

2-04
17 March 2004

FIRST REVIEW REPORT

APPLICATION A476

ACIDIFIED SODIUM CHLORITE AS A PROCESSING AID

1. Objectives of Review

The Australia and New Zealand Food Regulation Ministerial Council have requested a First review of a draft variation to Standard 1.3.3 – Processing Aids, of the *Australia New Zealand Food Standards Code*, clarifying approval for the use of sodium chlorite as a processing aid. FSANZ was required to review the decision by 2 March 2004.

Application A476 – Acidified sodium chlorite as a processing aid, seeks amendment of Standard 1.3.3 to clarify the regulatory status of acidified sodium chlorite and the maximum permitted residual level of sodium chlorite (currently provided in units of available chlorine).

The review is sought on the grounds that the draft standard –

- (a) does not protect public health and safety; and
- (b) does not promote consistency between domestic and international food standards where these are at variance.

2. Options

There are 3 options proposed for consideration under this Review:

- 1. reaffirm approval of the draft variations to Standard 1.3.3 of the Code as notified to the Council; or
- 2. reaffirm approval of the draft variations to Standard 1.3.3 of the Code subject to amendments relating to the review grounds as notified by the Council; or
- 3. withdraw approval of the draft variations to Standard 1.3.3 of the Code as notified to the Council.

3. Review on grounds requested by the Ministerial Council

3.1 Protection of public health and safety

Public health and safety is protected by the clarification of the permission for sodium chlorite. Sodium chlorite is currently permitted in the Code under Standard 1.3.3 - Processing Aids for use in bleaching, washing and peeling.

The safety assessment report of the Final Assessment Report for Application A476 concluded that if acidified sodium chlorite is used under the conditions considered to be Good Manufacturing Practice (GMP) that no residues would be detected in the raw foods following treatment and prior to sale and therefore there would be no toxicological concerns. There has been no additional information produced after final assessment that would modify this conclusion. There are no significant public health and safety concerns associated with the use of the antimicrobial agent.

3.2 Promoting consistency between domestic and international food standards where these are at variance.

Approval promotes consistency with international food standards. Processing parameters (such as pH and treatment concentration) are not generally specified in Standard 1.3.3 – Processing aids which is consistent with the principle of minimum effective regulation.

There are no international food standards for sodium chlorite as a processing aid. The United States permits sodium chlorite as an indirect food additive and provides processing parameters stated for its GRAS status. In the United States - Code of Federal Regulations Volume 21, 173.325 approves a range of acidified sodium chlorite solutions of 500 to 1200 ppm at a pH of 2.3 to 2.9 for poultry meats; red meats; processed, comminuted or formed meat products; intact fruits and vegetables; and processed fruit and vegetables. Seafood is permitted to be treated at 50 ppm of acidified sodium chlorite.

Processing parameters (such as pH and treatment concentration) could be prescribed within the standard. However, this would be inconsistent with how other processing aids are regulated. It would be inconsistent to include processing parameters in the Code – under Standard 1.3.3 which would establish a precedent for future processing aid applications. To prescribe the processing parameters for acidified sodium chlorite is not necessary, as its use could be more effectively managed by requiring a maximum permitted residue level to the limit of determination.

4. Impact analysis

The parties affected by this First Review are consumers, manufacturers and governments. FSANZ finds that there is no apparent difference between the likely impacts of Option 1 and Option 2. The impact analysis finds both options protect public health and safety and both promote consistency between domestic and international food standards where these are at variance. Option 1 most closely delivers the specific objectives of this First Review given it also achieves the objective of minimum effective regulation.

Option 3 to withdraw approval of the draft variations would be inconsistent as sodium chlorite is already approved as a processing aid in Standard 1.3.3 and this application seeks to clarify that permission.

The preferred option is therefore Option 1.

5. Conclusion and recommendation

Option 1 is the preferred option as it is more effective in meeting the specific objectives of this First Review. Therefore, it is recommended that the Board reaffirm its approval of the draft variations to Standard 1.3.3 Processing aids, which clarify but maintain the permission of sodium chlorite as a processing aid, to be adopted into the Code for the following reasons:

5.1 Statement of Reasons

- the approval protects public health and safety with regard to the use of acidified sodium chlorite;

- the approval promotes consistency between domestic and international food standards where these are at variance;
- the proposed variation is not expected to significantly affect costs to the public, government or industry;
- the proposed variation will reduce uncertainty for food manufacturers, and clarify the regulation for enforcement purposes, resulting in increased compliance with the Code and greater confidence in the Australian and New Zealand food standards setting system; and
- the preferred option is consistent with the principle of minimum effective regulation.

Attachments

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

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

To commence: on gazettal

[1] **Standard 1.3.3** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *inserting in the* Table to clause 14 –

Sodium chlorite	Anti-microbial agent for meat, fish, fruit and vegetables	Limit of determination of chlorite, chlorate, chlorous acid and chlorine dioxide
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[1.2] *inserting after the* Table to clause 14 -

Editorial note:

The limit of determination is the lowest concentration of a chemical that can be qualitatively detected using a laboratory method and/or item of laboratory equipment (that is, its presence can be detected but not quantified).