMH as processing aid.

2. Amend Standard A16 to permit the use of BCDMH as a processing aid (washing agent).

SCIENTIFIC ASSESSMENT

Toxicological Report (Refer to Attachment 3)

There appears to be limited toxicological concerns from the use of BCDMH as a processing aid for use as sanitising water used to wash fruit and vegetables. A provisional ADI for DMH (the major residue of BCDMH) was established using the NOEL from the best available sub-chronic study and using a safety factor of 2000. Based on this ADI, dietary intakes calculations show that only 42% of the ADI would be reached.

ANZFA also performed a dietary exposure calculation (using DIAMOND) based on residues in fruit and vegetables of DMH and conservative values in other commodities for inorganic bromide (50 mg/kg for cereal grains and 400 mg/kg for spices). A total dietary exposure was calculated at 0.16mg/kg bw/day (16% of ADI for bromide) for average consumers and 0.39mg/kg bw/day (38% of ADI for bromide) for high consumers (95th percentile).

In conclusion, considering the available toxicological and dietary exposure data and the current Table 5[1] entry in the NRA's *MRL Standard*, there are no toxicological grounds not to approve BCDMH as a processing aid in Standard A16.

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[1] Table 5 – Uses of substances where maximum residue limits are not necessary, is used in situations where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or are otherwise of no toxicological significance.

Food Technology Report (Refer to Attachment 4)

At present there are a number of agents which may be used for the disinfection of water used in the food industry such as chlorine (hypochlorites), chlorine dioxide and ozone. The sanitisers used primarily for both the postharvest washing of fruit and vegetables and in fruit and vegetable processing are hypochlorites. However, while providing a relatively cheap and effective means of controlling the microbiological quality of wash waters, the use of hypochlorites (particularly calcium hypochlorite) has several disadvantages. These include:

- difficulty in maintaining an effective concentration at pH levels above pH 7.5;
- corrosion of water and packaging systems;
- problems with use in heated water systems; and
- calcium spotting and tainting of produce.

The use of chlorine dioxide can overcome some of the disadvantages of hypochlorites in that it is effective within a broader pH range (pH 6.0-8.0), and it is non-tainting and non-corrosive at the levels used. However, because it is unstable and needs to be generated on site it is a more expensive option than hypochlorites. Ozone is also relatively unaffected at pH range 6.0-8.0 and is very effective at low concentrations. It is also unstable and, like chlorine dioxide, needs to be generated on site. Occupational health and safety concerns with the use of ozone in the food industry may be a determining factor in its use.

BCDMH is a stable compound, effective across a broad pH range and at much lower concentrations than chlorine. BCDMH would provide a viable alternative to the use of other disinfecting agents such as hypochlorites, chlorine dioxide and ozone, presently listed in Group II of Standard A16.

Residues

BCDMH breaks down to produce hypobromous and hypochlorous acids (which would lead to the formation of halides on the treated produce) and dimethylhydantoin (DMH), with DMH being the major residue. Based on the available residue data supplied by the NRA, residues of DMH would be lower than 1 mg/kg on produce passing through dip solutions of BCDMH at the proposed levels of use. Theoretical “maximum” residues of 2 mg/kg may result in vegetables such as broccoli.

Standard A14 of the *Food Standards Code* sets residue levels for inorganic bromide of 20 mg/kg in fruits and vegetables. Residues of inorganic bromide resulting from the use of BCDMH would be far below this value. Chlorine residues should be, similarly, quite low and well below the 1.0 mg/kg (available chlorine) limit applied to other chlorine compounds listed in Table II, Group II processing aids in Standard A16.

Based on the available residue data and to be consistent with existing residue limits, it is proposed that residue limits of 2.0 mg/kg (dimethylhydantoin), 1.0 mg/kg (available chlorine) and 1.0 mg/kg (inorganic bromide) are listed beside BCDMH in Table II, Group II of Standard A16.

EVALUATION OF ISSUES RAISED IN PUBLIC SUBMISSIONS

- **Withholding period for BCDMH**

BCDMH is already registered for use as an agricultural chemical by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) and can legally be used on fruits and vegetables in post-harvest wash systems. ANZFA approached the NRA with respect to information on the withholding period (WHP). The NRA advised ANZFA that there was some limited residue data however, because of the products listing in Table 5 of the *MRL Standard* (where residues do not or should not occur in foods; or where the residues are identical or indistinguishable from natural food components; or are otherwise of no toxicological significance), there was no allocated WHP.

- **Assessment of BCDMH against other washing agents**

A comparison of BCDMH against chlorine, ozone and chlorine dioxide was made in the Food Technology Report. This report concluded that BCDMH was a viable alternative to these washing agents.

