

**16 June 2022**  
**205-22**

Approval report – Application A1215

## Cetylpyridinium chloride (CPC) as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Safe Foods Corporation to amend the Australia New Zealand Food Standards Code to permit the use of cetylpyridinium chloride (CPC) as a processing aid (antimicrobial treatment) for raw poultry.

On 16 March 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received five submissions.

FSANZ approved the draft variation on 8 June 2022. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 16 June 2022.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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<sup>1</sup> Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

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## Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD Risk assessment and Technical Assessment Report

# Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Safe Foods Corporation (Safe Foods) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of cetylpyridinium chloride (CPC) as a processing aid for the antimicrobial treatment of raw poultry.

Safe Foods markets an aqueous solution containing CPC (as the active constituent) and propylene glycol under the proprietary name Cecure (referred to hereafter as the CPC preparation). The CPC preparation is diluted with water to achieve a wash solution with a concentration of up to 1% (w/v<sup>2</sup>) CPC for use as an antimicrobial agent to treat the inner (cavity) and outer surfaces of raw poultry carcasses and raw poultry pieces.

FSANZ has undertaken an assessment to determine whether CPC achieves the technological purpose, as a processing aid, of an antimicrobial treatment for raw poultry and to identify any potential public health and safety concerns associated with its use.

Raw poultry may inherently carry a wide range of microorganisms, some of which are potential human pathogens. The application of CPC to the surface of skin-on raw poultry carcasses and pieces at concentrations ranging from 0.1 to 1% (w/v) in the wash solution was demonstrated to effectively reduce the prevalence and levels of microorganisms, including relevant pathogens. FSANZ therefore concludes that the proposed use of CPC as a processing aid, for use as an antimicrobial agent for skin-on raw poultry, is technologically justified.

As CPC performs the antimicrobial function at the time of treatment (during the processing of poultry) and does not perform a technological purpose in the food for sale, it functions as a processing aid as defined in the Code.

There is a relevant specification for CPC in the Food Chemicals Codex (United States Pharmacopeial Convention, 2020), a primary source of specifications listed in Schedule 3 of the Code.

Studies on the potential for the proposed use of CPC to cause resistance to the compound, or cross resistance to antimicrobial compounds of importance to human health, demonstrate that the proposed use of CPC does not introduce an unacceptable risk of the development of antimicrobial resistance in the six pathogens tested: *Salmonella* Typhimurium, *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Listeria monocytogenes* and *Campylobacter jejuni*.

Propylene glycol is added to Safe Foods' CPC preparation to act as a wetting agent or humectant, and to maintain solubility and stability in the preparation. Propylene glycol is currently permitted for use both as a food additive permitted at good manufacturing practice (GMP) and as a processing aid in accordance with the Code.

As propylene glycol is listed as a food additive permitted at GMP in the Code and an acceptable daily intake (ADI) for propylene glycol has been established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), an assessment of potential public and safety concerns in relation to propylene glycol from the use of Safe Foods' CPC preparation was also undertaken.

There were no public health and safety concerns identified from the estimated dietary

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<sup>2</sup> weight per volume

exposure to either CPC or the propylene glycol in Safe Foods' CPC preparation at the proposed use levels.

FSANZ had assessed the application in accordance with the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and prepared a draft variation. Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 16 March to 13 April 2022. Five submissions were received in response. No submitters were opposed to use of CPC as a processing aid for use as an antimicrobial treatment for raw poultry. FSANZ has had regard to the issues raised in submissions.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the Code to permit the use of CPC as a processing aid with the technological purpose of antimicrobial agent for raw poultry meat with the skin attached. The permission will be subject to a maximum permitted level of CPC in the poultry skin of 13.4 mg per kg, based on the highest concentration of CPC used in the risk assessment. The permission will also be subject to the conditions that the concentration of CPC in the aqueous wash solution used does not exceed 1% (w/v) and that the raw poultry meat is rinsed in potable water after treatment with CPC. These additional risk management measures will assist poultry processors to meet the maximum permitted level of CPC.

Given current permissions in the Code for the use of propylene glycol as a food additive permitted at GMP and a processing aid, FSANZ considers no amendments to the Code to permit the use of propylene glycol in Safe Foods' CPC preparation are needed.

# 1 Introduction

## 1.1 The Applicant

Safe Foods Corporation (Safe Foods) is a global company headquartered in the United States. They provide a number of antimicrobial products for use in the food industry.

## 1.2 The Application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit cetylpyridinium chloride (CPC) as a processing aid for use as an antimicrobial treatment for the surface of raw poultry. Safe Foods did not specifically request a level of use of CPC for incorporation into the Code.

Safe Foods sells an aqueous solution containing CPC (as the active constituent) and propylene glycol under the proprietary name Cecure (referred to hereafter as the CPC preparation).

The CPC preparation is diluted with potable water to achieve a wash solution with a concentration of up to 1% (w/v<sup>3</sup>) CPC for use as an antimicrobial agent to treat the inner (cavity) and outer surfaces of raw poultry carcasses and raw poultry pieces. Safe Foods stated that the diluted CPC preparation would be applied at the poultry processing premises either by:

- spraying the solution onto whole carcasses following evisceration, either prior to entry to the chiller or post chilling
- dipping of poultry pieces into the solution following evisceration and chilling of whole carcasses.

The raw poultry carcasses or pieces are rinsed in potable water following the treatment outlined above.

## 1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements in the Code relevant to this application are summarised below.

### 1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’ unless that substance’s use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP (good manufacturing practice).

Standard 1.3.3 and Schedule 18 list the permitted processing aids. Section S16—2 lists additives permitted at GMP.

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<sup>3</sup> weight per volume

Propylene glycol is used in the processing or manufacture of the CPC (as a wetting agent or humectant) and it functions in the preparation after processing (to maintain the preparation's solubility and stability) at which point the preparation can be a food for sale.

Propylene glycol is listed as an 'additive permitted at GMP' in section S16—2. This means that it can be used as a food additive in the CPC preparation subject to the requirement that its use be consistent with GMP.

As it is an additive permitted at GMP, section 1.3.3—4 of the Code also permits the use of propylene glycol as a processing aid in any food (including the CPC preparation) provided that the propylene glycol is used only at a level necessary to achieve the relevant technological purpose in the processing of that food.

