

27 May 2010
[12-10]

APPLICATION A1020 PRESENCE OF 4-HEXYLRESORCINOL IN COOKED CRUSTACEA ASSESSMENT REPORT

Executive Summary

Purpose

4-hexylresorcinol is currently a generally permitted food additive for use in uncooked crustacea. However, at the time Application A1020 (the Application) was received, it was unclear whether the *Australia New Zealand Food Standards Code* (the Code) permitted the presence of 4-hexylresorcinol in cooked crustacea as a result of carry-over from its permitted addition to raw crustacea.

The Application sought to amend Schedule 2 (Miscellaneous Additives permitted in accordance with GMP in processed foods specified in Schedule 1) of Standard 1.3.1 (Food Additives) of the Code to permit the presence of 4-hexylresorcinol in cooked crustacea.

Assessing the Application

In assessing the Application, Food Standards Australia New Zealand (FSANZ) has had regard to the matters prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Decision

To reject the Application because it does not warrant the variation of a food regulatory measure on the basis that the problem raised in the Application has already been addressed by an amendment to the Code made as part of Proposal P1008 – Code Maintenance VIII.

Reasons for Decision

- At the time the Application was received there was reasonable doubt whether the Code permitted the presence of 4-hexylresorcinol in cooked crustacea as a result of carry-over from its permitted addition to raw crustacea.
- After FSANZ received the Application, FSANZ addressed this issue by amending clause 7 (Carry-over of food additives) of Standard 1.3.1 of the Code, as part of Proposal P1008 – Code Maintenance VIII.

- Clause 7 of Standard 1.3.1 now provides:

Other than by direct addition, a food additive may be present in any food as a result of carry-over from a raw material or an ingredient, provided that the level of the food additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice

- Clause 7 of Standard 1.3.1 therefore clarifies the permission of the presence of 4-hexylresorcinol in cooked crustacea as a result of carry-over from its permitted addition to raw crustacea.

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Introduction

On 5 January 2009, FSANZ received Application A1020 from Seafarm Pty Ltd (the Applicant).

The Application sought the addition of the food additive 4-hexylresorcinol (INS 586) to Schedule 2 (Miscellaneous Additives permitted in accordance with GMP in processed foods specified in Schedule 1) of Standard 1.3.1.

The ground for the Application was that although the Code permitted the addition of 4-hexylresorcinol to uncooked crustacea, the resulting treated crustacea could not be cooked prior to consumption because the presence of 4-hexylresorcinol in cooked crustacea was not permitted by the Code.

1. The Issue / Problem

4-hexylresorcinol is a food additive permitted to be used for uncooked crustacea, and is used to maintain the raw product's quality by stopping the flesh darkening (melanosis).

Because the presence of 4-hexylresorcinol in cooked crustacea was not expressly permitted, it was unclear whether 4-hexylresorcinol could be present in cooked crustacea as a result of carry-over from the raw material.

2. Current Standard

At the time this Application was received, clause 7 (Carry-over of food additives) of Standard 1.3.1 commenced with

Other than by direct addition, a food additive may be present in any food as a result of carry-over from an ingredient

In the period since this Application was received, FSANZ promulgated various amendments to the Code in Proposal P1008 – Code Maintenance VIII. One of the changes was to clause 7 of Standard 1.3.1, partly in response to the issue of carry-over raised in this Application.

The Approval Report for Proposal P1008 stated, in part¹:

However, the existing clause 7 only refers to 'ingredients' as a potential source of carry over additives in a 'final food'. There is therefore doubt as to whether the existing clause 7 of Standard 1.3.1 allows additives to be present in a cooked or processed single ingredient food, where the presence of these additives is as a result of the use of an additive in uncooked or unprocessed raw material. Given this doubt, it is considered that the Code should be amended to address this anomaly.

Clause 7 was amended by adding the words 'a raw material or', as follows (emphasis added):

¹ Additional discussion may be found on pages 5 and 6 of the Report at <http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1008codemai4163.cfm>.

7. Carry-over of food additives

Other than by direct addition, a food additive may be present in any food as a result of carry-over from a raw material or an ingredient, provided that the level of the food additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice.

3. Objective

The objective of this assessment is to determine whether or not a further amendment is required to the Code in order to permit the presence of 4-hexylresorcinol in cooked crustacea as a result of its permitted addition to raw crustacea.

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

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

Risk Assessment

4. Risk Assessment Summary

As there is no increase in exposure or use of 4-hexylresorcinol no risk assessment is required.

Risk Management

5. Need for Code change

5.1 Matters to have regard to

To assess this Application, FSANZ had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation of the food regulatory measure;
- whether other measures would be more cost-effective than a variation to the food regulatory measure;
- any relevant New Zealand standards; and
- any other relevant matters

6. Options

FSANZ believes its only option is to reject the Application as no regulatory measure is required to meet the objective of the Application.

7. Impact Analysis

As there is no proposed change to the use of 4-hexylresorcinol an impact analysis has not been conducted.

Communication and Consultation Strategy

8. Consultation

Consultation was undertaken with the Applicant.

Conclusion

9. Conclusion and Preferred Option

FSANZ believes that at the time the Application was received there was reasonable doubt whether the Code permitted the presence of 4-hexylresorcinol in cooked crustacea as a result of carry-over from its permitted addition to raw crustacea.

However since the Application was received, the amendment to clause 7 (Carry-over of food additives) of Standard 1.3.1, has clarified the permission for the carry-over of 4-hexylresorcinol into cooked crustacea from its permitted addition to raw crustacea.

Because of this amendment, the problem raised in the Application has been rectified. No further amendment is required.

Decision

To reject the Application because it does not warrant the variation of a food regulatory measure on the basis that the problem raised in the Application has already been addressed by an amendment to the Code made as part of Proposal P1008 – Code Maintenance VIII.