- **Safety of BCDMH**

Before recommending changes to the *Food Standards Code* any public health and safety concerns are identified and addressed. The toxicological report concluded that there were no toxicological concerns and that exposure to BCDMH is low (even in high consuming individuals) when estimates were made of total dietary intakes from residues that may occur in fruit and vegetables.

- **Classification of BCDMH as a processing aid**

A processing aid is defined in Standard A16 – Processing Aids of the *Food Standards Code* as “a substance 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”. One of the proposed uses of BCDMH is to sanitise the wash waters used for the production of minimally processed fruits and vegetables and to reduce the microbial load on the produce being treated. There are no residues of BCDMH on the final product that would have any technological effect. The use of BCDMH as a washing agent fulfils the definition of a processing aid.

REGULATORY IMPACT ANALYSIS

1. Issue identification

Alternatives to regulation are not considered appropriate with regard to the use of BCDMH as a water treatment agent. Currently, processing aids permitted for use in Australia are listed in Standard A16 of the *Food Standards Code*. New entries in the Tables to Standard A16 are required to undergo an evaluation to determine efficacy and to ensure that there are no public health and safety concerns with permitting their use. The standard is intended to reflect current use and to prohibit inappropriate use of processing aids.

Parties likely to be affected by the possible options as listed above are consumers, manufacturers and State/Territory and New Zealand Health Departments.

Option 1

- Maintain the *status quo* and not permit the use of BCDMH as processing aid.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefits	No perceived costs
Industry	No perceived benefits	There are other washing agents permitted for use, such as chlorine, which industry can currently use. The use of BCDMH, however, may result in lower treatment costs and less corrosion of equipment. Maintaining the status quo would deny industry any advantages that the use of BCDMH may give.
Consumers	No perceived benefits other than for individuals that wish to avoid all chemical residues that may be present in food and would therefore object to the use of any new agent.	An alternative water sanitiser to chlorine which should result in lower residues may be seen as desirable to consumers. Denying the use of BCDMH could be perceived as a cost in this context.

Option 2

- Amend Standard A16 to permit the use of BCDMH as a processing aid.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefit	No perceived cost
Industry	Permitting the use of BCDMH would provide food manufacturers with an alternative washing agent which could lower treatment costs and help minimise equipment corrosion.	Providing industry with a greater choice of washing agents would incur no costs.
Consumers	The microbiological safety and quality of minimally processed fruit and vegetable products has become of increasing importance. Increasing the choice of washing agents, which may assist this, would be of benefit to consumers. Chlorine is currently the most commonly used water treatment agent. Certain chlorine by-products, such as chloramines, are considered undesirable by consumers. Alternatives to the use of chlorine may therefore been seen as a benefit.	No perceived costs apart from the objection some individuals may have to the increase in number of chemical agents permitted for use on food.

2. Evaluation

Maintaining the *status quo* (Option 1) appears to provide no benefit to government, industry and consumers. Option 1 denies industry access to an alternative washing agent which is of low toxicity, is effective at lower concentrations than commonly used chlorine agents, and may contribute to lower production costs.

Option 2, which proposes to amend the *Food Standards Code* to permit the use of BCDMH as a processing aid, appears to impose no significant costs on government, industry or consumers and may be of benefit to industry and consumers.

Assessment of the costs and benefits of Options 1 and 2 indicates that there would be a net benefit in permitting the use of BCDMH as a processing aid.

ASSESSMENT OF ANZFA'S SECTION 10 OBJECTIVES

(a) the protection of public health and safety

Toxicological evaluation of BCDMH indicates that there are no significant public health and safety concerns associated with its use as a processing aid for water treatment.

(b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception

There is no requirement for labelling of processing aids in the *Food Standards Code*. Provision of this information would not be meaningful to consumers.

(c) the promotion of fair trading in food

If approved, BCDMH may be used by all members of the industry and no issues in relation to fair trading were raised. To not allow approval may disadvantage manufacturers.

(d) the promotion of trade and commerce in the food industry

The approval of BCDMH will provide industry with an alternative washing agent that may provide benefits over existing agents. This could facilitate trade and commerce in the food industry.

(e) the promotion of consistency between domestic and international food standards where these are at variance.

There is currently no approval for use of BCDMH as a processing aid in other countries. Codex does not have a processing aid standard but do maintain an Inventory of Processing Aids. Bromo-chloro-dimethylhydantoin is not included in this inventory, though nor is other washing agents such as chlorine dioxide, ozone and chlorine.