There is currently no permission in the Code for CPC to be used as a processing aid in raw poultry or any other food with the technological purpose of an antimicrobial agent.

### **1.3.2 Identity and purity requirements**

Paragraph 1.1.1—15(1)(b) requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3.

Subsection S3—2(1) and section S3—3 set out specifications for substances in primary and secondary sources, respectively, for the purposes of subsection 1.1.1—15(2). There is a specification for CPC in the Food Chemicals Codex (United States Pharmacopeial Convention, 2020), which is a primary source of specifications listed in paragraph S3—2(1)(c) of the Code.

### **1.3.3 Labelling requirements**

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements prevail.

## **1.4 Overseas approvals**

### **1.4.1 United States of America**

CPC is regulated in the US Food and Drug Administration Code of Federal Regulations (2020), 21CFR 173.375, as a result of a petition from Safe Foods. It is permitted as an antimicrobial agent to treat the surface of raw poultry carcasses. The solution containing the CPC must also contain propylene glycol at a concentration of 1.5 times that of CPC. The additive may be used either as:

- a fine mist spray applied to carcasses prior to immersion in a chiller at a level not exceeding 0.3 gram CPC per pound of carcass provided it is used in systems that collect and recycle solution that is not carried out of the system with the treated poultry carcasses
- a liquid solution applied to raw poultry carcasses either prior to or after chilling at an amount not to exceed 5 gallons<sup>4</sup> of solution per carcass, provided it is used in systems that recapture at least 99% of the solution. The concentration of CPC in the solution

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<sup>4</sup> equivalent to 18.9 litres

must not exceed 0.8% by weight. When application of the CPC is not followed by immersion in a chiller, the carcass must be rinsed in potable water following treatment.

The conditions outlined above were proposed in the petition by Safe Foods to the United States Food and Drug Administration (FDA), with the maximum volume of solution applied and the recapture requirement due to concerns associated with residual propylene glycol in treated poultry becoming a component of animal feed, in particular cat food.

Safe Foods has also provided FSANZ with a letter of no objection from the United States Department of Agriculture, Food Safety and Inspection Service (FSIS) (dated 17 December 2020) stating that FSIS had no objection to the application of CPC to skin-on and skinless raw poultry parts, under the amount and conditions specified in the FSIS Directive 7120.1<sup>5</sup> and the 21CFR 173.375.

#### **1.4.2 Canada**

Safe Foods provided a copy of a letter from Health Canada dated 2 December 2008, stating that based on information provided by Safe Foods, they would have no objection to the use of up to 1% CPC in an aqueous solution containing 1.5 times the weight of propylene glycol on raw poultry carcasses before or after air or immersion chilling of the carcasses, providing certain conditions were met (to meet a specification, rinsing of carcasses after application, no violations of Section 4 – Prohibited sales of food of the Canadian *Food and Drugs Act* and the CPC solution is recaptured and recycled and safely disposed of according to the Secure Recycling System).

#### **1.4.3 Europe**

The European Food Safety Authority (EFSA) completed an assessment of the safety and efficacy of Safe Foods' CPC preparation following an application for approval of that preparation to be used for the removal of microbial surface contamination of raw poultry products (EFSA, 2012). EFSA had no safety concerns for humans from the proposed use of the CPC preparation and based on information provided by Safe Foods, both the CPC preparation and CPC were found to be efficacious in reducing contamination with pathogenic microorganisms on fresh broiler carcasses. EFSA did however conclude that based on the available limited data, the intended use of CPC in poultry slaughterhouses would pose risks for the environmental compartments surface water, sediment and soil.

The use of the CPC preparation has not yet subsequently been approved in Europe. Safe Foods has informed FSANZ that they have been asked by EFSA to provide data relating to environmental concerns, which they were finalising before sending to EFSA, and data regarding bacterial resistance to CPC (which has been provided to FSANZ). FSANZ has considered the issue of bacterial resistance and concluded that the proposed use of CPC does not introduce an unacceptable risk of the development of antimicrobial resistance in the six pathogens tested (refer to Section 2.2.2 and SD for further detail).

#### **1.4.4 Other countries**

Safe Foods provided a list of countries that have approved the use of their CPC preparation including Mexico, Panama, Costa Rica, Colombia, Israel, Peru, Russia, South Africa, Saudi Arabia and Jordan.

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<sup>5</sup> Available at <https://www.fsis.usda.gov/policy/fsis-directives/7120.1>

## **1.5 Reasons for accepting Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

## **1.6 Procedure for assessment**

The Application was assessed under the General Procedure in the FSANZ Act.

## **1.7 Decision**

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of CPC as a processing aid (antimicrobial treatment) for raw poultry as requested by the applicant.

The draft variation as proposed following assessment was approved with one amendment to correct a typographical error. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.



## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 16 March to 13 April 2022. Five submissions were received. No submitters opposed approval of CPC as a processing aid for use as an antimicrobial treatment for poultry, however four submitters requested further consideration of some elements of the proposed regulation. A summary of the issues raised in submissions and the FSANZ response are in Table 1.

**Table 1: Summary of issues**

Issue	Raised by	FSANZ response
<p><b>Query approval as a processing aid not food additive</b>            CPC continues working on the surface of poultry, even after being 'rinsed off', so does not comply with FSANZ's definition of a processing aid. Raises question why it requires a rinse if proposed for use as a processing aid.</p> <p>Believe there are two courses of action to address this issue –            a. Approve CPC as a food additive rather than a processing aid.            b. If approved as a processing aid, define and mandate rinse step to ensure there is not enough CPC left to continue killing pathogens after rinsing.</p>	<p>Hygiene Technologies</p>	<p>The rinse step is a risk management measure to assist poultry processors to comply with the maximum permitted level (MPL). The MPL was developed as a result of the risk assessment including the dietary exposure assessment which relied on residual levels of CPC following a rinse step.</p> <p>Evidence provided by the submitter on the potential for ongoing antimicrobial action of CPC on lettuce, apples and beef is not applicable to the intended use.</p> <p>Evidence from studies of bacterial behaviour in CPC-treated poultry products demonstrates the lack of an ongoing antimicrobial effect of CPC after the initial treatment (see A1215 Supporting document - Risk and Technical Assessment Report<sup>6</sup> (SD)).</p>

