

16 March 2022
193-22

Call for submissions – Application A1215

Cetylpyridinium chloride (CPC) as a processing aid

FSANZ has assessed an application made by Safe Foods Corporation to permit the use of cetylpyridinium chloride (CPC) as a processing aid (antimicrobial treatment) for raw poultry and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website at [how to make a submission](#). You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 13 April 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting document

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

SD1 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/v¹) CPC for use as an antimicrobial agent to treat the inner (cavity) and outer surfaces of raw poultry carcasses and 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.

As propylene glycol is listed as a food additive permitted at GMP (good manufacturing practice) 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.

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 levels ranging from 0.1 to 1% (w/v) concentration 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 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 engender 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 GMP and as a processing aid in accordance with the Code.

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

¹ weight per volume

proposed use levels.

FSANZ has assessed the application in accordance with the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and prepared a draft variation to the Code to permit the proposed use of CPC. If approved, the draft variation would 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 is 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 is also 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 an 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.

FSANZ now seeks submissions to assist consideration of the draft variation to the Code.

1 Introduction

1.1 Safe Foods

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 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/v²) CPC for use as an antimicrobial agent to treat the inner (cavity) and outer surfaces of raw poultry carcasses and 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 poultry carcasses or pieces are rinsed in potable water following the treatment outlined above.

1.3 The current Code requirements

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.

For the purposes of this application, 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) and at which point the

² weight per volume

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 that use be consistent with GMP.

As it is an additive permitted at GMP, section 1.3.3—4 of the Code 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 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 gallons³ 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 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 Food and Drug Administration (FDA), with the maximum limit of solution applied and the rinse

³ equivalent to 18.9 litres

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 December 17, 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 7120.1⁴ 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

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 regarding bacterial resistance to CPC (which has been provided to FSANZ) and data relating to environmental concerns which they were finalising before sending to EFSA. 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 2.1.2 and SD1 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.

⁴ Available at <https://www.fsis.usda.gov/policy/fsis-directives/7120.1>

1.5 Reasons for accepting the 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 is being assessed under the General Procedure in the FSANZ Act.

2 Summary of the assessment

2.1 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.

2.1.1 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 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.

2.1.2 Risk assessment

Studies on the potential for the proposed use of CPC to engender 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 (90th 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.

2.2 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 considers it is appropriate to prepare a draft variation to the Code to permit its use.

2.2.1 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 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.

2.2.2 Food permitted to be treated

The food proposed to be permitted to be treated with CPC is raw poultry meat with the skin attached. This would mean whole raw poultry carcasses or raw poultry pieces, skin on, may be treated with CPC, subject to conditions for the treatment process and the maximum permitted level (MPL), as 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 method of analysis for testing CPC residue analyses the skin of the carcass only i.e. the skin is removed from the poultry carcass before analysis.

The term 'poultry meat' is defined for the purposes of the drafting to mean the whole poultry carcass or parts of the poultry carcass, with the skin attached, and that is intended for human consumption. The definition does not include offal.

Offal is normally removed from the carcass before treatment and was not included in the risk assessment. It is not proposed to permit offal to be treated with CPC.

2.2.3 Maximum permitted level (MPL)

The proposed permission to use CPC as an antimicrobial agent for raw poultry meat would 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 would apply to the skin only, as the method of analysis for testing CPC residue analyses the skin only.

2.2.4 Permitted concentration of CPC in wash solution and rinse step

The risk assessment was based on residues of CPC on poultry following treatment at a

concentration in the poultry wash solution of up to 1% (w/v) CPC and following a rinse of the poultry carcass or pieces in potable water following treatment. FSANZ therefore proposes to require that the concentration of CPC in the aqueous wash solution applied to the raw poultry meat must not exceed 1% (w/v) and that following treatment with CPC, the raw poultry meat must be rinsed in potable water. These additional risk management measures would assist poultry processors to meet the MPL.

The unit of % w/v is used in the 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.

2.2.5 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 address food safety⁵. FSANZ is therefore not proposing to specify the type of premises or person permitted to treat poultry with CPC.

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 dosage.

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.

2.2.6 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 (SD1), 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

⁵ 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.