CONCLUSIONS

The full assessment report concludes that permitting the use of BCDMH as a washing agent is technologically justified and poses no significant risk to public health and safety.

Approval of BCDMH as a washing agent in Standard A16 will provide manufacturers with an alternative processing aid for the disinfection of water, which is non-corrosive at the levels used, remains effective at high pH (to pH 8.5), is more effective at lower concentrations and has a very low phytotoxicity.

WORLD TRADE ORGANISATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

In conclusion, the proposed variation to the Code constitutes a minor change to the Code and is not expected to impact on trade issues for either technical or sanitary or phytosanitary reasons. Therefore a notification to the World Trade Organization on grounds relating to the WTO **is not** required.

<u>Attachments to the Report:</u>

1. Draft Variation to the Australian *Food Standards Code*

2. Explanatory Notes

3. Toxicological Report

4. Food Technology Report

ATTACHMENT 1

DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE

To commence: On gazettal

Standard A16 *of the Food Standards Code is varied by:-*

(a) inserting in the Schedule Bromo-chloro-dimethylhydantoin in column 1 of Group II and 1.0 (available chlorine), 1.0 (inorganic bromide), 2.0 (dimethylhydantoin) in column 2.

Standard A11 *of the Food Standards Code is varied by:-*

Inserting-

Addendum 8 means *Addendum 8* to this standard;

Inserting in columns 1 and 2 respectively of the Schedule-

Bromo-chloro-dimethylhydantoin Addendum 8; *and*

inserting immediately after Addendum 7-

Addendum 8

SPECIFICATIONS FOR BROMO-CHLORO-DIMETHYLHYDANTOIN

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

Formula:	$C_5H_6BrClN_2O_2$
Formula weight:	241.5

Chemical Properties

Appearance:	Solid or free flowing granules
Colour:	White
Odour:	Faint halogenous odour
Melting Point	163-164^{0}C
Specific gravity	1.8-2
Solubility in water	0.2g/100g at 25ºC

Stability	Stable when dry and uncontaminated

Chemical Tests:

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.

Assay:

Procedure:	Various analytical methods exist for analysis, namely, GLC, HPLC, UV and NMR. HPLC offers the best sensitivity.

ATTACHMENT 2

EXPLANATORY NOTES - DRAFT

APPLICATION A 393 - Bromo-chloro-dimethylhydantoin (BCDMH) as a processing aid

FOR RECOMMENDING A VARIATION TO STANDARD A16-PROCESSING AIDS

The Australia New Zealand Food Authority has before it application **A 393** (received on 29 June 1999) from Wobelea Pty Ltd to amend the *Food Standards Code* so as to approve the use of bromo-chloro-dimethylhydantoin (BCDMH) as a processing aid (washing agent) in Standard A16. ANZFA has completed a full assessment of the application and has prepared draft variations to the Australian *Food Standards Code*.

At present there are a number of agents, which may be used for the disinfection of water used in the food industry such as chlorine (hypochlorites), chlorine dioxide and ozone. The sanitisers used primarily for both the postharvest washing of fruit and vegetables and in fruit and vegetable processing are hypochlorites. However, while providing a relatively cheap and effective means of controlling the microbiological quality of wash waters, the use of hypochlorites does present several disadvantages. These include:

- difficulty in maintaining an effective concentration at pH levels above pH 7.5;
- corrosion of water and packaging systems;
- problems with use in heated water systems; and
- calcium spotting and tainting of produce.

The use of other agents such as chlorine dioxide can overcome some of the disadvantages of hypochlorites in that it is effective within a broad pH range (pH 6.0-8.0), and is non-tainting and non-corrosive at the levels used. However, because it is unstable and needs to be generated on site it is a more expensive option than hypochlorites. Ozone is also relatively unaffected at pH range 6.0-8.0 and is very effective at low concentrations. It is also unstable and, like chlorine dioxide, needs to be generated on site. Occupational health and safety concerns with the use of ozone in the food industry may be a determining factor in its use.

BCDMH is a stable compound, effective across a broad pH range and at much lower concentrations than chlorine (proposed levels of use of BCDMH are 5-15 ppm). The approval of BCDMH as a washing agent in Group II of Standard A16 will provide manufacturers with an alternative processing aid for the disinfection of water, which may provide advantages over the agents currently used.

The toxicological evaluation of BCDMH concluded that, based on available toxicological and dietary exposure data, there were no health and safety concerns from the proposed use. Residue limits of 1.0 mg/kg available chlorine, 1.0 mg/kg inorganic bromine and 2 mg/kg dimethylhydantoin are proposed, based on the available residue data and consistent with good manufacturing practice.