<sup>6</sup> <https://www.foodstandards.gov.au/code/applications/Pages/a1215.aspx>

Issue	Raised by	FSANZ response
		<p>FSANZ notes that the US Department of Agriculture Food Safety and Inspection Service implemented a change in 2016 to ensure neutralisation of CPC (and other antimicrobials) during sample preparation under its poultry carcass sampling program, based on the work of Gamble et al (2017). Using that neutralising method, Rincon et al (2020) showed similar results to those referred to in SD—initial reduction in bacterial load followed by increases in bacterial populations on CPC-treated poultry carcasses over a period of 10 days. This provides further evidence that residues of CPC on poultry products do not inhibit bacterial growth on the products after initial treatment, and that it functions as a processing aid, rather than a food additive.</p>
<p><b>New Zealand (NZ) poultry operators who use CPC may unwittingly jeopardise their chances at participating in some export markets</b></p> <p><b>a. Poultry for human consumption</b> – Much of the developed world has spent the last 10-20 years moving away from using quaternary ammonium compounds in food. Seems a backward step to look at approving one of these compounds for direct food application and could impact NZ's fledgling poultry product export business.</p> <p><b>b. Poultry meat used in pet food</b> – Dietary exposure assessments for humans are not adequate for propylene glycol if the poultry meat is supplied for pet food, as dogs and cats have far lower tolerance to this than humans.</p>	<p>Hygiene Technologies</p>	<p>The use of Cecure, the applicant's proprietary product containing CPC and propylene glycol, will be voluntary. Poultry processors will have the option to use it or not, taking into consideration relevant factors which may include export requirements for poultry for human consumption and/or potential for treated poultry to be used in pet food.</p> <p>FSANZ is not responsible for the assessment, safety or regulation of pet food in Australia or New Zealand. In Australia, the Australian Standard for the Manufacturing &amp; Marketing of Pet Food (AS5812:2017), published by Standards Australia<sup>7</sup>, applies to the safety of pet food. In New Zealand, the Ministry for Primary Industries is responsible for the regulation of pet food<sup>8</sup>.</p>

<sup>7</sup> Available at [https://infostore.saiglobal.com/en-au/Standards/AS-5812-2017-99333\\_SAIG\\_AS\\_AS\\_208845/](https://infostore.saiglobal.com/en-au/Standards/AS-5812-2017-99333_SAIG_AS_AS_208845/)

<sup>8</sup> Further information is available at [Manufacturing pet food, animal feed, and nutritional supplements | Animals | NZ Government \(mpi.govt.nz\)](https://www.mpi.govt.nz/standards-and-regulation/manufacturing-pet-food-animal-feed-and-nutritional-supplements/)

Issue	Raised by	FSANZ response
<p>FSANZ already has approved a number of compounds as processing aids which can be used on poultry, which are less expensive, just as effective, do not require capture and recirculation equipment, are widely accepted by overseas export markets, and do not have the rinse requirements or persistence issues that CPC does. The fact that the submitting company now has very little market-share with CPC in their own home country so they are looking for growth speaks volumes about the commercial benefits the market sees in this technology.</p>	<p>Hygiene Technologies</p>	<p>FSANZ must consider all applications to amend the Code in accordance with FSANZ Act. The fact there are alternative options available to poultry processors is not a reason in itself to reject the application. Approval of the application provides the poultry industry with another option for antimicrobial treatments.</p>
<p>Supports approval of CPC however notes the assessment did not include consideration of the time of exposure of the product to CPC, 'which is critical for efficiency' and is regulated in some countries. For example, under the current United States Department of Agriculture (USDA) regulations, CPC is utilised as a dipping application cannot have more than 10 s of contact with broiler meat.</p>	<p>New Zealand Food Safety</p>	<p>Available evidence on the efficacy of CPC as an antimicrobial treatment for raw poultry meat is consistent with USDA guidance for drench application (minimum of 2 to 5 seconds at a CPC concentration not exceeding 0.8%), but does not provide an adequate evidence base to support a maximum of 10 seconds contact time for dip tank application (see Section 2.4.1 of SD).</p> <p>Poultry processing businesses would need to determine appropriate application protocols to ensure compliance with the MPL and to achieve their required pathogen reduction goals as part of their food safety management/HACCP (Hazard Analysis and Critical Control Point) systems.</p> <p>FSANZ understands from the applicant that the 10 second contact time is based on the expected immersion time of the poultry carcasses or parts in the CPC solution when using a dip tank (rather than specifically for safety reasons).</p>

Issue	Raised by	FSANZ response
<p>Seeks clarification on whether submersion of the raw poultry in an immersion chiller after treatment with CPC counts as the required rinse in potable water. Notes the rinse is only required:</p> <ul style="list-style-type: none"> <li>for carcasses that are to be air-chilled after treatment or to carcasses that are to be treated [with CPC] after chilling (whether air or immersion chilled), according to Health Canada requirements,</li> <li>when application of the CPC is not followed by immersion in a chiller, according to the US FDA requirements.</li> </ul> <p>Requests clarification on whether the Code will include conditions such as those staged above to remove an unnecessary step of rinsing treated product prior to immersion in a water chiller.</p>	Safe Foods	<p>The relevant requirement is that the raw poultry meat is 'rinsed in potable water' after treatment with CPC. Water immersion chilling is commonly used to chill carcasses following evisceration and washing, with the carcass placed in counter-current flow of chlorinated (50-70 ppm total available chlorine, 0.4–4.0 ppm free available chlorine) cold water (FSANZ 2005). FSANZ considers that submersion of poultry in an immersion chiller as described above may achieve the requirement for the treated poultry to be rinsed in potable water. The onus would be on the poultry processor to ensure that the immersion chiller step was a potable water rinse and the MPL is not exceeded following that step.</p> <p>FSANZ has therefore not amended the draft variation to specifically state the situations in which a rinse in potable water is required. The explanatory statement has been amended to refer to the rinsing requirement being met by submersion in an immersion chiller.</p>
<p>Requests permission based on the application parameters (up to 1% CPC and up to 5 gallons of Cecure solution per bird) instead of the resulting levels of CPC on the product (13.4 mg/kg), as measurement of residual levels of CPC on the product requires the use of a High-Performance Liquid Chromatography (HPLC) equipment, to which most poultry processing facilities would not have easy access. Since tests submitted in the CPC application have shown that using the Cecure solution at or below the concentration and volume limits above results in compliance with the residue limit of 13.4 mg per kg, submit that regulation based on the application parameters would be more practical in the processing environment.</p>	Safe Foods	<p>The approved draft variation includes conditions for the use of CPC which are designed to help ensure the MPL is not exceeded. Poultry processing businesses would need to determine appropriate application protocols as part of their food safety management/HACCP systems. This may include testing of residue limits as verification of those protocols. The approved draft variation does not prescribe the frequency for monitoring compliance with the MPL by the poultry processor nor the methods of analysis for determining the CPC residue.</p> <p>The MPL also allows for enforcement authorities to check compliance if they choose to do so.</p> <p>FSANZ has therefore retained the MPL in the approved draft variation.</p>