If approved, the proposed drafting in Attachment 1 would 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 is not proposing any amendments to the Code with respect to permissions for the use of propylene glycol.

2.2.7 Labelling

The exemption from declaring processing aids in the statement of ingredients will apply, in accordance with the Code, to products treated with CPC (refer to Section 1.3.4 of this report). No amendments to the Code with respect to labelling of poultry treated with CPC are proposed.

2.2.8 Conclusion

A draft variation to the Code has been prepared to permit the proposed use of CPC (Attachment A). If approved, the proposed draft variation would permit the use of CPC as a processing aid with the technological purpose of antimicrobial agent for raw poultry meat with the skin attached in accordance with the Code. The permission would 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 would 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 would provide the poultry industry with an additional option for reducing microorganisms, including pathogens, in raw poultry.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application.

All calls for submissions are 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 are called to obtain the views of the public, including interested parties on issues raised by the application and the impacts of regulatory options.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius 'general standard' for processing aids. There is however, an international Codex guideline for processing aids – *Guidelines on Substances used as Processing Aids (CAC/GL 75-2010)* – as detailed in Section 2.4.3 below which is applicable to the use of processing aids. Amending the Code to permit the use of CPC as a processing aid as an antimicrobial agent for raw poultry is unlikely to have a significant effect on international trade. The USA and a number of other countries permit the use of CPC (or Cecure®) as a processing aid for raw poultry and other foods. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 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:

2.4.1 Section 29

2.4.1.1 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 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 is 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 considers permitting the use of CPC as a processing aid in the processing of raw poultry meat. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is 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 seeks 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, if this application is approved, consumers' safety may improve from 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 current assessment is 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. However, feedback received during this Call for Submissions may change or add to this conclusion.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded that there are no public health and safety concerns relating to the use of CPC as a processing aid as an antimicrobial agent in raw poultry meat or from the propylene glycol in Safe Foods' CPC preparation at the proposed use levels.

2.4.2.2 The provision of adequate information relating to food to enable consumers to

make informed choices

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

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 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 SD1. 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). In contrast to food additives, there is no Codex Alimentarius 'general standard' for processing aids. There is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010) which 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 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 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 Minerals⁶ 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:

⁶ Available on the [Food regulation website](#) (accessed 13 October 2021).

- 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.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4 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.

United States Pharmacopeial Convention (2020) Food Chemicals Codex 12th ed, United States Pharmacopeial Convention, Rockville, MD.

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 8 October 2021).

Attachments

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

Attachment A – Draft variation to the Australia New Zealand Food Standards Code



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

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 a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard 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)

| Food | Maximum permitted level (mg/kg) | Conditions of use |
|------------------|--|---|
| 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 – Draft 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 seeks 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 of the FSANZ Act and has prepared a draft variation.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunset 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 sunset 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 sunset 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 prepared 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 draft variation also proposes amending Schedule 2 of the Code as a consequence of the above amendments.

4. Documents incorporated by reference

The 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); the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition); and the Commission Regulation (EU) No 231/2012.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1215 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

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 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 draft variation would add a new section 1.3.3—13 into Standard 1.3.3.

If approved, proposed new section 1.3.3—13 would 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 proposed new section S18—11 (see item [2] below).

However, the proposed permission is 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 draft variation would add the following new unit of measurement and its corresponding meaning into the table to section S2—2:

“w/v weight per volume”.

The proposed new unit of measurement would be added in alphabetical order.

This amendment is consequential to the proposed amendment to Schedule 18 in item [3]

(see below).

7.3 *Item [3]*

Item 3 of the draft variation would add a proposed new section S18—11 into Schedule 18.

Proposed new subsection S18—11(1) provides that the food, maximum permitted levels and conditions, for proposed new section 1.3.3—13, are set out in the table to subsection S18—11(3).

Proposed new subsection S18—11(3) includes a table listing the food for which cetylpyridinium chloride would 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 proposed new section S18—11 lists 'Raw poultry meat'.

Proposed new subsection S18—11(2) defines the term 'poultry meat' for the purposes of the proposed new section 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.

Column 2 of the table to proposed 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 proposed 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.

The unit of % weight per volume (w/v) is used in the draft 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

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