PROPOSED DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE *(refer to drafting at Attachment 1)*

REGULATION IMPACT ANALYSIS

The Authority develops food regulations suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community, which includes the consumers, food industry and governments in both countries. The regulation impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Regulatory Practice*.

Consideration of the Regulatory Impact for this application concludes that the amendment to the Code is cost effective, of benefit to both producers and consumers, and is the preferred regulatory option.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter does not need to be notified to the WTO as a Sanitary or Phytosanitary (SPS) notification or a Technical Barriers to Trade (TBT) notification because it does not impact on human or animal health and will not have significant effect on the trade of other members.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code,* which will provide compositional and labelling standards for food in both Australia and New Zealand.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984.*

- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984,* but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984,* but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may be imported into Australia from New Zealand if it complies with the New Zealand *Food Regulations 1984* or *Dietary Supplements Regulations 1985.*
- **Food manufactured in Australia and sold in Australia** must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974,* and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has completed a full assessment of the application, prepared draft variations to the Australian *Food Standards Code* and will now conduct an inquiry to consider the draft variations and its regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A393** at one of the following addresses:

Australia New Zealand Food Authority	Australia New Zealand Food Authority
PO Box 7186	PO Box 10559
Canberra Mail Centre ACT 2610The Terrace	WELLINGTON 6036
AUSTRALIA	NEW ZEALAND
Tel (02) 6271 2222 Fax (02) 6271 2278	Tel (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by **18 October 2000.**

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.

ATTACHMENT 3

TOXICOLOGICAL REPORT

The National Registration Authority (NRA) provided a toxicological report on BCDMH (technical) produced in 1993 by the, then, Chemical Assessments Units of the Therapeutic Goods Administration (TGA). This was based on data that was submitted at the time of registration for approval for use of BCDMH in swimming pools, spas and hot tubs.

Following this initial registration for use and subsequent submission of appropriate new data, BCDMH was registered with the NRA for use as a biocide for fruits, vegetables and ornamentals in August 1997 (Table 5 entry). Under the NRA Table 5 regulations BCDMH is allowed only in situations where residues do not or should not occur in foods; or where the residues are identical or indistinguishable from natural food components; or are otherwise of no toxicological significance.

Metabolism

BCDMH (technical) is the source material used in Wobleleas' YM-FAB Nylate Halogen-based Broad Spectrum Biocide. BCDMH produces hypobromous acid (650 g/kg available bromine) and hypochlorous acid (260g/kg available chlorine) in water. The main stable degradation product in water is 5,5-dimethyl-2,4-imidazolidinedione (DMH) with bromide and chlorine produced at the same time.
DMH is considered to be the major residue in BCDMH treated produce.

Acute studies

Acute oral LD50s of BCDMH were 1037 and 860 mg/kg bw in male and female rats, respectively. Acute oral LD50s were cited as 7,800 mg/kg bw, 12,650 mg/kg bw and 8430 mg/kg bw in rats, rabbits and in guinea pigs, respectively.

Sub-chronic studies

Charles River CD rats (20/sex/group) received 0, 500, 5000 or 50,000 ppm DMH in drinking water for 13 weeks.

Ten males and 3 females in the high-dose group died. At high-dose animals showed thinness and emaciation, urogenital staining, hunching, decreased motor activity, ataxia, irritability and reduced bodyweight gains and food and water consumption. Histo-pathological changes in high-dose animals included atrophy of the thymus, spleen and lymph nodes, renal necrosis of the tip of the papilla, pelvic transitional cell hyperplasia, hyperplasia of the epithelial lining of the renal papilla, atrophy of the uterine wall and gastric necrotic inflammation.

The NOEL of 500 ppm was determined which corresponded to approximately 50mg/kg bw/day in the diet.

Based on this sub-chronic study and using a safety factor of 2000, an ADI of 0.025mg/kg bw/day can be established for DMH.

Genotoxicity studies

BCDMH was not mutagenic in *Salmonella typhimurium* strains at concentrations of 5-5000µg/plate, with or without S9 mix. However, the compound did induce base-pair substitutions in *E coli* at concentrations of 25-3000ug/plate, with or without metabolic activation.

DMH did not induce chromosome aberrations in CHO cells at concentrations of 10-800ug/ml, with or without metabolic activation, and did not induce unscheduled DNA repair in cultured human epithelioid cells at concentrations of 10-480ug/ml.

Other available studies

The applicant provided summaries of 2 other long-term carcinogenicity studies that have been undertaken on DMH in 1996 by Bromine Compounds Pty Ltd, Israel.