Issue	Raised by	FSANZ response
<p>Evidence suggests the potential for acquired tolerance to the antimicrobial treatment of exposure, which may impact future sanitation performance and pathogen management<sup>9</sup>. The risk of development of antibiotic-resistant mutations in human pathogens as a consequence of CPC use could not be assessed due to limited information provided.</p>	<p>Victorian Department of Health, the Victorian Department of Jobs, Precincts and Regions, and PrimeSafe</p>	<p>The potential for exposure to biocides such as CPC leading to the development of antibiotic-resistance in human pathogens was considered in the SD. FSANZ assessed available evidence – including AMR studies provided as confidential commercial information (CCI) by the applicant – and concluded that this risk was low. Data showed no development of pathogen resistance to CPC or any stable reduction in susceptibility to antibiotics tested. The article supplied by the submitter provided no direct evidence of the development of resistance to CPC – or cross-resistance to other antimicrobials – in bacteria through the use of CPC as an antimicrobial processing aid in poultry processing.</p>
<p>Question why a minimum concentration of CPC has not been set given exposure to sub-lethal concentrations of antimicrobial agents is a risk factor for the development of acquired tolerance to the exposed compound and cross-resistance to therapeutic antibiotics<sup>9</sup>.</p>	<p>Victorian Department of Health, the Victorian Department of Jobs, Precincts and Regions, and PrimeSafe</p>	<p>FSANZ assessed available evidence – including AMR studies provided as CCI by the applicant – and concluded that this risk was low. Data showed no development of pathogen resistance to CPC or any stable reduction in susceptibility to antibiotics tested across a wide range of concentrations of CPC, including sub-lethal concentrations. The article supplied by the submitter provided no direct evidence of the development of resistance to CPC – or cross-resistance to other antimicrobials – in bacteria through the use of CPC as an antimicrobial processing aid in poultry processing.</p>

<sup>9</sup> Reference provided by submitter: Rhouma, M., Romero-Barríos, P., Gaucher, M.L. and Bhachoo, S., 2021. Antimicrobial resistance associated with the use of antimicrobial processing aids during poultry processing operations: cause for concern?. *Critical Reviews in Food Science and Nutrition*, 61(19), pp.3279-3296.

Issue	Raised by	FSANZ response
<p>It is not clear whether the assessment considered end use application (cooking by the consumer) and any safety risks related to heat stability of CPC. Quaternary ammonium compounds are known to degrade at elevated temperatures by a Hoffman elimination. In the case of CPC, this degradation occurs at around 130°C to form hexadecane and pyridine hydrochloride. The latter may cause an allergic reaction, particularly among individuals with asthma.</p>	<p>Victorian Department of Health, the Victorian Department of Jobs, Precincts and Regions, and PrimeSafe</p>	<p>The applicant has indicated that based on the structure of CPC it is considered to be a stable compound. Heating treated chicken samples at 95°C did not alter the results of HPLC analysis for CPC.</p> <p>Based on information provided by the applicant, FSANZ considers it is unlikely that degradation of CPC would occur via the Hoffman elimination reaction during cooking due to the conditions required for the reaction. The Hoffman elimination reaction of a quaternary ammonium compound (QAC) requires methyl iodide (CH<sub>3</sub>I) for alkylation of the QAC and reaction with either silver hydroxide (AgOH) or silver oxide (Ag<sub>2</sub>O) under heated conditions to provide a basic hydroxide ion (OH<sup>-</sup>) to replace the counter anion of the QAC salt (normally a halide ion such as Cl<sup>-</sup> or Br<sup>-</sup>), resulting in hexadecane and pyridine hydrochloride products. Under normal cooking conditions, the silver hydroxide and methyl iodide would not be present<sup>10</sup>.</p> <p>In addition, it has been reported that in cases where nitrogen is part of a ring, as is the case with the nitrogen atom in the pyridine ring of CPC, at least two applications of the Hoffman elimination reaction would be required to remove the nitrogen from the ring as a separate amine product<sup>10</sup>.</p> <p>Finally, FSANZ is not aware of any reports of adverse events linked to consumption of CPC-treated poultry in the countries where it has been approved.</p>

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[https://chem.libretexts.org/Bookshelves/Organic\\_Chemistry/Map%3A\\_Organic\\_Chemistry\\_\(Vollhardt\\_and\\_Schore\)/21%3A\\_Amines\\_and\\_Their\\_Derivatives/2.1.08%3A\\_Quaternary\\_Ammonium\\_Salts%3A\\_Hofmann\\_Elimination](https://chem.libretexts.org/Bookshelves/Organic_Chemistry/Map%3A_Organic_Chemistry_(Vollhardt_and_Schore)/21%3A_Amines_and_Their_Derivatives/2.1.08%3A_Quaternary_Ammonium_Salts%3A_Hofmann_Elimination) accessed 22 April 2022