In an 18 month dietary study in mice and a 24 month study in rats it was concluded that tumour incidences were similar between the control and treated groups and did not reveal any changes related to the administration of DMH. The NOEL for both studies was greater than 1000mg/kg bw/day.

Dietary calculations and residue data

Presently no existing MRLs or residue definitions exist for BCDMH. However, MRLs for inorganic bromide for fruits and vegetables have been set at 20 mg/kg. The ADI for bromide is 1 mg/kg bw/day.

The NRA evaluated the available residue data provided by the applicant in various treated fruits and vegetables and concluded that maximum residues in treated vegetables were 2 mg/kg and in fruits 0.2 mg/kg (based on residues of the major degradation product DMH).

Based on the provisional ADI of 0.025mg/kg bw/day, the maximum residues of DMH in treated fruits and vegetables would result in a Theoretical Maximum Daily Intake (TMDI) of 42% of the ADI.

ANZFA has also performed a dietary exposure calculation (using DIAMOND) based on the above maximum residues in fruit and vegetables of DMH and conservative values in other commodities for inorganic bromide (50 mg/kg for cereal grains and 400 mg/kg for spices). A total dietary exposure was calculated at 0.16mg/kg bw/day (16% of ADI for bromide) for average consumers and 0.39mg/kg bw/day (38% of ADI for bromide) for high consumers (95^{th} percentile).

Interactions with other chemicals (drugs)

Hydantoins are used therapeutically, particularly as antiepileptic agents (diphenylhydantoins). The most widely used of these is phenytoin, marketed in Australia as the preparation Dilantin. Information obtained from the 1998 edition of MIMS indicated that the oral dosage for adults of Dilantin is 4 to 5 mg/kg bw/day in two to three divided doses and in children 5 mg/kg bw/day.

Phenytoin is extensively bound to plasma proteins and can be displaced by drugs competing for protein-binding sites, such as some analgesics. Drugs may also interact with phenytoin by inhibiting its metabolism – phenytoin hydroxylation is saturable and is therefore readily inhibited by agents, which compete for its metabolic pathways (this has been reported, for example, with some antibacterial agents). There is no information to indicate whether dimethylhydantoin (DMH) would interact with phenytoin in these ways. Looking at possible dietary exposure, however, shows that for high consumers of fruits and vegetables (worst case scenario), the intake of residues of DMH would be less than 0.39 mg/kg bw/day. Therefore, there would appear to be a >10-fold safety factor between consumption of BCDMH residues and levels of diphenylhydantoin which are used therapeutically (4 to 5 mg/kg bw/day).

Conclusions

There appears to be limited toxicological concerns from the use of BCDMH as a processing aid for use as sanitising water used to wash fruit and vegetables. A provisional ADI for DMH (the major degradation product of BCDMH) was established using the NOEL from the best available sub-chronic study and using a safety factor of 2000. Based on this ADI, dietary intakes calculations show that only 42% of the ADI would be reached.

In conclusion, considering the available toxicological data and the current Table 5 entry in the MRL standard there are no toxicological grounds not to approve BCDMH as a processing aid in Standard A16.

ATTACHMENT 4

BCDMH – Food Technology Evaluation

Bromo-chloro-dimethylhydantoin (BCDMH) is proposed for use as a processing aid (washing agent) for use in the post-harvest washing of fruits and vegetables and in the manufacture of minimally processed fruits and vegetables. The use of BCDMH is to sanitise the wash waters used and to reduce the microbial load on the produce being treated.

Fresh fruits and vegetables

Many fruits and vegetables are washed after harvest to remove dirt and organic debris prior to packing and storage. Fungicides may also be applied after washing. The quality of the water used in these washing, dipping or rinsing systems is paramount as wash water can harbour many fruit and vegetable pathogens.

Although many bacteria and fungi can cause postharvest rot of fruit and vegetables, the major postharvest losses are caused by species of the fungi *Alternaria*, *Botrytis*, *Diplodia*, *Monilinia*, *Mucor*, *Penicillium*, *Phomopsis*, *Rhizopus* and *Sclerotinia* and of the bacteria *Erwinia* and *Pseudomonas*. Postharvest infection results when these micro-organisms are able to invade produce via any break (often microscopic) in the skin, though it can also occur through direct penetration of the skin (eg. *Sclerotinia*).

Control of postharvest wastage is achieved through using specific storage temperatures (low or high depending on the produce), modified atmospheres, correct humidity, good sanitation and development of wound barriers. For some produce the application of fungicides may be used. When fruits and vegetables are subject to wash systems, disinfection of the wash water is critical for minimising exposure of the produce to fruit and vegetable pathogens.