Issue	Raised by	FSANZ response
<p>Recognise the technological justification for CPC in raw poultry processing, although noting it would not replace the requirement for chlorinated water in poultry processing in Victoria as outlined in Australian Standard AS 4465:2005 Australian Standard for Construction of Premises and Hygienic Production of Poultry Meat for Human Consumption – Victoria. On this basis, support the progression of A1215, contingent on the provision of further information from FSANZ to address the health and safety concerns outlined above.</p>	<p>Victorian Department of Health, the Victorian Department of Jobs, Precincts and Regions, and PrimeSafe</p>	<p>Noted. Further information requested to address the health and safety concerns raised elsewhere in the Victorian Department of Health, the Victorian Department of Jobs, Precincts and Regions, and PrimeSafe submission is provided above.</p>
<p>Supports the opportunity for industry to use CPC for various reasons (included supporting evidence).</p>	<p>Biggs Food Consultancy Ltd</p>	<p>Noted.</p>

## 2.2 Food technology and risk assessment

FSANZ has undertaken an assessment to determine whether CPC achieves the technological purpose, as a processing aid, of an antimicrobial treatment for raw poultry and to identify any potential public health and safety concerns associated with its use.

As an acceptable daily intake (ADI) for propylene glycol has been established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), an assessment of potential public and safety concerns in relation to propylene glycol from the use of the applicant's CPC preparation was also undertaken.

A summary of this assessment is provided below.

### 2.2.1 Technical assessment

Raw poultry inherently carries a wide range of microorganisms, some of which are potential human pathogens. Analysis of the evidence provides adequate assurance that the application of CPC to the surface of skin-on raw poultry carcasses and pieces at levels ranging from 0.1 to 1% (w/v) in the wash solution can effectively reduce the prevalence and levels of microorganisms, including relevant pathogens. FSANZ therefore concludes that the proposed use of CPC as a processing aid, for use as an antimicrobial agent for skin-on raw poultry, is technologically justified.

As CPC performs the antimicrobial function at the time of treatment (during the processing of poultry) and does not perform a technological purpose in the food for sale, it functions as a processing aid as defined in the Code.

There is a relevant specification for CPC in the Food Chemicals Codex (United States Pharmacopeial Convention, 2020), a primary source of specifications listed in Schedule 3 of the Code.

Propylene glycol is added to Safe Foods' CPC preparation to act as a wetting agent or humectant in the processing of the CPC preparation and to maintain solubility and stability in the preparation after processing. Propylene glycol is currently permitted for use both as a food additive permitted at GMP and as a processing aid, in accordance with the Code.

### 2.2.2 Risk assessment

Studies on the potential for the proposed use of CPC to cause resistance to the compound or cross resistance to antimicrobial compounds of importance to human health demonstrate that the proposed use of CPC does not introduce an unacceptable risk of the development of antimicrobial resistance in the six pathogens tested: *Salmonella* Typhimurium, *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Listeria monocytogenes* and *Campylobacter jejuni*.

In short-term dietary toxicity studies of CPC in rats and dogs, reduced food consumption and decreased body weight and body weight gain were observed at higher concentrations. These effects may possibly be due to issues with palatability of the test item. Increased caecum weights were observed in rats. The cause of this finding was unclear but it was not possible to definitively conclude that these changes were not treatment-related or adverse. In addition, haematological changes were observed in dogs. The no observed adverse effect level (NOAEL) in a 90-day dietary toxicity in dogs was 8 mg/kg bw/day.

*In vitro* genotoxicity studies of the final CPC preparation found no evidence of mutagenicity or clastogenicity. Proprietary *in vitro* and *in vivo* genotoxicity studies of CPC unavailable to



FSANZ were reviewed by the EU Scientific Committee on Consumer Safety (SCCS), and considered to demonstrate that CPC does not have genotoxic potential. No long-term studies of toxicity or carcinogenicity are available for review, but no histopathological changes indicative of lesions that could lead to neoplasia were identified in the short-term dietary toxicity studies reviewed by FSANZ.

Limited details summarising developmental toxicity studies of CPC in rats and rabbits were submitted to FSANZ. In addition, the EU SCCS review of CPC considered results of a proprietary developmental toxicity study in rats. These summaries state that no developmental toxicity was observed, but the full study reports were not available to FSANZ for evaluation. A summary of a combined developmental and reproductive toxicity study of a vinyl copolymer containing CPC in rats, conducted over three generations, states that no effects on fertility or developmental toxicity were observed. No histopathological changes in reproductive tissues were reported in the short-term dietary toxicity studies reviewed by FSANZ.

Given the limited data on long-term toxicity, carcinogenicity and developmental and reproductive toxicity available to FSANZ, it is not appropriate to establish a health-based guidance value (HBGV) for CPC. However, the NOAEL of 8 mg/kg bw/day identified in the 90-day dietary toxicity study in dogs is considered a suitable point of departure for use in a margin of exposure (MOE) assessment. This NOAEL is also protective of the changes observed in the rat studies.

For propylene glycol, an acceptable daily intake (ADI) of 0 – 25 mg/kg bw has been established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

A dietary exposure assessment was undertaken for both CPC and propylene glycol based on residue levels in poultry from use of Safe Foods' CPC preparation. The assessment for propylene glycol also included dietary exposure from existing food additive uses. For CPC, estimated dietary exposures ranged between 0.0025 and 0.014 mg/kg bw/day across mean and high (90<sup>th</sup> percentile) exposures for all scenarios and Australian and New Zealand population groups assessed. When compared with the NOAEL, these dietary exposures equate to MOEs between 600 and 3200. The MOEs are sufficiently large to account for the uncertainties in the database for CPC, and indicate that there are no safety concerns from the proposed use of CPC as a poultry treatment. For propylene glycol, estimated dietary exposures from Safe Foods' CPC preparation and additive sources combined ranged between <1 and 27 mg/kg bw/day for mean and high exposures across all scenarios and population groups assessed. This equates to between 1 and 110% of the ADI. The upper end of this range is based on a very conservative estimate, primarily as that estimate is based on maximum industry use levels in 100% of food products in each food class, a single day of food consumption data, and a restricted age group. The contribution from Safe Foods' CPC preparation was <1% of the ADI.

In conclusion, there were no public health and safety concerns identified from the estimated dietary exposure to either CPC or the propylene glycol in Safe Foods' CPC preparation at the proposed use levels.

## **2.3 Risk management**

After assessing an application, FSANZ must either prepare a written draft measure or reject the application. FSANZ's assessment concluded the proposed use of CPC as a processing aid (antimicrobial agent) for raw poultry meat is technologically justified and there were no public health and safety concerns identified from the use of the CPC at the proposed use levels. FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of CPC as a processing aid (antimicrobial agent) for skin-

on raw poultry meat; and called for submissions on the draft variation.

Following the call for submissions and having regard to all submissions received, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (other than to correct a minor typographical error).

### **2.3.1 Nomenclature and specifications**

FSANZ notes that the International Union of Pure and Applied Chemistry (IUPAC), the universally-recognized authority on chemical nomenclature and terminology, uses the name cetylpyridinium chloride (CAS number 123-03-5). This is the name that is used in the approved draft variation to the Code.

There are relevant identity and purity specifications for CPC in the Food Chemicals Codex (United States Pharmacopeial Convention, 2020), a primary source of specifications listed in Schedule 3 of the Code, which would have to be complied with.

### **2.3.2 Food permitted to be treated**

The food permitted to be treated with CPC is raw poultry meat (carcasses or pieces) with the skin attached, subject to conditions for the treatment process and the maximum permitted level (MPL) outlined below.

The permission is limited to skin-on poultry only because the risk assessment was based on skin-on poultry only, using residue data provided by Safe Foods.

The term 'poultry meat' is defined for the purposes of the new permission to mean the whole poultry carcass or parts of the poultry carcass, with the skin attached, that is intended for human consumption.

Offal is normally removed from the carcass before treatment and was not included in the risk assessment. The approved draft variation will not permit offal to be treated with CPC.

### **2.3.3 Maximum permitted level (MPL)**

The permission to use CPC as a processing aid for use as an antimicrobial agent for raw poultry meat will be subject to the requirement that the MPL is 13.4 mg of CPC per kg of poultry skin (13.4 mg/kg). This limit is based on the highest concentration of CPC used in the dietary exposure assessment i.e. the maximum residue level on the poultry skin after treatment as provided by Safe Foods. The MPL will apply to the skin only, as the method of analysis for testing CPC residue of skin-on poultry analyses the skin only.

### **2.3.4 Permitted concentration of CPC in wash solution and rinse step**

The risk assessment was based on residues of CPC on raw poultry following treatment at a concentration in the poultry wash solution of up to 1% (w/v) CPC and following a rinse of the raw poultry carcass or pieces in potable water following treatment.

The concentration of CPC in the aqueous wash solution applied to the raw poultry meat must therefore not exceed 1% (w/v) and following treatment with CPC, the raw poultry meat must be rinsed in potable water. These additional risk management measures would assist poultry processors in not exceeding the MPL.

The unit of % w/v is referred to in the approved draft variation, as the CPC is in a solid/crystallised state before being dissolved to an aqueous form and then diluted with

potable water for use.

### **2.3.5 Other considerations**

Safe Foods informed FSANZ that they typically market to poultry processors where the initial and further processing of the poultry is performed since the application method requires spray or dipping equipment that is either supplied by Safe Foods or is readily available in those processing facilities. In Australia, poultry processors have responsibilities under Part 4.2 of the Code to take all reasonable measures to ensure inputs do not make the poultry product unsuitable. In New Zealand, poultry processors must have either a registered risk management programme (RMP) and/or a registered food control plan (FCP) (subject to whether they are primary and/or secondary poultry processors), which addresses food safety<sup>11</sup>. FSANZ has therefore not specified the type of premises or person permitted to treat poultry with CPC in the approved draft variation.

In Australia, poultry processors need to comply with waste water requirements in Section 3.2.3—5 of the Code. These require effective disposal of all waste water and to avoid waste water polluting the water supply or contaminating food. In New Zealand, poultry processors must operate under a registered risk management programme which should include waste management (generally either treatment through an internal waste water system or disposal through local council approval)<sup>11</sup>.

As is standard practice, a technical data sheet and safety data sheet would be available to poultry processors regarding the appropriate use of CPC, including the recommended use level.

The assessment of CPC was restricted to human food safety. This assessment therefore does not address any risks to the environment that may occur as the result of CPC's use as a processing aid in food, or any risks to animals from poultry food products treated with Safe Foods' CPC preparation becoming a component of animal feed.

Industry's use of CPC as a processing aid would be subject to and will have to comply with all relevant legal requirements including Australian and New Zealand animal feed, environment and hazardous waste laws, and the assessments and approvals required by those laws.

### **2.3.6 Propylene glycol**

Safe Foods' proprietary CPC preparation is a liquid preparation containing CPC as the active constituent. It also contains food-grade propylene glycol. The propylene glycol acts as a wetting agent or humectant and also functions in the CPC preparation to maintain solubility and stability. Propylene glycol is identified in section S16—2 as an additive permitted at GMP.

FSANZ determined the need to assess the propylene glycol component in the CPC preparation given it is permitted to be used as a food additive, at GMP, in the Code and an Acceptable Daily Intake (ADI) for propylene glycol has been established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

As outlined in the Risk and Technical Assessment Report (SD), a dietary exposure assessment was then undertaken for propylene glycol based on residue levels in poultry from use of the poultry wash and existing food additive uses. Overall, dietary exposures from

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<sup>11</sup> Further information is available at [Poultry and egg processing requirements | Food business | NZ Government \(mpi.govt.nz\)](https://www.mpi.govt.nz/poultry-and-egg-processing-requirements/)

existing food additive uses and use of the CPC preparation at the proposed level combined did not raise any public health and safety concerns. The contribution from the proposed use of the CPC preparation only was less than 1% of the JECFA ADI for propylene glycol.

The approved draft variation will permit the use of CPC generally and is not specific to Safe Foods' CPC preparation. Given current permissions in the Code for the use of propylene glycol as a food additive permitted at GMP and a processing aid, FSANZ considers no amendments to the Code to permit the use of propylene glycol in Safe Foods' CPC preparation are needed.

Based on the above discussion, FSANZ has not included any amendments to the Code, in the approved draft variation, with respect to permissions for the use of propylene glycol.