A processing aid is defined in Standard A16 – Processing Aids of the Food Standards Code as "a substance used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment of processing, but does not perform a technological function in the final food". The post-harvest washing of fruits and vegetables does not meet the definition of a food processing operation in this context and therefore the use of BCDMH in post-harvest washing is as an agricultural chemical. The National Registration Authority for Agricultural and Veterinary Chemicals have evaluated BCDMH and registered its use in post-harvest wash systems as an agricultural chemical.

Minimally processed fruits and vegetables

For the purposes of this report, minimally processed fruits and vegetables are those that have undergone a minimal processing step such as trimming, peeling, slicing, shredding, washing or a combination of these. Such products include salad mixes, stir-fry mix, vegetable florets and pieces, diced fruits and bean shoots. These products are generally prepared and packaged for convenient consumption.

One of the main features of minimally processed fruits and vegetables include the presence of cut surfaces or damaged plant tissues which compromise shelf life by leading to enzymatic browning, white surface discolouration, senescence, degradation in texture and flavour, and microbial spoilage. Minimising these physiological activities is achieved through reducing physical damage, ensuring correct storage conditions and the use of chemical agents where permitted.

The rinsing of produce during the production of minimally processed fruits and vegetables is an important step in minimising physical damage. Washing with chlorinated water removes the enzymes and nutrients that are released during minimal processing and which coat exposed surfaces. If left, these exudates would result in rapid degradation. Washing also eliminates the majority of micro-organisms present, contributing to improved shelf life and, potentially, removing pathogenic bacteria that may be present.

A wide range and number of micro-organisms have been associated with minimally processed fruit and vegetable products including *Pseudomonas*, *Erwinia*, *Enterobacter* and *Bacillus* bacteria; yeasts such as *Cryptococcus*, *Rhodotorula* and *Candida*, and a wide range of moulds including *Fusarium*, *Alternaria*, *Mucor* and *Rhizopus*. Potential food-borne pathogens such as *Salmonella*, *Listeria monocytogenes*, *Escherichia coli* and *Clostridium botulinum* have also been isolated from a variety of these products.

Wash water quality

It is essential to maintain an effective concentration of a broad-spectrum antimicrobial agent in water used for washing fruit and vegetables to minimise the microbial load in the wash water and prevent re-contamination of product and to reduce as much as possible the microbial flora on the fruits and vegetables being treated. Several disinfecting compounds are available though chlorine compounds are the most widely used disinfectants for this purpose, being active across a wide microbial spectrum and relatively inexpensive. Tabled below are the main disinfecting compounds that may be used as washing agents, currently permitted by Standard A16 – Processing Aids.

Disinfecting Agent	Standard A16 permission
Chlorine	Group II – Bleaching Agents, Washing and Peeling agents
Chlorine dioxide	
Calcium hypochlorite	
Sodium chlorite	
Sodium hypochlorite	
Hydrogen peroxide	
Peracetic acid	
Ozone	
Sodium hydroxide	Generally permitted processing aids
Phosphoric & sulphuric acids	

An evaluation of the most commonly used water sanitising compounds – chlorine, ozone and chlorine dioxide – is provided below, along with an assessment of BCDMH.

Chlorine compounds

Calcium and sodium hypochlorites are the compounds most widely used for chlorination of wash waters. Sodium hypochlorites are generally sold as liquids, containing 10 to 14% available chlorine, and calcium hypochlorites are sold in powder form, containing about 30% available chlorine. When the hypochlorites are added to water they produce hypochlorous acid (HOCl), which is considered to be the germicidal agent. Germicidal activity is directly proportional to the concentration of unionised HOCl in the solution. The mode of action through which HOCl kills micro-organisms has not been clearly defined but involves it binding with cell proteins, interfering with cell metabolism and inhibiting enzymes.

The level of active chlorine (HOCl level) generally accepted, as the level to achieve disinfection in wash waters for fruit and vegetable processing is 100mg/kg. This level may vary depending on the produce and the likely pathogen load and on exposure time. Citrus fruit, for example, is very susceptible to decay by *Penicillium* and a chlorine concentration of 200 mg/kg is recommended to achieve sterilisation in wash water and dips. Maintaining an effective concentration of chlorine, however, is not easy. When hypochlorites dissolve in water both HOCl and hypochlorite ions are produced, the proportion of each being dependent on the pH of the solution.