### **2.3.7 Labelling**

The exemption from declaring processing aids in the statement of ingredients will apply, in accordance with the Code, to raw poultry products treated with CPC (refer to Section 1.3.3 of this report). No amendments to the Code with respect to labelling of poultry treated with CPC have been included in the approved draft variation.

### **2.3.8 Conclusion**

The approved draft variation (Attachment A) will permit the use of CPC as a processing aid with the technological purpose of antimicrobial agent for raw poultry meat (whole carcasses and pieces) with the skin attached in accordance with the Code. The permission will be subject to the following conditions:

- a) the concentration of CPC in the aqueous wash solution used does not exceed 1% (w/v)
- b) the raw poultry meat is rinsed in potable water after treatment with CPC.

The permission will also be subject to a maximum permitted level of CPC in the poultry skin of 13.4 mg per kg.

Raw poultry may carry a wide range of microorganisms, some of which are potential human pathogens that can cause illness in consumers. Approving the application will provide the poultry industry with an additional option for reducing microorganisms, including pathogens, in raw poultry.

## **2.4 Risk communication**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions were notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards' development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

The draft variation was considered for approval by FSANZ having regard to all submissions made during the call for submissions period.

## **2.5 FSANZ Act assessment requirements**

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

### **2.5.1 Section 29**

#### **2.5.1.1 Consideration of costs and benefits**

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for approving processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a processing aid that has been determined to be safe for use in the food supply.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considered permitting the use of CPC as a processing aid in the processing of raw poultry meat.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the processing aid in the processing of raw poultry meat.

##### *2.4.1.1.1 Costs and benefits of permitting CPC as a processing aid*

Approving the application will provide the food industry with an alternative antimicrobial treatment for raw poultry meat. Due to the voluntary nature of the permission, industry would only use this processing aid where they believe a net benefit exists for them.

Consumers may benefit from any cost savings that industry passes on from using this treatment instead of other treatment methods.

Raw poultry can carry a wide range of microorganisms, some of which are potential human pathogens that can cause illness in consumers. Therefore, approving this application may result in improving consumers' safety due to a greater availability of tools to reduce microorganisms in raw poultry.

There are some environmental risks from disposal of waste water containing the CPC preparation. If industry were to use this processing aid, they would need to ensure adequate systems to treat and/or safely dispose of waste water containing CPC.

Permitting the processing aid may also result in a small cost to government in terms of adding it to the current range of processing aids that are monitored for compliance, including possibly monitoring for adequate waste disposal.

#### **2.4.1.1.2 Conclusions from cost benefit considerations**

FSANZ's assessment at the call for submissions was that, if the draft variation is approved, the direct and indirect benefits that would arise from permitting the use of CPC as a processing aid for raw poultry meat would most likely outweigh the associated risks and costs. No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the call for submissions.

#### **2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

#### **2.5.1.3 Any relevant New Zealand standards**

The regulatory measures apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

#### **2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.5.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### **2.5.2.1 Protection of public health and safety**

FSANZ has undertaken a safety assessment (SD) and concluded that there are no public health and safety concerns relating to the use of CPC as a processing aid for use as an antimicrobial agent in raw poultry meat or from the propylene glycol in Safe Foods' CPC preparation at the approved use levels.

#### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

FSANZ is not imposing any specific labelling requirements for poultry treated using CPC. The generic exemption from declaring processing aids in the statement of ingredients applies in accordance with the Code, consistent with the current approach in the Code.

#### **2.5.2.3 The prevention of misleading or deceptive conduct**

There were no issues identified with this application relevant to this objective.

### **2.5.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the risk analysis. The risk assessment is provided in SD. Safe Foods submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

- **the promotion of consistency between domestic and international food standards**

In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). The Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010) sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

There is also an internationally recognised specification for CPC in the Food Chemicals Codex (United States Pharmacopeial Convention, 2020) (refer to Section 1.3.2 of this report).

- **the desirability of an efficient and internationally competitive food industry**

The conclusion of the risk assessment was that there are no public health and safety issues associated with using CPC as a processing aid for use as an antimicrobial agent for raw poultry meat. It is therefore appropriate that Australian and New Zealand poultry industries are given the opportunity to benefit from the proposed use of this processing aid. Whether or not an individual poultry processing company uses the processing aid will depend on a number of economic and other factors.

- **the promotion of fair trading in food**

FSANZ did not identify any issues for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals<sup>12</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the proposed use of this processing aid is consistent with the specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

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<sup>12</sup> Available on the [Food regulation website](#) (accessed 4 April 2022).

## 6 References

EFSA (2012) Scientific opinion on the evaluation of the safety and efficacy of Cecure® for the removal of microbial surface contamination of raw poultry products. EFSA Journal 10(3): 2612. doi:10.2903/j.efsa.2012.2612.

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FSANZ (2005) Proposal P282 – Primary Production and Processing Standard for Poultry. Draft Assessment report. Attachment 3: Scientific Assessment of the Public Health and Safety of Poultry Meat in Australia. Available at [www.foodstandards.gov.au/code/proposals/Pages/proposalp282primaryp2442.aspx](http://www.foodstandards.gov.au/code/proposals/Pages/proposalp282primaryp2442.aspx) Accessed 20 April 2022.

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Rincon A, Kumar S, Ritz CW, Jackson JS, Jackson CR, Frye JG, Hinton A Jr, Singh M, Cosby DE, Cox NA, Thippareddi H (2020) Antimicrobial interventions to reduce *Salmonella* and *Campylobacter* populations and improve shelf life of quail carcasses. Poult Sci 99(11):5977-5982. DOI: 10.1016/j.psj.2020.07.012.

US Food and Drug Administration Code of Federal Regulations (2020), Title 21 – Food and Drugs, Volume 3, Part 173 – Secondary Direct Food Additives Permitted in Food for Human Consumption, Subpart D – Specific Usage Additives, Sec 173.375 Cetylpyridinium chloride. Available at [CFR - Code of Federal Regulations Title 21](#) (accessed 11 April 2022).

### Attachments

- A. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement



## Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code



### Food Standards (Application A1215 – Cetylpyridinium chloride (CPC) as a processing aid) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Delegate's name and position]

Delegate of the Board of Food Standards Australia New Zealand

#### Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Application A1215 – Cetylpyridinium chloride (CPC) as a processing aid) Variation*.