1. $Cl_2 + H_20 \rightleftharpoons HOCl + H^+ + Cl^-$

2. $HOCl \rightleftharpoons H^+ + OCl^-$ (dissociation of hypochlorous acid dependent on pH)

At a pH of about 7.5, the proportion of HOCl drops significantly with increasing pH, decreasing the effective chlorine level. Keeping an effective concentration of HOCl in the wash water means, therefore, keeping effective pH control. Generally for disinfection purposes this is pH 7.2 to 7.6 where HOCL represents 47 to 69% of free available chlorine.

While the use of chlorine provides a relatively inexpensive and extremely effective means of disinfecting (if used correctly), it does have disadvantages. As discussed, the concentration of chlorine can be difficult to maintain. As water used in wash water systems for post-harvest washes may need to be sourced from a variety of sources including creeks, rivers and bore waters in which conditions may be alkaline (pH 8.2 +), this can decrease the effectiveness of chlorine. The continual dosing of wash systems with hypochlorites to maintain an effective concentration may also cause the accumulation of chloramines on fruit which cause tainting. In addition, the amount of debris present on produce can add to the formation of chlorinated by-products that can cause tainting and increase the demand on the biocide.

The use of hypochlorites can also cause corrosion in fruit bins, water systems and in-line packing equipment as chlorine is a strong oxidising agent. Calcium hypochlorite can be a particular problem in heated water systems such as tomato dump tanks where the deposition of calcium can effect the heater controls. Calcium spotting of produce, particularly dark fruits, can also result from the use of calcium hypochlorite.

Ozone

Ozone (O_3) is a strong antimicrobial agent, active in the gaseous or aqueous phase against bacteria, moulds, yeasts, parasites and viruses. It has been used for decades for the treatment of drinking water and municipal and industrial wastewater. When compared with chlorine and other disinfectants, lower concentrations of ozone and shorter contact times are sufficient in controlling or reducing microbial populations. It has, for example, been shown to be more effective against micro-organisms at concentrations of 0.64 – 1.11 ppm compared to Cl_2 at 100ppm.

Ozone decomposes in solution in a stepwise fashion, producing hydroperoxyl ($^{\cdot}HO_2$), hydroxyl ($^{\cdot}OH$) and superoxide ($^{\cdot}O_2^-$) radicals. The reactivity of ozone is attributed to the strong oxidising power of these free radicals. Having a high oxidation potential, ozone reacts with micro-organisms fast, resulting in a high death rate. This high reactivity, however, is also a disadvantage in using ozone as a disinfectant in the food industry because its instability makes it difficult to predict how ozone may react in the presence of organic matter. It is difficult to generalise that a particular concentration of ozone at a given rate will always be effective in inhibiting a definite concentration of micro-organisms in a food product.

The susceptibility of micro-organisms to ozone may vary depending on the pH of the medium, temperature, the presence of additives and the organic matter surrounding the cells. The stability of aqueous ozone increases with decreasing pH and ozone inactivation of micro-organisms seems to be enhanced at acidic pH values. Its effectiveness, however, is relatively unaffected at pH 6.0 to 8.0. Ozone decomposition is accelerated as temperatures increase and its solubility increases with decreasing temperature.

As ozone is extremely unstable, when it is used in industry it is usually generated at the point of application and in closed systems, largely through photochemical and electric discharge methods such as with a corona discharge ozone generator. Because of its extremely toxic effects when inhaled, ozone detection and destruction systems and respirators are also needed on site for the safety of workers. Other disadvantages that may result from using ozone include the surface oxidation of foods resulting in changes in the surface colour of some fruits and vegetables.

Chlorine dioxide

Chlorine dioxide (ClO_2) is a powerful oxidising agent, which readily dissolves in water to form a solution which is biocidal to a wide range of micro-organisms. Its applications in the food industry have included the sterilisation of fluming and can-cooling water and the control of taste and odour in process water used in soft drink bottling, brewing and distilling.

Chlorine dioxide is unstable and so is generated on site by reacting sodium chlorite with chlorine to form chlorine dioxide and sodium chlorite:

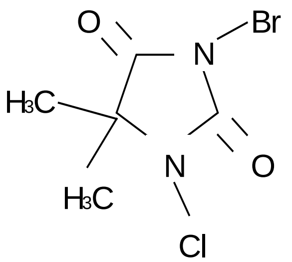
$$2NaClO_2 + Cl_2 \rightarrow 2ClO_2 + 2NaCl$$

Chlorine dioxide does not hydrolyse in water to form hypochlorous acid but remains dissolved as a gas and may decompose to its chlorite and chlorate ionic forms. There have been health concerns with the production of chlorate and chlorite by-products however recent technological advances have been able to overcome this by producing ClO_2 from the reaction of tetrachlorodecaoxide with HOBr (hypobromous acid).

Chlorine dioxide is largely unaffected by pH (is effective over the pH range 3 to 13) and is effective in waters with high organic levels. It acts by dissolving the cell wall of micro-organisms and has a much shorter kill time than liquid chlorine. ClO_2 is effective at much lower concentrations than chlorine (1-3 ppm) and does not cause problems with tainting and corrosion.

Bromo-chloro-dimethylhydantoin (BCDMH)

Bromo-chloro-dimethylhydantoin (BCDMH) has been used as an alternative compound to Cl_2 for water sanitising such as for spas, heated pools and cooling towers. When dissolved in water, BCDMH releases hypobromous (HOBr) and hypochlorous (HOCl) acids, which work synergistically in achieving sterilisation of water dips. BCDMH, however, has a low solubility and requires an erosion feeder to dissolve it in water.



Structural formula of BCDMH

The Br-N bond of BCDMH is weaker than that of the Cl-N bond so that Br^+ is first displaced from BCDMH when reacting with water:

1. $BCDMH + H_2O \rightarrow CDMH + HOBr$
2. $CDMH + H_2O \rightarrow DMH + HOCl$

This gives a quicker build up of HOBr than HOCl, contributing to a stronger immediate concentration of HOBr and a quicker killing effect against micro-organisms. After the dissociation of bromine, there is a slower release of chlorine from BCDMH, giving longer-term disinfection. After a period of time, an accumulation of DMH (dimethyl hydantoin) occurs because of the hydrolysis of the N-halogen bonds. If the DMH concentration builds to a level which impedes further reaction, the longer term disinfection activity of BCDMH is compromised. This may be addressed by draining off some water and adding fresh water.

Bromine enhances the disinfectant activity of chlorine, allowing less chlorine to be used. BCDMH is therefore more active at lower concentrations than, for example, calcium hypochlorite. The levels of use for both post-harvest washing and use on minimally processed fruit and vegetables is proposed at between 5 – 15 mg/L, much less than that needed with hypochlorites.

BCDMH has been shown to be completely effective at eliminating high concentrations of *Penicillium* spores (up to 10^7 cfu[2]/ml) at concentrations of 5 to 7 mg/L BCDMH with a contact time of 10 to 15 minutes. Evaluations testing the effectiveness of BCDMH against test suspensions (inoculum density 10^5 – 10^6 organisms per ml) of *Staphylococcus aureus*, *Escherichia coli*, *Listeria monocytogenes* and *Salmonella kahla* have shown a 99.9% kill rate using BCDMH concentrations of 10 ppm (measured as chlorine) and contact times less than 5 minutes[3].

As the level of use of BCDMH is much less than that of hypochlorites, there are fewer problems with equipment corrosion and tainting. In addition, the disinfectant activity of BCDMH is not as affected by pH changes as chlorine so that its use in alkaline wash waters (e.g. pH 8.5) does not decrease its effectiveness.

Conclusions

At present there are a number of agents, which may be used for the disinfection of water used in the food industry such as chlorine (hypochlorites), chlorine dioxide and ozone. The sanitisers used primarily for both the postharvest washing of fruit and vegetables and in fruit and vegetable processing are hypochlorites, particularly calcium hypochlorite. However, while providing a relatively cheap and effective means of controlling the microbiological quality of wash waters, the use of hypochlorites does present several disadvantages. These include:

- difficulty in maintaining an effective concentration at pH levels above pH 7.5;
- corrosion of water and packaging systems;
- problems with use in heated water systems; and
- calcium spotting and tainting of produce.

The use of chlorine dioxide can overcome some of the disadvantages of hypochlorites in that it is effective within a broad pH range (pH 6.0-8.0), and is non-tainting and non-corrosive at the levels used. However, because it is unstable and needs to be generated on site it is a more expensive option than hypochlorites. Ozone is also relatively unaffected at pH range 6.0-8.0 and is very effective at low concentrations. It is also unstable and, like chlorine dioxide, needs to be generated on site. Occupational health and safety concerns with the use of ozone in the food industry may be a determining factor in its use.

BCDMH is a stable compound, effective across a broad pH range and at much lower concentrations than chlorine. BCDMH would provide a viable alternative to the use of other disinfecting agents such as hypochlorites, chlorine dioxide and ozone, presently listed in Group II of Standard A16.

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[2] Colony forming units

[3] Microbiological evaluations supplied by the applicant and conducted by Microtech Laboratories Pty Ltd.

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