**2 Variation to standards in the *Australia New Zealand Food Standards Code***

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**Standard 1.3.3—Processing aids**

**[1] At the end of Division 3**

Add:

**1.3.3—13 Anti-microbial agent—cetylpyridinium chloride**

Cetylpyridinium chloride may be \*used as a processing aid to perform the technological purpose of an anti-microbial agent during the processing of a food for sale listed in section S18—11 if:

- (a) cetylpyridinium chloride is not present in the food at a level greater than the maximum permitted level indicated in that section for that food; and
- (b) any conditions for use specified in that section are complied with.

**Schedule 2—Units of measurement**

**[2] Table to section S2—2**

Add:

w/v weight per volume

**Schedule 18—Processing aids**

**[3] After section S18—10**

Add:

**S18—11 Permission to use cetylpyridinium chloride as an anti-microbial agent**

- (1) For section 1.3.3—13, the food, maximum permitted levels and conditions are set out in the table to subsection (3).
- (2) In this section:

***Poultry meat*** means the whole or any part of a poultry carcass which:

  - (a) has skin attached; and
  - (b) is intended for human consumption; and
  - (c) is not, or does not include, offal.

**Note** Subsection 1.1.2—3(2) defines 'offal'.
- (3) The table is:

**Permission to use cetylpyridinium chloride as an anti-microbial agent (section 1.3.3—13)**

<b><i>Food</i></b>	<b><i>Maximum permitted level (mg/kg)</i></b>	<b><i>Conditions of use</i></b>
Raw poultry meat	13.4 (in the skin)	(1) The concentration of cetylpyridinium chloride in the aqueous wash solution that is applied to the raw poultry meat must not exceed 1% w/v.  (2) The raw poultry meat, after being treated with cetylpyridinium chloride, must be rinsed in potable water.

## Attachment B – Explanatory Statement

### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1215 which sought to amend the Code to permit the use of cetylpyridinium chloride as a processing aid, for use as an anti-microbial treatment for raw poultry. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

### 2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunseting provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunseting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunseting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

### **3. Purpose**

The Authority has approved the draft variation amending Standard 1.3.3 and Schedule 18 of the Code to permit the use of cetylpyridinium chloride as a processing aid, for use as an anti-microbial treatment for raw poultry meat in accordance with the Code.

The approved draft variation also amends Schedule 2 of the Code as a consequence of the above amendments.

### **4. Documents incorporated by reference**

The approved draft variation itself does not incorporate any documents by reference.

However, section 1.1.1—15 of the Code requires certain substances (such as processing aids) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2019) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition).

### **5. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1215 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 March 2022 for a four-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

### **6. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

### **7. Variation**

#### *7.1 Item [1]*

Item 1 of the of the Schedule to the variation will add a new provision, section 1.3.3—13, into Standard 1.3.3.

New section 1.3.3—13 will permit cetylpyridinium chloride to be used as a processing aid, to perform the technological purpose of an anti-microbial agent, during the processing of food for sale listed in the table to new section S18—11 (see *item [3]* below).

However, the new permission will be subject to compliance with the corresponding maximum permitted level and conditions for use for the food concerned listed in that table.

## 7.2 *Item [2]*

Item 2 of the of the Schedule to the variation will add the following new unit of measurement and its corresponding meaning into the table to section S2—2 in alphabetical order:

“w/v                      weight per volume”.

This amendment is consequential to the amendment to Schedule 18 in *item [3]* (see below).

## 7.3 *Item [3]*

Item 3 of the of the Schedule to the variation will add a new provision, section S18—11, into Schedule 18.

New section S18—11 relates to the permitted use of cetylpyridinium chloride as an anti-microbial agent in food.

New subsection S18—11(1) provides that the food, maximum permitted levels and conditions, for new section 1.3.3—13 (see *item [1]* above), are set out in the table to subsection S18—11(3).

New subsection S18—11(3) includes a table listing the food for which cetylpyridinium chloride will be permitted to be used as an anti-microbial agent (Column 1); the maximum permitted level above which cetylpyridinium chloride must not present in the corresponding food (Column 2); and the conditions for the use of cetylpyridinium chloride in the corresponding food (Column 3).

Column 1 of the table to new section S18—11 lists ‘Raw poultry meat’.

New subsection S18—11(2) defines the term ‘poultry meat’ for the purposes of new section S18—11 as meaning the whole or any part of a poultry carcass with the skin attached; that is intended for human consumption; and either is not or does not include offal.

A Note to the definition of ‘poultry meat’ explains that subsection 1.1.2—3(2) defines ‘offal’.

Column 2 of the table to new section S18—11 specifies that the maximum permitted level of cetylpyridinium chloride that may be present in the skin of raw poultry meat is 13.4 mg per kg.

Column 3 of the table to new section S18—11 lists the following two conditions of use for the use of cetylpyridinium chloride as an anti-microbial agent for raw poultry meat:

- the concentration of cetylpyridinium chloride in the aqueous wash solution applied to the raw poultry meat must not be more than 1% w/v; and
- the raw poultry meat must be rinsed in potable water after treatment with cetylpyridinium chloride.

*Requirement that raw poultry meat must be rinsed in potable water after treatment with cetylpyridinium chloride*

The Authority notes that water immersion chilling is commonly used to chill poultry carcasses following evisceration and washing, with the carcass placed in counter-current flow of chlorinated (50-70 ppm total available chlorine, 0.4–4.0 ppm free available chlorine) cold water (FSANZ 2005).

Submersion of raw poultry meat in an immersion chiller, as described above, may satisfy this

requirement. However, the onus would be on the poultry processor to ensure that the immersion chiller step is a *potable water* rinse and the maximum permitted level of cetylpyridinium chloride that may be present in the skin of raw poultry meat is not exceeded following that step.

The unit of % weight per volume (w/v) is referred to in the variation as the cetylpyridinium chloride is in a solid/crystallised state before being dissolved to an aqueous form and then diluted with potable water for use.

The effect of these amendments is that cetylpyridinium chloride will be permitted to be used as a processing aid, i.e. an anti-microbial treatment, for raw poultry meat in accordance with the Code.